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, 2020

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 6, 2020, the registrant had 127,388,620 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.

Item 1. Financial Statements.

VIR BIOTECHNOLOGY, INC.

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

	September 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 462,521	$ 109,335
Short-term investments	364,074	274,101
Restricted cash and cash equivalents, current	9,363	6,181
Prepaid expenses and other current assets	13,614	13,378
Total current assets	849,572	402,995
Intangible assets, net	33,944	35,694
Goodwill	16,937	16,937
Property and equipment, net	16,948	16,308
Operating right-of-use assets	14,762	—
Restricted cash and cash equivalents, noncurrent	1,201	7,300
Long-term investments	—	24,290
Other assets	9,895	8,547
TOTAL ASSETS	$ 943,259	$ 512,071
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	6,796	$ 5,881
Accrued and other liabilities	44,339	26,495
Deferred revenue, current portion	5,563	6,181
Contingent consideration, current portion	20,300	8,200
Derivative liability	—	12,449
Total current liabilities	76,998	59,206
Deferred revenue, noncurrent	3,815	12,670
Operating lease liabilities, noncurrent	12,092	—
Contingent consideration, noncurrent	31,712	9,380
Deferred tax liability	3,305	3,305
Other long-term liabilities	2,982	3,568
TOTAL LIABILITIES	130,904	88,129
Commitments and contingencies (Note 9)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2020 and December 31, 2019; no shares issued and outstanding as of September 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 126,991,631 and 107,648,925 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	13	11
Additional paid-in capital	1,374,362	793,051
Accumulated other comprehensive loss	(485)	(601)
Accumulated deficit	(561,535)	(368,519)
TOTAL STOCKHOLDERS' EQUITY	812,355	423,942
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 943,259	$ 512,071

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,	
	2020	2019	2020	2019
Revenues:				
Grant revenue	$ 1,740	$ 1,166	$ 7,690	$ 6,771
License revenue from a related party	—	—	22,747	—
Contract revenue	188	237	44,197	340
Total revenue	1,928	1,403	74,634	7,111
Operating expenses:				
Research and development	70,684	39,863	215,316	95,541
General and administrative	18,859	9,220	47,894	25,790
Total operating expenses	89,543	49,083	263,210	121,331
Loss from operations	(87,615)	(47,680)	(188,576)	(114,220)
Other income (expense):				
Interest income	412	2,012	2,548	6,564
Other income (expense), net	2,616	(2,659)	(6,904)	(3,251)
Total other income (expense)	3,028	(647)	(4,356)	3,313
Loss before benefit from (provision for) income taxes	(84,587)	(48,327)	(192,932)	(110,907)
Benefit from (provision for) income taxes	(22)	13	(84)	(5)
Net loss	$ (84,609)	$ (48,314)	$ (193,016)	$ (110,912)
Net loss per share, basic and diluted	$ (0.67)	$ (4.60)	$ (1.66)	$ (11.53)
Weighted-average shares outstanding, basic and diluted	125,810,907	10,500,848	116,427,529	9,615,379

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,	
	2020	2019	2020	2019
Net loss	$ (84,609)	$ (48,314)	$ (193,016)	$ (110,912)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	(196)	(159)	99	95
Amortization of actuarial loss	6	—	17	—
Other comprehensive income (loss)	(190)	(159)	116	95
Comprehensive loss	$ (84,799)	$ (48,473)	$ (192,900)	$ (110,817)

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' Equity (Deficit)
(in thousands, except share amounts)
(unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Share	Amount	Share	Amount	Capital	Income (Loss)	Deficit	(Deficit)
Balance at June 30, 2020	—	$ —	117,727,086	$ 12	$ 1,040,988	$ (295)	$ (476,926)	$ 563,779
Issuance of common stock in connection with a follow-on offering, net of issuance costs of $21,786	—	—	8,214,285	1	323,213	—	—	323,214
Vesting of restricted common stock	—	—	561,255	—	427	—	—	427
Exercise of stock options	—	—	489,005	—	1,152	—	—	1,152
Stock-based compensation	—	—	—	—	8,582	—	—	8,582
Other comprehensive loss	—	—	—	—	—	(190)	—	(190)
Net loss	—	—	—	—	—	—	(84,609)	(84,609)
Balance at September 30, 2020	—	$ —	126,991,631	$ 13	$ 1,374,362	$ (485)	$ (561,535)	$ 812,355

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Share	Amount	Share	Amount	Capital	Income (Loss)	Deficit	(Deficit)
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)

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' Equity (Deficit)
(in thousands, except share amounts)
(unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Share	Amount	Share	Amount	Capital	Income (Loss)	Deficit	(Deficit)
Balance at December 31, 2019	—	$ —	107,648,925	$ 11	$ 793,051	$ (601)	$ (368,519)	$ 423,942
Reclassification of derivative liability to additional paid-in capital	—	—	—	—	29,245	—	—	29,245
Issuance of common stock in connection with the achievement of a milestone	—	—	1,111,111	—	—	—	—	—
Issuance of common stock in connection with a collaboration agreement	—	—	6,626,027	1	206,698	—	—	206,699
Issuance of common stock for cashless exercise of warrant	—	—	211,774	—	—	—	—	—
Issuance of common stock in connection with a follow-on offering, net of issuance costs of $21,786	—	—	8,214,285	1	323,213	—	—	323,214
Vesting of restricted common stock	—	—	1,791,880	—	1,316	—	—	1,316
Exercise of stock options	—	—	1,387,629	—	3,540	—	—	3,540
Stock-based compensation	—	—	—	—	17,299	—	—	17,299
Other comprehensive income	—	—	—	—	—	116	—	116
Net loss	—	—	—	—	—	—	(193,016)	(193,016)
Balance at September 30, 2020	—	$ —	126,991,631	$ 13	$ 1,374,362	$ (485)	$ (561,535)	$ 812,355

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Share	Amount	Share	Amount	Capital	Income (Loss)	Deficit	(Deficit)
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 costs 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 common stock	—	—	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)

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,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (193,016)	$ (110,912)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,185	2,435
Amortization of intangible assets	918	918
Impairment of intangible assets	832	—
Amortization of premiums (accretion of discounts) on investments, net	1,052	(571)
Noncash lease expense	2,498	—
Change in estimated fair value of contingent consideration	44,432	819
Payment of contingent consideration in excess of acquisition date fair value	(6,453)	—
Change in estimated fair value of derivative liability	16,796	—
Change in estimated fair value of convertible preferred stock warrant liability	—	3,401
Common stock issued in connection with license agreement	—	617
Stock-based compensation	17,299	6,040
Other	17	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(416)	(109)
Other assets	(2,168)	(1,399)
Accounts payable	1,041	428
Accrued liabilities and other long-term liabilities	13,183	5,678
Operating lease liabilities	(2,343)	—
Deferred revenue	(5,746)	1,908
Net cash used in operating activities	(108,889)	(90,747)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(4,119)	(7,388)
Purchases of investments	(363,399)	(495,934)
Maturities of investments	296,763	320,933
Proceeds from disposal of an asset held for sale	180	—
Net cash used in investing activities	(70,575)	(182,389)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock in connection with a collaboration agreement	206,699	—
Proceeds from issuance of common stock, net of issuance costs	323,214	—
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	317,335
Payment of contingent consideration	(3,547)	—
Proceeds received from financing lease obligation	—	1,202
Payment of principal on financing lease obligation	(173)	(38)
Payment of offering costs related to initial public offering	—	(3,686)
Proceeds from repayment of promissory notes	—	3,265
Proceeds from exercise of stock options	3,540	1,066
Net cash provided by financing activities	529,733	319,144
Net increase in cash, cash equivalents and restricted cash and cash equivalents	350,269	46,008
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	122,816	59,362
Cash, cash equivalents and restricted cash and cash equivalents at end of period	$ 473,085	$ 105,370
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment purchases included in accounts payable and accrued liabilities	$ 598	$ 200
Reclassification of derivative liability to additional paid-in capital	$ 29,245	$ —
Operating lease liabilities obtained in exchange of right-of-use asset	$ 437	$ —
Deferred offering costs in accounts payable and accrued liabilities	$ —	$ 1,938
Advanced proceeds applied to convertible preferred stock issuance	$ —	$ 10,140
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH TO THE CONDENSED CONSOLIDATED BALANCE SHEETS:		
Cash and cash equivalents	$ 462,521	$ 93,698
Restricted cash and cash equivalents, current	9,363	8,822
Restricted cash and cash equivalents, noncurrent	1,201	2,850
Total cash, cash equivalents and restricted cash	$ 473,085	$ 105,370

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. Vir has assembled four technology platforms that are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. Its current development pipeline consists of product candidates targeting severe acute respiratory syndrome coronavirus 2 ("SARS-CoV-2"), hepatitis B virus ("HBV"), influenza A virus, human immunodeficiency virus ("HIV"), and tuberculosis ("TB").

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 $126.4 million in net proceeds, after deducting underwriting discounts, commissions and 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 purchase 244,444 shares of convertible preferred stock was converted into a warrant to purchase 244,444 shares of common stock.

Follow-On Offering

On July 10, 2020, the Company issued and sold 8,214,285 shares of the Company's common stock pursuant to a registration statement on Form S-1 (File No. 333-239689) and a registration statement on Form S-1 filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended (File No. 333-239747) (collectively, the "Registration Statements"). The Registration Statements became effective on July 7, 2020. The price of the shares sold in the follow-on offering was $42.00 per share and the Company received total gross proceeds from the offering of approximately $345.0 million. After deducting underwriting discounts and commissions of $20.7 million and offering expenses of $1.1 million, the net proceeds were $323.2 million.

Need for Additional Capital

The Company has incurred net losses since inception and expects such losses to continue over the next several years. As of September 30, 2020, the Company had an accumulated deficit of $561.5 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. The Company had, excluding restricted cash, $826.6 million of cash, cash equivalents, and short-term investments at September 30, 2020. Based on the Company's business plans, management believes that its cash, cash equivalents, and short-term investments as of September 30, 2020 will be sufficient to fund its operations 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, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020 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 Company's audited consolidated financial statements and related notes included in the Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 26, 2020.

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 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.

Concentration of Credit Risk and Other Risks and Uncertainties

With the global spread of the current COVID-19 pandemic, the Company has implemented a number of plans and policies designed to address and mitigate the impact of the COVID-19 pandemic on its business. The Company anticipates that the COVID-19 pandemic will have an impact on the clinical development timelines for some of its clinical programs. The extent to which the COVID-19 pandemic impacts the Company's business, clinical development and regulatory efforts, corporate development objectives and the value of and market for its common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States, Europe and other countries, and the effectiveness of actions taken globally to contain and treat the disease.

In addition, the Company is subject to a number of other challenges and risks similar to other biopharmaceutical companies in the early stage, including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, the need to obtain marketing approval for its product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company's products and protection of proprietary technology. If the Company does not successfully obtain regulatory approval, commercialize or partner any of its product candidates, it will be unable to generate revenue from product sales or achieve profitability. In addition, to the extent the current COVID-19 pandemic adversely affects the Company's business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties discussed above.

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and short and long-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 investments, and issuers of the investments to the extent recorded on the condensed consolidated balance sheets. As of September 30, 2020, 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 condensed consolidated balance sheet date are considered short-term investments, with all others considered to be long-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 other income (expense), net and interest income, respectively, on the condensed consolidated statements of operations.

The Company, through its investment in Brii Biosciences Limited, holds privately held equity securities in which the Company does not have a controlling interest or significant influence. The Company's investment in Brii Biosciences Limited is recorded at cost and adjusted for impairments and observable price changes with the same or similar security from the same issuer. The valuation of the Company's investment in Brii Biosciences Limited utilizes significant unobservable inputs or data in an inactive market and the valuation requires the Company's judgment due to the absence of market prices and inherent lack of liquidity. Additionally, the determination of whether an orderly transaction is for the same or similar investment requires significant management judgment including the nature of the rights and obligations of its investments, the extent to which differences in those rights and obligations would affect the fair values of those investments, and the impact of any differences based on the stage of operational development of the investee. See Note 7—Collaboration and License Agreements for additional information on the Company's investment in Brii Biosciences Limited.

Restricted Cash and Cash Equivalents

Restricted cash and cash equivalents represent money market funds to secure a standby letter of credit and a security deposit with financial institutions, both pursuant to office and laboratory space lease agreements. Additionally, funds received from certain grants are restricted as to their use and are therefore classified as restricted cash and cash equivalents.

Revenue Recognition

Grant Revenue

Grants received, including cost reimbursement agreements, are assessed to determine if the agreement should be accounted for as an exchange transaction or a contribution. An agreement is accounted for as a contribution if the resource provider does not receive commensurate value in return for the assets transferred. Contributions are recognized as grant revenue when all donor-imposed conditions have been met.

License and Contract Revenue

In accordance with Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 606"), the Company recognizes revenue when the Company's customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods and services. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation.

For collaborative arrangements that fall within the scope of ASC 808, Collaborative Arrangements ("ASC 808"), the Company first determines which elements of the collaboration are deemed to be a performance obligation with a customer within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808 and are not subject to the guidance in ASC 606, the Company applies the revenue recognition model under ASC 606 or other guidance, as deemed appropriate. The Company has entered into a number of license and collaboration agreements that fall within the scope of ASC 606. The Company evaluates the promised goods or services in these agreements to determine which ones represent distinct performance obligations. These agreements may include the following types of promised goods or services: (i) grants of licenses, (ii) performance of research and development services, and (iii) participation on joint research and/or development committees. They also may include options to obtain licenses to the Company's intellectual property.

Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. These estimates are re-assessed each reporting period as required. These agreements may include the following types of consideration: non-refundable upfront payments, reimbursement for research services, research, development or regulatory milestone payments, and royalty and commercial sales milestone payments.

If there are multiple distinct performance obligations, the Company allocates the transaction price to each distinct performance obligation based on their estimated standalone selling prices. For performance obligations satisfied over time, the Company estimates the efforts needed to complete the performance obligation and recognizes revenue by measuring the progress towards complete satisfaction of the performance obligation using an input measure.

For arrangements that include sales-based royalties, including commercial milestone payments based on pre-specified level of sales, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon performance of the licensee.

Acquisitions

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method, assets acquired, including in-process research and development ("IPR&D") projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date in the Company's condensed consolidated financial statements. Any excess fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with the business combination are recorded at their fair values on the acquisition date and are remeasured each subsequent reporting period until the related contingencies are resolved and are classified as contingent consideration on the condensed consolidated balance sheets. The changes in fair values of contingent consideration related to achievement of various milestones related to product candidates are recorded within research and development expense.

When the Company determines that assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction is accounted for as an acquisition of assets. Therefore, the initial cost of acquired IPR&D is expensed, and no goodwill is recorded. Any contingent consideration is recognized only when it becomes payable or is paid.

Embedded Derivatives

The Company evaluates its acquisitions, collaborative arrangements and other business development transactions to determine if embedded components of these contracts meet the definition of a derivative under ASC 815, Derivatives and Hedging. In general, embedded derivatives are required to be bifurcated from the host instrument if (i) the embedded feature is not clearly and closely related to the host contract and (ii) the embedded feature, if considered a freestanding instrument, meets the definition of a derivative. Embedded derivatives are reported on the condensed consolidated balance sheets at their estimated fair values. Contingent consideration related to asset acquisitions that meet the definition of an embedded derivative are classified as contingent consideration on the condensed consolidated balance sheets. Any change in estimated fair values, as determined at each measurement period, are recorded in the condensed consolidated statements of operations based on the nature of the related contingencies. Changes in fair values of embedded derivatives related to achievement of various milestones for product candidates are recorded within research and development expense. Otherwise, changes in fair values are recorded within other income (expense), net.

