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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2024

OR

o 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.)**
1800 Owens Street, Suite 900, 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 x No o

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 x No o

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

Large accelerated filer	x	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	o
		Emerging growth company	o

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. o

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

As of April 26, 2024, the registrant had 136,058,680 shares of common stock, $0.0001 par value per share, outstanding.

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CAUTIONARY 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, potential of, and expectations for, our pipeline and technology platforms, the timing, potential of and expectations for planned clinical trials and preclinical studies, 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, expected market size and growth for our potential products, the timing of availability of clinical data, program updates and data disclosures, and our plans for our hepatitis B virus, hepatitis delta virus, influenza, COVID-19 and human immunodeficiency virus portfolios, 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,” “might”, “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. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements, or the scientific data presented. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

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

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

VIR BIOTECHNOLOGY, INC.

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

	March 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 160,711	$ 241,576
Short-term investments	985,125	1,270,980
Restricted cash and cash equivalents, current	13,335	13,268
Equity investments	3,927	9,853
Prepaid expenses and other current assets	49,999	52,549
Total current assets	1,213,097	1,588,226
Intangible assets, net	22,465	22,565
Goodwill	16,937	16,937
Property and equipment, net	92,477	96,018
Operating lease right-of-use assets	70,346	71,182
Restricted cash and cash equivalents, noncurrent	6,428	6,448
Long-term investments	359,724	105,275
Other assets	12,495	12,409
TOTAL ASSETS	$ 1,793,969	$ 1,919,060
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 7,114	$ 6,334
Accrued and other liabilities	72,260	104,220
Deferred revenue, current	14,694	64,853
Total current liabilities	94,068	175,407
Deferred revenue, noncurrent	1,526	1,526
Operating lease liabilities, noncurrent	109,171	111,673
Contingent consideration, noncurrent	27,610	25,960
Other long-term liabilities	14,238	14,258
TOTAL LIABILITIES	246,613	328,824
Commitments and contingencies (Note 8)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of March 31, 2024 and December 31, 2023; no shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 135,843,560 and 134,781,286 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	14	13
Additional paid-in capital	1,852,839	1,828,862
Accumulated other comprehensive loss	(2,397)	(815)
Accumulated deficit	(303,100)	(237,824)
TOTAL STOCKHOLDERS' EQUITY	1,547,356	1,590,236
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,793,969	$ 1,919,060

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 March 31,	
	2024	**2023**
Revenues:		
Collaboration revenue	$ (987)	$ 46,574
Contract revenue	52,191	138
Grant revenue	5,172	16,245
Total revenues	56,376	62,957
Operating expenses:		
Cost of revenue	59	1,907
Research and development	100,125	157,643
Selling, general and administrative	36,273	46,778
Total operating expenses	136,457	206,328
Loss from operations	(80,081)	(143,371)
Other income:		
Change in fair value of equity investments	(5,915)	(13,103)
Interest income	21,283	21,307
Other expense, net	(287)	(8,021)
Total other income	15,081	183
Loss before (provision for) benefit from income taxes	(65,000)	(143,188)
(Provision for) benefit from income taxes	(276)	2,232
Net loss	(65,276)	(140,956)
Net loss attributable to noncontrolling interest	—	(56)
Net loss attributable to Vir	$ (65,276)	$ (140,900)
Net loss per share attributable to Vir, basic and diluted	$ (0.48)	$ (1.06)
Weighted-average shares outstanding, basic and diluted	135,280,648	133,552,839

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

VIR BIOTECHNOLOGY, INC.

Condensed Consolidated Statements of Comprehensive Loss
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Net loss	$ (65,276)	$ (140,956)
Other comprehensive (loss) income:		
Unrealized (loss) gain on investments	(1,411)	5,894
Amortization of actuarial (loss) gain	(171)	9
Total other comprehensive (loss) income	(1,582)	5,903
Comprehensive loss	(66,858)	(135,053)
Comprehensive loss attributable to noncontrolling interest	—	(56)
Comprehensive loss attributable to Vir	$ (66,858)	$ (134,997)

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)

	Vir Stockholders' Equity						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Noncontrolling interest	Total Stockholders' Equity
	Share	Amount					
Balance at December 31, 2023	134,781,286	$ 13	$ 1,828,862	$ (815)	$ (237,824)	$ —	$ 1,590,236
Vesting of restricted common stock	950,254	1	—	—	—	—	1
Exercise of stock options	112,020	—	220	—	—	—	220
Stock-based compensation	—	—	23,757	—	—	—	23,757
Other comprehensive loss	—	—	—	(1,582)	—	—	(1,582)
Net loss	—	—	—	—	(65,276)	—	(65,276)
Balance at March 31, 2024	135,843,560	$ 14	$ 1,852,839	$ (2,397)	$ (303,100)	$ —	$ 1,547,356

