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, 2021

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 1, 2021, the registrant had 130,880,159 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.

RISK FACTOR SUMMARY

Investing in our securities involves a high degree of risk. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found under the heading "Risk Factors" in Part II of this Quarterly Report on Form 10-Q.

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 net losses for the foreseeable future and therefore, may not be able 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 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.
- We are committing substantial financial resources and personnel and making substantial capital commitments with third parties in furtherance of our pursuit of a potential therapy for COVID-19, the disease caused by the virus SARS-CoV-2, and we may be unable to secure sufficient capital, market demand or manufacturing capacity to successfully develop and commercialize a therapy that treats the virus in a timely manner, if at all.
- Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of EUA product(s) and our product candidates in a timely manner. If we are not able to obtain required regulatory approvals and marketing authorizations, 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.
- The market price of our common stock has been, and in the future, may be, volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.
- 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.

Item 1. Financial Statements.

VIR BIOTECHNOLOGY, INC.

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

	September 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 714,521	$ 436,575
Short-term investments	55,560	300,286
Restricted cash and cash equivalents, current	6,112	7,993
Receivable from collaboration	93,003	—
Equity investments	169,369	—
Prepaid expenses and other current assets	27,772	27,511
Total current assets	1,066,337	772,365
Intangible assets, net	33,421	33,820
Goodwill	16,937	16,937
Property and equipment, net	26,610	17,946
Operating right-of-use assets	57,566	61,947
Restricted cash and cash equivalents, noncurrent	6,999	6,919
Other assets	2,343	8,827
TOTAL ASSETS	$ 1,210,213	$ 918,761
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 4,225	$ 5,077
Accrued and other liabilities	64,845	76,936
Deferred revenue, current portion	96,154	6,451
Contingent consideration, current portion	68,500	10,600
Total current liabilities	233,724	99,064
Deferred revenue, noncurrent	3,815	3,815
Operating lease liabilities, noncurrent	68,604	66,556
Contingent consideration, noncurrent	20,720	25,374
Deferred tax liability	3,253	3,253
Other long-term liabilities	3,823	3,847
TOTAL LIABILITIES	333,939	201,909
Commitments and contingencies (Note 8)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2021 and December 31, 2020; no shares issued and outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 130,826,122 and 127,416,740 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	13	13
Additional paid-in capital	1,541,422	1,385,301
Accumulated other comprehensive loss	(1,307)	(1,278)
Accumulated deficit	(663,854)	(667,184)
TOTAL STOCKHOLDERS' EQUITY	876,274	716,852
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,210,213	$ 918,761

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,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Collaboration revenue	$ 102,398	$ —	$ 107,731	$ —
Contract revenue	315	188	169,581	44,197
Grant revenue	903	1,740	5,356	7,690
License revenue from a related party	—	—	—	22,747
Total revenue	103,616	1,928	282,668	74,634
Operating expenses:				
Cost of revenue	7,836	—	8,988	—
Research and development	98,669	70,684	319,665	215,316
Selling, general and administrative	50,496	18,859	105,016	47,894
Total operating expenses	157,001	89,543	433,669	263,210
Loss from operations	(53,385)	(87,615)	(151,001)	(188,576)
Other income (expense):				
Change in fair value of equity investments	164,072	—	164,072	—
Interest income	11	412	272	2,548
Other income (expense), net	64	2,616	(9,430)	(6,904)
Total other income (expense)	164,147	3,028	154,914	(4,356)
Income (loss) before provision for income taxes	110,762	(84,587)	3,913	(192,932)
Provision for income taxes	(334)	(22)	(583)	(84)
Net income (loss)	$ 110,428	$ (84,609)	$ 3,330	$ (193,016)
Net income (loss) per share, basic	$ 0.85	$ (0.67)	$ 0.03	$ (1.66)
Net income (loss) per share, diluted	$ 0.82	$ (0.67)	$ 0.02	$ (1.66)
Weighted-average shares outstanding, basic	130,665,831	125,810,907	129,520,837	116,427,529
Weighted-average shares outstanding, diluted	133,854,419	125,810,907	133,318,979	116,427,529

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Net income (loss)	$ 110,428	$ (84,609)	$ 3,330	$ (193,016)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	13	(196)	(71)	99
Amortization of actuarial loss	14	6	42	17
Other comprehensive income (loss)	27	(190)	(29)	116
Comprehensive income (loss)	$ 110,455	$ (84,799)	$ 3,301	$ (192,900)

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

VIR BIOTECHNOLOGY, INC.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(unaudited)

	Common Stock Share	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at June 30, 2021	130,479,975	$ 13	$ 1,512,928	$ (1,334)	$ (774,282)	$ 737,325
Issuance of common stock to settle a contingent consideration	42,737	—	1,860	—	—	1,860
Vesting of restricted common stock	1,852	—	—	—	—	—
Exercise of stock options	301,558	—	3,690	—	—	3,690
Stock-based compensation	—	—	22,944	—	—	22,944
Other comprehensive income	—	—	—	27	—	27
Net income	—	—	—	—	110,428	110,428
Balance at September 30, 2021	130,826,122	$ 13	$ 1,541,422	$ (1,307)	$ (663,854)	$ 876,274

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

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

VIR BIOTECHNOLOGY, INC.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(unaudited)

	Common Stock Share	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2020	127,416,740	$ 13	$ 1,385,301	$ (1,278)	$ (667,184)	$ 716,852
Issuance of common stock in connection with a collaboration agreement	1,924,927	—	85,213	—	—	85,213
Issuance of common stock to settle a contingent consideration	42,737	—	1,860	—	—	1,860
Vesting of restricted common stock	89,261	—	—	—	—	—
Exercise of stock options	1,352,457	—	9,635	—	—	9,635
Stock-based compensation	—	—	59,413	—	—	59,413
Other comprehensive loss	—	—	—	(29)	—	(29)
Net income	—	—	—	—	3,330	3,330
Balance at September 30, 2021	130,826,122	$ 13	$ 1,541,422	$ (1,307)	$ (663,854)	$ 876,274

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

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,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 3,330	$ (193,016)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	3,891	3,185
Amortization of intangible assets	399	918
Impairment of intangible assets	—	832
Amortization of premiums (accretion of discounts) on investments, net	(859)	1,052
Noncash lease expense	4,471	2,498
Change in fair value of equity investments	(164,072)	—
Change in estimated fair value of contingent consideration	63,246	44,432
Payment of contingent consideration in excess of acquisition date fair value	(8,140)	(6,453)
Change in estimated fair value of derivative liability	—	16,796
Stock-based compensation	59,413	17,299
Other	486	17
Changes in operating assets and liabilities:		
Receivable from collaboration	(93,003)	—
Prepaid expenses and other current assets	1,878	(416)
Other assets	(1,051)	(2,168)
Accounts payable	(959)	1,041
Accrued liabilities and other long-term liabilities	(13,490)	13,183
Operating lease liabilities	(383)	(2,343)
Deferred revenue	89,559	(5,746)
Net cash used in operating activities	(55,284)	(108,889)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(8,750)	(4,119)
Purchases of investments	(55,729)	(363,399)
Maturities of investments	301,243	296,763
Proceeds from disposal of an equipment	4	—
Proceeds from disposal of an asset held for sale	—	180
Net cash provided by (used in) investing activities	236,768	(70,575)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock in connection with a collaboration agreement	85,213	206,699
Proceeds from issuance of common stock, net of issuance costs	—	323,214
Payment of contingent consideration	—	(3,547)
Payment of principal on financing lease obligation	(187)	(173)
Proceeds from exercise of stock options	9,635	3,540
Net cash provided by financing activities	94,661	529,733
Net increase in cash, cash equivalents and restricted cash and cash equivalents	276,145	350,269
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	451,487	122,816
Cash, cash equivalents and restricted cash and cash equivalents at end of period	$ 727,632	$ 473,085
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Common stock issued for payment of contingent consideration	$ 1,860	$ —
Property and equipment purchases included in accounts payable and accrued liabilities	$ 4,191	$ 598
Operating lease liabilities obtained in exchange of right-of-use asset	$ 90	$ 437
Reclassification of derivative liability to additional paid-in capital	$ —	$ 29,245
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH TO THE CONDENSED CONSOLIDATED BALANCE SHEETS:		
Cash and cash equivalents	$ 714,521	$ 462,521
Restricted cash and cash equivalents, current	6,112	9,363
Restricted cash and cash equivalents, noncurrent	6,999	1,201
Total cash, cash equivalents and restricted cash	$ 727,632	$ 473,085

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

1. Organization

Vir Biotechnology, Inc. (“Vir” or the “Company”) is a commercial-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Its development pipeline consists of product candidates targeting coronavirus disease 2019 (“COVID-19”), hepatitis B virus (“HBV”), influenza A virus, and human immunodeficiency virus (“HIV”). Vir has assembled four technology platforms that are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes.

In May 2021, the Company received an Emergency Use Authorization (“EUA”) from the U.S. Food and Drug Administration for sotrovimab (previously VIR-7831) for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. The Company also received a positive scientific opinion from the Committee for Human Medicinal Products in the European Union for sotrovimab in May 2021. The Company has since received marketing authorizations in Australia, Japan and Saudi Arabia (under the brand name, Xevudy®), and emergency or temporary use authorizations in a dozen other countries to date.

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 (the “Securities Act”) (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.

Sales Agreement

In November 2020, the Company entered into a sales agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”), under which the Company may from time to time offer and sell shares of its common stock, par value $0.0001 per share, having an aggregate offering price of up to $300.0 million, through or to Cowen, acting as sales agent or principal. The shares will be offered and sold under the Company’s shelf registration statement on Form S-3 and a related prospectus filed with the Securities and Exchange Commission (the “SEC”) on November 10, 2020. The Company will pay Cowen a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide Cowen with customary indemnification and contribution rights. As of September 30, 2021, no shares have been issued under the Sales Agreement.

Need for Additional Capital

The Company has incurred operating losses since inception and expects such losses to continue over the next several years. As of September 30, 2021, the Company had an accumulated deficit of $663.9 million. Management expects to incur additional losses in the future to conduct research and development and recognizes the potential need to raise additional capital to fully implement its business plan. The Company had, excluding restricted cash, $939.5 million of cash, cash equivalents, and investments as of September 30, 2021, and by also excluding the equity investment in Brii Biosciences Limited ("Brii Bio Parent"), the Company had $770.1 million. Based on the Company’s business plans, management believes that the $770.1 million as of September 30, 2021 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 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, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 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, 2020, filed with the SEC on February 25, 2021.

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, Credit Loss and Other Risks and Uncertainties

With the global spread of the ongoing 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 continue to 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 ongoing 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, cash equivalents and 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, 2021, the Company has no off-balance sheet concentrations of credit risk.

The Company is exposed to credit losses primarily through receivables from customers and collaborators and through its available-for-sale debt securities. The Company's expected loss allowance methodology for the receivables is developed using historical collection experience, current and future economic market conditions, a review of the current aging status and financial condition of the entities. Specific allowance amounts are established to record the appropriate allowance for customers that have a higher probability of default. Balances are written off when determined to be uncollectible. The Company's expected loss allowance methodology for the debt securities is developed by reviewing the extent of the unrealized loss, the size, term, geographical location, and industry of the issuer, the issuers' credit ratings and any changes in those ratings, as well as reviewing current and future economic market conditions and the issuers' current status and financial condition. The Company considered the current and expected future economic and market conditions surrounding the COVID-19 pandemic and determined that the estimate of credit losses was not significantly impacted. During the nine months ended September 30, 2021 and 2020, there was no allowance for losses on available-for-sale debt securities attributable to credit risk.

Investments

Investments include available-for-sale debt securities and equity investments, which are carried at estimated fair value.

Available-for-Sale Debt Securities

The Company's valuations of marketable debt 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 interest income on the condensed consolidated statements of operations. The Company's policy is not to measure an allowance for credit losses for interest receivable and to write off any uncollectible interest receivable as a reversal of interest income in the period in which it determines the interest will not be collected.

Equity Investments

Under Accounting Standards Update No. 2016-01, Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities, the Company measures its investment in equity securities at fair value at each reporting date based on the market price at period end if it has a readily determinable fair value. Otherwise, the investments in equity securities are measured at cost less impairment, adjusted for observable price changes for identical or similar investments of the same issuer unless the Company has significant influence or control over the investee. Changes in fair value resulting from observable price changes are presented as change in fair value of equity investments and changes in fair value resulting from foreign currency translation are included in other income (expense), net on the condensed consolidated statements of operations.