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, Leases ("ASC 842"). ASC 842 requires lessees to recognize all leases, including operating leases, on the balance sheet as a right-of-use ("ROU") asset and lease liability, unless the lease is a short-term lease, defined as having a term of 12 months or less. The Company early adopted the standard on January 1, 2020 using the optional modified retrospective transition method by recognizing a cumulative effect adjustment to the opening balance of accumulated deficit as of that date. Results for the three and nine months ended September 30, 2020 are presented under ASC 842. The prior period amounts were not adjusted and continue to be reported in accordance with previous lease guidance, ASC 840, Leases.

The Company elected the package of practical expedients allowed under ASC 842, which permits the Company to account for its existing operating leases as operating leases under the new guidance, without reassessing the Company's prior conclusions about lease identification, lease classification and initial direct cost.

Adoption of ASC 842 resulted in the recognition of operating lease ROU assets and operating lease liabilities of $16.8 million and $17.5 million, respectively, on the Company's condensed consolidated balance sheet as of January 1, 2020. The difference between the ROU assets and lease liabilities is attributed to the elimination of deferred rent. The adoption of the new standard did not have an impact on the Company's beginning accumulated deficit or statement of operations.

The Company determines if an arrangement is or contains a lease at inception by assessing whether the arrangement contains an identified asset and whether it has the right to control the identified asset. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Lease liabilities are recognized at the lease commencement date based on the present value of future lease payments over the lease term. ROU assets are based on the measurement of the lease liability and also include any lease payments made prior to or on lease commencement and exclude lease incentives and initial direct costs incurred, as applicable.

As the implicit rate in the Company's leases is generally unknown, the Company uses an incremental borrowing rate estimated based on the information available at the lease commencement date in determining the present value of future lease payments. When calculating its estimated incremental borrowing rates, the Company considers its credit risk, the lease term, the total lease payments and the impact of collateral, as necessary. The lease terms may include options to extend or terminate the lease when the Company is reasonably certain it will exercise such options. Rent expense for the Company's operating leases is recognized on a straight-line basis within operating expenses over the reasonably assured lease term.

The Company elected to not separate lease and non-lease components for any leases within its existing classes of assets and, as a result, accounts for the lease and non-lease components as a single lease component. The Company has also elected to not apply the recognition requirement to any leases within its existing classes of assets with a term of 12 months or less.

Recently Adopted Accounting Pronouncements

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. The Company early adopted ASU 2017-04 on January 1, 2020 and the adoption had no impact on its condensed consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820) (“ASU 2018-13”), which modifies, removes and adds certain disclosure requirements on fair value measurements. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The Company adopted ASU 2018-13 on January 1, 2020 and the adoption resulted in additional disclosures related to the Company’s Level 3 financial instruments. See Note 3 – Fair Value Measurements.

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606 (“ASU 2018-18”). The amended guidance precludes presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The new guidance is effective for the Company for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company adopted ASU 2018-18 as of January 1, 2020 and the adoption had no impact on the consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

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, including the Company’s financial instruments. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will likely 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. As an emerging growth company, Topic 326 would have been effective for the Company for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. However, in light of the Company’s public float as of June 30, 2020, the Company expects that it will no longer be an emerging growth company on December 31, 2020. Therefore, the Company will be required to adopt ASU 2016-13 in its consolidated financial statements for the year ended December 31, 2020. The Company is currently assessing the impact that the adoption of ASU 2016-13 will have on its consolidated financial statements and related disclosures. The Company does not expect the adoption of ASU 2016-13 to have a material impact on its 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.

The following tables summarize the Company's Level 1 and Level 2 financial assets measured at fair value on a recurring basis by level within the fair value hierarchy:

		September 30, 2020			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
		(in thousands)			
Assets:					
Money market funds(1)	Level 1	$ 472,272	$ —	$ —	$ 472,272
U.S. government treasuries	Level 2	363,840	235	(1)	364,074
Total financial assets		$ 836,112	$ 235	$ (1)	$ 836,346

(1) Includes $10.6 million of restricted cash equivalents.

		December 31, 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	$ 106,127	$ —	$ —	$ 106,127
U.S. government treasuries (2)	Level 2	298,256	140	(5)	298,391
Bank time deposits	Level 2	2,500	—	—	2,500
Total financial assets		$ 406,883	$ 140	$ (5)	$ 407,018

(1) Includes $13.5 million of restricted cash equivalents.
(2) Includes $24.3 million classified as long-term investments.

As of September 30, 2020, there were no investments that have been in a continuous unrealized loss position for longer than 12 months. Total net unrealized gains of $0.2 million were recorded in accumulated other comprehensive income (loss) at September 30, 2020. As of September 30, 2020, no securities have contractual maturities of longer than one year.

Level 3 liabilities consist of contingent consideration and derivative liability as of December 31, 2019. As of September 30, 2020, Level 3 liabilities consist of contingent consideration.

Contingent Consideration

Contingent consideration includes potential milestone payments in connection with the acquisitions of Humabs Biomed SA ("Humabs") and TomegaVax, Inc. ("TomegaVax"). See further discussion in Note 4—Acquisitions.

The estimated fair value of the contingent consideration related to the Humabs acquisition was determined by calculating the probability-weighted clinical, regulatory and commercial milestone payments based on the assessment of the likelihood and estimated timing that certain milestones would be achieved. In May 2020, the Company achieved one of the specified clinical milestones for the HBV product. As such, the Company paid $10.0 million related to this milestone event in June 2020. In October 2020, the Company achieved another specified clinical milestone for the SARS-CoV-2 product and paid $10.0 million. See Note 15—Subsequent Event. As of September 30, 2020, the Company calculated the estimated fair value of the remaining clinical and regulatory milestones using the following significant unobservable inputs:

Unobservable input	Value or Range (Weighted-Average)[1]
Discount rates	10% - 12% (10%)
Probability of achievement	14% - 100% (56%)

(1) Unobservable inputs were weighted based on the relative fair value of the clinical and regulatory milestone payments.

As of December 31, 2019, the Company calculated the estimated fair value of the clinical and regulatory milestones using discount rates ranging from 7.7% to 11.1%.

For the commercial milestones, the Company used a Monte Carlo simulation because of the availability of a discrete revenue forecast and the increased likelihood that the clinical trials would commence. As of September 30, 2020, the Monte Carlo simulation assumed a commercial product launch and associated discrete revenue forecast, as well as the following significant unobservable inputs:

Unobservable input	Value or Range (Weighted-Average)[1]
Volatility	60%
Discount rate	11%
Probability of achievement	14% - 32% (30%)

(1) Unobservable inputs were weighted based on the relative fair value of the commercial milestone payments.

As of December 31, 2019, the Company's Monte Carlo simulation assumed a commercial product launch and associated discrete revenue forecast, an expected revenue volatility of 55%, and a discount rate of 13%. The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. As of September 30, 2020 and December 31, 2019, the estimated fair value of the contingent consideration related to the Humabs acquisition was $42.5 million and $14.9 million, respectively, with changes in the estimated fair value recorded in research and development expense in the condensed consolidated statements of operations.

The estimated fair value of the contingent consideration related to the TomegaVax acquisition was determined by using a Monte Carlo simulation model which included estimates of both the probability and timing to achieve the required per share price of the Company's common stock, and incorporates assumptions as to expected volatility and discount rate. The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. Although the TomegaVax acquisition was accounted for as an asset acquisition, such contingent consideration met the definition of an embedded derivative financial instrument. As of September 30, 2020, the fair value of the contingent consideration was estimated using the following significant unobservable inputs:

Unobservable input	Range (Weighted-Average)[1]
Volatility	85%
Discount rates	0.0% - 0.2% (0.1%)

(1) Unobservable inputs were weighted based on the relative fair value of the underlying milestones.

As of December 31, 2019, the fair value of the contingent consideration was estimated using expected volatility of 81%, and discount rates ranging from 1.6% to 1.7%. As of September 30, 2020 and December 31, 2019, the estimated fair value of the contingent consideration related to the TomegaVax acquisition was $9.5 million and $2.7 million, respectively, with changes in the estimated fair value recorded in other income (expense), net in the condensed consolidated statements of operations.

The estimated fair value of the contingent consideration related to the Humabs and TomegaVax acquisitions involves significant estimates and assumptions which give rise to measurement uncertainty.

Derivative Liability

The derivative liability relates to the Milestone Shares (as defined in Note 7) in connection with the collaboration and license agreement (the "Alnylam Agreement") with Alnylam Pharmaceuticals, Inc. ("Alnylam"). See Note 7—Collaboration and License Agreements.

The estimated fair value of the derivative liability was calculated based on the estimated probabilities of the likelihood and timing to achieve the development milestone, a discount for lack of marketability, and the fair value of the Milestone Shares using the Company's closing stock price as of December 31, 2019 and March 10, 2020, the date the Company achieved the development milestone. As of December 31, 2019, the estimated fair value of the derivative liability was $12.4 million. On March 10, 2020, the Company remeasured and reclassified the derivative liability of $29.2 million to additional paid-in capital upon achievement of the development milestone.

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

	Contingent Consideration	Derivative Liability	Total
Balance at December 31, 2019	$ 17,580	$ 12,449	$ 30,029
Changes in fair value	44,432	16,796	61,228
Payment of contingent consideration related to Humabs acquisition	(10,000)	—	(10,000)
Reclassification of derivative liability to additional paid-in capital upon achievement of development milestone	—	(29,245)	(29,245)
Balance at September 30, 2020	$ 52,012	$ —	$ 52,012

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. The primary asset purchased in the acquisition was an in-process cytomegalovirus ("CMV") vector-based vaccine platform for use in HBV, HIV, and TB.

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 before 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 concerning 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.

The Company determined that the future milestone payments contain net settlement provisions and therefore, they were required to be accounted for as embedded derivatives under the relevant accounting guidance. As of September 30, 2020, the estimated fair value of the embedded derivative was $9.5 million.

Acquisition of Humabs

In August 2017, the Company acquired all of the outstanding equity of 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. In addition to the cash payment and issuance of common stock to the former Humabs shareholders at the acquisition date, 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, which the Company elected as a SARS-CoV-2 product.

In May 2020, the Company achieved one of the specified clinical milestones for the HBV product. As such, the Company paid $10.0 million related to this milestone event in June 2020. The estimated fair value of the remaining contingent consideration was $42.5 million as of September 30, 2020. In October 2020, the Company achieved another specified clinical milestone for the SARS-CoV-2 product and paid $10.0 million related to this milestone event. See Note 15—Subsequent Event.

Acquisition of Agenovir

In January 2018, the Company entered into an agreement and plan of merger (the "Agenovir Merger Agreement") with Agenovir Corporation ("Agenovir"), under 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.

At the acquisition date, the Company paid cash and issued shares of Series A-2 convertible preferred stock to the former Agenovir stockholders. 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. The Company terminated the HPV program in February 2020 and no longer has any further obligations related to this program under the Agenovir Merger Agreement.

None of the milestones have been achieved as of September 30, 2020, therefore no amounts were recognized relating to the contingent consideration.

5. Goodwill and Intangible Assets

Goodwill

Goodwill of $16.9 million represents the excess of the purchase price over the estimated fair value of the net assets acquired from Humabs. The Company tests goodwill for impairment on an annual basis or sooner, if deemed necessary. There was no impairment for the three and nine months ended September 30, 2020 and 2019.

Intangible Assets

The following table summarizes the carrying amount of the Company's finite-lived intangible assets (in thousands):

	September 30, 2020	December 31, 2019
	(in thousands)	
Developed technology	$ 7,000	$ 7,000
Less accumulated amortization	(3,456)	(2,539)
Less impairment of intangible assets	(832)	—
Developed technology, net	$ 2,712	$ 4,461

Finite-lived intangible assets are carried at cost less accumulated amortization. Of the total cost of developed technology, $4.8 million and $2.2 million resulted from the acquisitions of Humabs and Statera Health, LLC, respectively. Amortization expense related to finite-lived intangible assets, included in research and development expenses in the consolidated statements of operations, totaled $0.3 million and $0.9 million for the three and nine months ended September 30, 2020, respectively, and $0.3 million and $0.9 million for the three and nine months ended September 30, 2019, respectively. Management reviews finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable, like that of property and equipment. During the quarter ended September 30, 2020, as a result of the availability of other research and analytics platforms, the Company abandoned certain of its acquired developed technologies and concluded that the full remaining book values of the assets were impaired. Therefore, $0.8 million was written off as an impairment charge which was classified as research and development expenses.

Indefinite-Lived Intangible Assets

As of September 30, 2020, the Company had indefinite-lived intangible assets of $31.2 million related to the purchased IPR&D from the Humabs acquisition. No impairment losses were recorded for the three and nine months ended September 30, 2020 and 2019.

6. Grant Agreements

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 under 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 zero and $0.9 million for the three and nine months ended September 30, 2019, respectively. No revenue was recognized for the three and nine months ended September 30, 2020.

Human Immunodeficiency Virus ("HIV") Grant

On January 26, 2018, the Company entered into a grant agreement with the Bill & Melinda Gates Foundation under which it was awarded a grant totaling up to $12.2 million for its HIV program (the "HIV Grant"). In February 2020, the parties amended the HIV Grant under which the Company was awarded a supplemental grant of $8.6 million. Under the amendment, the HIV Grant will remain in effect until December 31, 2021, 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 $0.8 million and $6.2 million for the three and nine months ended September 30, 2020, respectively, and $0.5 million and $3.4 million for the three and nine months ended September 30, 2019, respectively.

Tuberculosis ("TB") Grant

On March 16, 2018, the Company entered into a grant agreement with the Bill & Melinda Gates Foundation under which it was awarded a grant totaling up to $14.9 million for its TB program (the "TB Grant"). The parties amended the agreement in May 2020 under which the grant term was extended to February 28, 2021, 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. The Company currently estimated that $3.8 million of the funds received in advance and previously recorded as deferred revenue would not be earned by February 2021 and is therefore included within accrued and other liabilities as of September 30, 2020.

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 $0.9 million and $1.0 million for the three and nine months ended September 30, 2020, respectively, and $0.4 million and $1.8 million for the three and nine months ended September 30, 2019, 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, 2020, the Company has acquired or been awarded grants from NIH totaling $5.1 million. These grants are cost plus fixed fee agreements under 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 a government audit.

The Company recognized grant revenue of $0.1 million and $0.5 million for the three and nine months ended September 30, 2020, respectively, and $0.2 million and $0.7 million for the three and nine months ended September 30, 2019, respectively.

7. Collaboration and License Agreements

GSK

On June 9, 2020, the Company, Glaxo Wellcome UK Limited and Beecham S.A. (together, "GSK") entered into a definitive collaboration agreement under the terms set forth in the preliminary collaboration agreement entered into by the Company and certain GSK entities in April 2020 (the "Preliminary Agreement") (such definitive collaboration agreement, the "GSK Agreement"). Concurrently with the execution of the Preliminary Agreement, the Company entered into a stock purchase agreement (the "Stock Purchase Agreement") with Glaxo Group Limited ("GGL"), an affiliate of GSK, under which GGL purchased 6,626,027 shares of the Company's common stock on April 29, 2020, at a price per share of $37.73, for an aggregate purchase price of approximately $250.0 million. After receipt of antitrust clearance on April 22, 2020, the Preliminary Agreement became effective as of April 29, 2020, which was also the closing date for the associated Stock Purchase Agreement between the parties ("Effective Date"). Under the terms of the GSK Agreement, the Company and GSK agreed to collaborate to research, develop and commercialize products for the prevention, treatment and prophylaxis of diseases caused by SARS-CoV-2, the virus that causes COVID-19, and potentially other coronaviruses. The collaboration is focused on the development and commercialization of three types of collaboration products under three programs: (1) antibodies targeting SARS-CoV-2, and potentially other coronaviruses (the "Antibody Program"); (2) vaccines targeting SARS-CoV-2, and potentially other coronaviruses (the "Vaccine Program"), and (3) products based on genome-wide CRISPR screening of host targets expressed in connection with exposure to SARS-CoV-2, and potentially other coronaviruses (the "Functional Genomics Program").