	Vir Stockholders' Equity						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Noncontrolling interest	Total Stockholders' Equity
	Share	Amount					
Balance at December 31, 2022	133,236,687	$ 13	$ 1,709,835	$ (9,122)	$ 377,237	$ —	$ 2,077,963
Vesting of restricted common stock	517,168	—	—	—	—	—	—
Exercise of stock options	177,102	—	2,310	—	—	—	2,310
Stock-based compensation	—	—	25,481	—	—	—	25,481
Other comprehensive income	—	—	—	5,903	—	—	5,903
Contributions from noncontrolling interest owners	—	—	—	—	—	100	100
Net loss	—	—	—	—	(140,900)	(56)	(140,956)
Balance at March 31, 2023	133,930,957	$ 13	$ 1,737,626	$ (3,219)	$ 236,337	$ 44	$ 1,970,801

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)

	Three Months Ended March 31,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (65,276)	$ (140,956)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in estimated constraint on profit-sharing amount	685	(31,541)
Depreciation and amortization	4,517	5,638
Amortization of premiums (accretion of discounts) on investments, net	238	(9,365)
Noncash lease expense	1,447	2,173
Change in fair value of equity investments	5,915	13,103
Change in estimated fair value of contingent consideration	1,650	(1,246)
Stock-based compensation	23,757	25,481
Other non-cash items, net	(176)	206
Changes in operating assets and liabilities:		
Receivable from collaboration	(401)	2,093
Prepaid expenses and other current assets	1,834	9,493
Other assets	(86)	(1,984)
Accounts payable	735	6,564
Accrued liabilities and other long-term liabilities	(30,003)	(4,036)
Operating lease liabilities	(4,067)	(3,105)
Deferred revenue	(50,159)	1,700
Net cash used in operating activities	(109,390)	(125,782)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of equipment	533	—
Purchases of property and equipment	(1,872)	(6,867)
Purchases of investments	(562,939)	(384,513)
Maturities and sales of investments	592,698	489,459
Net cash provided by investing activities	28,420	98,079
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of principal on financing lease obligation	(69)	(66)
Proceeds from exercise of stock options	221	2,310
Contributions from noncontrolling interest owners	—	100
Net cash provided by financing activities	152	2,344
Net decrease in cash, cash equivalents and restricted cash and cash equivalents	(80,818)	(25,359)
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	261,292	867,968
Cash, cash equivalents and restricted cash and cash equivalents at end of period	$ 180,474	$ 842,609
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH AND CASH EQUIVALENTS TO THE CONDENSED CONSOLIDATED BALANCE SHEETS:		
Cash and cash equivalents	$ 160,711	$ 824,913
Restricted cash and cash equivalents, current	13,335	10,957
Restricted cash and cash equivalents, noncurrent	6,428	6,739
Total cash, cash equivalents and restricted cash and cash equivalents	$ 180,474	$ 842,609

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

VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

1. *Organization*

Business Overview

Vir Biotechnology, Inc. ("Vir" or the "Company") is an immunology company focused on powering the immune system to transform lives by treating and preventing infectious diseases and other serious conditions, including viral-associated diseases. Vir has assembled two technology platforms that are designed to modulate the immune system by exploiting critical observations of natural immune processes. Its current clinical development pipeline consists of product candidates targeting hepatitis delta virus ("HDV"), hepatitis B virus ("HBV"), and human immunodeficiency virus ("HIV"). Vir has several preclinical candidates in its pipeline, including those targeting influenza A and B, coronavirus disease 2019 ("COVID-19"), respiratory syncytial virus and human metapneumovirus ("RSV" and "MPV", respectively), and human papillomavirus ("HPV").

In January 2023, a majority-owned subsidiary, Encentrio Therapeutics, Inc. ("Encentrio"), was incorporated in the State of Delaware. The Company initially owned 80% of Encentrio's outstanding voting shares. During the three months ended June 30, 2023, the Company increased its ownership of Encentrio's outstanding voting shares to 100%. The primary purpose of Encentrio is to conduct research and development of oncology therapeutics.

Liquidity and Capital Resources

In November 2023, the Company entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC, as sales agent ("TD Cowen"), pursuant to which the Company may from time to time offer and sell shares of its common stock for an aggregate offering price of up to $300.0 million, through or to TD 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 ("SEC") on November 3, 2023. The Company will pay TD 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 TD Cowen with customary indemnification and contribution rights. As of March 31, 2024, no shares have been sold under the Sales Agreement.