Restricted Cash and Cash Equivalents

Restricted cash and cash equivalents represent money market funds to secure standby letters of credit and security deposits with financial institutions, both under 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

Collaboration, License and Contract Revenue

Under 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. Generally, the classification of the transactions under the collaborative arrangements is determined based on the nature of contractual terms of the arrangement, along with the nature of the operations of the participants. When the Company is considered an agent in the arrangement, it records its share of collaboration revenue in the period in which such sales occur, which is when the performance obligation has been satisfied. The Company is considered an agent when the collaboration partner controls the product before transfer to the customers and has the ability to direct the use of and obtain substantially all of the remaining benefits from the product. Collaboration revenue is based upon the revenue reported by the Company's collaboration partner, net of cost of sales and allowable expenses (including distribution, selling and marketing expenses) in the period. In order to record collaboration revenue, the Company utilizes certain information from its collaboration partner, including revenue from the sale of the product, and costs incurred for development and sales activities. For the periods covered in the financial statements presented, there have been no material changes to prior period estimates of revenues and expenses.

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, profit-sharing arrangements, 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 ("SSP"). 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 the performance of the licensee.

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.

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. 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 the achievement of various milestones are recorded within research and development expenses or selling, general and administrative expenses based on the nature of the relevant underlying activities.

When the Company determines that entities acquired do not meet the definition of a business, the transaction is accounted for as an acquisition of assets. Therefore, the consideration paid to acquire IPR&D is expensed, and no goodwill is recorded. Any contingent consideration is generally 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 is 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 the achievement of various development milestones for product candidates are recorded within research and development expenses. Otherwise, changes in fair values are recorded within other income (expense), net.

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.

Cash Equivalents, Bank Time Deposits and Available-for-Sale Debt Securities

The following tables summarize the Company's cash equivalents, bank time deposits and available-for-sale debt securities measured at fair value on a recurring basis, and classified as Level 1 and Level 2 within the fair value hierarchy as of September 30, 2021 and December 31, 2020:

		September 30, 2021			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
			(in thousands)		
Assets:					
Money market funds[(1)]	Level 1	$ 711,547	$ —	$ —	$ 711,547
Bank time deposits	Level 2	5,000	—	—	5,000
U.S. government treasuries	Level 2	50,546	14	—	50,560
Total financial assets		$ 767,093	$ 14	$ —	$ 767,107

(1) Includes $13.1 million of restricted cash equivalents.

	Valuation Hierarchy	December 31, 2020			
		Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
		(in thousands)			
Assets:					
Money market funds[(1)]	Level 1	$ 421,835	$ —	$ —	$ 421,835
U.S. government treasuries	Level 2	300,201	91	(6)	300,286
Total financial assets		$ 722,036	$ 91	$ (6)	$ 722,121

(1) Includes $14.9 million of restricted cash equivalents.

Accrued interest receivable excluded from both the fair value and amortized cost basis of the available-for-sale debt securities are presented within prepaid expenses and other current assets in the condensed consolidated balance sheets, and amounted to $0.8 million as of December 31, 2020. As of September 30, 2021, the accrued interest receivable was immaterial. The Company did not write off any accrued interest receivable during the nine months ended September 30, 2021 and 2020.

As of September 30, 2021, there were no investments that have been in a continuous unrealized loss position for longer than 12 months. Total net unrealized gains recorded in accumulated other comprehensive income (loss) were immaterial as of September 30, 2021. As of September 30, 2021, no securities have contractual maturities of longer than one year.

Equity Investments

As of September 30, 2021, the Company's equity investment consisted solely of ordinary shares of Brii Bio Parent. The Company acquired the securities as partial consideration for entering into the collaboration, option and license agreement (the “Brii Agreement”) with Brii Bio Parent and Brii Biosciences Offshore Limited (“Brii Bio”) in May 2018. The Company concluded it does not have a controlling interest or significant influence over Brii Bio based on its ownership percentage and other factors. See further discussion in Note 6—Collaboration and License Agreements. In July 2021, Brii Bio Parent completed its initial public offering ("Brii Bio Parent IPO") on the Stock Exchange of Hong Kong Limited, prior to which the securities were accounted for as equity securities without a readily determinable fair value. Upon the completion of the Brii Bio Parent IPO, the securities were considered to be marketable equity securities and subsequently measured at fair value at each reporting date. As of September 30, 2021, the Company remeasured the equity investment at a fair value of $169.4 million. For the three months ended September 30, 2021, the Company recognized an unrealized gain of $164.1 million as other income in the condensed consolidated statement of operations, net of an unrealized loss of $0.4 million related to foreign currency translation for the period. As of September 30, 2021, the Company classifies its equity investment in Brii Bio Parent as a Level 1 asset within the fair value hierarchy, as the value is based on a quoted market price in an active market.

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 Company classifies the contingent consideration as Level 3 financial liabilities within the fair value hierarchy as of September 30, 2021 and December 31, 2020.

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. As of September 30, 2021, the Company calculated the estimated fair value of the clinical and regulatory milestones using the following significant unobservable inputs:

Unobservable input	Range (Weighted-Average)[1]
Discount rates	5% - 9% (6%)
Probability of achievement	22% - 80% (67%)

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

For the commercial milestones, the Company used a Monte Carlo simulation because of the availability of a discrete revenue forecast. As of September 30, 2021, the Monte Carlo simulation assumed a future full-scale 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	65%
Discount rate	11%
Probability of achievement	22% - 80% (74%)

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

The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. As of September 30, 2021 and December 31, 2020, the estimated fair value of the contingent consideration related to the Humabs acquisition was $83.3 million and $29.2 million, respectively, with changes in the estimated fair value recorded in research and development expense, and selling, general and administrative 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. In February 2021, the Company achieved one of the milestones related to a specified per-share price of its common stock resulting in a $10.0 million payable to the former TomegaVax's stockholders which was paid out in July 2021. As of September 30, 2021, the fair value of the remaining contingent consideration was estimated using the following significant unobservable inputs:

Unobservable input	Value
Volatility	100%
Discount rates	0.1%

As of September 30, 2021 and December 31, 2020, the estimated fair value of the contingent consideration related to the TomegaVax acquisition was $5.9 million and $6.8 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.

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

	Contingent Consideration
Balance at December 31, 2020	$ 35,974
Changes in fair value recognized in research and development expenses	33,920
Changes in fair value recognized in selling, general and administrative expenses	20,230
Changes in fair value recognized in other income (expense), net	9,096
Payment of contingent consideration upon achievement of milestone	(10,000)
Balance at September 30, 2021	$ 89,220

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 vector-based vaccine platform for use in HBV, HIV, and tuberculosis. The acquisition was accounted for as an asset purchase.

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/or the stage of the Company's clinical development at the time of the relevant event triggering the payment. The share price of the Company's publicly traded common stock will be determined using the average of the daily volume-weighted average trading price of the Company's common stock for each trading day during a consecutive 90-day period. The foregoing payments are payable (i) during any date after the completion of an initial public offering by the Company or any successor or affiliate controlling the TomegaVax technology, provided that no payment will be due before the first anniversary of the initial public offering, (ii) upon the sale of all assets related to the TomegaVax technology or (iii) upon a merger or stock sale of the Company or any successor or affiliate controlling the TomegaVax technology, in each case subject to certain conditions with respect to the timing of the payments. The payments under the TomegaVax Letter Agreement can be made in cash or shares of the Company's common stock, at the discretion of the Company's board of directors.

In February 2021, the Company achieved one of the milestones related to the specified per-share price of its common stock, which resulted in a $10.0 million payable to TomegaVax's former stockholders. In July 2021, the Company made the milestone payment to the former TomegaVax stockholders through a combination of $8.1 million cash payment and issuance of 42,737 shares of common stock with a total fair value of $1.9 million. The remaining milestone payments of up to $20.0 million in the aggregate will be triggered if (i) the per-share price of the Company's publicly traded common stock is at least $45 (as adjusted in the case of any stock dividend, stock split or other similar recapitalization) and upon the achievement of a certain milestone related to the stage of the Company's clinical development at the time of the relevant event triggering the payment and/or (ii) the per-share price of the Company's publicly traded common stock is at least $90 (as adjusted in the case of any stock dividend, stock split or other similar recapitalization).

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, 2021, the estimated fair value of the embedded derivative was $5.9 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 ("mAbs") 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. 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. The estimated fair value of the remaining contingent consideration was $83.3 million as of September 30, 2021.

5. Grant Agreements

Bill & Melinda Gates Foundation Grants

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. In June 2021, the parties further amended the agreement under which the grant term was extended from December 31, 2021 to October 31, 2022, 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 $0.7 million and $0.8 million for the three months ended September 30, 2021 and 2020, and $2.2 million and $6.2 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021 and December 31, 2020, the Company has deferred revenue of $3.0 million and $3.8 million, respectively, under this grant agreement.

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 June 2021 under which the grant term was extended from February 28, 2021 to January 31, 2022, 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. As of September 30, 2021, the Company had $1.4 million of unused funds received in advance and previously recorded as deferred revenue within accrued and other liabilities. As of September 30, 2021 and December 31, 2020, the Company has deferred revenue of $1.7 million and $2.6 million, respectively, under this grant agreement.

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 $0.2 million and $0.9 million for the three months ended September 30, 2021 and 2020, and $3.0 million and $1.0 million for the nine months ended September 30, 2021 and 2020, respectively.

6. Collaboration and License Agreements

Collaboration Agreements with GSK

2020 GSK Collaboration

On June 9, 2020, the Company, Glaxo Wellcome UK Limited and Beecham S.A. (referred to individually and together, as "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 "2020 Preliminary Agreement") (such definitive collaboration agreement, the "2020 GSK Agreement"). Concurrently with the execution of the 2020 Preliminary Agreement, the Company entered into a stock purchase agreement (the "2020 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 2020 Stock Purchase Agreement between the parties ("Effective Date"). Under the terms of the 2020 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 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 2020 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 for 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 2020 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 2020 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 2020 GSK Agreement superseded and replaced the 2020 Preliminary Agreement between the parties.

The Company considered the ASC 606 criteria for combining contracts and determined that the 2020 GSK Agreement and 2020 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 2020 Preliminary Agreement and 2020 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 the transaction price of the 2020 GSK Agreement.

The Company concluded that the 2020 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 2020 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 2020 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 second quarter of 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.

The remaining units of account of the 2020 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 the 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.

In May 2021, the Company and GSK received an EUA in the United States for sotrovimab, the first collaboration product under the Antibody Program. As the lead party for all commercialization activities, GSK incurs all of the sales and marketing expenses and is the principal on sales transactions with third parties. As the Company is the agent under the agreement, the Company recognizes its contractual share of the profit-sharing amounts or royalties (in case of an opt-out) as revenue, net of any cost of sales and allowable expenses (including distribution, selling, and marketing expenses) in the period the sale occurs. During the three months and nine months ended September 30, 2021, the Company recorded its share of net profit of $102.4 million and $107.7 million as collaboration revenue in the condensed consolidated statements of operations.

Costs associated with co-development activities performed under the agreement are included in research and development expenses on the condensed consolidated statements of operations, with any reimbursement of costs by GSK reflected as a reduction of such expenses. Under the 2020 GSK Agreement, the Company recognized additional net research and development expenses of $12.0 million and $49.2 million during the three and nine months ended September 30, 2021, respectively. 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.

2021 Expanded GSK Collaboration

On February 14, 2021, the Company and GSK entered into a binding preliminary collaboration agreement (the "2021 Preliminary Agreement"), under which the parties agreed to expand the 2020 GSK Agreement to collaborate on three separate programs: (1) a program to research, develop and commercialize mAbs for the prevention, treatment or prophylaxis of the influenza virus (the "Influenza Program"), excluding VIR-2482 unless GSK exercises its option as described below; (2) an expansion of the parties' current Functional Genomics Program to focus on functional genomics screens directed to targets associated with respiratory viruses (the "Expanded Functional Genomics Program"); and (3) additional programs to develop neutralizing mAbs directed to up to three non-influenza target pathogens selected by GSK (the "Selected Pathogens" and such programs, the "Additional Programs").

Concurrently with the execution of the 2021 Preliminary Agreement, the Company entered into a stock purchase agreement (the "2021 Stock Purchase Agreement") with GGL under which GGL agreed to purchase shares of the Company's common stock for an aggregate purchase price of approximately $120.0 million. The consummation of the transactions under each of the 2021 Preliminary Agreement and the 2021 Stock Purchase Agreement were subject to the satisfaction of customary closing conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, which expiration was effective on March 24, 2021. The 2021 Preliminary Agreement and 2021 Stock Purchase Agreement consummated on March 25, 2021, which the Company used as the measurement date for accounting purposes. On March 31, 2021, the Company closed the sale of 1,924,927 shares of its common stock to GGL.