For a period of four years following the Effective Date, the parties will conduct certain research and development activities under mutually agreed development plans and associated budgets for each of the three programs, and under the oversight of a joint steering committee ("JSC"). The Company will be primarily responsible for the development and clinical manufacturing activities for the Antibody Program, and for conducting the initial development activities directed to a vaccine in the Vaccine Program. GSK will be primarily responsible for the commercialization activities for the Antibody Program (except in connection with sales of antibody products licensed to WuXi Biologics (Hong Kong) Limited in greater China), the later-stage development, manufacturing and commercialization activities for the Vaccine Program and the development, manufacturing and commercialization activities for the Functional Genomics Program. Subject to an opt-out mechanism, the parties will share all development costs, manufacturing costs and costs and expenses for the commercialization of the collaboration products, with the Company bearing 72.5% of such costs for the antibody products, 27.5% of such costs for the vaccine products, and equal sharing of such costs for the functional genomics products.

On a collaboration product-by-collaboration product basis, each party will have the one-time right, at specified points in development, to opt- out of its co-funding obligations, and the other party may, at its election, either pursue such program unilaterally, or also cease research and development activities and funding of such collaboration product. If the opt-out provisions are not exercised by either party subject to the terms of the GSK Agreement, the parties would share all profits and losses arising from any collaboration product in the same ratios in which the parties bore development costs for such collaboration program. For each collaboration product as to which a party exercises its opt-out right, the commercializing party will pay to the opt-out party royalties on net sales of the applicable collaboration product at rates based on factors such as the stage of development of such collaboration product at the time the opt-out party exercises such right, and whether the opt-out party is the lead party, or a portion of the sublicense revenue if the commercializing party chooses to sublicense or otherwise divest rights to such collaboration product. On an antibody product-by-antibody product basis, the Company has a co-promotion right with respect to such antibody product in the United States, under which the Company will have the right to perform up to 20% of details in connection with such antibody product.

The GSK Agreement will remain in effect with respect to each collaboration program for as long as there is a collaboration product being developed or commercialized by the lead party, or the non-opt-out party, in such program. Either party has the right to terminate the GSK Agreement in the case of the insolvency of the other party, an uncured material breach of the other party with respect to a collaboration program or collaboration product, or as mutually agreed by the parties. The GSK Agreement superseded and replaced the Preliminary Agreement between the parties.

The Company considered the ASC 606 criteria for combining contracts and determined that the GSK Agreement and Stock Purchase Agreement should be combined into a single contract because they were negotiated and entered into in contemplation of one another. The fair market value of the common stock issued to GGL was $206.7 million, based on the closing stock price of $36.70 on the date of execution of the Preliminary Agreement and Stock Purchase Agreement and taking into account a discount for the lack of marketability due to the restrictions in place on the underlying shares, resulting in a $43.3 million premium received by the Company. The Company accounted for the common stock issued to GGL based on its fair market value on the transaction date and determined that the premium paid by GSK should be attributed to transaction price of the GSK Agreement.

The Company concluded that the GSK Agreement contained four units of account: (i) the license granted to GSK under the Antibody Program (the "Antibody License"); (ii) the research and development activities (including clinical manufacturing) under the Antibody Program; (iii) the research and development activities under the Vaccine Program; and (iv) the research and development activities under the Functional Genomics Program. The Company considered the guidance in ASC 606 to determine which of these elements of the GSK Agreement are performance obligations with a customer. The Company determined that the Antibody License is within the scope of ASC 606 and accordingly, accounted for the Antibody License as a distinct performance obligation under ASC 606. The Antibody License is a functional intellectual property and is distinct from the associated research and development activities to be performed under the program due to its significant standalone functionality. All other elements of the GSK Agreement including the research and development activities, and participation in the JSC and subcommittees for each collaboration program were not determined to be distinct performance obligations with a customer.

The transaction price for the Antibody License at inception was determined to be $43.3 million, representing the premium on the sale of common stock to GSK. The Company determined that GSK can benefit from the Antibody License at the time of grant and therefore, the related performance obligation is satisfied at a point in time. As such, the Company recognized the $43.3 million as contract revenue during the three months ended June 30, 2020. Additionally, the Company is entitled to consideration from GSK related to profit and loss sharing arrangements (including royalties) contingent upon future sales of collaboration products under the Antibody Program. In accordance with ASC 606, the Company will recognize the revenue when the related sales occur as these amounts have been determined to relate predominantly to the Antibody License granted to GSK. The Company will re-evaluate the transaction price in each reporting period.

The remaining units of account of the GSK Agreement were determined to be within the scope of ASC 808 as the Company and GSK are both active participants in the development, manufacturing and commercialization activities and are exposed to significant risks and rewards that are dependent on commercial success of the activities of the arrangement. Furthermore, the Company and GSK participate in the commercial profit and loss sharing arrangement for each program commensurate with each party's cost-sharing responsibilities during research and development. Because ASC 808 does not provide recognition and measurement guidance, the Company determined that the guidance in ASC 730, Research and Development, was appropriate to analogize to based on the nature of the cost-sharing provisions of the agreement. The Company has concluded that payments to or reimbursements from GSK related to these services will be accounted for as an increase to or reduction of research and development expenses, respectively. The Company also concluded that any payments from GSK related to the profit and loss sharing arrangement (including royalties) contingent upon the commercialization of the products under the Vaccine and Functional Genomics Programs will be analogized to ASC 606 and therefore, will be recognized when the related sales occur.

Costs associated with co-development activities performed under the agreement are included in research and development expenses in the condensed consolidated statements of operations, with any reimbursement of costs by GSK reflected as a reduction of such expenses. During the three and nine months ended September 30, 2020, the Company recognized $1.2 million as additional research and development expense and $2.6 million as a reduction of research and development expense, respectively, under the GSK Agreement. The Company has a payable to GSK of $2.6 million included in accrued liabilities as of September 30, 2020.

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 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 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, the Company transferred to Alnylam a specified percentage of such equity consideration allocable to such program as discussed below.

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 the 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 that 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. The Company also recorded a contract liability of $6.6 million within deferred revenue which represents deferred consideration for the four options that the Company granted to Brii Bio. The deferred consideration will be recognized when Brii Bio exercises its options or the options expire. The Company accounts for its investment in Brii Bio Parent's ordinary shares at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment in Brii Bio Parent.

In February 2020, the Company, Alnylam and Brii Bio Parent executed a share transfer agreement under the terms of the Alnylam Agreement (see Alnylam section below). Under the share transfer agreement, the Company transferred a portion of its ordinary shares held in Brii Bio Parent to Alnylam in connection with the execution of the Brii Agreement. As of September 30, 2020 and December 31, 2019, the carrying value of the investment in Brii Bio was $5.7 million and $6.6 million, respectively, which is included in other assets on the condensed 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.

Option Exercise by Brii Bio

In June 2020, Brii Bio exercised its option to obtain exclusive rights to develop and commercialize compounds and products arising from VIR-2218 in the China Territory. As consideration for the Company's grant to Brii Bio of an exclusive license related to VIR-2218 in the China Territory, the Company received a $20.0 million option exercise fee in connection with the option exercise. Also, the Company is eligible to receive the following payments related to VIR-2218 in the China Territory: a $30.0 million regulatory milestone payment, up to $175.0 million in sales-based milestone payments, and royalties on net sales ranging from high-teens to high-twenties.

The Company evaluated the transaction under ASC 606 and identified one performance obligation consisting of the license granted to Brii Bio. Under the Brii Agreement, Brii Bio is responsible for performing all research and development activities and the Company does not have any other performance obligations within the context of ASC 606 under the arrangement after the option exercise. The transaction price is determined to be $22.7 million which consists of the $20.0 million option exercise fee and $2.7 million of the deferred revenue allocated to the VIR-2218 option at inception of the Brii Agreement. The Company determined that the license is considered a functional intellectual property that is a distinct performance obligation. Specifically, the Company believes the license is capable of being distinct, as Brii Bio has the capabilities to develop the license either on its own or by contracting other third-parties. Brii Bio can benefit from the license at the time of grant and therefore, the related performance obligation is satisfied at a point in time. Additionally, all potential future milestones and other payments are constrained because the Company cannot conclude it is probable that a significant reversal in the amount recognized would not occur. The Company will re-evaluate the transaction price in each reporting period.

During the three months ended June 30, 2020, the Company recognized the $22.7 million as license revenue from a related party. The Company separately paid $10.0 million, half of the option exercise proceeds, to Alnylam in June 2020 in connection with the Alnylam Agreement that was recognized as research and development expense during the three months ended June 30, 2020.

Alnylam

October 2017 Agreement

In October 2017, the Company entered into the Alnylam Agreement 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 the 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. 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 Parent, to Alnylam. Accordingly, the Company recognized a liability of $0.8 million which remained outstanding as of December 31, 2019. In February 2020, the Company settled this liability by transferring to Alnylam a specified percentage of its equity consideration received from Brii Bio Parent.

Upon the achievement of a certain development milestone, as further discussed below, the Company was obligated to 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 "Milestone Shares"). 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.

The term of the Alnylam Agreement will continue, on a product-by-product and country-by-country basis, until the 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.

At the inception of the Alnylam Agreement, the Milestone Shares did not meet the net settlement criteria to be accounted for as an embedded derivative. Therefore, there was no liability recorded from the inception of the Alnylam Agreement through September 30, 2019. Upon completion of the Company's IPO in October 2019, the net settlement criteria of the definition of an embedded derivative had been met for the Milestone Shares. The initial fair value of the embedded derivative was estimated to be $13.6 million and was charged to research and development expense in the fourth quarter of 2019. The estimated fair value of the derivative liability was $12.4 million as of December 31, 2019. On March 10, 2020, the Company achieved the specified development milestone relating to the Milestone Shares and was obligated to issue the Milestone Shares within 60 days of such milestone event. Consequently, the Company remeasured and reclassified the derivative liability to additional paid-in capital. The estimated fair value of the derivative liability was $29.2 million as of March 10, 2020. In May 2020, the Company issued Alnylam 1,111,111 shares of the Company's common stock. In addition to these Milestone Shares, the Company was also obligated to pay Alnylam $15.0 million as of March 31, 2020 in connection with the achievement of the specified development milestone. The $15.0 million milestone was paid in April 2020.

Second Amendment

In March 2020, the Company and Alnylam entered into a second amendment to the Alnylam Agreement (as amended, the "Amended Alnylam Agreement") to expand the parties' existing collaboration to include the development and commercialization of RNAi therapeutics targeting SARS-CoV-2, the virus that causes the disease COVID-19, and potentially other related coronaviruses, utilizing Alnylam's recent advances in lung delivery of novel conjugates of siRNA – the molecules that mediate RNAi (the "COV Products").

Pursuant to the Amended Alnylam Agreement, the parties will each be responsible for pre-clinical development costs incurred by such party in performing its allocated responsibilities under an agreed-upon initial pre-clinical development plan for COV Products. The parties will equally share certain costs incurred in connection with the manufacture of non-GMP drug product required for pre-clinical development prior to filing of an investigational new drug application for the first COV Product in the coronavirus program. Following the completion of initial pre-clinical development activities, if the Company exercises its option to progress one or more candidates from the coronavirus program into further development, the Company will be responsible for conducting all development, manufacturing and commercialization activities for COV Products, at its sole expense, subject to Alnylam's right to opt-in, during a specified period, to share equally with the Company the profits and losses in connection with development and commercialization of COV Products.

If the Company exercises its option for the coronavirus program, and successfully develops one or more COV Products arising from such program, then unless Alnylam exercises its profit-sharing option, the Company will be required to pay Alnylam up to $15.0 million in the aggregate for the achievement of specified development milestones for the COV Products. Following commercialization, the Company will also be required to pay Alnylam specified sales milestones on the achievement of specified levels of annual net sales, and a tiered royalty at specified rates on annual net sales of the applicable COV Products.

Third Amendment

On April 1, 2020, the Company and Alnylam entered into a third amendment to the Alnylam Agreement to further expand the parties' existing collaboration to include the development and commercialization of RNAi therapeutics targeting up to three human host factor targets relating to susceptibility to coronaviruses, for use in connection with the treatment, palliation, diagnosis or prevention of COVID-19, and other diseases caused by coronaviruses. The products arising from the activities directed to the host factor targets may utilize Alnylam's recent advances in lung delivery of novel conjugates of siRNA – the molecules that mediate RNAi (the "Host Factor Products").

Pursuant to this amendment, the parties will each be responsible for pre-clinical development costs incurred by such party in performing its allocated responsibilities under an agreed-upon initial pre-clinical development plan for Host Factor Products. The parties will equally share certain costs incurred in connection with the manufacture of non-GMP drug product required for pre-clinical development prior to the filing of an investigational new drug application for the first Host Factor Product in the coronavirus program. Following the completion of initial pre-clinical development activities, if the Company exercises its option to progress one or more candidates arising from the coronavirus program into further development, the Company will be responsible for conducting all development, manufacturing and commercialization activities for Host Factor Products, at its sole expense, subject to Alnylam's right to opt-in, during a specified period, to share equally with the Company the profits and losses in connection with development and commercialization of Host Factor Products.

If the Company exercises its program option for the coronavirus program, and successfully develops one or more Host Factor Products arising from such program, then unless Alnylam exercises its profit-sharing option, the Company will be required to pay Alnylam up to $15.0 million in the aggregate for the achievement of specified development milestones for the Host Factor Products. Following commercialization, the Company will also be required to make specified milestone payments to Alnylam on the achievement of specified levels of annual net sales, and a tiered royalty at specified rates on annual net sales of the applicable Host Factor Products.

Research and Development Expenses Recognized for the Period

In addition to the Milestone Shares and $15.0 million milestone payable to Alnylam in the first quarter of 2020, and the $10.0 million payment resulting from Brii Bio's option exercise in the second quarter of 2020, the Company incurred expenses under the Alnylam Agreement of $0.8 million and $5.6 million during the three and nine months ended September 30, 2020, respectively. During the three and nine months ended September 30, 2019, the Company incurred expenses under the Alnylam Agreement of $7.5 million and $10.7 million, respectively.

WuXi Biologics

In February 2020, the Company entered into a development and manufacturing collaboration agreement with WuXi Biologics (Hong Kong) Limited ("WuXi Biologics") (the "WuXi Biologics Collaboration Agreement"), for the clinical development, manufacturing, and commercialization of the Company's proprietary antibodies developed for SARS-CoV-2. Under the WuXi Biologics Collaboration Agreement, WuXi Biologics will conduct cell-line development, process and formulation development, and initial manufacturing for clinical development. WuXi Biologics will have the right to commercialize products incorporating such antibodies in greater China pursuant to an exclusive license granted for the selected antibodies that have been developed. The Company will have the right to commercialize such products in all other markets worldwide.

WuXi Biologics will perform mutually agreed development and manufacturing activities, under individual statements of work. In addition, the parties agreed that WuXi Biologics will pay the Company tiered royalties at percentages ranging from the high single-digits to mid-teens on annual net sales of all products sold by WuXi Biologics in greater China. The royalties are payable for a specified, standard royalty term. In addition, if WuXi Biologics sublicenses its commercialization rights to a third party, WuXi Biologics will pay the Company a percentage of the sublicense revenue received from such third party. The WuXi Biologics Collaboration Agreement will continue until the expiration of WuXi's payment obligations to the Company, unless terminated earlier. If terminated earlier, the WuXi Biologics Collaboration Agreement may be terminated by (i) the written agreement of both parties, (ii) WuXi Biologics following the one year anniversary of the WuXi Biologics Collaboration Agreement effective date with respect to the entire agreement or on a product by product basis with 90 days' prior written notice or (iii) by either party if the other party materially breaches the WuXi Biologics Collaboration Agreement and fails to cure such breach within sixty days.