As of March 31, 2024, the Company had $ 1.51 billion in cash, cash equivalents, and investments, which the Company believes will be sufficient to fund its operations for a period through at least twelve months from the issuance date of these unaudited condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The Company's unaudited 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 unaudited condensed consolidated financial statements include the accounts of Vir and its majority-owned subsidiaries. For consolidated entities where Vir owns or is exposed to less than 100.0% of the economics, the Company records net income (loss) attributable to noncontrolling interests, net of tax in its unaudited condensed consolidated statements of operations equal to the percentage of the economic or ownership interest retained in such entities by the respective noncontrolling parties. 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 unaudited condensed consolidated results of operations for the three months ended March 31, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024, 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 unaudited 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, 2023, filed with the SEC on February 26, 2024.

VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

Use of Estimates

The preparation of the unaudited 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 unaudited condensed consolidated financial statements and the reported amounts of revenues and expenses 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

The Company is subject to a number of challenges and risks similar to other biopharmaceutical companies, 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 product candidates 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 maintain profitability.

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 financial institutions. Such deposits may, at times, exceed federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents. Management believes that the Company is not currently exposed to significant credit risk as the Company's investments are held in custody at third-party financial institutions.

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 unaudited condensed consolidated balance sheets. As of March 31, 2024, the Company has no off-balance sheet concentrations of credit risk.

Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents, which consist of amounts invested primarily in money market funds and are stated at fair value.

Investments

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

Available-for-Sale Debt Securities

The Company's valuations of marketable securities are generally derived from independent pricing services based on quoted prices in active markets for similar securities at period end. Generally, investments with original maturities beyond three months at the date of purchase and that mature at, or less than 12 months from, the unaudited 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 other comprehensive 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 unaudited condensed consolidated statements of operations. The cost of securities sold is based on the specific identification method.

Equity Investments

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 expense, net on the unaudited 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 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, including the royalty exception guidance and variable consideration guidance under ASC 606 as described below, or other guidance, as deemed appropriate. When the Company is considered an agent in elements of collaboration arrangements within the scope of ASC 808, it records its share of collaboration revenue in the period in which such sales occur. 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. In these instances, collaboration revenue is based upon the net sales reported by the Company's collaboration partners, net of cost of goods sold and allowable expenses (e.g., manufacturing, distribution, medical affairs, selling, and marketing expenses) in the period. In order to record collaboration revenue, the Company utilizes certain information from its collaboration partner, including actual net product sales and costs incurred for sales activities, and makes key judgments based on business updates related to commercial and clinical activities such as expected commercial demand, commercial supply plan, manufacturing commitments, risks related to expired or obsolete inventories, and risks related to potential product returns or contract terminations. The Company uses these estimates to determine whether payments due to it under its collaboration arrangements, such as profit-share payments, should be recognized as revenue in the period that they become due or whether any portion of the payments due should be constrained from revenue recognition because it is not probable that recognizing such amounts will not result in a significant reversal of cumulative revenues recognized in future reporting periods.

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. Prior to recognizing revenue, the Company estimates 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 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 and development 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"). The Company estimates the SSP for each distinct performance obligation by considering information such as market conditions, entity-specific factors, and information about its customer that is reasonably available. The Company considers estimation approaches that allow it to maximize the use of observable inputs. These estimation approaches may include the adjusted market assessment approach, the expected cost plus a margin approach or the residual approach. The Company also considers whether to use a different estimation approach or a combination of approaches to estimate the SSP for each distinct performance obligation. Developing certain assumptions (e.g., treatable patient population, expected market share, probability of success and product profitability, and discount rate based on weighted-average cost of capital) to estimate the SSP of a distinct performance obligation requires significant judgment.

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 levels 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.

Contingent Consideration Obligations

Contingent consideration obligations incurred in connection with a business combination are recorded at their fair values on the acquisition date, are remeasured each subsequent reporting period until the related contingencies are resolved and are classified as contingent consideration on the unaudited 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.