The 2021 Preliminary Agreement was superseded on May 18, 2021 upon execution of the definitive collaboration agreement (the "2021 GSK Agreement", or collectively with the 2021 Preliminary Agreement, the "2021 GSK Collaboration"). The material terms of the 2021 GSK Agreement, including the promised goods and services, are discussed below and is consistent with those of the 2021 Preliminary Agreement.

Under the 2021 GSK Collaboration, the parties will conduct certain research and development activities under mutually agreed development plans and associated budgets for the programs within the expanded collaboration for a period of three years following the effective date. Under the Influenza Program, the parties will collaborate to research, develop and commercialize mAbs for the prevention, treatment or prophylaxis of influenza, including the Company's influenza mAbs (with respect to VIR-2482, only if GSK exercises its option). The Company may conduct the development and clinical manufacturing activities for VIR-2482 up to the completion of a Phase 2 clinical trial. Provided that the Company conducts and completes a Phase 2 clinical trial for VIR-2482, GSK will have the exclusive option to obtain exclusive rights to co-develop and commercialize VIR-2482 under the Influenza Program (the "VIR-2482 Option"). GSK will be the lead party for development, clinical and commercial manufacturing and commercialization activities for products under the Influenza Program (other than VIR-2482 unless and until GSK exercises the VIR-2482 Option, if applicable). The parties will mutually agree upon the allocation of responsibility for the development of products under the Expanded Functional Genomics Program, and for the development and early-stage manufacturing of products under the Additional Programs if and when GSK decides which Selected Pathogens to pursue. GSK will be primarily responsible for commercial manufacturing and commercialization activities for products under the Expanded Functional Genomics Program and Additional Programs, if and when selected by GSK. For each collaboration program, upon execution of the definitive agreement, the Company will grant GSK certain license rights related to the development, manufacturing and commercialization of products arising from the program.

The parties will share 50% of all development costs in accordance with the budget for each of the collaboration programs (other than for the Selected Pathogens and VIR-2482, unless GSK exercises the VIR-2482 Option), with each party having the right to opt-out of its co-funding obligations at specified points in development. In such case, the party continuing with the program will pay to the opt-out party a royalty on net sales of products arising from such program at specified rates based on the stage of development at which the opt-out is exercised. Following the exercise of an opt-out right by a party, the other party may, at its election, either pursue development and commercialization of such product or program unilaterally, or also cease the conduct and funding of such collaboration product or program. In the absence of any opt-out, the parties will also share 50% of all profits and losses arising from any collaboration product.

GSK was obligated to make an upfront payment to the Company of $225.0 million, 50% of which became payable at the effective date of the 2021 Preliminary Agreement and 50% of which became payable following the execution of the 2021 GSK Agreement. If GSK exercises the VIR-2482 Option, GSK will pay the Company an option exercise fee of $300.0 million unless certain agreed product criteria for VIR-2482 are not met, in which case the parties will negotiate an alternative option exercise fee. Upon achievement of a pre-defined regulatory milestone for the first product in the Influenza Program, which may be (i) VIR-2482 (if GSK exercised the VIR-2482 Option), (ii) a next-generation mAb, or (iii) any other influenza mAb approved by the JSC to be included in the collaboration, arising from the Influenza Program, GSK will make a milestone payment to the Company of up to $200.0 million.

The Company concluded that the 2021 GSK Agreement is a collaboration arrangement as defined in ASC 808, Collaborative Agreements, under which certain elements are required to be accounted for under ASC 606 where the counterparty is a customer for a good or service that is a distinct unit of account. In addition, the 2021 GSK Agreement is considered a contract modification to the 2021 Preliminary Agreement and will be accounted for prospectively, as a termination of the 2021 Preliminary Agreement and commencement of a new contract. There was no impact to the accounting assessment of the original contract as no goods or services had been delivered to GSK, no performance obligations were satisfied, and accordingly, no contract revenue was recognized under ASC 606 prior to the execution of the 2021 GSK Agreement.

The Company considered the ASC 606 criteria for combining contracts and determined that the 2021 GSK Collaboration and 2021 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 $85.2 million, based on the closing stock price of $52.70 on March 25, 2021 and taking into account a discount for the lack of marketability due to the restrictions in place on the underlying shares, resulting in a $34.8 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 the transaction price of the 2021 GSK Agreement.

The Company concluded that the 2021 GSK Agreement contained the following units of account: (i) the VIR-2482 Option; (ii) three distinct rights granted to GSK related to the Selected Pathogens (each, a "Selected Pathogens Right"); (iii) the license and know-how to the next-generation mAbs under the Influenza Program (the "Next Gen License"); (iv) the research and development activities for next-generation mAbs under the Influenza Program; and (v) the research and development activities, including license rights and know-how, under the Expanded Functional Genomics Program. The Company considered the guidance in ASC 606 to determine which of these elements of the 2021 GSK Agreement are performance obligations with a customer. The Company determined that the distinct performance obligations under ASC 606 consisted of (i) the Next Gen License and (ii) the three Selected Pathogens Rights, each representing a material right. All other elements of the 2021 GSK Agreement including the VIR-2482 Option, 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 2021 GSK Agreement included fixed consideration consisting of the $225.0 million upfront fee paid by GSK and $34.8 million, representing the premium on the sale of common stock to GSK for a total of $259.8 million. All potential future milestones and other payments under the 2021 GSK Agreement are constrained since the Company could not conclude it was probable that a significant reversal in the amount recognized would not occur.

The respective estimated SSP for each of the performance obligations was determined to allocate the transaction price. The estimated SSP of each performance obligation was determined considering relevant market conditions, entity-specific factors and information about the customer, while maximizing the use of available observable inputs. For the Next Gen License, the Company determined that GSK can benefit from the license at the time the license is granted, and therefore, the related performance obligation is satisfied at a point in time. If any of the Selected Pathogens Rights are exercised, the Company will evaluate the related promises to identify the performance obligations to be transferred and the timing of revenue recognition. If any of the Selected Pathogens Rights expire prior to being exercised, the Company will recognize any deferred revenue allocated to that right as revenue at the time of expiration.

The research and development activities for the next generation mAbs under the Influenza Program and the Expanded Functional Genomics Program 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 the 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 related products will be analogized to ASC 606 and therefore, will be recognized when the related sales occur.

Upon execution of the 2021 GSK Agreement, the Company granted the Next Gen License to GSK and therefore, recognized $168.3 million as contract revenue during the three months ended June 30, 2021. As of September 30, 2021, the total unrecognized transaction price of $91.5 million is classified as current deferred revenue on the Company's condensed consolidated balance sheet related to the remaining performance obligations, being the material rights resulting from the Selected Pathogens Rights, none of which have been exercised by GSK as of September 30, 2021.

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, 2021, the Company recognized a reduction of net research and development expense of $0.4 million and $1.3 million, respectively, under the 2021 GSK Agreement.

Under both GSK agreements, the Company has a receivable from collaboration of $93.0 million as of September 30, 2021.

Brii Biosciences

In May 2018, the Company entered into the Brii Agreement with Brii Bio Parent and 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 under a share transfer agreement in February 2020.

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).

From May 2018 until July 2021, the Brii Bio Parent IPO closing date, Brii Bio Parent and its wholly-owned subsidiary Brii Bio were determined to be variable interest entities ("VIE") due to their reliance on future financing and having insufficient equity at risk. However, the Company did not have the power to direct activities that most significantly impact the economic success of these entities and was not considered the primary beneficiary of these entities. Therefore, the Company did not consolidate Brii Bio Parent or Brii Bio. Subsequent to the Brii Bio Parent IPO, the Company determined that these entities are no longer VIEs. In addition, as Brii Bio Parent is a publicly-traded company, the Company's investment in its ordinary shares became a marketable equity investment with readily determinable fair value and is then subsequently measured to fair value at each reporting date (see Note 3—Fair Value Measurements). Prior to the Brii Bio Parent IPO, the Company accounted for its investment in Brii Bio Parent, which had a carrying value of $5.7 million, at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment from the same issuer.

Under the Brii Agreement, the Company also has a contract liability of $3.8 million within noncurrent deferred revenue which represents deferred consideration for the remaining three options that the Company granted to Brii Bio. The deferred consideration will be recognized when Brii Bio exercises its options or the options expire.

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. In consideration of 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 the inception of the Brii Agreement. The Company determined that the license is considered a functional intellectual property that is a distinct performance obligation under ASC 606. 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 and nine months ended September 30, 2021, the Company recognized zero and $0.4 million, respectively, as contract revenue from the supply of biological materials to Brii Bio. During the three and nine months ended September 30, 2020, the Company recognized zero and $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 connection with the Alnylam Agreement that was recognized as research and development expense during the second quarter of 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.

Under 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 the Company 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 trials. 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.

Under 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 valued at $0.8 million, to Alnylam.

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.

In March 2020, the Company achieved the specified development milestone relating to the Milestone Shares, which was accounted for as an embedded derivative. Consequently, the Company remeasured and reclassified the derivative liability to additional paid-in capital based on the estimated fair value of $29.2 million. The Company issued Alnylam 1,111,111 shares of its common stock and paid Alnylam $15.0 million in the second quarter of 2020.

Second and Third Amendments

In March and April 2020, the Company and Alnylam entered into the second and third amendments to the Alnylam Agreement (as amended, the "Amended Alnylam Agreement") to expand the parties' existing collaboration to include the development and commercialization of siRNA products targeting SARS-CoV-2, and potentially other related coronaviruses, and up to three targeting human host factors for SARS-CoV-2 (collectively, the "COVID Collaboration Targets").

In December 2020, the Company and Alnylam entered into a letter amendment (the "Letter Agreement"), amending the Amended Alnylam Agreement, to modify certain funding and governance provisions in connection with the siRNA products directed to the COVID Collaboration Targets, including VIR-2703 (the "COV Target"), and to modify certain rights of each party with respect to products arising from such programs. Pursuant to the Letter Agreement, Alnylam was responsible for conducting pre-clinical research activities set forth in the existing workplan for the COV Target (the "COV Workplan") at its discretion and sole expense, and the Company was no longer obligated to reimburse Alnylam for any share of costs incurred by Alnylam in conducting activities under the COV Workplan after July 1, 2020. In July 2021, Alnylam elected to discontinue the development of the COV Target, and all other related research and development activities in accordance with their rights under the Letter Agreement. As a result, the COV Target and related siRNA program is no longer included within the Amended Alnylam Agreement and all rights to the siRNA program directed to the COV Target reverted to Alnylam.

Research and Development Expenses Recognized for the Period

The Company incurred expenses under the Alnylam Agreement of $0.7 million and $2.4 million during the three and nine months ended September 30, 2021, respectively. 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 of $0.8 million and $5.6 million under the Alnylam Agreement during the three and nine months ended September 30, 2020, 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 under 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 Biologics' 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, in September 2020, and in March 2021 (the "Rockefeller Agreement"). Under 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. In addition, for the achievement of specified development, regulatory and commercial success milestone events, the Company will be required to pay up to $80.3 million, in the aggregate, for up to six infectious disease products. Any follow-on products beyond six products may result in additional milestone event payments. 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.

Under the Rockefeller Agreement, the Company recognized a total of $0.7 million and $4.7 million during the three and nine months ended September 30, 2021, and zero and $1.3 million during the three and nine months ended September 30, 2020, respectively, as research and development expenses related to certain development milestone payments, annual license maintenance fees, and estimated sublicense fees.

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, which was amended in September 2020 (the "MedImmune Agreement"), with MedImmune, LLC ("MedImmune"), under 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 MedImmune Agreement.

In consideration for the grant of the licenses under the 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, of which $5.0 million was paid in the third quarter of 2019, 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 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 MedImmune Agreement in its entirety or on a product-by-product basis, for convenience, upon 120 days' notice. Either party may terminate the 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 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 MedImmune Agreement.

Xencor

August 2019 License Agreement

In August 2019, the Company entered into a patent license agreement, which was amended in February 2021 (the "2019 Xencor Agreement") with Xencor, Inc. ("Xencor"). Under the 2019 Xencor Agreement, as amended, the Company obtained a non-exclusive, sublicensable (only to its affiliates and subcontractors) license to incorporate Xencor's licensed 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 licensed technologies, for each of the influenza A and HBV research programs. These technologies are used in the Company's VIR-2482, incorporating Xencor's Xtend technology, and VIR-3434, incorporating Xencor's Xtend and other Fc technologies, product candidates.

In consideration for the grant of the license, the Company paid Xencor an upfront fee. 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 ranging from low- to mid-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.

Under the 2019 Xencor Agreement, the Company recognized $0.5 million and $0.5 million during the three and nine months ended September 30, 2021, and zero and $0.3 million during the three and nine months ended September 30, 2020, respectively, as research and development expenses related to certain development milestone payments.