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 candidates VIR-3434 and VIR-7832.

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.

In May 2020, the Company achieved one of the specified development milestones related to the HBV program. The Company recognized $1.3 million related to this milestone event and annual license maintenance fees as research and development expense during the nine months ended September 30, 2020. For the nine months ended September 30, 2019, the Company recognized $1.0 million of license maintenance fees as research and development expense. No expenses were recognized during the three months ended September 30, 2020 and 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 Company will be obligated to make development, regulatory, and commercial milestone payments of up to $331.5 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 under 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.

Xencor

August 2019 License Agreement

In August 2019, the Company entered into a patent license agreement (the "2019 Xencor Agreement") with Xencor, Inc., ("Xencor"). Under the 2019 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, which 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.

In August 2019, the Company achieved one of the specified development milestones related to the influenza A program. As such, the Company paid $0.8 million related to the upfront fee and this milestone event in September 2019. In May 2020, the Company achieved one of the specified development milestones related to the HBV program. As such, the Company paid $0.3 million related to this milestone event in June 2020. The milestone payments are expensed to research and development.

March 2020 License Agreement

In March 2020, the Company entered into a patent license agreement (the "2020 Xencor Agreement") with Xencor under which the Company obtained a non-exclusive, sublicensable (only to the Company's affiliates and subcontractors) license to incorporate Xencor's half-life extension Fc region-related technologies into, and to evaluate, antibodies that target any component of a coronavirus, including SARS-CoV-2, SARS-CoV and MERS-CoV, 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 coronavirus research programs. These technologies are used in the Company's VIR-7831 and VIR-7832 product candidates.

In consideration for the grant of the license, the Company will be obligated to pay royalties based on net sales of licensed products in the mid-single-digits. The royalties are payable, on a product-by-product and country-by-country basis, until the later of the expiration of the last to expire valid claim in the licensed patents covering such product in such country or 12 years.

The 2020 Xencor Agreement and 2019 Xencor Agreement will remain in force, on a product-by-product and country-by-country basis, until the expiration of all royalty payment obligations under each of the respective agreements. The Company may terminate each agreement in its entirety, or on a target-by-target basis, for convenience upon 60 days' written notice. Either party may terminate each 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 each 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 each respective agreement.

8. Balance Sheet Components

Property and Equipment, net

Property and equipment, net consists of the following:

	September 30, 2020	December 31, 2019
	(in thousands)	
Laboratory equipment	$ 14,174	$ 11,986
Computer equipment	556	540
Furniture and fixtures	1,444	1,351
Leasehold improvements	7,274	7,121
Construction in progress	1,517	142
Property and equipment, gross	24,965	21,140
Less accumulated depreciation and amortization	(8,017)	(4,832)
Total property and equipment, net	$ 16,948	$ 16,308

Depreciation and amortization expenses was $1.1 million and $3.2 million for the three and nine months ended September 30, 2020, respectively, and $0.9 million and $2.4 million for the three and nine months ended September 30, 2019, 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, 2020, the current and long-term portions of the financing obligation were $0.3 million and $0.7 million, respectively.

Accrued and Other Liabilities

Accrued and other liabilities consist of the following:

	September 30, 2020	December 31, 2019
	(in thousands)	
Research and development expenses	$ 23,227	$ 12,530
Payroll and related expenses	9,607	9,410
Excess funds payable under grant agreements	3,893	94
Operating lease liabilities, current	3,459	—
Restricted stock liability	119	1,434
Financing lease obligation, current	253	237
Other professional and consulting expenses	2,894	1,634
Other accrued expenses	887	1,156
Total accrued and other liabilities	$ 44,339	$ 26,495

9. Commitments and Contingencies

Lease Agreements

The Company has various lease arrangements for office and laboratory space located in California, Oregon, Missouri and Switzerland with contractual lease periods expiring between 2021 and 2028. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain lease agreements also provide the Company with the option to renew for additional periods ranging from one to five years. These renewal options are not considered in the remaining lease term unless it is reasonably certain that the Company will exercise such options. In addition, the Company entered into a sale-leaseback transaction in August 2019. See further discussion in Note 8—Balance Sheet Components.

Throughout the term of the lease agreements, the Company is responsible for paying certain operating costs, in addition to rent, such as common area maintenance, taxes, utilities and insurance. These additional charges are considered variable lease costs and are recognized in the period in which the costs are incurred.

The following table contains a summary of the lease costs recognized under ASC 842 and additional information related to operating leases for the three and nine months ended September 30, 2020:

(in thousands)	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2020
Operating lease cost	$ 1,151	$ 3,432
Short-term lease cost	118	435
Variable lease cost	460	1,700
Total least cost	$ 1,729	$ 5,567
Other Information		
Weighted average remaining lease term (in years)		4.3 years
Weighted average incremental borrowing rate		7.7%

Cash paid for amounts included in the measurement of operating lease liabilities for the nine months ended September 30, 2020 was $3.4 million and was included in net cash used in operating activities in the Company's condensed consolidated statement of cash flows.

The maturity of the Company’s operating lease liabilities as of September 30, 2020 was as follows (in thousands):

	Amounts
2020 (excluding the nine months ended September 30, 2020)	$ 1,155
2021	4,472
2022	4,219
2023	4,271
2024	3,007
Thereafter	1,095
Total lease payments	18,219
Less: imputed interest	(2,668)
Present value of operating lease liabilities	$ 15,551

The following amounts were recorded in the condensed consolidated balance sheet as of September 30, 2020 (in thousands):

Operating Leases	
Operating right-of-use assets	$ 14,762
Accrued and other liabilities	$ 3,459
Operating lease liabilities, noncurrent	12,092
Total operating lease liabilities	$ 15,551

Rent expense under ASC 840 was $1.2 million and $3.2 million for the three and nine months ended September 30, 2019, respectively.

Manufacturing and Supply Letter Agreements

Letter Agreement, Assignment and Master Services Agreement with Samsung

On April 9, 2020, the Company and Samsung Biologics Co., Ltd. ("Samsung") entered into a binding letter agreement (the "Samsung Letter Agreement"), pursuant to which Samsung will perform development and manufacturing services for the Company's SARS-CoV-2 antibody program. Under the terms of the Samsung Letter Agreement, the Company had committed to purchase a firm and binding capacity reservation for a specified number of manufacturing slots in 2021 and 2022. The Company was obligated to pay a total of approximately $362 million for such capacity reservation on a take-or-pay basis regardless of whether such manufacturing slots are utilized by the Company, subject to annual adjustment based on the Korean Consumer Price Index, which also includes certain fees relating to project management and technology transfer. The amounts will be payable during 2021 and 2022 and invoiced on a per-batch basis, with shortfalls invoiced at the end of the year in which such shortfall occurs.

On August 4, 2020, the Company, GlaxoSmithKline Trading Services Limited ("GSKTSL") and Samsung entered into an Assignment and Novation Agreement effective as of July 31, 2020 pursuant to which the Company assigned and transferred to GSKTSL all of the Company's right, title, and interest in, to and under the Samsung Letter Agreement, and GSKTSL became the Company's successor in interest in and to all of the Company's rights, duties, and obligations in, to and under the Samsung Letter Agreement. On August 4, 2020, GSKTSL entered into a Master Services Agreement with Samsung effective as of July 31, 2020 (the "Samsung MSA"), thereby superseding the Samsung Letter Agreement, and pursuant to which, among other things, Samsung will perform development and manufacturing services for clinical and commercial supply of antibody products under the Company's SARS-CoV-2 antibody program.

Letter Agreement, Assignment and Master Services Agreement with WuXi Biologics

On June 15, 2020, the Company and WuXi Biologics entered into a binding letter of intent (the "WuXi Biologics Letter Agreement"), pursuant to which WuXi Biologics will perform certain development and manufacturing services for the Company's SARS-CoV-2 antibody program. Under the terms of the WuXi Biologics Letter Agreement, the Company had committed to purchase a firm and binding capacity reservation for the manufacture of a specified number of batches of drug substance of the Company's SARS-CoV-2 antibody in 2020 and 2021. In addition, the Company had the right to order an additional specified number of batches of drug substance, provided it makes such election by a specified date in the fourth calendar quarter in 2020. WuXi Biologics is obligated to reserve such manufacturing slots on a non-cancellable basis, and will manufacture the agreed number of batches of drug substance in accordance with an agreed manufacturing schedule. The Company was obligated to pay a total of approximately $130.0 million for such capacity reservation, if all batches are manufactured, inclusive of estimated raw material costs, with between 70% and 80% of the batch production fees owed to WuXi Biologics on a take-or-pay basis regardless of whether such manufacturing slots are utilized by the Company. The amounts will be payable during 2020 and 2021 and invoiced on a per-batch basis. The SARS-CoV-2 antibody drug substance contemplated to be manufactured in accordance with the terms of the WuXi Biologics Letter Agreement will be utilized in connection with progressing the development and commercialization of the SARS-CoV-2 antibody product under the Company's collaboration with GSK.

On August 4, 2020, the Company, GSKTSL and WuXi Biologics entered into an Assignment and Novation Agreement effective as of July 29, 2020 pursuant to which the Company assigned and transferred to GSKTSL all of the Company's right, title, and interest in, to and under the WuXi Biologics Letter Agreement, and GSKTSL became the Company's successor in interest in and to all of the Company's rights, duties, and obligations in, to and under the WuXi Biologics Letter Agreement. On August 4, 2020, GSKTSL entered into a non-exclusive Master Services Agreement for Commercial Manufacture of Drug Substance with WuXi Biologics effective as of July 29, 2020 (the "WuXi Biologics MSA"), thereby superseding the WuXi Biologics Letter Agreement, and pursuant to which, among other things, WuXi Biologics will perform development and manufacturing services for clinical and commercial supply of antibody products under the Company's SARS-CoV-2 antibody program.

GSKTSL entered into the WuXi Biologics MSA and Samsung MSA in connection with the performance of the obligations of the Company and GSK, pursuant to the GSK Agreement. In accordance with the terms of the GSK Agreement, the Company will continue to be responsible for 72.5% of the costs under each of the WuXi Biologics MSA and Samsung MSA, and GSK will bear 27.5% of such costs under each of the Samsung MSA and the WuXi Biologics MSA, subject to certain conditions and exceptions.

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 obligation 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 condensed consolidated balance sheets, condensed consolidated statements of operations, or condensed consolidated statements of cash flows.

10. Related Party Transactions

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 11—Convertible Preferred Stock.

11. Convertible Preferred Stock

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

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 net proceeds of $327.5 million in two closings. The Company was authorized to sell up to 4,020,009 additional shares of Series B convertible preferred stock in one or more additional closings.

Upon closing of the IPO, all of the outstanding convertible preferred stock automatically converted into 88,112,733 shares of common stock. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding.

12. Common Stock Warrant

In September 2016, the Company issued a warrant to purchase an aggregate of 244,444 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 had an expiration date of September 11, 2026. The warrant was initially accounted for as a liability and was subject to remeasurement at each reporting period, with changes in estimated fair value recognized as a component of other income (expense), net. Upon completion of the IPO in October 2019, the warrant automatically converted into a warrant to purchase 244,444 shares of common stock. Therefore, the convertible preferred stock warrant liability was reclassified to additional paid-in capital. In May 2020, the holder exercised its warrant in a cashless exercise for which the Company issued an aggregate of 211,774 shares of common stock.

13. Stock-Based Awards

Stock Option Activity

Activity under the Company's stock option plans is set forth below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2019	7,186,298	$ 5.25	8.5	
Granted	4,175,235	$ 32.53		
Exercised	(1,387,629)	$ 2.55		
Forfeited	(514,889)	$ 13.78		
Outstanding at September 30, 2020	9,459,015	$ 17.22	8.7	$ 174,230
Vested and expected to vest at September 30, 2020	9,459,015	$ 17.22	8.7	$ 174,230
Vested and exercisable at September 30, 2020	2,194,929	$ 4.52	7.8	$ 65,422

As of September 30, 2020, the Company expects to recognize the remaining unamortized stock-based compensation expense of $107.9 million related to stock options, over an estimated weighted average period of 2.7 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,	
	2020	2019	2020	2019
Expected term of options (in years)	5.0 - 6.1	6.0	5.0 - 6.1	5.9 - 6.0
Expected stock price volatility	99.7% - 108.6%	88.5%	88.8% - 108.6%	88.5% - 89.4%
Risk-free interest rate	0.3% - 0.4%	1.9%	0.3% - 1.2%	1.9% - 2.5%
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 the Company's industry peers as the Company does not have a sufficient historical trading history for its own stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

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, 2019	2,075,511	$ 0.95
Vested	(1,791,880)	0.91
Unvested as of September 30, 2020	283,631	$ 1.15

The 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, under the terms of the notes, the Company received $3.3 million as repayment of the outstanding promissory notes and accrued interest. The Company has a liability of $0.1 million for the portion of the promissory note repayment which relates to restricted common stock subject to future vesting through October 31, 2020. The Company will reduce the restricted stock liability as the common stock vests.

As of September 30, 2020, there was $0.2 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 0.6 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 consolidated statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
Research and development	$ 4,181	$ 926	$ 8,369	$ 1,925
General and administrative	4,401	1,262	8,930	4,115
Total stock-based compensation	$ 8,582	$ 2,188	$ 17,299	$ 6,040

14. 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:

	As of September 30,	
	2020	2019
Convertible preferred stock	—	88,112,733
Options issued and outstanding	9,459,015	6,316,944
Restricted shares subject to future vesting	283,631	2,690,767
Warrants to purchase convertible preferred stock	—	244,444
Total	9,742,646	97,364,888

15. Subsequent Event

Milestone Payment to Humabs

In October 2020, the Company achieved one of the specified clinical milestones for the SARS-CoV-2 product under its acquisition agreement with Humabs and paid $10.0 million related to this milestone event. See Note 4—Acquisitions for additional information on the Company's acquisition agreement with Humabs.

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 as part of our Annual Report on Form 10-K for the year ended December 31, 2019. 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 among the leading causes of death worldwide and can cause trillions of dollars of direct and indirect economic burden each year – as evidenced by the current coronavirus disease 2019, or COVID-19, pandemic. 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 severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2 (the virus that causes COVID-19), hepatitis B virus, or HBV, influenza A virus, human immunodeficiency virus, or HIV, and tuberculosis, or TB.

- For SARS-CoV-2, VIR-7831, a SARS-CoV-2-neutralizing monoclonal antibody, or mAb, started the lead-in phase of a Phase 2/3 clinical trial program, which is referred to as the COVID-19 Monoclonal antibody Efficacy Trial - Intent to Care Early, or COMET-ICE study, in August 2020 for the early treatment of COVID-19 in patients who are at high risk of hospitalization. In October 2020, the COMET-ICE study continued into Phase 3 based on a positive evaluation of safety and tolerability data from the Phase 2 lead-in. We anticipate that interim Phase 3 data may be available as early as January 2021. Results for the primary endpoint are expected in the first quarter of 2021. We plan to initiate two additional Phase 3 trials in the COMET clinical development program for VIR-7831 – one for the treatment of hospitalized patients as a sub-study of the National Institutes of Health-sponsored ACTIV-3 trial, which is expected to begin as soon as regulatory and ethical approvals are in place, and another for prophylaxis or prevention of symptomatic infection, which is expected to begin in the first quarter of 2021. VIR-7832, a vaccinal SARS-CoV-2-neutralizing mAb, is planned to initiate a Phase 1b/2a clinical trial in the first quarter of 2021. VIR-2703, a SARS-CoV-2-targeting siRNA, is in preclinical studies led by Alnylam Pharmaceuticals, Inc., or Alnylam.