New Accounting Pronouncement Not Yet Adopted

In December 2023, the Financial Accounting Standards Board issued Accounting Standards Update No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (“ASU 2023-09”), which modifies the rules on income tax disclosures to require entities to disclose (1) specific categories in the rate reconciliation, (2) the income or loss from continuing operations before income tax expense or benefit (separated between domestic and foreign) and (3) income tax expense or benefit from continuing operations (separated by federal, state and foreign). ASU 2023-09 also requires entities to disclose their income tax payments to international, federal, state and local jurisdictions, among other changes. The guidance is effective for annual periods beginning after December 15, 2024. Early adoption is permitted. ASU 2023-09 should be applied on a prospective basis, but retrospective application is permitted. The Company is currently evaluating the impact the adoption of ASU 2023-09 may have on its consolidated financial statements and related disclosures.

3. Fair Value Measurements

The Company determines the fair value of 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.

VIR BIOTECHNOLOGY, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

Cash Equivalents and Available-for-Sale Securities

The following tables summarize the Company's Level 1 and Level 2 financial assets measured at fair value on a recurring basis within the fair value hierarchy as of March 31, 2024 and December 31, 2023 (in thousands):

		March 31, 2024			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Money market funds[1]	Level 1	$ 142,405	$ —	$ —	$ 142,405
U.S. government treasuries	Level 2	986,450	112	(384)	986,178
U.S. government agency bonds and discount notes	Level 2	97,634	57	(75)	97,616
Yankee bonds	Level 2	10,967	—	(12)	10,955
Asset-backed securities	Level 2	15,849	4	(2)	15,851
Corporate bonds	Level 2	236,306	74	(273)	236,107
Equity securities	Level 1	N/A	N/A	N/A	3,927
Total financial assets		$ 1,489,611	$ 247	$ (746)	$ 1,493,039

(1) Includes $19.8 million of restricted cash equivalents.

		December 31, 2023			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Money market funds[1]	Level 1	$ 278,187	$ —	$ —	$ 278,187
U.S. government treasuries	Level 2	1,162,124	1,017	(80)	1,163,061
U.S. government agency bonds and discount notes	Level 2	181,189	27	(50)	181,166
Equity securities	Level 1	N/A	N/A	N/A	9,853
Total financial assets		$ 1,621,500	$ 1,044	$ (130)	$ 1,632,267

(1) Includes $19.7 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 unaudited condensed consolidated balance sheets. Accrued interest receivable amounted to $5.7 million and $4.0 million as of March 31, 2024 and December 31, 2023, respectively. The Company did not write off any accrued interest receivable during the three months ended March 31, 2024 and 2023.

The Company recognized total net unrealized losses of $ 0.5 million and total net unrealized gains of $ 0.9 million in accumulated other comprehensive loss as of March 31, 2024 and December 31, 2023, respectively. The gross unrealized losses related to U.S. government treasuries, U.S. government agency bonds and discount notes, and securities issued by institutions with investment-grade credit ratings as of March 31, 2024 and December 31, 2023 were due to changes in interest rates. The Company determined that the gross unrealized losses on the investments as of March 31, 2024 were temporary in nature. The Company currently does not intend, and it is highly unlikely that it will be required, to sell these securities before recovery of their amortized cost basis. As of March 31, 2024, no securities have contractual maturities of longer than two years.

As of March 31, 2024, the Company's equity investment consisted solely of ordinary shares of Brii Biosciences Limited ("Brii Bio Parent"). The equity securities of Brii Bio Parent are listed on the The Stock Exchange of Hong Kong Limited and are considered to be marketable equity securities and measured at fair value at each reporting date. As of March 31, 2024, the Company remeasured the equity investment at a fair value of $3.9 million. The Company recognized an unrealized loss of $5.9 million and $13.1 million, for the three months ended March 31, 2024 and 2023, respectively, as other income in the unaudited condensed consolidated statement of operations. For the three months ended March 31, 2024 and 2023, the unrealized losses related to foreign currency translation for the respective periods were not material.

Contingent Consideration Obligations

Contingent consideration obligations include potential milestone payments in connection with the acquisition of Humabs Biomed SA ("Humabs"). The Company classifies the contingent consideration as Level 3 financial liabilities within the fair value hierarchy as of March 31, 2024 and December 31, 2023.

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 March 31, 2024, the Company calculated the estimated fair value of the remaining clinical and regulatory milestones related to tobevibart (formally as VIR-3434), an investigational subcutaneously administered HBV-neutralizing monoclonal antibody, or mAb, using the following significant unobservable inputs:

Unobservable input	Range (Weighted-Average)[1]
Discount rates	10.9% - 11.4% (11.1%)
Probability of achievement	14.4% - 60.0% (42.5%)

(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. As of March 31, 2024, the Monte Carlo simulation assumed a commercial product launch and associated discrete revenue forecasts, as well as the following significant unobservable inputs for the remaining commercial milestones related to tobevibart:

Unobservable input	Value
Volatility	70.0%
Discount rate	10.0%
Probability of achievement	29.1%

The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. As of March 31, 2024 and December 31, 2023, the estimated fair value of the contingent consideration related to the Humabs acquisition was $27.6 million and $26.0 million, respectively, with changes in the estimated fair value recorded in research and development expenses in the unaudited condensed consolidated statements of operations.