March 2020 License Agreement

In March 2020, the Company entered into a patent license agreement, which was amended in February 2021 (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 licensed 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 licensed technologies, for each of the coronavirus research programs. These technologies are used in the Company's sotrovimab, incorporating Xencor's Xtend technology, and VIR-7832, incorporating Xencor's Xtend and other Fc technologies, 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 at 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. During the three and nine months ended September 30, 2021, the Company recognized $6.3 million and $7.2 million, respectively, as cost of revenue for royalties due to Xencor from the sale of sotrovimab.

The amended 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.

7. Balance Sheet Components

Property and Equipment, net

Property and equipment, net consists of the following:

	September 30, 2021	December 31, 2020
	(in thousands)	
Laboratory equipment	$ 19,296	$ 16,769
Computer equipment	990	556
Furniture and fixtures	1,443	1,444
Leasehold improvements	7,834	7,274
Construction in progress	10,153	1,135
Property and equipment, gross	39,716	27,178
Less accumulated depreciation and amortization	(13,106)	(9,232)
Total property and equipment, net	$ 26,610	$ 17,946

Depreciation and amortization expenses were $1.4 million and $3.9 million for the three and nine months ended September 30, 2021, and $1.1 million and $3.2 million for the three and nine months ended September 30, 2020, respectively.

Accrued and Other Liabilities

Accrued and other liabilities consist of the following:

	September 30, 2021	December 31, 2020
	(in thousands)	
Research and development expenses	$ 27,330	$ 49,384
Payroll and related expenses	15,127	17,060
Accrued royalties	8,069	—
Excess funds payable under grant agreements	1,398	3,467
Operating lease liabilities, current	3,554	3,625
Other professional and consulting expenses	4,052	2,595
Other expenses	5,315	805
Total accrued and other liabilities	$ 64,845	$ 76,936

8. Commitments and Contingencies

Lease Agreements

The Company has various lease arrangements for office and laboratory spaces located in California, Oregon, Missouri and Switzerland with contractual lease periods expiring between 2021 and 2033. 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. Most of these renewal options are not considered in the remaining lease term unless it is reasonably certain that the Company will exercise such options. In February 2021, the Company entered into a new lease arrangement for office and laboratory spaces in Oregon. The Oregon lease is expected to commence in the first quarter of 2022 when the Company obtains access to the leased space. In addition to the operating lease agreements, the Company entered into a sale-leaseback transaction in August 2019.

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 maturity of the Company's operating lease liabilities as of September 30, 2021 was as follows (in thousands):

	Amounts
2021 (excluding the nine months ended September 30, 2021)	$ 1,861
2022	9,709
2023	11,383
2024	10,561
2025	8,038
Thereafter	67,454
Total lease payments	109,006
Less: imputed interest	(36,744)
Less: net tenant improvement allowance yet to be received	(10,287)
Present value of operating lease liabilities	$ 61,975

The following amounts were recorded in the condensed consolidated balance sheets for the periods ended:

	September 30, 2021	December 31, 2020
	(in thousands)	
Operating Leases		
Current operating lease liabilities, net of tenant improvement allowances [1]	$ 10,183	$ 7,913
Operating right-of-use assets	57,566	61,947
Accrued and other liabilities	$ 3,554	$ 3,625
Operating lease liabilities, noncurrent	68,604	66,556
Total operating lease liabilities	$ 72,158	$ 70,181

(1)Current portion of lease liabilities recorded in prepaid expenses and other current assets for which the lease incentives to be received exceed the minimum lease payments to be paid over the next twelve months.

Manufacturing and Supply Letter Agreements

In April 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. In August 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.

In June 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. In August 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.

In August 2020, GSKTSL entered into a Master Services Agreement with Samsung (the "Samsung MSA") and a non-exclusive Master Services Agreement for Commercial Manufacture of Drug Substance with WuXi Biologics (the "WuXi Biologics MSA") in connection with the performance of the obligations of the Company and GSK, pursuant to the 2020 GSK Agreement. In accordance with the terms of the 2020 GSK Agreement, the Company will continue to be responsible for 72.5% of the costs under each of the Samsung MSA and the WuXi Biologics 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.

9. Related Party Transaction

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, a member of the Company's board of directors serves on Brii Bio Parent's board of directors. Effective June 22, 2021, the Company's Chief Executive Officer is no longer a member of Brii Bio Parent's board of directors.

10. 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	Aggregate Intrinsic Value
			(Years)	(in thousands)
Outstanding at December 31, 2020	9,798,282	$ 19.10	8.6	
Granted	3,011,990	$ 59.76		
Exercised	(1,352,457)	$ 7.12		
Forfeited	(1,004,492)	$ 33.21		
Outstanding at September 30, 2021	10,453,323	$ 31.01	8.4	$ 181,305
Vested and expected to vest at September 30, 2021	10,453,323	$ 31.01	8.4	$ 181,305
Vested and exercisable at September 30, 2021	3,762,118	$ 15.57	7.6	$ 106,286

As of September 30, 2021, the Company expects to recognize the remaining unamortized stock-based compensation expense of $189.4 million related to stock options, over an estimated weighted-average period of 2.6 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,	
	2021	2020	2021	2020
Expected term of options (in years)	5.3 - 6.1	5.0 - 6.1	5.3 - 6.1	5.0 - 6.1
Expected stock price volatility	106.9% - 111.5%	99.7% - 108.6%	103.1% - 111.5%	88.8% - 108.6%
Risk-free interest rate	0.8% - 1.0%	0.3% - 0.4%	0.6% - 1.2%	0.3% - 1.2%
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 Awards and Restricted Stock Units Activities

The Company's restricted stock awards (RSAs") and restricted stock units ("RSUs") were summarized as follows:

	Shares		Weighted Average Grant Date Fair Value	
	RSU	RSA	RSU	RSA
Unvested as of December 31, 2020	—	89,261	$ —	$ 1.48
Granted	1,250,184	—	$ 61.67	$ —
Vested	—	(89,261)	$ —	$ 1.48
Canceled	(76,855)	—	$ 65.61	$ —
Unvested as of September 30, 2021	1,173,329	—	$ 61.41	$ —

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

As of September 30, 2021, there was $62.0 million of total unrecognized compensation cost related to unvested RSUs, all of which is expected to be recognized over a remaining weighted-average period of 3.4 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 and the Company's Employee Stock Purchase Plan ("ESPP") in the condensed consolidated statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)			
Research and development	$ 11,165	$ 4,181	$ 30,455	$ 8,369
Selling, general and administrative	11,779	4,401	28,958	8,930
Total stock-based compensation	$ 22,944	$ 8,582	$ 59,413	$ 17,299

11. Net Income (Loss) Per Share

Basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net income (loss) per common share is computed by dividing the net income (loss) by the sum of the weighted average number of common shares outstanding during the period plus any potential dilutive effects of common stock equivalents outstanding during the period calculated in accordance with the treasury stock method. The following is a calculation of the basic and diluted net income (loss) per share (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net income (loss), basic and diluted	$ 110,428	$ (84,609)	$ 3,330	$ (193,016)
Weighted-average shares outstanding, basic	130,665,831	125,810,907	129,520,837	116,427,529
Weighted-average effect of dilutive securities:				
Options to purchase common stock	3,173,930	—	3,757,681	—
Restricted shares subject to future vesting	14,658	—	36,138	—
Contingently issuable shares	—	—	4,323	—
Weighted-average shares outstanding, diluted	133,854,419	125,810,907	133,318,979	116,427,529
Net income (loss) per share, basic	$ 0.85	$ (0.67)	$ 0.03	$ (1.66)
Net income (loss) per share, diluted	$ 0.82	$ (0.67)	$ 0.02	$ (1.66)

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Options issued and outstanding	6,316,134	9,459,015	5,278,033	9,459,015
Estimated shares issuable under the ESPP	71,582	—	71,582	—
Restricted shares subject to future vesting	1,067,204	283,631	1,025,454	283,631
Total	7,454,920	9,742,646	6,375,069	9,742,646

12. Subsequent Events

New Lease Agreement

In October 2021, the Company entered into a new sublease agreement for its office and laboratory space in St. Louis, Missouri which expires in December 2028, with no options to extend or renew the lease. Total future rent payments under the agreement amount to $27.6 million. In addition, the Company is entitled to a tenant improvement allowance of $14.7 million from the sublessor.

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, 2020. 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 commercial-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 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.

Our current development pipeline consists of product candidates targeting COVID-19, hepatitis B virus, or HBV, influenza A virus, and human immunodeficiency virus, or HIV. 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. We have built an industry-leading team that has deep experience in immunology, infectious diseases, and product development and commercialization. Given the global impact of infectious diseases, we are committed to developing cost-effective treatments that can be delivered at scale.

COVID-19

Sotrovimab (previously VIR-7831) is an investigational severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2, neutralizing monoclonal antibody, or mAb, that incorporates Xencor's Xtend™ technology.

- To date, binding agreements have been received for the sale of more than 420,000 doses of sotrovimab worldwide, including a portion of those procured by the U.S. government. In addition, more than 220,000 doses have been reserved through other agreements. We and GSK continue to work actively with governments around the world to make sotrovimab available to patients in need.
- Multiple countries granted marketing authorizations for sotrovimab, under the brand name Xevudy®, during the third quarter:
  - In August, the Australian Therapeutic Goods Administration granted provisional marketing authorization for the treatment of adults and adolescents with COVID-19.
  - In August, Saudi Arabia granted conditional marketing authorization for the treatment of adults and adolescents with COVID-19.
  - In September, the Japanese Ministry of Health, Labour and Welfare granted Special Approval for Emergency for the treatment of mild to moderate COVID.
- In addition to receiving emergency use authorization, or EUA, in the U.S. and a positive scientific opinion under Article 5(3) of Regulation 726/2004 from the Committee for Human Medicinal Products, or CHMP, in the European Union, or EU, sotrovimab has been granted emergency or temporary use authorization in a dozen other countries.
- The European Medicines Agency's CHMP is conducting a rolling review of data on sotrovimab to support a forthcoming marketing authorization application, or MAA. The rolling review process is expected to be complete in the fourth quarter of 2021, when an invitation to submit the MAA by the CHMP may be issued.
- We and GSK now plan to submit a Biologics License Application, or BLA, to the U.S. Food and Drug Administration, or FDA, in the first half of 2022.
- Updated in vitro data, published in bioRxiv, demonstrate that sotrovimab retains activity against all current variants of concern and interest of the SARS-CoV-2 virus as defined by the World Health Organization (WHO), plus others, including, but not limited to, Delta (B.1.617.2), Delta Plus (AY.1 or AY.2) and Mu (B.1.621).

- We and GSK continue to advance trials evaluating intramuscular administration of sotrovimab to increase patient access and convenience. Initial data from the Phase 2 COMET-PEAK pharmacokinetic trial in outpatients with mild-to-moderate COVID-19 and the Phase 3 COMET-TAIL trial for early treatment of mild-to-moderate COVID-19 in high-risk, non-hospitalized adult and adolescent patients are expected in the fourth quarter of 2021.
- Together, we and GSK are also supporting clinical studies evaluating whether sotrovimab, administered as prophylaxis, can help prevent symptomatic COVID-19 infection in uninfected immunocompromised adults – an area of significant unmet need. Preliminary human PK data presented at the International Society for Influenza and other Respiratory Virus Diseases-WHO conference in October 2021 suggest a single 500 mg dose of sotrovimab could provide prophylactic protection for at least six months.
- We and GSK have established a strategic manufacturing network that will enable the manufacture of approximately two million doses of sotrovimab to support emergency supply in the first year following U.S. EUA. We are actively working to expand our capacity to increase supply through 2022 so that we can continue to serve more patients.

VIR-7832 is an investigational vaccinal SARS-CoV-2-neutralizing mAb that incorporates Xencor's Xtend and other Fc technologies. VIR-7832 shares the same characteristics as sotrovimab and has been engineered to potentially be a therapeutic T cell vaccine to further help treat and/or prevent COVID-19. The United Kingdom's National Health Service-supported AGILE initiative evaluating VIR-7832 in a Phase 1b/2a trial of adults with mild-to-moderate COVID-19 remains ongoing. To date, no safety signals have been reported for either the 50mg or 150mg dose cohorts. Additional data are expected in the first half of 2022. In July 2021, our investigational new drug application for VIR-7832 was cleared with the FDA.

HBV

VIR-2218, an investigational HBV-targeting siRNA, is currently in a Phase 2 trial. We also continued to progress a Phase 2 combination trial of VIR-2218 with pegylated interferon-alpha to evaluate the potential for this combination to result in a functional cure for HBV. VIR-2218 is also being explored in additional clinical trials with collaborators.