- For HBV, VIR-2218, an HBV-targeting siRNA, is currently in an ongoing Phase 2 clinical trial. Initial Phase 2 data have demonstrated substantial, durable, and dose dependent reduction of hepatitis B virus surface antigen, or HBsAg, and VIR-2218 has been generally well-tolerated. In July 2020, we initiated a Phase 2 clinical trial to combine VIR-2218 with pegylated interferon-alpha, an approved immune modulatory agent. Initial clinical data are anticipated in 2021. In addition, in May 2020, we initiated a Phase 1 clinical trial for VIR-3434, an HBV-neutralizing mAb. The results of this clinical trial are expected to enable us to initiate a Phase 2 combination trial of VIR-3434 in combination with VIR-2218 in 2021.

- For influenza A virus, VIR-2482, a mAb designed for the prevention of influenza A, is currently in a Phase 1/2 clinical trial and has been generally well-tolerated. Initiation of the Phase 2 trial for VIR-2482, which was delayed due to the impact of COVID-19, is now expected in the fourth quarter of 2021 with proof-of-concept results anticipated in the first half of 2022.

- For HIV, VIR-1111, an HIV T cell vaccine based on HCMV, is planned to initiate a Phase 1 trial in the fourth quarter of this year.

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 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. In October 2019, we completed our IPO pursuant to which we received net proceeds of $126.4 million, after deducting underwriting discounts, commissions and offering expenses. In July 2020, we completed a follow-on offering of our common stock and issued 8,214,285 shares of our common stock for net proceeds of $323.2 million, after deducting underwriting discounts, commissions and offering expenses. As of September 30, 2020, excluding restricted cash, we had $826.6 million in cash, cash equivalents and short-term investments. Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments as of September 30, 2020 will enable us to fund our operations through at least the next 12 months from the issuance date of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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 $193.0 million and $110.9 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $561.5 million. Our primary use of our capital resources is to fund our operating expenses, which consist primarily of expenditures related to identifying, acquiring, developing, manufacturing 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. For example, we and our partner have executed a number of collaboration agreements with additional large-scale CDMOs to plan for future scale-up and capacity, particularly to support development and potential commercialization.

Recent SARS-CoV-2 Activities

Since February 2020, we have entered into a number of collaboration agreements to accelerate the development, manufacture, and potential commercialization of therapies to treat and prevent SARS-CoV-2 and other coronaviruses. We have also made substantial efforts to protect our intellectual property in this area, as evidenced by the expansion of our patent portfolio.

Development and Commercialization

- In June 2020, we, Glaxo Wellcome UK Limited and Beecham S.A. (collectively referred to as GSK), entered into a definitive collaboration agreement, or the GSK Agreement, pursuant to which we agreed to collaborate to research, develop and commercialize products for the prevention, treatment and prophylaxis of diseases caused by SARS-CoV-2 and potentially other coronaviruses. The collaboration is focused on the development and commercialization of three types of collaboration products under three programs: (1) antibodies targeting SARS-CoV-2, and potentially other coronaviruses, or the Antibody Program; (2) vaccines targeting SARS-CoV-2, and potentially other coronaviruses, and (3) products based on genome-wide CRISPR screening of host targets expressed in connection with exposure to SARS-CoV-2. The initial antibodies under the Antibody Program are VIR-7831 and VIR-7832, which have demonstrated high affinity for the SARS-CoV-2 spike protein and are highly potent in neutralizing SARS-CoV-2 in live-virus cellular assays.

- In March and April 2020, we entered into two further amendments to our collaboration and license agreement with Alnylam to expand our existing collaboration of five infectious disease targets to nine, including one targeting SARS-CoV-2 and potentially other coronaviruses, and up to three targeting human host factors for SARS-CoV-2.

Manufacturing

- In February 2020, we entered into a development and manufacturing collaboration with WuXi Biologics (Hong Kong) Limited, or WuXi Biologics, for the clinical development, manufacturing, and commercialization of our proprietary antibodies developed for SARS-CoV-2. In addition, in June 2020, we entered into a binding letter of intent with WuXi Biologics, or the WuXi Biologics Letter Agreement, under which WuXi Biologics will perform certain development and manufacturing services for our SARS-CoV-2 antibody program. In July 2020, we assigned the WuXi Biologics Letter Agreement to GlaxoSmithKline Trading Services Limited, or GSKTSL, and GSKTSL entered into a non-exclusive Master Services Agreement for Commercial Manufacture of Drug Substance with WuXi Biologics, or the WuXi Biologics MSA, thereby superseding the WuXi Biologics Letter Agreement, and pursuant to which, among other things, WuXi Biologics will perform development and manufacturing services for clinical and commercial supply of antibody products under our SARS-CoV-2 antibody program. In accordance with the terms of the GSK Agreement, we will continue to be responsible for 72.5% of the costs under the WuXi Biologics MSA, and GSK will bear 27.5% of such costs, subject to certain conditions and exceptions.
- In May 2020, we entered into a clinical development and manufacturing agreement with Biogen, Inc., or Biogen, under which Biogen will perform process development activities and specified manufacturing services under agreed statements of work for certain pre-commercial and clinical supply of SARS-CoV-2 antibodies.
- In April 2020, we entered into a binding letter agreement, or the Samsung Letter Agreement, with Samsung Biologics Co., Ltd., or Samsung, under which Samsung will perform development and manufacturing services for our SARS-CoV-2 antibody program. In July 2020, we assigned the Samsung Letter Agreement to GSKTSL, and GSKTSL entered into a Master Services Agreement with Samsung, or the Samsung MSA, thereby superseding the Samsung Letter Agreement, and pursuant to which, among other things, Samsung will perform development and manufacturing services for clinical and commercial supply of antibody products under our SARS-CoV-2 antibody program. In accordance with the terms of the GSK Agreement, we will continue to be responsible for 72.5% of the costs under the Samsung MSA, and GSK will bear 27.5% of such costs, subject to certain conditions and exceptions.

COVID-19 Business Update

With the global spread of the current COVID-19 pandemic, we have implemented a number of plans and policies designed to address and mitigate the impact of the COVID-19 pandemic on our employees and our business. We continue to closely monitor the COVID-19 situation and will evolve our plans and policies as needed going forward. As a result of these developments, in March 2020, we implemented work-from-home policies for most of our employees. We have also implemented plans to reopen our offices to allow employees to return when appropriate. Although these plans are based on a phased approach consistent with local government requirements, and focused on employee safety, and contemplate returning to remote work should new restrictions be implemented, there is uncertainty regarding recent phased reopening, which may be rolled back, and restrictions re-implemented. We are also working to provide our employees with the support they need to ensure continuity of business operations. We are working closely with our CDMOs to manage our supply chain activities and mitigate any potential disruptions to our clinical trial supplies as a result of the COVID-19 pandemic. If the COVID-19 pandemic persists for an extended period of time and begins to impact essential distribution systems, we could experience disruptions to our supply chain and operations, and associated delays in the manufacturing of clinical trial supply. For some of our clinical development programs, we are experiencing, and may continue to experience, a disruption or delay in our ability to initiate trial sites and enroll and assess patients. For example, the initiation of the Phase 1 trial for VIR-1111 and Phase 2 trial for VIR-2482, which were delayed due to the impact of COVID-19, are now expected in the fourth quarter of 2020 and fourth quarter of 2021, respectively. In addition, we rely on contract research organizations or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic.

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 Note 6—Grant Agreements and Note 7—Collaboration and License 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) license and contract revenue. Grant revenue is comprised of revenue derived from grant agreements with government-sponsored and private organizations. License and contract revenue is comprised of revenue generated from license rights issued and 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, and contingent consideration from business acquisitions;
- 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, our ongoing assessments as to each product candidate's commercial potential and the impact of public health epidemics, such as the COVID-19 pandemic. 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, cash equivalents and investments.

Other Income (Expense), Net

Other income (expense), net consists of gains and losses from foreign currency transactions and the remeasurement of contingent consideration related to our acquisition of TomegaVax, Inc., or TomegaVax.

Provision for Income Taxes

Provision for income taxes consisted of immaterial international income tax.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2020 and 2019

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
	(in thousands)					
Revenue:						
Grant revenue	$ 1,740	$ 1,166	$ 574	$ 7,690	$ 6,771	$ 919
License revenue from a related party	—	—	—	22,747	—	22,747
Contract revenue	188	237	(49)	44,197	340	43,857
Total revenue	1,928	1,403	525	74,634	7,111	67,523
Operating expenses:						
Research and development	70,684	39,863	30,821	215,316	95,541	119,775
General and administrative	18,859	9,220	9,639	47,894	25,790	22,104
Total operating expenses	89,543	49,083	40,460	263,210	121,331	141,879
Loss from operations	(87,615)	(47,680)	(39,935)	(188,576)	(114,220)	(74,356)
Other income (expense):						
Interest income	412	2,012	(1,600)	2,548	6,564	(4,016)
Other income (expense), net	2,616	(2,659)	5,275	(6,904)	(3,251)	(3,653)
Total other income (expense)	3,028	(647)	3,675	(4,356)	3,313	(7,669)
Loss before benefit from (provision for) income taxes	(84,587)	(48,327)	(36,260)	(192,932)	(110,907)	(82,025)
Benefit from (provision for) income taxes	(22)	13	(35)	(84)	(5)	(79)
Net loss	$ (84,609)	$ (48,314)	$ (36,295)	$ (193,016)	$ (110,912)	$ (82,104)

Revenue

Total revenue was $1.9 million and $1.4 million for the three months ended September 30, 2020 and 2019, respectively, and $74.6 million and $7.1 million for the nine months ended September 30, 2020 and 2019, respectively. The increase in total revenue for the three months ended September 30, 2020 was primarily due to the timing of research activities under the HIV and TB grants with the Bill & Melinda Gates Foundation. The increase in total revenue for the nine months ended September 30, 2020 was primarily due to $43.3 million of revenue related to the license granted to GSK under our collaboration agreement, and $22.7 million of revenue related to Brii Biosciences Offshore Limited's, or Brii Bio's, exercise of its option to obtain exclusive rights to develop and commercialize compounds arising from VIR-2218 in greater China.

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,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
	(in thousands)					
Licenses, collaborations and contingent consideration	$ 20,579	$ 12,666	$ 7,913	$ 80,137	$ 12,356	$ 67,781
Personnel	17,323	11,762	5,561	46,488	31,879	14,609
Contract manufacturing	10,844	2,193	8,651	32,488	14,987	17,501
Clinical costs	7,414	3,080	4,334	14,913	5,912	9,001
Other	14,524	10,162	4,362	41,290	30,407	10,883
Total research and development expenses	$ 70,684	$ 39,863	$ 30,821	$ 215,316	$ 95,541	$ 119,775

Comparison of three months ended September 30, 2020 and 2019

Research and development expenses were $70.7 million and $39.9 million for the three months ended September 30, 2020 and 2019, respectively. This increase was primarily due to the following factors:

- contract manufacturing expense increased by $8.7 million, which was primarily attributable to an increase of $8.2 million related to initiation of manufacturing activities and process development for our SARS-CoV-2 programs;
- licenses, collaboration and contingent consideration expenses increased by $7.9 million, which was primarily attributable to increases of $18.8 million related to the change in fair value of the contingent consideration from our acquisition of Humabs Biomed SA, or Humabs, and $1.2 million in costs under our collaboration with GSK, partially offset by $5.7 million decrease in costs incurred under our collaboration agreement with Alnylam, $5.0 million milestone achieved in the third quarter of 2019 under our 2018 license agreement, or the 2018 MedImmune Agreement, with MedImmune, LLC, and $1.4 million decrease in various license fees and milestone with third parties;
- personnel-related expenses increased by $5.6 million, which was primarily attributable to an increase in our headcount;
- other research and development expenses increased by $4.4 million, which was primarily attributable to increases of $2.0 million in external research costs due to increased clinical and manufacturing activities, and $1.0 million in supplies and equipment costs to support our programs related to COVID-19; and
- clinical costs increased $4.3 million, which was primarily attributable to activities related to our VIR-7831, VIR-1111 and VIR-3434 clinical trials.

Comparison of nine months ended September 30, 2020 and 2019

Research and development expenses were $215.3 million and $95.5 million for the nine months ended September 30, 2020 and 2019, respectively. This increase was primarily due to the following factors:

- licenses, collaboration and contingent consideration expenses increased by $67.8 million, which primarily attributable to increases of $36.9 million related to the change in fair value of the contingent consideration from our acquisition of Humabs, $31.8 million on achievement of the first development milestone related to our Alnylam Agreement, and $10.0 million payment to Alnylam resulting from Brii Bio's exercise of its option for VIR-2218, partially offset by $5.0 million milestone achieved in the third quarter of 2019 under our 2018 MedImmune Agreement, $2.6 million reimbursement of costs pursuant to our collaboration with GSK and $2.3 million decrease in costs incurred under our collaboration agreement with Alnylam;
- contract manufacturing expense increased by $17.5 million, which was primarily attributable to an increase of $27.0 million related to initiation of manufacturing activities and process development for our SARS-CoV-2 programs, partially offset by a decrease of $9.0 million related to the manufacturing for HBV, HIV and influenza A drug products initiated in 2018 and completed in the first half of 2019;
- personnel-related expenses increased by $14.6 million, which was primarily attributable to an increase in our headcount;
- other research and development expenses increased by $10.9 million, which was primarily attributable to increases of $4.0 million in external research costs due to increased clinical and manufacturing activities, $3.3 million in supplies and equipment costs to support our programs related to COVID-19, and $2.7 million in the allocation of facilities costs due to an increase in our headcount; and
- clinical costs increased by $9.0 million, which was primarily attributable to activities related to our VIR-7831, VIR-1111 and VIR-3434 clinical trials.

General and Administrative Expenses

General and administrative expenses were $18.9 million and $9.2 million for the three months ended September 30, 2020 and 2019, respectively, and $47.9 million and $25.8 million for the nine months ended September 30, 2020 and 2019, respectively. The increase was primarily due to increases in personnel-related expenses related to additional headcount, legal fees, external consulting and other expenses due to costs associated with operating as a public company.

Interest Income

Interest income was $0.4 million and $2.0 million for the three months ended September 30, 2020 and 2019, respectively, and $2.5 million and $6.6 million for the nine months ended September 30, 2020 and 2019, respectively. The decrease was primarily due to lower interest rates on investment balances in the three and nine months ended September 30, 2020 compared to the same periods in 2019.

Other Income (Expense), Net

Other income, net was $2.6 million for the three months ended September 30, 2020 compared to other expense, net of $2.7 million for the three months ended September 30, 2019. Other expense, net was $6.9 million and $3.3 million for the nine months ended September 30, 2020 and 2019, respectively. The increase in other income or expense was primarily related to the change in fair value of the contingent consideration related to our acquisition of TomegaVax.

Liquidity, Capital Resources and Capital Requirements

Sources of Liquidity

As of September 30, 2020, excluding restricted cash, we had $826.6 million in cash, cash equivalents and short-term investments, and an accumulated deficit of $561.5 million. We have financed our operations primarily through sales of our common stock and convertible preferred securities and payments received under our grant and collaboration agreements.