VIR-3434, an investigational HBV-neutralizing mAb that incorporates Xencor's Xtend and other Fc technologies, is currently in a Phase 1 trial. In July 2021, we initiated the Phase 2 MARCH trial to evaluate the combination of VIR-2218 and VIR-3434 as a functional cure regimen for chronic HBV infection. Initial data are expected in the first half of 2022.

Influenza A virus

VIR-2482, an investigational mAb designed for the prevention of influenza A that incorporates Xencor's Xtend technology, is currently in a Phase 1/2 trial and has been generally well-tolerated. Due to an anticipated relatively low incidence of influenza in the Northern Hemisphere this winter, we are deferring initiation of our Phase 2 trial of VIR-2482. In May 2021, we signed a collaboration agreement, or the 2021 GSK Agreement, with GSK to expand our existing collaboration to include the research and development of new therapies for influenza and other respiratory viruses. For details regarding this agreement, see Note 6—Collaboration and License Agreements to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

HIV

VIR-1111, an investigational HIV T cell vaccine based on human cytomegalovirus, or HCMV, is currently in a Phase 1 trial. This proof-of-concept trial is designed to evaluate whether this new approach can elicit potentially protective immune responses that differ from other HIV vaccines. Initial clinical data from the first cohort are expected in the fourth quarter of 2021.

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.

We have financed our operations primarily through sales of our common stock from our initial public offering and subsequent follow-on offering and convertible preferred securities and payments received under our grant and collaboration agreements. As of September 30, 2021, excluding restricted cash, we had $939.5 million in cash, cash equivalents and investments, and by also excluding the equity investment in Brii Biosciences Limited, or Brii Bio Parent, we had $770.1 million. Based upon our current operating plan, we believe that the $770.1 million as of September 30, 2021 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 have received an EUA from the FDA, and a positive scientific opinion from the CHMP in the EU for sotrovimab. In addition, sotrovimab has received marketing authorizations in Australia, Japan and Saudi Arabia (under the brand name, Xevudy®), and emergency or temporary use authorizations from governments in a dozen countries. Although we (through our partner GSK) have recently entered into procurement agreements to supply sotrovimab to governments around the world and began to recognize revenue for sotrovimab, the extent of future revenue remains uncertain. We have not obtained regulatory approval for any other product candidates, and we do not expect to generate significant revenue from the sale of our other product candidates until we complete clinical development, submit regulatory filings and receive approvals from the applicable regulatory bodies for such product candidates, if ever. We had net income of $3.3 million and net loss of $193.0 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $663.9 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. Although we recently began recognizing revenue for sotrovimab and have a substantial deferred revenue under our 2021 GSK Agreement, we expect to continue to incur net operating losses for at least the next several years as the extent of future revenue remains uncertain. 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 functions 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 of our platforms: antibodies, T cells and siRNAs. We have established our own internal chemistry, manufacturing and control capabilities and are working with contract development and manufacturing organizations, or CDMOs, to supply our early-stage product candidates in the near term. We continue to expand our internal capabilities and resources in process development, analytical development, quality, manufacturing and supply chain, which are supported by our San Francisco, California, and Portland, Oregon facilities that include laboratories for process development, production of 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 through Phase 3 clinical trials. Material for Phase 3 clinical trials and commercial supply will generally require large-volume, low-cost-of-goods production. For example, for our COVID-19 program, we and our partner GSK have executed manufacturing agreements with large-scale CDMOs to support future scale-up and capacity, particularly for potential commercialization.

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, which continue to evolve based on the current climate and response to the ongoing COVID-19 pandemic, 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 the 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. 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 5—Grant Agreements and Note 6—Collaboration and License Agreements to our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Components of Operating Results

Revenue

We have received an EUA from the FDA, and a positive scientific opinion from the CHMP in the EU for sotrovimab. In addition, sotrovimab has received marketing authorizations in Australia, Japan and Saudi Arabia (under the brand name, Xevudy®), and emergency or temporary use authorizations from governments in a dozen countries. We (through our partner GSK) have recently entered into procurement agreements to supply sotrovimab to governments around the world and we have begun recognizing revenue from our profit share under our 2020 GSK Agreement. However, the extent of future revenue remains uncertain. We have not obtained regulatory approval for any other product candidates, and we do not expect to generate any significant revenue from the sale of our other 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 the following:

Collaboration revenue includes recognition of our profit share from the sales of sotrovimab pursuant to the 2020 GSK Agreement. Our contractual share of 72.5% from the sales of sotrovimab is based upon the revenue reported to us by GSK, net of cost of sales and allowable expenses (including distribution, selling, and marketing expenses) in the period.

Contract revenue includes recognition of the upfront fees from license rights issued to GSK and revenue generated from research and development services.

Grant revenue is comprised of revenue derived from grant agreements with government-sponsored and private organizations.

License revenue from a related party comprised 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 recognized in the prior year.

Operating Expenses

Cost of Revenue

Cost of revenue currently represents payments due to certain of our third-party licensors, who are entitled to future royalties based on net sales of sotrovimab by us or our collaboration partners. We recognize these royalties as cost of revenue when we recognize the corresponding revenue that gives rise to payments due to our licensors.

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 our product candidates in development and prior to regulatory approval, which include:

- expenses related to license and collaboration agreements, and change in fair value of 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 have received an EUA from the FDA, and a positive scientific opinion from the CHMP in the EU for sotrovimab. In addition, sotrovimab has received marketing authorizations in Australia, Japan and Saudi Arabia (under the brand name, Xevudy®), and emergency or temporary use authorizations from governments in a dozen countries. However, we may never succeed in achieving BLA or other similar approvals for sotrovimab or 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 significant revenue from the commercialization and sale of sotrovimab or any 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.

Selling, General and Administrative

Our selling, general and administrative expenses consist primarily of personnel-related expenses for personnel in executive, finance and other administrative functions, facilities and other allocated expenses, other expenses for outside professional services, including legal, audit and accounting services, insurance costs and change in fair value of contingent consideration from business acquisitions. Personnel-related expenses consist of salaries, benefits and stock-based compensation.

We expect our selling, 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 commercialization activities for our EUA product or any of our product candidates, if approved. 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.

Change in Fair Value of Equity Investments

Change in fair value of equity investments consists of the remeasurement of our investment in Brii Bio Parent's ordinary shares based on the quoted market price at each reporting date.

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 international income tax.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2021 and 2020

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
	(in thousands)					
Revenue:						
Collaboration revenue	$ 102,398	$ —	$ 102,398	$ 107,731	$ —	$ 107,731
Contract revenue	315	188	127	169,581	44,197	125,384
Grant revenue	903	1,740	(837)	5,356	7,690	(2,334)
License revenue from a related party	—	—	—	—	22,747	(22,747)
Total revenue	103,616	1,928	101,688	282,668	74,634	208,034
Operating expenses:						
Cost of revenue	7,836	—	7,836	8,988	—	8,988
Research and development	98,669	70,684	27,985	319,665	215,316	104,349
Selling, general and administrative	50,496	18,859	31,637	105,016	47,894	57,122
Total operating expenses	157,001	89,543	67,458	433,669	263,210	170,459
Loss from operations	(53,385)	(87,615)	34,230	(151,001)	(188,576)	37,575
Other income (expense):						
Change in fair value of equity investments	164,072	—	164,072	164,072	—	164,072
Interest income	11	412	(401)	272	2,548	(2,276)
Other income (expense), net	64	2,616	(2,552)	(9,430)	(6,904)	(2,526)
Total other income (expense)	164,147	3,028	161,119	154,914	(4,356)	159,270
Income (loss) before provision for income taxes	110,762	(84,587)	195,349	3,913	(192,932)	196,845
Provision for income taxes	(334)	(22)	(312)	(583)	(84)	(499)
Net income (loss)	$ 110,428	$ (84,609)	$ 195,037	$ 3,330	$ (193,016)	$ 196,346

Revenue

The increase in collaboration revenue for the three and nine months ended September 30, 2021 compared to the same periods in 2020 was due to our profit-sharing arrangement with GSK for the sale of sotrovimab under our 2020 GSK Agreement, for which there were no comparable revenues recognized in the prior year. Our contractual share of 72.5% from the sales of sotrovimab is based upon the revenue reported to us by GSK, net of cost of sales and allowable expenses (including distribution, selling, and marketing expenses) in the period.

The increase in contract revenue for the nine months ended September 30, 2021 compared to the same period in 2020 was primarily due to $168.3 million related to the license granted to GSK upon execution of our 2021 GSK Agreement, partially offset by $43.3 million related to the license granted to GSK upon execution of our 2020 GSK Agreement in the prior year. The increase in contract revenue for the three months ended September 30, 2021 compared to the same period in 2020 was not material.

The decrease in grant revenue for the three months ended September 30, 2021 compared to the same period in 2020 was primarily due to the timing of research activities under the HIV and TB grants with the Bill & Melinda Gates Foundation. The decrease in grant revenue for the nine months ended September 30, 2021 compared to the same period in 2020 was primarily due to a supplemental award received in the first quarter of 2020 under the HIV grant for reimbursement, in part, of the prior period costs.

The decrease in license revenue from a related party was due to the $22.7 million of revenue related to Brii Bio's exercise of its option to obtain exclusive rights to develop and commercialize compounds arising from VIR-2218 in greater China recognized in the prior year.

Cost of Revenue

The increase in cost of revenue for the three and nine months ended September 30, 2021 compared to the same periods in 2020 was due to third-party royalties owed based on the sales of sotrovimab, which received an EUA in the United States in May 2021, under our 2020 GSK Agreement.

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,		
	2021	2020	Change	2021	2020	Change
			(in thousands)			
Licenses, collaborations and contingent consideration	$ 14,350	$ 20,579	$ (6,229)	$ 85,421	$ 80,137	$ 5,284
Personnel	28,763	17,323	11,440	82,591	46,488	36,103
Contract manufacturing	3,878	10,844	(6,966)	19,520	32,488	(12,968)
Clinical costs	35,553	7,414	28,139	81,700	14,913	66,787
Other	16,125	14,524	1,601	50,433	41,290	9,143
Total research and development expenses	$ 98,669	$ 70,684	$ 27,985	$ 319,665	$ 215,316	$ 104,349

Comparison of three months ended September 30, 2021 and 2020

This increase in research and development expenses for the three months ended September 30, 2021 compared to the same period in 2020 was primarily due to the following factors:

- clinical costs increased by $28.1 million, which was primarily attributable to activities related to our sotrovimab, VIR-2218 and VIR-3434 clinical trials;
- personnel-related expenses increased by $11.4 million, which was primarily attributable to an increase in our headcount;
- other research and development expenses increased by $1.6 million, which was primarily attributable to the allocation of facilities and other costs due to an increase in our headcount and higher lease expense;
- licenses, collaborations and contingent consideration expenses decreased by $6.2 million, which was primarily attributable to a decrease of $18.7 million in fair value of the contingent consideration from our acquisition of Humabs Biomed SA, or Humabs, due to the achievement of certain clinical milestone in prior year, and changes in assumptions and probabilities used in calculating the fair value of the remaining liability. This decrease was partially offset by increases of $10.4 million in costs under our collaboration arrangements with GSK and $1.3 million in third-party milestone payments; and
- contract manufacturing expense decreased by $7.0 million, which was primarily related to the completion of manufacturing activities for our COVID-19 product candidates in the third quarter of 2020.

Comparison of nine months ended September 30, 2021 and 2020

This increase in research and development expenses for the nine months ended September 30, 2021 compared to the same period in 2020 was primarily due to the following factors:

- clinical costs increased by $66.8 million, which was primarily attributable to activities related to our sotrovimab, VIR-2218 and VIR-3434 clinical trials;
- personnel-related expenses increased by $36.1 million, which was primarily attributable to an increase in our headcount;
- other research and development expenses increased by $9.1 million, which was primarily attributable to increases of $5.8 million in the allocation of facilities and other costs due to an increase in our headcount and higher lease expense, and $2.7 million in sublicense fees due under a license agreement;

- licenses, collaborations and contingent consideration expenses increased by $5.3 million, which was primarily attributable to increases of $50.6 million in costs under our collaboration arrangements with GSK, and $1.0 million in third-party milestone payments, partially offset by decreases of $31.8 million due to achievement of the first development milestone under our collaboration agreement with Alnylam Pharmaceuticals, Inc., or the Alnylam Agreement, in the first quarter of 2020, $10.0 million payment to Alnylam resulting from Brii Bio's exercise of its option for VIR-2218 in the second quarter of 2020, $3.7 million in fair value of the contingent consideration from our acquisition of Humabs due to the achievement of certain clinical milestones in prior year as well as changes in assumptions and probabilities used in calculating the fair value of the remaining liability, and $1.3 million in collaboration costs under our Alnylam Agreement; and
- contract manufacturing expense decreased by $13.0 million, which was primarily related to the completion of manufacturing activities for our COVID-19 product candidates in the third quarter of 2020.

Selling, General and Administrative Expenses

The increase in selling, general and administrative expenses for the three and nine months ended September 30, 2021 compared to the same periods in 2020 was primarily due to an increase of $20.2 million in fair value of the contingent consideration related to sales-based milestones from our acquisition of Humabs. The remaining increase was due to personnel-related expenses related to additional headcount, external consulting services, and allocated facilities costs due to higher lease expense.

Change in Fair Value of Equity Investments

In July 2021, Brii Bio Parent became a publicly traded company on the Stock Exchange of Hong Kong Limited. In connection with the initial public offering, our investment in shares of Brii Bio Parent became a marketable equity investment and subsequently remeasured to fair value at each reporting period. For the three and nine months ended September 30, 2021, we recognized an unrealized gain of $164.1 million due to the change in fair value of the equity investment. No comparable amount was incurred for the same periods in 2020.

Interest Income

The decrease in interest income was primarily due to lower interest rates and higher amortization of premium on investment balances in the three and nine months ended September 30, 2021 compared to the same periods in 2020.

Other Income (Expense), Net

The increase in other expenses for the three and nine months ended September 30, 2021 compared to the same periods in 2020 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, 2021, excluding restricted cash, we had $939.5 million in cash, cash equivalents and investments, and by also excluding the equity investment in Brii Bio Parent, we had $770.1 million. As of September 30, 2021, we had an accumulated deficit of $663.9 million. To date, we have financed our operations primarily through sales of our common stock from our initial public offering and follow-on offering; sales of our convertible preferred securities; and payments received under our grant and collaboration agreements.

In November 2020, we entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, pursuant to which we may from time to time offer and sell shares of our common stock for an aggregate offering price of up to $300.0 million, through or to Cowen, acting as sales agent or principal. As of September 30, 2021, no shares have been issued under the Sales Agreement.

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 the $770.1 million as of September 30, 2021 noted above 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 commercialization activities, including product manufacturing, marketing, sales and distribution, for our EUA product and any of our product candidates for which we receive marketing approval;
- the amount of revenue received from commercial sales of our EUA product or any 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,	
	2021	2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (55,284)	$ (108,889)
Investing activities	236,768	(70,575)
Financing activities	94,661	529,733
Net increase in cash and cash equivalents and restricted cash and cash equivalents	$ 276,145	$ 350,269

Operating Activities

During the nine months ended September 30, 2021, net cash used in operating activities was $55.3 million. This consisted primarily of a net income of $3.3 million and non-cash charges of $131.0 million, offset by payment of contingent consideration of $8.1 million for a milestone achieved related to our TomegaVax acquisition, an unrealized gain of $164.1 million on our equity investment, and an increase in our net operating assets of $17.4 million. The change in our net operating assets of $17.4 million was primarily due to increase in collaboration receivable by $93.0 million resulting from our profit share from the sale of sotrovimab, and decrease in accrued liabilities and other long-term liabilities by $13.5 million due to timing of payments, partially offset by increases in deferred revenue by $89.6 million driven by the upfront fee received under the 2021 GSK Agreement, and prepaid expenses and other current assets by $1.9 million. The non-cash charges of $131.0 million primarily consisted of $63.2 million for revaluation of contingent consideration, $59.4 million for stock-based compensation expense, $4.5 million for noncash lease expense, and $3.9 million for depreciation and amortization.

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.

Investing Activities

During the nine months ended September 30, 2021, net cash provided by investing activities was $236.8 million. This consisted primarily of $301.2 million in proceeds received from investments that matured during the period, partially offset by purchases of investments of $55.7 million and property and equipment of $8.8 million.

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 that matured during the period.

Financing Activities

During the nine months ended September 30, 2021, net cash provided by financing activities was $94.7 million. This consisted primarily of proceeds received from the issuance of our common stock to Glaxo Group Limited (an affiliate of GSK), or GGL, of $85.2 million in March 2021 and from exercises of stock options of $9.6 million.

During the three and 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 GGL 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.

Contractual Obligations and Commitments

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, 2020.

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.

Critical Accounting Policies and Estimates

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

There have been no significant changes in our critical accounting policies during the nine months ended September 30, 2021, as compared with those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on February 25, 2021.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Interest Rate Risk

We had cash, cash equivalents and restricted cash and cash equivalents of $727.6 million as of September 30, 2021, which primarily consisted of money market funds. We also had short-term investments of $55.6 million as of September 30, 2021. 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, 2021.

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 primarily 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, 2021 and 2020.

Equity Investment Risk

We hold ordinary shares of Brii Bio Parent, which we acquired in connection with our collaboration, option and license agreement. These equity securities are measured at fair value with any changes in fair value recognized in our condensed consolidated statements of operations. The fair value of these equity securities was approximately $169.4 million as of September 30, 2021. Changes in the fair value of these equity securities are impacted by the volatility of the stock market and changes in general economic conditions, among other factors. A hypothetical 10% increase or decrease in the stock prices of these equity securities would increase or decrease their fair value as of September 30, 2021 by approximately $16.9 million.

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, 2021 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.

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 net losses for the foreseeable future and therefore, may not be able to maintain profitability.

Since inception in April 2016, we have incurred significant net losses and have never generated any significant revenue from product sales. We had net income of $3.3 million and net loss of $193.0 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $663.9 million. Although we (through our partner GSK) have recently entered into procurement agreements to supply sotrovimab to governments around the world and began to recognize revenue for sotrovimab, the extent of future revenue remains uncertain.

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. We have received an Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, and a positive scientific opinion from the Committee for Human Medicinal Products, or CHMP, in the European Union, or EU, for sotrovimab. In addition, sotrovimab has received marketing authorizations in Australia, Japan and Saudi Arabia (under the brand name, Xevudy®), and emergency or temporary use authorizations from governments in a dozen countries. It could be several years, if ever, before we are able to commercialize any of our other products. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. 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 and trials 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 commercial-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. We have received an EUA from the FDA, and a positive scientific opinion from the CHMP in the EU for sotrovimab. In addition, sotrovimab has received marketing authorizations in Australia, Japan and Saudi Arabia (under the brand name, Xevudy®), and emergency or temporary use authorizations from governments in a dozen other countries. We are in the early stages of seeking approval under a biologics license application, or BLA, and expanding our commercialization capabilities for sotrovimab. As an organization, we have not yet demonstrated an ability to successfully 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 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, 2021, excluding restricted cash, we had cash, cash equivalents and investments of $939.5 million, and by also excluding the equity investment in Brii Biosciences Limited, or Brii Bio Parent, we had $770.1 million. Based upon our current operating plan, we believe that the $770.1 million as of September 30, 2021 will fund our current operating plans through at least the next 12 months from the issuance date of our consolidated financial statements for the period ended September 30, 2021. 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 EUA product or 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 commercialization activities, including product manufacturing, marketing, sales and distribution, for our EUA product and any of our product candidates for which we receive marketing approval;
- the amount of revenue received from commercial sales of our EUA product or any 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.

The COVID-19 pandemic and the evolution of new and existing variants of COVID-19 has 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 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 commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

We received an EUA from the FDA for sotrovimab (previously VIR-7831). If the FDA revokes or terminates our EUA for sotrovimab for the early treatment of COVID-19, such as when the federally-declared COVID-19 public health emergency ends, we will be required to stop commercial distribution of sotrovimab in the United States unless we can obtain FDA approval for this product and its currently authorized uses.

Sotrovimab is currently made available pursuant to an EUA we received from the FDA on May 26, 2021 for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at risk for progression to severe COVID-19, including hospitalization or death. We cannot predict how long this EUA will remain effective for, and we may not receive advance notice from the FDA regarding revocation of our EUA. If our EUA is terminated or revoked, sotrovimab will no longer be available in the United States until and if we have obtained FDA approval of a BLA. Changing policies and regulatory requirements could limit, delay or prevent further commercialization of sotrovimab and could adversely impact our business, financial condition, results of operations and prospects.

Our near-term success is dependent on the successful roll-out and commercialization of sotrovimab for the early treatment of COVID-19. If we are unable to successfully roll-out and commercialize sotrovimab, our business, financial condition, results of operations and prospects may be adversely affected.

Our near-term success is dependent on the successful roll-out and commercialization of sotrovimab, which is our only currently available product. The commercial success of sotrovimab will depend on a number of factors, some of which are outside of our control, including the following:

- our ability to comply with all regulatory requirements applicable to our EUA, including applicable FDA marketing, manufacturing and post-market requirements and other requirements of our EUA;
- whether we are required by the FDA or other similar regulatory authorities to conduct additional clinical trials or to modify the design of our current trials to support the approval of sotrovimab;
- the receipt of additional marketing authorizations and approvals from the FDA and other similar regulatory authorities;
- our ability to achieve and maintain compliance with all regulatory requirements applicable to sotrovimab;
- perceptions by the public and members of the medical community, including physicians, as to the safety and efficacy of sotrovimab;

- demand from the public and members of the medical community for sotrovimab;
- the availability, perceived advantages, relative cost, relative convenience and relative efficacy of sotrovimab compared to other COVID-19 therapies;
- the ability of sotrovimab to be effective in patients with COVID-19 and its variants;
- positive or negative media coverage of sotrovimab;
- the effectiveness of our marketing and sales efforts;
- our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of sotrovimab;
- the ability to enter into additional procurement contracts with government entities or be approved for inclusion in government stockpile programs, and our ability to meet our obligations under such contracts and programs;
- our reliance on GSK and other partners for development, commercialization and manufacturing of sotrovimab;
- our ability to obtain, maintain and enforce our intellectual property rights;
- our ability to maintain a continued supply of sotrovimab that meets our quality control requirements;
- the ability of third-party manufacturing partners to meet demand in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements;
- limitation on use or warnings required by the FDA;
- our current and future arrangements with healthcare providers, physicians and third-party payors; and
- availability of, or changes in, coverage or reimbursement rates for sotrovimab from government or other commercial or healthcare payors.

In addition, COVID-19 treatment standards are susceptible to rapid clinical developments. Sotrovimab may be rendered inferior or obsolete, even if it were to gain widespread market acceptance initially. If we are unable to successfully roll-out and commercialize sotrovimab, our business, financial condition, results of operations and prospects may be adversely affected.

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

In response to the ongoing 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 sotrovimab and VIR-7832. We have received an EUA from the FDA, and a positive scientific opinion from the CHMP in the EU for sotrovimab. In addition, sotrovimab has received marketing authorizations in Australia, Japan and Saudi Arabia (under the brand name, Xevudy®), and emergency or temporary use authorizations from governments in a dozen other countries. Also, we (through our partner GSK) have recently entered into procurement agreements to supply sotrovimab to governments around the world. We have not received regulatory approval for any other product candidates, and we may be unable to successfully develop and commercialize a therapy that treats the virus in a timely manner, if at all.

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 market demand and role that antibody therapies will play in the treatment of COVID-19. There are no assurances that there will be sufficient market demand for our COVID-19 therapies. Market demand and utilization of our COVID-19 therapies may be adversely impacted by factors such as the mAbs of other third parties, the rollout of vaccines and oral antivirals, the emergence of new viral variants, and the current challenges in the delivery and administration of mAbs to patients.

Our ability to develop a successful therapy will also 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. Our current estimated aggregate commitments to GSK under two separate master services agreements with Samsung Biologics Co., Ltd. and WuXi Biologics (Hong Kong) Limited, or WuXi Biologics, for drug substance, drug product and raw material were approximately $371 million as of September 30, 2021, excluding the approximate “access fee” payable to Biogen, Inc. that is payable only if we use Biogen, Inc.’s technology. For additional information regarding our obligations under these agreements, see the section titled

“Business—Our Collaboration, License and Grant Agreements” and “Business—Manufacturing—Manufacturing Agreements” in our Annual Report on Form 10-K for the year ended December 31, 2020, or 2020 Form 10-K.