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 $126.4 million in net proceeds, after deducting underwriting discounts and commissions of approximately $10.0 million and offering expenses of approximately $6.4 million. In April 2020, we issued 6,626,027 shares of our common stock to Glaxo Group Limited (an affiliate of GSK) at a price per share of $37.73, for an aggregate purchase price of approximately $250.0 million. In July 2020, we completed a follow-on offering of our common stock and issued 8,214,285 shares of our common stock for net proceeds of $323.2 million, after deducting underwriting discounts, commissions and offering expenses.

Our primary use of our capital resources is to fund our operating expenses, which consist primarily of expenditures related to identifying, acquiring, developing, manufacturing 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 our existing cash, cash equivalents and short-term investments as of September 30, 2020 will enable us to fund our operations through at least the next 12 months from the issuance date of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. 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. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic and rapidly evolving nature of our business and the COVID-19 pandemic environment generally. We will also need to raise additional capital to complete the development and commercialization of our product candidates and fund certain of our existing manufacturing and other commitments. 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. In addition, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of 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,	
	2020	2019
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (108,889)	$ (90,747)
Investing activities	(70,575)	(182,389)
Financing activities	529,733	319,144
Net increase in cash and cash equivalents and restricted cash and cash equivalents	$ 350,269	$ 46,008

Operating Activities

During the nine months ended September 30, 2020, net cash used in operating activities was $108.9 million. This consisted primarily of a net loss of $193.0 million and a payment on contingent consideration of $6.5 million related to a milestone achieved related to our Humabs acquisition, partially offset by a decrease in our net operating assets of $3.6 million and non-cash charges of $87.0 million. The change in our net operating assets of $3.6 million was primarily due to an increase in accrued liabilities and other long-term liabilities by $13.2 million and an increase in accounts payable of $1.0 million due to higher research and development activities, which was partially offset by a decrease in deferred revenue of $5.7 million related to revenue recognized from the Bill & Melinda Gates Foundation grants, and a decrease in operating lease liabilities of $2.3 million due to lease payments. The non-cash charges of $87.0 million primarily consisted of $44.4 million for revaluation of contingent consideration, $16.8 million for the change in fair value of the derivative liability under the Alnylam Agreement, $17.3 million for stock-based compensation expense, and $3.2 million for depreciation and amortization.

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 $6.5 million and non-cash charges of $13.7 million. The change in our net operating assets of $6.5 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.

Investing Activities

During the nine months ended September 30, 2020, net cash used in investing activities was $70.6 million. This consisted primarily of purchases of investments of $363.4 million and purchases of property and equipment of $4.1 million, partially offset by $296.8 million in proceeds received from investments which matured during the period.

During the nine months ended September 30, 2019, net 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.

Financing Activities

During the nine months ended September 30, 2020, net cash provided by financing activities was $529.7 million. This consisted primarily of proceeds received from the issuance of our common stock to GSK of $206.7 million in April 2020, the issuance of our common stock related to our follow-on offering of $323.2 million and from exercises of stock options of $3.5 million, partially offset by a payment of contingent consideration related to our Humabs acquisition of $3.5 million.

During the nine months ended September 30, 2019, net cash provided by 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.

Contractual Obligations and Commitments

Except as discussed in Note 9—Commitments and Contingencies to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, there have been no material changes from the contractual obligations previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019.

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 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 that 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 comply with certain 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.

In light of our public float at June 30, 2020, we expect that we will no longer be an emerging growth company on December 31, 2020.

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.

Except as noted below and in Note 2 to the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, there have been no significant changes in our critical accounting policies during the nine months ended September 30, 2020, as compared with those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 26, 2020.

Revenue Recognition

License and Contract Revenue

In accordance with Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, or ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods and services. To determine revenue recognition for arrangements within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as we satisfy a performance obligation.

For collaborative arrangements that fall within the scope of ASC 808, Collaborative Arrangements, or ASC 808, we first determine which elements of the collaboration are deemed to be a performance obligation with a customer within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808 and are not subject to the guidance in ASC 606, we apply the revenue recognition model under ASC 606 or other guidance, as deemed appropriate. We have entered into a number of license and collaboration agreements that fall within the scope of ASC 606. We evaluate the promised goods or services in these agreements to determine which ones represent distinct performance obligations. These agreements may include the following types of promised goods or services: (i) grants of licenses, (ii) performance of research and development services, and (iii) participation on joint research and/or development committees. They also may include options to obtain licenses to our intellectual property.

Prior to recognizing revenue, we makes estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. These estimates are re-assessed each reporting period as required. These agreements may include the following types of consideration: non-refundable upfront payments, reimbursement for research services, research, development or regulatory milestone payments, and royalty and commercial sales milestone payments.

If there are multiple distinct performance obligations, we allocate the transaction price to each distinct performance obligation based on their estimated standalone selling prices, or SSP. For performance obligations satisfied over time, we estimate the efforts needed to complete the performance obligation and recognize revenue by measuring the progress towards complete satisfaction of the performance obligation using an input measure.

For arrangements that include sales-based royalties, including commercial milestone payments based on pre-specified level of sales, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon performance of the licensee.

Management may be required to exercise considerable judgment in estimating revenue to be recognized. Judgment is required in identifying performance obligations, estimating the transaction price, estimating the SSP of identified performance obligations, which may include development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success, and estimating the progress towards satisfaction of performance obligations.

Leases

On January 1, 2020, we adopted ASC 842, Leases, or ASC 842, using the optional transition method and applied the standard only to leases that existed at that date. Under the optional transition method, we do not need to restate the comparative periods in transition and will continue to present financial information and disclosures for periods before January 1, 2020 in accordance with ASC 840. We elected the package of practical expedients allowed under ASC 842, which permits us to account for our existing operating leases as operating leases under the new guidance, without reassessing our prior conclusions about lease identification, lease classification and initial direct cost. As a result of the adoption of the new lease accounting guidance, on January 1, 2020 we recognized operating lease right-of-use assets, or ROU, of $16.8 million and operating lease liabilities of $17.5 million. The difference between the ROU assets and lease liabilities is attributed to the elimination of deferred rent.

We determine if an arrangement is or contains a lease at inception by assessing whether the arrangement contains an identified asset and whether we have the right to control the identified asset. ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Lease liabilities are recognized at the lease commencement date based on the present value of future lease payments over the lease term. ROU assets are based on the measurement of the lease liability and also include any lease payments made prior to or on lease commencement and exclude lease incentives and initial direct costs incurred, as applicable.

As the implicit rate in our leases is generally unknown, we use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. When calculating the estimated incremental borrowing rates, we consider our credit risk, the lease term, the total lease payments and the impact of collateral, as necessary. The lease terms may include options to extend or terminate the lease when we are reasonably certain we will exercise such options. Rent expense for our operating leases is recognized on a straight-line basis within operating expenses over the reasonably assured lease term.

We elected to not separate lease and non-lease components for any leases within our existing classes of assets and, as a result, account for the lease and non-lease components as a single lease component. We also elected to not apply the recognition requirement to any leases within our existing classes of assets with a term of 12 months or less.

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 relate to interest rate sensitivities.

Interest Rate Risk

We had cash, cash equivalents and restricted cash and cash equivalents of $473.1 million as of September 30, 2020, which consisted of money market funds. We also had short-term investments of $364.1 million as of September 30, 2020. 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 and our holdings in U.S. government treasury bonds mature prior to our expected need for liquidity, 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, 2020.

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 and Australian subsidiaries and consequently the Swiss Franc and Australian dollar. Transaction gains and losses are included in other income (expenses), net on the condensed consolidated statements of operations and were not material for the nine months ended September 30, 2020 and 2019.

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

There were no changes in our internal control over financial reporting that occurred during our third fiscal quarter ended September 30, 2020 that materially affected, or are reasonably likely to materially affect, 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.

Summary of Risk Factors

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks include, among others, the following:

- 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.
- 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 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.
- Our pursuit of a potential therapy for COVID-19, the disease caused by the virus SARS-CoV-2, is at an early stage, and we are committing substantial financial resources and personnel and making substantial capital commitments with third parties in furtherance thereof.
- 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 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.
- 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.
- Clinical product development involves a lengthy and expensive process. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials.
- Our business could be materially adversely affected by the effects of health pandemics or epidemics, including the current COVID-19 pandemic and future outbreaks of the disease.
- We intend to rely on third parties to produce clinical and commercial supplies of our product candidates.
- 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.

- 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.

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 $193.0 million and $110.9 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $561.5 million. 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;
- experience delays or interruptions to preclinical studies, clinical trials, our receipt of services from third-party service providers or our supply chain due to the COVID-19 pandemic; 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 eight 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.

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, 2020, excluding restricted cash, we had cash, cash equivalents and short-term investments of $826.6 million. Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments as of September 30, 2020 will fund our current operating plans through at least the next 12 months from the issuance date of our condensed consolidated financial statements for the period ended September 30, 2020. 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. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic and rapidly evolving nature of our business and the COVID-19 pandemic environment generally. We will also need to raise additional capital to complete the development and commercialization of our product candidates and fund certain of our existing manufacturing and other commitments. 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.

The COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. 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.

Our pursuit of a potential therapy for COVID-19, the disease caused by the virus SARS-CoV-2, is at an early stage, and we are committing substantial financial resources and personnel and making substantial capital commitments with third parties in furtherance thereof and we may be unable to secure sufficient capital or manufacturing capacity to develop and commercialize a therapy that successfully treats the virus in a timely manner, if at all.

In response to the recent outbreak of COVID-19, the disease caused by the virus SARS-CoV-2, we are pursuing various potential therapies to address the disease, including through mAbs using our antibody platform (in collaboration with several partners), such as VIR-7831 and VIR-7832, and siRNA using our siRNA platform (in collaboration with Alnylam), such as VIR-2703. Our testing and development of these potential therapies is in early stages, and we may be unable to produce a therapy that successfully treats the virus in a timely manner, if at all. For example, we initiated a Phase 3 clinical trial in October 2020 for VIR-7831, for which we anticipate that interim data may be available as early as January 2021. We have not yet initiated any clinical trials for VIR-7832 or VIR-2703, although we plan to commence a Phase 1b/2a clinical trial in the first quarter of 2021 for VIR-7832 and continue pre-clinical studies for VIR-2703 led by Alnylam Pharmaceuticals, Inc., or Alnylam.

We are also committing substantial financial resources, both internally and externally, and personnel to the development of a potential therapy for COVID-19, which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of COVID-19 as a global health concern. In particular, our ability to develop an effective therapy will depend on the success of our manufacturing capabilities, for which we are dependent on third-party manufacturing organizations and which will require significant additional funding. For example, in April 2020 we entered into a binding letter agreement, or the Samsung Letter Agreement, with Samsung Biologics Co. Ltd., or Samsung, pursuant to which we were obligated to pay directly to Samsung, prior to our assignment of such agreement, a total of approximately $362.0 million for a firm and binding capacity reservation for a specified number of manufacturing slots in 2021 and 2022 for our SARS-CoV-2 antibody program regardless of whether we utilize such manufacturing slots. In June 2020, we entered into a binding letter of intent, or the WuXi Biologics Letter Agreement, with WuXi Biologics (Hong Kong) Limited, or WuXi Biologics, pursuant to which we committed to purchase a firm and binding capacity reservation for the manufacture of a specified number of batches of drug substance of our SARS-CoV-2 antibody in 2020 and 2021. We were obligated to pay directly to WuXi, prior to our assignment of such agreement, a total of approximately $130.0 million for such capacity reservation, if all batches are manufactured, inclusive of estimated raw material costs, with between 70% and 80% of the batch production fees owed to WuXi Biologics on a take-or-pay basis regardless of whether we utilize such manufacturing slots. In July 2020, we assigned each of the Samsung Letter Agreement and the WuXi Biologics Letter Agreement to GlaxoSmithKline Trading Services Limited, or GSKTSL, and GSKTSL entered into a Master Services Agreement with Samsung, or the Samsung MSA, and a non-exclusive Master Services Agreement for Commercial Manufacture of Drug Substance with WuXi Biologics, or the WuXi Biologics MSA, thereby superseding each of the Samsung Letter Agreement and

the WuXi Biologics Letter Agreement, and pursuant to which, among other things, Samsung and WuXi Biologics will perform development and manufacturing services for clinical and commercial supply of antibody products under our SARS-CoV-2 antibody program under each of the Samsung MSA and WuXi Biologics MSA. In accordance with the terms of the definitive collaboration agreement with Glaxo Wellcome UK Limited and Beecham S.A. (collectively referred to as GSK), we will continue to be responsible for 72.5% of the costs under each of the Samsung MSA and WuXi Biologics MSA, and GSK will bear 27.5% of such costs, subject to certain conditions and exceptions. In May 2020, we entered into a clinical development and manufacturing agreement with Biogen Inc., or Biogen, pursuant to which we could be required to pay approximately $100.0 million to Biogen as an "access fee" based on our current working assumptions of manufacturing titer and yield per batch if we successfully manufacture all batches of SARS-CoV-2 antibody drug substance under the Samsung MSA, in addition to other payments to Biogen pursuant to statements of work under the Biogen agreement. Our current estimated aggregate commitments to GSK under the Samsung MSA and WuXi Biologics MSA for drug substance, drug product and raw material are approximately $482.0 million, excluding the approximate "access fee" payable to Biogen.

While we believe securing such manufacturing capacity and technological expertise is crucial to the potential success of our SARS-CoV-2 antibody development programs, such capital commitments plus any future commitments, in the aggregate, may, in the future, exceed our available cash and cash equivalents and short-term investments. We may also need to enter into additional manufacturing arrangements in the future in order to create an effective supply chain for our COVID-19 product candidates that will adequately support demand. We will need to raise substantial additional capital to fund the development of our product candidates and meet our capital commitments to our manufacturing partners in connection therewith. 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. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our potential therapies, if developed, may not be partially or fully effective, and may ultimately prove unsuccessful or unprofitable. Furthermore, there are no assurances that our therapy will be approved for inclusion in government stockpile programs, which may be material to the commercial success of the approved product candidate, either in the United States or abroad.

In addition, another party may be successful in producing a more efficacious therapy for SARS-CoV-2 or in producing a therapy in a more timely manner, which may also lead to the diversion of funding away from us and toward other companies or lead to decreased demand for our potential therapies. There are efforts by several public and private entities to develop a therapy for COVID-19, including AstraZeneca plc, Eli Lilly, Johnson & Johnson, Moderna, Inc., Pfizer Inc., Regeneron Pharmaceuticals, Inc., and Sanofi S.A., some of which are further along in the clinical development process than we are. These other entities may be more successful at developing, manufacturing or commercializing a therapy for COVID-19. Several of these other organizations are much larger than we are and have access to larger pools of capital, including U.S. government funding, and broader manufacturing infrastructure. There are no assurances that we will secure U.S. government funding or a broad enough manufacturing infrastructure, which may adversely impact our ability to commercialize a therapy for COVID-19. In addition, several organizations have already secured significant commitments from governments to purchase COVID-19 vaccines. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our development and manufacturing efforts or to ultimately commercialize a therapy for COVID-19, if approved.

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 our product candidates. 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 four 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 initiated a Phase 2 clinical trial to combine VIR-2218 with pegylated interferon-alpha and we are planning trials that combine VIR-2218 with VIR-3434. We are also evaluating additional combinations 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:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- 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 or 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;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;
- 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, after an inspection of our clinical trial operations, trial sites or manufacturing facilities, after review of an IND or amendment, CTA or amendment, or equivalent application or amendment or the finding that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- 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;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; or

- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including the current COVID-19 pandemic and future outbreaks of the disease, which already caused us to delay initiation of the Phase 2 trial for VIR-2482 and Phase 1 trial for VIR-1111, and could cause other or additional disruptions.