While we believe securing such manufacturing capacity and technological expertise is essential 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 investments. We may also need to enter into additional manufacturing arrangements in the future in order to create an effective supply chain for sotrovimab and our other COVID-19 product candidates that will adequately support demand. In the event that there is not enough demand for the manufacturing capacity that we have already secured or regulatory approval of our product candidates is delayed or unsuccessful, we may remain obligated to pay for such excess manufacturing capacity, which could adversely affect our business, financial condition, results of operations and prospects. We will need to raise substantial additional capital to fund the development of sotrovimab and 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 and our ability to obtain additional capital could be adversely affected if there is a significant decline in the demand for our products or other significantly unfavorable changes in economic conditions. 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 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 we will secure significant supply commitments from governments or that our therapy will be approved for inclusion in government stockpile programs, which may be material to the commercial success of sotrovimab and our product candidates, 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 that is easier to deliver and administer to patients in a timelier 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. Numerous large and small pharmaceutical and biotechnology companies are developing COVID-19 therapy programs, including prophylactic vaccines, oral antivirals, immunomodulators, and antibodies some of which are further along in the development process than we are. For example, in November 2020, Regeneron Pharmaceuticals, Inc., or Regeneron, received EUA from the FDA for REGEN-COV (casirivimab with imdevimab), a cocktail of two monoclonal antibodies, which has been shown to reduce hospitalization and death risk by 70% in early treatment clinical trials. In addition, there are oral antiviral therapies being developed by others such as Merck & Co, Inc., or Merck, whose oral antiviral molnupiravir showed topline efficacy of 50% reduction in risk for hospitalization or death risk in early treatment clinical trials, and for which Merck has been successful in securing government support and funding. AstraZeneca plc’s, or AstraZeneca's, AZD7442, a cocktail of two monoclonal antibodies, showed topline efficacy of 50% reduction in risk for hospitalization or death risk in early treatment clinical trials. Other companies like AstraZeneca and Adagio Therapeutics, or Adagio, have been successful in securing government support and funding, respectively, and are in the process of developing antibody therapies that, if successful, could be effective against known viral variants and be administered via intramuscular, or IM, injection. There are also efforts by other companies in developing prophylactic vaccines against COVID-19. For example, in December 2020, Pfizer Inc. and Moderna, Inc. and in February 2021, Janssen Biotech Inc. received EUA from the FDA for their COVID-19 vaccines which have been proven to be 95%, 94% and 85% effective, respectively, in clinical trials. 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 there will be sufficient market demand for our COVID-19 therapies, that we will secure U.S. government funding, that our manufacturing and supply chain infrastructure will remain uninterrupted and reliable, or that the third parties we rely on to manufacture our COVID-19 therapies will be able to satisfy our demand and not have stock-outs due to raw material shortages and/or greater than anticipated demand or quality issues given the operational challenges and raw material shortages that have been experienced during the COVID-19 pandemic, all of 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 antibodies, oral antivirals, and 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 successfully commercialize a therapy for COVID-19. Additionally, the availability of superior or competitive therapies, or preventative measures such as vaccines or oral antivirals, coupled with the transient nature of pandemics, could negatively impact or eliminate demand for our COVID-19 therapies. For additional information regarding our competition see the section below titled “—Risks Related to the Development and Commercialization — We face substantial competition, which may result in others developing or commercializing products before or more successfully than us.”

Risks Related to the Development and Commercialization

Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of our EUA product and 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 successfully commercialize our EUA product and product candidates, if approved, 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 initiated clinical trials for multiple product candidates. We have received an EUA from the FDA, and a positive scientific opinion from the CHMP in the EU for sotrovimab. In addition, sotrovimab has received marketing authorizations in Australia, Japan and Saudi Arabia (under the brand name, Xevudy®), and emergency or temporary use authorizations from governments in a dozen other countries. However, we have not obtained BLA approval for any product candidate to date. We operate in a highly regulated field, and it is possible that any product candidate we may seek to develop in the future will not obtain regulatory approval.

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 for further development, manufacturing or commercialization of our product candidates 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.

Even if we eventually complete clinical testing and receive approval of a new drug application, or NDA, 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 applicable regulatory 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 or if there is an insufficient demand for 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 candidate 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.

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 a Phase 2 clinical trial 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 and market authorizations.

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. 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. If we do not conduct clinical trials with a large enough patient sample size, we may not achieve statistically significant results or the same level of statistical significance, if any, that would have been possible to achieve in a larger trial.

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 which could mean we will suffer setbacks. Any such setbacks could negatively impact 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 is 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.

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.

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 necessary regulatory approvals, 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 few have received regulatory approval and market authorizations. 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 trials 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 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, 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 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 trials, 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 sotrovimab and VIR-7832 for the treatment of COVID-19, VIR-2218 and VIR-3434 for the treatment of HBV, VIR-2482 for the prevention of influenza A, and VIR-1111 for the prevention of human immunodeficiency virus, or HIV. In particular, clinical trials for prophylaxis 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.

The continued spread of COVID-19 globally, or the evolution of new variants of COVID-19 that are more contagious, have more severe effects or are resistant to treatments or vaccinations, could adversely impact our preclinical or clinical trial operations in the United States, including our ability to enroll and retain patients as well as CROs and clinical trial site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography.

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.

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 pursuant to which we license a number of technologies to form our technology platforms. These agreements contain obligations that require us to make substantial payments in the event certain milestone events are achieved. We may in the future be required to make these payments, which could adversely affect our financial condition. In addition, we cannot be certain that we will achieve the results or benefits that justifies entering into these agreements. For additional information regarding these and other collaboration, license and grant agreements, see the section titled “Business—Our Collaboration, License and Grant Agreements” in our 2020 Form 10-K.

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 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;
- 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;

- disputes may arise between us and our strategic collaborators 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; 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 the number of people who have these diseases, the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, and the market demand for 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 trials 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. Additionally, the availability of superior or competitive therapies from our competitors could negatively impact or eliminate market demand for our product candidates. 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. The availability of superior or competitive therapies (including other antibody therapies or other oral antivirals), or preventative measures such as vaccines, coupled with the unpredictable nature of pandemics and the prevalence of new variants of COVID-19, could negatively impact or eliminate demand for our COVID-19 therapies. Product candidates that we successfully develop and commercialize may compete with existing therapies, including prophylactic vaccines, competing antibody therapies, oral antivirals, and new therapies that may become available in the future. In addition, one or more of our competitors may be successful in producing a more efficacious therapy for SARS-CoV-2 and current and future variants or in producing a therapy that is easier to deliver and administer to patients in a timelier manner.

Our commercialization potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. The key competitive factors affecting the success of all our programs are likely to be efficacy, safety, convenience and timing. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. For example, there are FDA-approved treatments for COVID-19 including an intravenously administered antiviral, remdesivir, marketed by Gilead Sciences, Inc., which is FDA approved for the treatment of COVID-19 in hospitalized settings, and several treatments and prophylactic vaccines are available under EUA. Currently, the antibody combination of casirivimab and imdevimab by Regeneron are available under EUA, for intravenously or subcutaneously administered regimen in the mild-to-moderate setting. Additionally, COVID-19 vaccines are available in the United States under EUA from Janssen Biotech, Inc., Moderna, Inc. and Pfizer Inc. (in partnership with BioNTech SE). Numerous large and small pharmaceutical and biotechnology companies are developing programs with various mechanisms of actions, including prophylactic vaccines, oral antivirals, immunomodulators, and antibodies. Companies with antibodies in clinical development include AbbVie, Inc., Adagio, AstraZeneca, Brii Bio, Celltrion Healthcare Co.,

Ltd., Eli Lilly and Regeneron. Companies with oral antivirals in clinical development include Merck, Pfizer Inc., and Roche Holding AG,. Companies with prophylactic vaccines in clinical development include AstraZeneca, GSK, Novavax, Inc. and Sanofi S.A.

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. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

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 additional information regarding our competitors, see the section titled "Business—Competition" in our 2020 Form 10-K.

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, such as the regulatory approval granted to sotrovimab in Australia, Japan and Saudi Arabia (under the brand name, Xevudy®), 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.

If any of our product candidates are approved but fail to achieve market acceptance among physicians, patients, third-party payors and others in the medical community, we will not be able to generate significant revenue, which would compromise our ability to become profitable.

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

Even if we obtain regulatory approval in a jurisdiction, the regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval trials, post-market surveillance or patient or drug restrictions. Additionally, the holder of an approved BLA is required to comply with FDA rules and is subject to FDA review and periodic inspections, in addition to other potentially applicable federal and state laws, to ensure compliance with current good manufacturing practices, or cGMP, and adherence to commitments made in the BLA.

If we or a regulatory agency discovers 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, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Moreover, product labeling, advertising and promotion for any approved product will be subject to regulatory requirements and continuing regulatory review. For example, a company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the United States or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Failure to comply with such requirements, when and if applicable, could subject us to a number of actions ranging from warning letters to product seizures or significant fines, among other actions. For additional information regarding regulatory approval and ongoing regulatory oversight, see the section titled "Business—Government Regulation and Product Approval" in our 2020 Form 10-K.

Any government investigation of alleged violations of laws or regulations 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 generate revenue.

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 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.

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 such as cybersecurity-related issues; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Conditions in the insurance markets relating to nearly all areas of traditional corporate insurance change rapidly and may result in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

Risks Related to Regulatory Compliance

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 various development and approval stages. We have received an EUA from the FDA, and a positive scientific opinion from the CHMP in the EU for sotrovimab. In addition, sotrovimab has received marketing authorizations in Australia, Japan and Saudi Arabia (under the brand name, Xevudy®), and emergency or temporary use authorizations from governments in a dozen countries. Sotrovimab is also currently in a Phase 2 clinical trial evaluating an IM formulation. In the second quarter of 2021, we initiated an additional Phase 3 clinical trial evaluating an IM formulation of sotrovimab and a Phase 1b/2a clinical trial for VIR-7832, also a SARS-CoV-2-neutralizing mAb. 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 preclinical 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 EUA 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. Our EUA for sotrovimab, for example, allows us to commercialize sotrovimab prior to FDA approval. However, the FDA may revoke an EUA 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 EUA 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, such as sotrovimab, is not yet approved by the FDA and if we and our commercialization and manufacturing partners have invested in the commercialization and manufacturing of such product candidate under an EUA.

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, see the section titled "—Risk Related to Our Intellectual Property—Patent terms may be inadequate to protect our competitive position on our product candidates or any products approved in the future for an adequate amount of time and additional competitors could enter the market with generic or biosimilar versions of such products.".

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 competitors are able to obtain marketing approval for generics referencing our small molecule product candidates, such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval. For additional information regarding competition, see the section titled "Business—Competition" in our 2020 Form 10-K.

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. For additional information regarding biosimilars and exclusivity, see the section titled "Business—Government Regulation and Product Approval—Biosimilars and Exclusivity" in our 2020 Form 10-K.

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. For additional information regarding competition, see the section titled "Business—Competition" in our 2020 Form 10-K.

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, 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 play a primary role in the recommendation and prescription of our EUA product and 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, such as the U.S. federal Anti-Kickback Statute, federal civil and criminal false claims laws, the healthcare fraud provisions of the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the Physician Payments Sunshine Act.

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 EUA product and additional product candidates, if approved. For additional information regarding these laws, see the section titled "Business—Government Regulation and Product Approval" in our 2020 Form 10-K. 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 EUA product and any product candidates that we commercialize, if approved, which could make it difficult for us to sell profitably.

Market acceptance and sales of our EUA product and any product candidates that we commercialize, if approved, may 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 our EUA product and 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 our EUA product and 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 our EUA product or 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, our EUA product or 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 our EUA product or 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 our EUA product or 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

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, particularly in light of the new Presidential administration, 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. It is possible that additional governmental action is taken in response to the COVID-19 pandemic. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Additionally, In August 2011, the President signed into law the Budget Control Act of 2011, as amended, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and, following passage of subsequent legislation, including the Bipartisan Budget Act of 2018, will continue through 2030 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. Further, in February 2021, the FDA issued guidance strongly recommending that individual monoclonal antibody products be developed with the expectation that they will be combined with one or more monoclonal antibody products that bind to different epitopes to minimize the risk of losing activity against emergent variants. This type of government action could have a negative impact on our business, financial condition, results of operations and prospectus. Additionally, as a result of litigation challenging the interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, on August 10, 2021, the Centers for Medicare & Medicaid Services, or CMS, published a proposed rule that seeks to rescind the Most Favored Nation Model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Further, it is possible that additional governmental action will be taken in response to 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 or marketing authorizations that may have been obtained and we may not achieve or sustain profitability. For additional information regarding other healthcare legislative reform measures, see the section titled "Business—Government Regulation and Product Approval—Healthcare Reform" in our 2020 Form 10-K.

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 our EUA product and any approved product, which could have an adverse effect on demand for our EUA product and 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 limited experience manufacturing 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 future product candidates. Certain of our product candidates may have to compete with existing and future products, such as the annual flu vaccine or any current or future 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 a collaborator and foreign CDMOs, including a CDMO in China which we, in part, 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 collaborators 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 suppliers and manufacturers entails risks to which we would not be exposed to if we manufactured product candidates ourselves, including:

- delay or inability to procure or expand sufficient manufacturing capacity;
- delays in process development;
- issues related to scale-up of manufacturing;
- excess manufacturing capacity due to insufficient market demand for our product candidates and responsibility for the associated costs;
- 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 suppliers and 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.

Changes in U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

The U.S. government has made statements and taken actions in recent years that have led to certain changes and may lead to additional changes to U.S. and international trade policies, including imposing several rounds of tariffs affecting certain products manufactured in China. In March 2018, the Trump administration announced the imposition of tariffs on steel and aluminum entering the United States and in June 2018 announced further tariffs targeting goods imported from China. Both China and the United States have each imposed tariffs indicating the potential for further trade barriers. It is unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry, and it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. While we have only recently started commercialization of sotrovimab under EUA, any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may affect the demand for our drug products, the competitive position of our drug products, and import or export of raw materials used in our drug development, particularly with respect to raw materials that we import from China, including pursuant to our manufacturing arrangements with WuXi Biologics. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

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. 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. We may also be subject to risks related to disputes between us and our licensors regarding the intellectual property subject to a license agreement.

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 with a priority date before March 16, 2013, 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. In addition, 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. 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 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 or any products approved in the future for an adequate amount of time and additional competitors could enter the market with generic or biosimilar versions of such products.

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 Drug Price Competition and Patent Term Restoration Act of 1984, or 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.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application, or ANDA, filed with the FDA to obtain permission to sell a generic version of such product candidate. 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. For additional information regarding the Hatch-Waxman Act and exclusivity, see the section titled "Business—Government Regulation and Product Approval—Hatch-Waxman Amendments and Exclusivity" in our 2020 Form 10-K.

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 are successfully challenged by litigation, the affected product could immediately face competition and its sales would likely decline rapidly. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could 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, derivation proceedings, post grant review and inter-partes review before the USPTO. 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. Third parties may also challenge inventorship through a derivation proceeding or other litigation proceeding challenging inventorship, which can include claims of misappropriation of intellectual property, filing a patent application without authorization of the true inventor, not listing inventors, or listing non-inventors as inventors. 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.

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 the U.S. government, the World Trade Organization, or WTO, or other governmental body imposes an intellectual property rights waiver, our ability to successfully commercialize our COVID-19 product candidates and protect our related technology could be adversely affected.

The WTO is currently considering a waiver of intellectual property rights for COVID-19 vaccines and the U.S. government recently took a stance in support of the waiver. The current proposal is for a temporary waiver of intellectual property rights that cover COVID-19 vaccines, however, the ultimate timing and scope of the waiver, if approved, is unknown. The scope and timing of such waiver will likely be subject to extensive negotiations given the complexity of the matter, which may result in prolonged uncertainty, which could adversely affect our business. If a waiver is approved and covers COVID-19 treatments or prophylactics, such as sotrovimab and VIR-7832, our ability to successfully commercialize our COVID-19 product candidates and protect our related technology could be adversely affected.

The current waiver proposal is the result of public health concerns from the COVID-19 pandemic and an effort to make vaccines more widely available worldwide. This proposal may also lead to similar waivers of intellectual property rights in the future in connection with other public health pandemics or epidemics or other situations of public health concern. Given that our business is focused on treating and preventing infectious diseases, there is a risk that our business and our ability to protect our technology could be adversely affected in situations beyond COVID-19.

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 rely and expect to continue to rely on trademarks as one means to distinguish any of our products and product candidates that are approved for marketing from the products of our competitors. Additionally, the process of obtaining trademark protection is expensive and time-consuming, and we may not be able to prosecute all necessary or desirable trademark applications at a reasonable cost or in a timely manner or obtain trademark protection in all jurisdictions that we consider to be important to our business. 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 product 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.

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 perform certain activities set forth in the Gates Agreement. For additional information regarding our obligations under the Gates Agreement, see the section titled "Business—Our Collaboration, License and Grant Agreements—Letter Agreement with the Bill & Melinda Gates Foundation" in our 2020 Form 10-K.

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, tuberculosis 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. In addition, we are exposed to market risks related to our investments, including changes in fair value of equity securities we hold, which is discussed in greater detail under Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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. We face many risks in connection with acquisitions and investments, whether or not consummated. 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, in connection with our acquisitions of TomegaVax, Humabs and Agenovir, we are required to make future contingent payments upon the achievement of certain milestones. We may in the future be required to make these payments, which could adversely affect our financial condition. For additional information regarding our obligations under these agreements, see the section titled “Business—Our Acquisition Agreements” in our 2020 Form 10-K.

Furthermore, 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, 2021, we had 395 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 consistent with local government requirements, and focused on employee safety, and contemplate returning to remote work should the COVID-19 situation change, there is uncertainty regarding the long-term impact that the COVID-19 pandemic has had on the nature of the office environment and remote working, which could present operational and workplace culture challenges as we seek to expand our organization. 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 CDMOs, 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.

Our business could be materially adversely affected by the effects of health pandemics or epidemics, including the current COVID-19 pandemic, the multiple SARS-CoV-2 variants that have further complicated the fight to subdue the global pandemic and any future outbreaks of the disease. The COVID-19 pandemic has resulted in travel restrictions, quarantines orders and other restrictions by governments to reduce the spread of the disease. As a result, the majority of our workforce has been working from home since March 2020.

The effects of the restrictions related to the COVID-19 pandemic 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. In addition, due to the COVID-19 pandemic and our remote workforce, we have experienced an increased risk to our information technology assets and data. We have implemented plans to reopen our offices when appropriate. We may face several challenges or disruptions upon a return back to the workplace, including re-integration challenges by our employees and distractions to management related to such transition. 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 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.
The continued 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 has already resulted 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 and the evolution of new and existing variants of COVID-19 that are resistant to existing treatments or vaccinations continue 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.

If our information systems, or those maintained on our behalf, fail or suffer security breaches, such events could result in, without limitation, the following: a significant disruption of our product development programs; an inability to operate our business effectively; unauthorized access to or disclosure of the personal information we process; and other adverse effects on our business, financial condition, results of operations and prospects.

Our computer and information technology systems, cloud-based computing services and those of our current and any future collaborators, service providers and other parties upon whom we rely are potentially vulnerable to malware, computer viruses, denial-of-service attacks (such as credential stuffing), ransomware attacks, user error or malfeasance, 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 our information, including intellectual property, proprietary business information and personal information. We may also experience server malfunction, software or hardware failures, supply-chain cyber-attacks, loss of data or other computer assets and other similar issues. We have recently experienced security breaches of our information technology systems, such as through business email compromises. 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 operations.

We may be required to expend significant resources (including financial), fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security breaches and to mitigate, detect, and remediate actual and potential vulnerabilities. Relevant laws, regulations, industry standards and contractual obligations, may require us to implement specific security measures or use industry-standard or reasonable measures to protect against security breaches. 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, data loss or corruption, delays, cessation of service and other harm to our business and our competitive position. If the information technology systems of our third-party vendors become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Although we maintain cybersecurity insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. Furthermore, if a security breach 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, we, our third-party vendors, and our partners' third-party vendors have experienced social engineering efforts (including phishing attacks) designed to gain unauthorized access to our systems and information, including recent business email and system compromises. Similarly, we and our partners' third-party vendors may be a target of other phishing attacks, social engineering attacks and other cyber-attacks in the future. If a data security breach affects our or third parties' systems upon which we rely, corrupts our data or results in the unauthorized disclosure or release of personally identifiable information, our reputation could be materially damaged or our operations, disrupted. In addition, such a breach may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media, individuals, collaborators or others pursuant to various federal, state and foreign data protection, privacy and security laws, regulations and guidelines, industry standards, our policies and our contracts, if applicable. Such laws may include HIPAA and the Health Information Technology for Economic and Clinical Health Act, or HITECH. Under these laws specifically, notice of certain security breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, or the HHS, and for extensive breaches, to the media or state attorneys general. Such a notice could further harm our reputation and our ability to compete. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to a material adverse effect on our reputation, business, or financial condition. Furthermore, a data security breach could result in fines, increased costs or loss of revenue and we could incur liability (such as through regulatory fines and penalties as well as private claims), our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Additionally, federal, state and foreign laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail.

We receive, process, store and use personal information and other data, which subjects us to governmental regulation and other legal obligations, liability and risks related to privacy, security, and data protection, and our actual or perceived failure to comply with such obligations could lead to government enforcement actions (that could include fines and penalties), a disruption of our clinical trials or commercialization of our products, private litigation, harm to our reputation, or other adverse effects on our business or prospects.

We receive, process, store and use personal information and other data about our clinical trial participants, employees, partners and others. We are, or may become, subject to numerous domestic and foreign laws and regulations regarding privacy, data protection, and data security, industry standards, as well as policies, contracts and other obligations that apply to the processing of personal information by us and on our behalf, the scope of which is changing, subject to differing applications and interpretations and may be inconsistent among countries, or conflict with other rules. We strive to comply with all applicable data protection 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 data protection requirements may result in governmental enforcement actions (including fines, penalties, judgments, settlements, additional reporting requirements and/or oversight, temporary or permanent bans on all or some processing of personal information, orders to destroy or not use personal information, 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, interrupt or stop clinical trials, limit our ability to develop or commercialize our products, or require us to revise or restructure our operations. 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. For additional information regarding these laws, see the section titled “Business—Government Regulation and Product Approval—Privacy Laws” in our 2020 Form 10-K.

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 preclinical 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.

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 have no assurances that we will become profitable in the near future, if ever. As of December 31, 2020, we had net operating loss carryforwards of $483.7 million for federal tax purposes and $216.8 million for state tax purposes. If not utilized, federal carryforwards will begin expiring in 2035 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 Coronavirus Aid, Relief and Economic Security Act include, 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. In addition, we are exposed to market risks related to our investments, including changes in fair value of equity securities we hold which may fluctuate from quarter to quarter and year to year, which is discussed in greater detail under Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Our stock price has been, and in the future, may be, subject to substantial volatility. From October 11, 2019, our first day of trading on The Nasdaq Global Select Market, through October 29, 2021, the closing price of our stock ranged from $11.83 per share to $83.07 per share. As a result of the volatility in our stock price, our stockholders could incur substantial losses.

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. 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.

In addition, public statements by us, government agencies, our competitors, the media or others relating to the ongoing COVID-19 pandemic (including regarding our and others' efforts to develop COVID-19 therapies) and the impact of such statements on investors' general perception of our company and our business have in the past resulted, and may in the future result, in significant fluctuations in our stock price. Given the global focus on the COVID-19 pandemic, information in the public arena on this topic, whether or not accurate, has had and will likely continue to have an outsized impact (positive or negative) on our stock price. Moreover, sales of a substantial number of shares of our common stock by our stockholders in the public market or the perception that these sales might occur, have in the past, and may in the future depress the market price of our common stock. Information related to our development, manufacturing, regulatory and commercialization efforts with respect to sotrovimab and VIR-7832, or information regarding such efforts by competitors with respect to their potential therapies, may meaningfully impact our stock price.

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.

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 have incurred and we will continue 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. 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. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act was enacted, pursuant to which the SEC adopted rules and regulations related to corporate governance and executive compensation, such as “say on pay” and proxy access. Emerging growth companies are permitted to implement many of these requirements over time, however, we are no longer an emerging growth company as of December 31, 2020 and expect to incur additional compliance-related expenses as a result.

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. As a public company, we may also be subject to more stringent state law requirements, such as California 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, and California Assembly Bill 979, which generally requires public companies with principal executive offices in California to include specified numbers of directors from “underrepresented communities.” We are currently compliant with the requirements, but there are no assurances that we will be compliant in the future. which generally requires public companies with principal executive offices in California to include specified numbers of 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.

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 are 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. We were previously not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting while we were an emerging growth company. However, we are no longer an emerging growth company as of December 31, 2020. 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. For a summary of these provisions, see the section titled “Anti-Takeover Provisions of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws—Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws” in Exhibit 4.3 Description of Capital Stock filed as part of our 2020 Form 10-K.

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).
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).

* 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 4, 2021

By: /s/ **George Scangos**

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

Date: November 4, 2021

By: /s/ **Howard Horn**

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

Exhibit 31.1

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

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

1. I have reviewed this quarterly report on 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 4, 2021

/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 quarterly report on 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 4, 2021

/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, 2021, 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.

In Witness Whereof, the undersigned have set their hands hereto as of the 4th day of November 2021.

/s/ **George Scangos**	/s/ **Howard Horn**
George Scangos, Ph.D.	**Howard Horn**
President, Chief Executive Officer and Director	**Chief Financial Officer and Secretary**
(Principal Executive Officer)	***(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."