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 two siRNAs, ONPATTRO (*patisiran*) in 2018 and Givlaari (*givosiran*) in 2019 (both developed by Alnylam), that have 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 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-7831, VIR-7832 and VIR-2703 for the treatment of COVID-19, 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. In addition, enrollment and retention of patients in clinical trials could be disrupted by man-made or natural disasters, or public health pandemics or epidemics or other business interruptions, including, the current COVID-19 pandemic and future outbreaks of the disease.

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 and may require us to pause our clinical trials 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, as amended. 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 $1.7 billion in milestone payments under the Alnylam Agreement, as amended, 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 $331.5 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.

Furthermore, pursuant to the Alnylam Agreement, as amended, 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 or coronavirus program 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 or the COV Products, 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 or the COV Products, we are unable to accurately predict the timing or amount of expenses related to the development of VIR-2218 or the COV Products 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 or the COV Products, 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. In June 2020, Brii Bio exercised its option to obtain exclusive rights to develop and commercialize compounds and products arising from VIR-2218 in the China Territory pursuant to 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 the following:

- 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. For example, there are efforts by several public and private entities to develop a therapy for COVID-19, including AstraZeneca plc, Eli Lilly, Johnson & Johnson, Moderna, Inc., Pfizer Inc., Regeneron Pharmaceuticals, Inc., and Sanofi S.A., some of which are further along in the clinical development process than we are. These other entities may be more successful at developing, manufacturing or commercializing a therapy for COVID-19.

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. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

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, including as a result of the 2020 U.S. elections. 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 collaboration agreements 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.

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;
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires; and
- disruptions resulting from the impact of public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic) on us or our strategic partners, third-party manufacturers, suppliers and other third parties upon which we rely.

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.

Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union may be a source of instability in international markets, create significant currency fluctuations and pose additional risks to our business.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed to between the United Kingdom and the European Union, the United Kingdom will be subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules will continue to apply. Negotiations between the United Kingdom and the European Union are expected to continue in relation to the customs and trading relationship between the United Kingdom and the European Union following the expiry of the Transition Period.

The uncertainty concerning the U.K's legal, political and economic relationship with the European Union after the Transition Period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise). These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

Such a withdrawal from the European Union is unprecedented, and it is unclear how the United Kingdom's access to the European single market for goods, capital, services and labor within the European Union, or single market, and the wider commercial, legal and regulatory environment, will impact our business.

Risks Related to Regulatory Compliance

The regulatory pathways for our product candidates targeting SARS-CoV-2, the virus that causes COVID-19, are continually evolving, and may result in unexpected or unforeseen challenges.

Our product candidates targeting SARS-CoV-2, the virus that causes COVID-19, are in the early testing and development stages. VIR-7831, a SARS-CoV-2-neutralizing mAb, is currently in a Phase 3 clinical trial, VIR-7832, also a SARS-CoV-2-neutralizing mAb, is planned to initiate a Phase 1b/2a clinical trial and discussions with regulatory bodies are ongoing, and VIR-2703, a SARS-CoV-2-targeting siRNA, is planned to continue pre-clinical studies led by Alnylam. The speed at which companies and institutions are acting to create and test many therapeutics and vaccines for COVID-19 is unusual, and evolving or changing plans or priorities within the FDA, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timelines for our COVID-19 product candidates. Results from our continued development and planned clinical trials may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. As part of these ongoing discussions, the FDA may require us to conduct additional pre-clinical studies and/or clinical trials than we originally anticipated, which could result in significant delay in our development program for these product candidates.

The FDA has the authority to grant an Emergency Use Authorization to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when, based on the totality of scientific evidence, there is evidence of effectiveness of the medical product, and there are no adequate, approved, and available alternatives. If we are granted an Emergency Use Authorization for one of our COVID-19 product candidates, we would be able to commercialize such candidate prior to FDA approval. Furthermore, the FDA may revoke an Emergency Use Authorization where it is determined that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long, if ever, an Emergency Use Authorization would remain in place. Such revocation could adversely impact our business in a variety of ways, including if one of our COVID-19 product candidates is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide one of our COVID-19 product candidates under an Emergency Use Authorization.

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, and their subcontractors that use, disclose or otherwise process individually identifiable health information;
- 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, which will be expanded beginning in 2022, to require applicable manufacturers to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;

- 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 70% 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.

There remain judicial and Congressional challenges, as well as 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, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act's mandated medical device tax and "Cadillac" tax on high-cost employer-sponsored health coverage and, effective January 1, 2021, also eliminates the health insurer tax. 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 risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On April 27, 2020, the United States Supreme Court reversed a Federal Circuit decision that previously upheld Congress' denial of $12 billion in "risk corridor" funding. 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. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case. It is unclear how such litigation 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. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended these reductions from May 1, 2020 through December 31, 2020, and extended the sequester through 2030. In addition, 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 established a quality payment program, also referred to as the Quality Payment Program. The quality payment program has two tracks, one known as the merit based incentive payment system for providers in the fee-for service Medicare program, and the advanced alternative payment model for providers in specific care models, such as accountable care organizations. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. 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 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. In addition, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained 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, or HHS, has solicited feedback on some of

these measures and has implemented 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. On July 24, 2020, the Trump administration announced four executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals, including a policy that would tie certain Medicare Part B drug prices to international drug prices, the details of which were released on September 13, 2020 and expanded the policy to cover certain Part D drugs; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. The FDA also recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. 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. In addition, it is uncertain how the results of the 2020 U.S. elections will impact these measures. 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. For example, it is possible that additional governmental action is taken to address the COVID-19 pandemic. 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.

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, 2, and 3 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 or any potential COVID-19 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. There is, however, no assurance that our third-party manufacturers will meet our working assumptions of manufacturing titer and yield per batch of our product candidates. Any reduction in anticipated manufacturing titer and yield delay may adversely impact our ability to meet market demand for any approved product. Furthermore, 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 which we rely on for the clinical development, manufacturing, and commercialization of our proprietary antibodies developed for SARS-CoV-2, 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, delay the procurement of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies.

Additionally, the biopharmaceutical industry in particular in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies 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. Evolving changes in China's economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the United Kingdom could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding , which could adversely affect our financial condition and cause us to delay our clinical development programs.

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 technology transfers, 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;
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics, including, for example, the ongoing COVID-19 pandemic; 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, 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 $135.0 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. For example, as a result of the achievement of certain development milestones achieved in June and October 2020, we paid an aggregate of $20.0 million to Humabs securityholders.

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, 2020, we had 297 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 all within the context of the rapidly evolving global pandemic of COVID-19. We continue to closely monitor the COVID-19 situation and will evolve our expansion plans as needed. As a result of the global pandemic, the majority of our workforce has been working from home since March 2020. Despite this, we must continue to effectively integrate, develop and motivate a growing number of new employees, and maintain the beneficial aspects of our corporate culture. We have implemented plans to reopen our offices to allow employees to return when appropriate. Although these plans are based on a phased approach consistent with local government requirements, and focused on employee safety, and contemplate returning to remote work should new restrictions be implemented, there is uncertainty regarding recent phased reopening, which may be rolled back, and restrictions re-implemented. We are also working to provide our employees with the support they need to ensure continuity of business operations. 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, recruit and train additional qualified personnel, or succeed at effectively integrating employees that have joined during the global pandemic. 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, public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic), 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 man-made or natural disasters or other business interruptions. 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 business could be materially adversely affected by the effects of health pandemics or epidemics, including the current outbreak of COVID-19 pandemic and future outbreaks of the disease, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations, or materially affect our operations globally, including at our headquarters in the San Francisco Bay Area, which is currently subject to a state executive order and a shelter-in-place order, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business could be materially adversely affected by the effects of health pandemics or epidemics, including the current outbreak of COVID-19 pandemic and future outbreaks of the disease, which was declared by the World Health Organization as a global pandemic, and is resulting in travel and other restrictions to reduce the spread of the disease, including a California executive order, a San Francisco Bay Area and several other state and local orders across the country, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. The San Francisco Bay Area shelter-in-place order took effect in March 2020, has been amended to gradually allow for the phased reopening of certain activities, but the broader shelter-in-place mandates continue to remain in effect with no current expiration date. Similarly, the broader effects of the March 2020 California executive order will continue for an indefinite period of time. As a result, a large part of our workforce in the United States has been working remotely since March 2020 and plans to fully reopen our offices have not yet been initiated. In addition, our Humabs BioMed S.A. subsidiary headquartered in Bellinzona, Switzerland who has employees who reside in both Switzerland and Italy is affected by restrictions and national quarantined regulations imposed by both the Swiss and Italian governments. As a result of these developments, in the early part of the year, most of our employees in Bellinzona, Switzerland were working remotely. In the summer, some of these restrictions were relaxed, and we were able to implement our plans to slowly reopen our offices to allow employees to return. Although our reopening plans have been consistent with local governments requirements and their phased approach to reopening, there is uncertainty regarding recent phased reopenings, which may be rolled back and restrictions reimplemented. The effects of the state executive order, a local shelter-in-place order, government-imposed quarantines and our work-from-home policies, including the evolving nature of such policies, may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. In particular, some of our CDMOs that we use to supply our early stage product candidates are located in China, where the COVID-19 outbreak was first reported and where there have been government-imposed quarantines. While many of these materials may be obtained by more than one supplier, including suppliers outside of China, port closures and other restrictions resulting from the coronavirus outbreak in the region or other regions may disrupt our supply chain or limit our ability to obtain sufficient materials for our product candidates.

In addition, our clinical trials have been affected by the ongoing COVID-19 pandemic. Site initiation and patient enrollment has been and may be further delayed due to prioritization of hospital resources toward the COVID-19 pandemic, and some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, has been delayed or disrupted, which has adversely impacted our clinical trial operations. For example, the initiation of the Phase 1 trial for VIR-1111 and Phase 2 trial for VIR-2482, which were delayed due to the impact of COVID-19, are now expected in the fourth quarter of 2020 and fourth quarter of 2021, respectively. Further delays to our trials may occur.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic, may be difficult to assess or predict, it is currently resulting in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. The ultimate impact of the ongoing COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. These effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

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, public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic), 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. The techniques used to sabotage or to obtain unauthorized access to information systems, and networks in which cyber threat actors store data or through which they transmit data change frequently and we may be unable to implement adequate preventative measures. 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. On May 13, 2020, the Federal Bureau of Investigation ("FBI") and the Department of Homeland Security's Cybersecurity and Infrastructure Security Agency ("CISA") announced that the FBI was investigating the targeting and compromise of U.S. organizations conducting COVID-19-related research by cyber actors affiliated with the People's Republic of China. On July 16, 2020, the National Security Agency, National Cyber Security Center, Communications Security Establishment and CISA released a joint cybersecurity advisory detailing the targeting by Russian Intelligence Services of organizations involved in COVID-19 vaccine development in the United States, Canada and the United Kingdom. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, including but not limited to information related to our product candidates targeting SARS-CoV-2, we could incur liability, our competitive and reputational position could be harmed, and the further development and commercialization of our product candidates could be delayed.

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 (and our service providers) 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 (and our service providers') actual or perceived failure to comply with such obligations could harm our reputation, subject us to significant fines and liability, and otherwise adversely affect our business.

We, and our service providers, receive, process, store and use personal information and other data about our clinical trial participants, employees, partners and others. We, and our service providers, 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 or pursuant to 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.

In addition, various states, such as California and Massachusetts, have implemented similar privacy and data protection laws and regulations that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. For example, California enacted legislation that became effective on January 1, 2020, the California Consumer Privacy Act, or CCPA, that, among other things, requires covered companies to provide new disclosures to California residents, affords California residents new abilities to opt-out of certain disclosures of personal information, and allows for a new cause of action for data breaches. The CCPA was amended several times throughout 2018, 2019, and 2020, and it is unclear whether further modifications will be made to this legislation or how it will be interpreted. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities depending on how it is interpreted and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data. The CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal information. In addition, the California Privacy Rights Act of 2020, or CPRA, was approved by California voters during the November 2020 ballot initiative in California. The CPRA will amend the CCPA by creating additional privacy rights for California consumers and additional obligations on businesses, which could subject us to additional compliance costs as well as potential fines, individual claims and commercial liabilities. It is expected that the CPRA would take effect on January 1, 2023. The GDPR, CCPA and many other laws and regulations relating to privacy and data protection are still being tested in courts, and they are subject to new and differing interpretations by courts and regulatory officials. Additionally, the interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. We are working to comply with the GDPR, CCPA and other privacy and data protection laws and regulations that apply to us, and we anticipate needing to devote significant additional resources to complying with these laws and regulations.

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 European Union. The GDPR imposes stringent data protection requirements for processing the information of individuals in the European Union, including clinical trial data, and to date, has increased compliance burdens on us, such as requiring the following: establishing a legal basis for processing personal data, mandating burdensome documentation requirements, adopting administrative, physical and technical safeguards to protect personal data, providing notification if a data breach were to occur to appropriate data protection authorities or individuals, taking certain measures when engaging third-party data processors, 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 health information, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. The GDPR increases our obligations with respect to clinical trials conducted in Europe (including the European Economic Area, or EEA, United Kingdom and Switzerland) by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. 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.

European data protection laws, including the GDPR, generally restrict the transfer of personal data from Europe, including the EEA, United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards allowing U.S. companies to import personal data from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal data transfers from Europe to the United States or most other countries. At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. However, the Court of Justice of the European Union recently invalidated the EU-U.S. Privacy Shield. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal information transfers from the EU to the United States or most other countries. At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. Following the Court of Justice of the European Union's decision, the Swiss Federal Data Protection and Information Commissioner, or the FDPIC, announced that the Swiss-U.S. Privacy Shield does not provide adequate safeguards for the purposes of personal data transfers from Switzerland to the United States. While the FDPIC does not have authority to invalidate the Swiss-U.S. Privacy Shield regime, the FDPIC's announcement casts doubt on the viability of the Swiss-U.S. Privacy Shield as a future compliance mechanism for Swiss-US data transfers. Authorities in the United Kingdom, whose data protection laws are similar to those of the European Union, may similarly invalidate use of the EU-U.S. Privacy Shield as a mechanism for lawful personal information transfers from those countries to the United States. As such, if we are unable to implement a valid solution for personal data transfers from Europe, including, for example, obtaining individuals' explicit consent to transfer their personal data from Europe to the United States or other countries, we will face increased exposure to regulatory actions, substantial fines and injunctions against processing personal data from Europe. Inability to import personal data from the EEA, United Kingdom or Switzerland may also restrict our clinical trials activities in Europe; limit our ability to collaborate with contract research organizations as well as other service providers, contractors and other companies subject to European data protection laws; and require us to increase our data processing capabilities in Europe at significant expense. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. 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.

Further, the United Kingdom's decision to leave the European Union, often referred to as Brexit, 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. While the United Kingdom Data Protection Act of 2018, which "implements" and complements the GDPR achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether the transfer of data from the EU to the United Kingdom will in future remain lawful under GDPR. During the period of "transition" (i.e., until December 31, 2020), EU law will continue to apply in the United Kingdom, including the GDPR, and transfers of data from the EU to the United Kingdom are permitted without the need for any "adequacy mechanism. Unless the EU Commission makes an "adequacy finding" in respect of the United Kingdom before January 1, 2021, from that date the United Kingdom will be a "third country" under the GDPR and transfers of data from the EU to the United Kingdom will require an "adequacy mechanism", such as the Standard Contractual Clauses. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

It is possible that the GDPR, CCPA or other laws and regulations relating to privacy and data protection may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with our current policies and practices and compliance with such laws and regulations could require us to change our business practices and compliance procedures in a manner adverse to our business. We cannot guarantee that we are in compliance with all such applicable data protection laws and regulations and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations. Furthermore, other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules, and regulations, which could increase our compliance costs and the risks associated with noncompliance. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. We cannot guarantee that we, our third-party collaborators, or our vendors are in compliance with all applicable data protection and privacy laws and regulations as they are enforced now or as they evolve. Further, for example, our privacy policies may be insufficient to protect any personal information we collect, or may not comply with applicable laws. Our non-compliance could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. In addition, if we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts.

Our actual or perceived failure to adequately comply with applicable laws and regulations relating to privacy and data protection, or to protect personal data and other data we process or maintain, could result in regulatory enforcement actions against us, including fines, penalties, orders that require a change in our practices, additional reporting requirements and/or oversight, imprisonment of company officials and public censure, claims for damages by affected individuals, other lawsuits or reputational and damage, all of which could materially affect our business, financial condition, results of operations and growth prospects.

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.

Recent changes and possible future changes in tax laws or regulations could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law a comprehensive tax reform bill, or the Tax Act, which significantly revised the Internal Revenue Code of 1986, as amended, or the Code. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. The foregoing items, as well as any other future changes in tax laws, including as a result of the 2020 U.S. elections, could have a material adverse effect on our business, cash flow, financial condition, or results of operations. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which provides temporary relief from certain aspects of the Tax Act that had imposed limitations on the utilization of certain losses, interest expense deductions, and minimum tax credits. The enactment of the CARES Act did not result in any material adjustments to our income tax provision for the period.

Our ability to use our net operating losses, or 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. As of December 31, 2019, we had net operating loss carryforwards of $241.6 million for federal tax purposes and $118.8 million for state tax purposes. If not utilized, federal carryforwards arising in tax years ending prior to 2018 will begin expiring in 2034 and state carryforwards will begin expiring in 2031. Our ability to use our federal and state net operating losses to offset potential future taxable income is dependent upon our generation of future taxable income before any expiration dates of the net operating losses, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses.

In general, under Sections 382 and 383 of 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 rolling 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 or as a result of the IPO and may experience ownership changes as a result of future offerings 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 and the CARES Act includes, among other things, changes to U.S. federal tax rates and the rules governing NOL carryforwards. For example, NOLs arising in tax years ending after December 31, 2017 can be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of current year taxable income for tax years beginning on or after January 1, 2021. 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 periods, as well as the new limitation on use of NOLs may impact our ability to utilize our NOLs to offset taxable income in the future. Because we have been generating taxable losses since inception, we do not expect any changes resulting from the new NOL provision to the current tax benefit and valuation allowance.

Risks Related to 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. The ongoing COVID-19 pandemic, for example, has negatively affected some sectors of the stock market and investor sentiment and has resulted in significant volatility. 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 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 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 an 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.

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. In light of our public float at June 30, 2020, we expect that we will no longer be an EGC on December 31, 2020. 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 EGC.

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 as a public company, 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, then 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. Each public company with principal executive offices in California is required to have at least one female on its board of directors, and by December 31, 2021, will be 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. We are currently compliant with the requirements, but there are no assurances that we will be compliant in the future. Additionally, on September 30, 2020, California Governor Gavin Newsom signed into law

Assembly Bill 979 which generally requires public companies with principal executive offices in California to include specified numbers of directors from "underrepresented communities." By December 31, 2021, each public company with principal executive offices in California is required to have at least one director from an underrepresented community. By December 31, 2022, a public company with more than four but fewer than nine directors will be required to have a minimum of two directors from underrepresented communities, and a public company with nine or more directors will need to have a minimum of three directors from underrepresented communities. If we fail to comply with either Senator Bill 826 or Assembly Bill 979, 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 EGC. 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. Furthermore, Section 22 of the Securities Act of 1933, as amended, or the Securities Act, creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further 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 of 1933, unless we consent in writing to the selection of an alternative forum. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

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. 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 further significant additional costs associated with resolving such action in other jurisdictions, all of which could harm our business.

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

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).
10.1	Assignment and Novation Agreement among the Company, GlaxoSmithKline Trading Services Limited and Samsung Biologics Co., Ltd., dated July 31, 2020 (incorporated herein by reference to Exhibit 99.2 to the Company's Form 8-K (File No. 001-39083), filed with the SEC on August 7, 2020).
10.2	Assignment and Novation Agreement among the Company, GlaxoSmithKline Trading Services Limited and WuXi Biologics (Hong Kong) Limited, dated July 29, 2020 (incorporated herein by reference to Exhibit 99.1 to the Company's Form 8-K (File No. 001-39083), filed with the SEC on August 7, 2020).
10.3+	Employment Letter Agreement between the Company and Steven Rice, dated August 22, 2019.
10.4+	Promotion Letter Agreement between the Company and Steven Rice, dated July 30, 2020.
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	Inline 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.

* 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 10, 2020

By: /s/ **George Scangos**

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

Date: November 10, 2020

By: /s/ **Howard Horn**

Howard Horn
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)

Exhibit 10.3

August 21, 2019

Steven Rice

Dear Steven,

This letter agreement (the "**Agreement**") sets forth the terms and conditions of your employment with Vir Biotechnology, Inc. ("**VirBio**" or the "**Company**").

1. Position, Location: You will serve as the Company's Head of Human Resources and will be responsible for all duties associated with that role, along with any other duties that are assigned to you from time to time by the Company's Board of Directors or the Compensation Committee thereof, as determinations or responsibilities may be delegated from the Board of Directors to the Compensation Committee (collectively, the "**Board**") and any subsidiary companies as applicable or from the CEO. This position is full-time. As an exempt salaried employee, you are expected to work the Company's normal business hours as well as additional hours as required by the nature of your work assignments, and you will not be eligible for overtime compensation. You will work out of VirBio's offices located at 499 Illinois Street, Suite 500, San Francisco, CA 94158. Of course, the Company may change your position, duties, and work location from time to time in its discretion.

2. Reporting Relationship and Start Date: You will report directly to the Chief Executive Officer and your start date will be September 15, 2019 (the "**Start Date**").

3. CIIAA; Company Policies: Our standard confidential information and inventions assignment agreement, attached to this letter as Exhibit A, must be signed prior to your start date (the "**CIIAA**"). In addition, you must comply with Company's personnel policies and procedures as they may be interpreted, adopted, revised or deleted from time to time in the Company's sole discretion.

4. Base Salary: You will receive an annualized base salary of $425,000. Salary is subject to deductions for taxes and other withholdings as required by law and is payable in accordance with VirBio's payroll cycle.

5. Annual Bonus: You will be eligible for an annual (calendar year) discretionary bonus, with a target amount equal to 40% of your annual base salary, contingent upon achievement, in the Company's sole discretion, of individual and Company performance objectives established by the Company, as well as any other criteria the Company deems relevant. Annual bonus payments are also contingent upon, and calculated with reference to, the availability of sufficient funds as determined by the Board. To receive payment of any bonus, you must be employed by the Company at the time bonuses are paid. Any bonus is not earned until paid and will be paid on or before March 15 of the year following the year for which the bonus is awarded. If your employment terminates for any reason prior to the payment date, you will not have earned, and will not be paid, any pro-rated bonus.

6. Retention Bonus: You are eligible to receive a one-time Retention Bonus of $200,000, subject to all applicable deductions and withholding. Although you will not earn the Retention Bonus until the one-year anniversary of your Start Date, it will be advanced to you within your first 30 days of employment in accordance with the Company's standard payroll procedures. To receive the Retention Bonus, you must be employed by the Company on the day of the payment, and to earn the Retention Bonus, you must be employed by the Company on the one-year anniversary of your Start Date. By signing this letter, you expressly agree to repay the Company the net amount of the Retention Bonus within thirty (30) days after your separation if you resign your employment for any reason within one year after your Start Date.

7. **Equity:** On or following commencement of your employment and subject to approval of the Board, the Company will grant you a stock option under the Vir Biotechnology, Inc., 2016 Equity Incentive Plan, or any successor equity plan (the "**Plan**") to purchase 2,000,000 shares of the Company's Common Stock (the "**Option**"). The Option will have an exercise price equal to the fair market value of the Company's common stock on the date of grant and will vest over four (4) years, with 25% of the total number of shares subject to the Option vesting on the one-year anniversary of your employment start date and, the remainder vesting in 36 equal monthly installments thereafter. Vesting will depend on your continued service with the Company and will be subject to the terms and conditions of the Plan and the written Stock Option Agreement governing the Option.

8. **Benefits:** During your employment, you shall be eligible to participate in the employee benefit plans maintained by VirBio as are in effect from time to time and generally available to similarly situated VirBio employees, subject in each case to the generally applicable terms and conditions of the plan in question and Company policies. In addition, you will be eligible for paid time off consistent with applicable law and the VirBio policy generally applicable to similarly situated VirBio employees. Any benefits offered by VirBio are subject to change without notice at the sole discretion of VirBio.

9. **At-Will Employment**. Your employment with VirBio will be at at-will, such that either you or the Company can terminate the relationship at any time with or without cause and with or without notice; *provided, however,* that in the event you elect to terminate your employment without Good Reason (as defined in the Severance Plan referenced in Section 10 below), you agree to provide the Company with at least thirty (30) days' advance written notice. Your employment at-will status can only be modified in a written agreement signed by you and by an officer of the Company.

10. **Severance**. You are eligible for severance benefits pursuant to the Company's Change in Control and Severance Benefit Plan, as approved by the Board on March 11, 2019, and as may be amended from time to time in the Company and Board's sole discretion (the "**Severance Plan**"). You hereby acknowledge and agree that any prior written or oral promise of severance benefits are hereby extinguished and superseded by your rights pursuant to the Severance Plan.

11. **Conflicts**. By signing this letter, you are representing that you have full authority to accept this position and perform the duties of the position without conflict with any other obligations and that you are not involved in any situation that might create, or appear to create, a conflict of interest with respect to your loyalty to or duties for the Company. You agree that while employed by the Company you will not engage in any other employment, consulting or other business that would interfere with your duties to the Company or create a conflict of interest. You specifically warrant that you are not subject to an employment agreement or restrictive covenant preventing full performance of your duties to the Company. You agree not to bring to the Company or use in the performance of your responsibilities at the Company any materials or documents of a former employer that are not generally available to the public, unless you have obtained express written authorization from the former employer for their possession and use. You also agree to honor all obligations to former employers during your employment with The Company.

12. **Outside Activities**. You agree to devote such of your business time, energy, and skill to the affairs of the Company and its subsidiaries as shall be necessary to perform the duties of such positions; *provided, however,* that you may engage in civic and not-for-profit activities (e.g. charitable and industry association activities) so long as such activities do not materially interfere with your obligations to the Company or create a conflict of interest. You further agree that if, during the term of your relationship with the Company, you wish to perform any consulting or outside activities for any business or for-profit entities, including serving on any advisory boards or boards of director of for-profit entities, any such additional activities shall require the Company's prior written consent. You are hereby expressly permitted to engage in the activities set forth in **Exhibit B** hereto, solely to the extent specified therein (collectively, the "**Outside Activities**"). It is agreed and understood that, so long as you devote sufficient time, energy, and skills to your duties to the Company, maintain your confidentiality obligations to the Company and do not use or access any resources or facilities of the Company in connection with the performance of such Outside Activities, (i) your performance of such Outside Activities as specifically set forth in **Exhibit B** and any assignment of intellectual property arising from such Outside Activities shall not be deemed a violation of this Agreement, your CIIAA, or any other agreement between you and the Company; and (ii) your performance of the Outside Activities shall not be deemed a violation of any fiduciary duty owed to the Company. Notwithstanding the foregoing, the Company retains the right to revoke, in its sole discretion, its consent to your engaging in any such Outside Activities, or to modify the scope of any Outside Activities you may perform for or in relation to any individual, organization or entity, including those set forth on **Exhibit B**. Any such revocation or amendment of scope will be communicated to you in writing, and will be deemed effective as of the date of delivery of such notice of revocation.

13. **Dispute Resolution:** To ensure the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, you and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment with the Company, or the termination of your employment, shall be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. § 1-16, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.** In addition, all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration (collectively, the "**Excluded Claims**"). In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration. You will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

14. **Tax:** All amounts payable under this letter are subject to all applicable deductions and withholding.

15. **Section 409A.** To the extent that any provision of this offer is ambiguous as to its exemption or compliance with Section 409A of the Internal Revenue Code of 1986, as amended, the provision will be read in such a manner so that all payments hereunder are exempt from Section 409A to the maximum permissible extent, and for any payments where such construction is not tenable, that those payments comply with Section 409A to the maximum permissible extent. To the extent any payment under this offer may be classified as a "short-term deferral" within the meaning of Section 409A, such payment will be deemed a short-term deferral, even if it may also qualify for an exemption from Section 409A under another provision of Section 409A. Payments pursuant to this offer (or referenced in this offer) are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the regulations under Section 409A.

16. **Preconditions.** The offer of employment set forth in this Agreement is contingent upon: (i) your execution of the Confidential Information and Inventions Assignment Agreement, along with your execution of this letter; (ii) your consent to a background check with results satisfactory to the Company in its sole discretion and (iii) your presentation of satisfactory documentary evidence of your identity and authorization to work in the U.S. within three (3) business days of your start date.

17. Miscellaneous. This Agreement, together with your CIIAA, the Severance Plan, and any documentation related to your equity interests, forms the complete and exclusive statement of your employment agreement with the Company. It supersedes any other agreements or promises made to you by anyone, whether oral or written. No term or provision of this Agreement may be amended waived, released, discharged or modified except in writing, signed by you and an authorized officer of the Company, except that the Company may, in its sole discretion, adjust salaries, incentive compensation, stock plans, benefits, job titles, locations, duties, responsibilities, and reporting relationships. This Agreement will be governed by the laws of California. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination shall not affect any other provision of this offer letter agreement and the provision in question shall be modified so as to be rendered enforceable in a manner consistent with the intent of the parties insofar as possible under applicable law. This Agreement may be delivered and executed via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and shall be deemed to have been duly and validly delivered and executed and be valid and effective for all purposes.

If you are in agreement with the terms set forth above, please sign below and return the signed Agreement.

/s/ George Scangos
George Scangos, CEO

Understood and Accepted:

/s/ Steven Rice	08-22-2019
Steven Rice	Date

Exhibit A — CIIAA

Exhibit B - Outside Activities

EXHIBIT A

CONFIDENTIAL INFORMATION AND INVENTION ASSIGNMENT AGREEMENT

EXHIBIT B

OUTSIDE ACTIVITIES

None.

Exhibit 10.4

July 30, 2020

Dear Steven,

I'm pleased to announce your promotion to Chief Administrative Officer.

As a result of the promotion, your base salary will increase by $30,000.00, bringing your new base salary to $460,000.00 effective August 1st and will be reflected in your August 14th paycheck. Your annual target incentive will remain at 40% of your base salary.

In recognition of this promotion, you have been granted an option under Vir's 2019 Equity Incentive Plan (the "Plan") to purchase 40,000 shares of Vir's Common Stock. The Option has an exercise price equal to the fair market value of Vir's common stock on the date of grant and will vest over four (4) years, with 25% of the total number of shares subject to the Option vesting on the one-year anniversary of the vesting commencement date and, the remainder vesting in 36 equal monthly installments thereafter. Vesting will depend on your continued service with Vir and will be subject to the terms and conditions of the Plan and the written Stock Option Agreement governing the Option.

Congratulations, and thank you again for your support and continuing contributions to Vir's success.

/s/ George Scangos

George Scangos

President & Chief Executive Officer

499 Illinois Suite 500, San Francisco, CA 94158

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 10, 2020

/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 10, 2020

/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, 2020, 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 10, 2020

In Witness Whereof, the undersigned have set their hands hereto as of the 10th day of November 2020.

/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."