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

The following table sets forth the changes in the estimated fair value of the Company's contingent consideration obligations (in thousands):

	Contingent Consideration
Balance at December 31, 2023	$ 25,961
Changes in fair value	1,649
Balance at March 31, 2024	$ 27,610

4. Grant Agreements

Bill & Melinda Gates Foundation Grants

The Company has entered into various grant agreements with the Bill & Melinda Gates Foundation ("BMGF"), under which it was awarded grants totaling up to $49.9 million to support its HIV vaccine program, tuberculosis vaccine program, HIV vaccinal antibody program and malaria vaccinal antibody program. The term of the grant agreements will expire at various dates through June 2027, unless terminated earlier by the BMGF 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 BMGF reasonably believes may threaten the success of the projects.

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Notes to Unaudited Condensed Consolidated Financial Statements

Concurrently with the execution of the grant agreement for the vaccinal antibody program, the Company entered into a stock purchase agreement with the BMGF, under which the BMGF purchased 881,365 shares of the Company's common stock on January 13, 2022, at a price per share of $45.38, for an aggregate purchase price of approximately $40.0 million. The fair market value of the common stock issued to the BMGF was $28.5 million, based on the closing stock price of $37.65 per share on the closing date and taking into account a discount for the lack of marketability due to the restrictions in place on the underlying shares, resulting in a $11.3 million premium received by the Company. The Company accounted for the common stock issued to the BMGF based on its fair market value on the closing date and determined that the premium paid by the BMGF should be included in the deferred revenue from the vaccinal antibody grant.

Payments received in advance that are related to future research activities along with the aforementioned premium received are deferred and recognized as revenue when the donor-imposed conditions are met, which is as the research and development activities are performed. The premium received by the Company is deferred and recognized over the same period as the grant proportionally. The Company recognized grant revenue of $1.9 million and $1.9 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024 and December 31, 2023, the Company had deferred revenue of $14.6 million and $13.1 million, respectively. As of March 31, 2024 and December 31, 2023, the Company had $ 7.6 million and $9.2 million, respectively, within accrued and other liabilities, which may need to be refunded to the BMGF.

Biomedical Advanced Research and Development Authority

In September 2022, the Company entered into a multi-year agreement (the "BARDA Agreement") under Other Transaction Authority with the Biomedical Advanced Research and Development Authority ("BARDA"), part of the U.S. Department of Health and Human Services' Administration for Strategic Preparedness and Response. Under the BARDA Agreement, the Company may receive up to an estimated $1.0 billion to advance the development of a full portfolio of innovative solutions to address influenza and potentially other infectious disease threats. The Base Period for the BARDA Agreement includes government funding of approximately $55.0 million to reimburse a portion of expenses incurred by the Company to support the development of VIR-2482, an investigational prophylactic monoclonal antibody designed with the aim to protect against seasonal and pandemic influenza, including expenses related to the Phase 2 pre-exposure prophylaxis trial of VIR-2482. The BARDA Agreement also provides for additional BARDA funding after the exercise by BARDA of up to twelve options to further support the development of pre-exposure prophylactic antibodies including and beyond VIR-2482 for the prevention of influenza illness and supporting medical countermeasures for other pathogens of pandemic potential.

In September 2023, the Company and BARDA entered into Amendment No. P00001 to the BARDA Agreement (the "Amended BARDA Agreement"), pursuant to which BARDA awarded the Company $50.1 million in new funding upon the exercise of an additional option. The Company will use $40.0 million to support the development of VIR-7229 through a Phase 1 clinical trial and $ 10.1 million to support the discovery of new monoclonal antibody against a second pathogen of pandemic potential. The Company may also receive up to $11.2 million of additional funding for the Base Period under the Amended BARDA Agreement to wind down activities related to the Phase 2 pre-exposure prophylaxis trial of VIR-2482. The Amended BARDA Agreement will expire in July 2027 and may be extended by mutual written agreement of the Company and BARDA, if funding is available and research opportunities within scope reasonably warrant, or, if any of the options are exercised (as described above), to cover the period of such exercised option set forth in the Amended BARDA Agreement. The Amended BARDA Agreement is terminable by the Company and BARDA at any time under specified circumstances, including for convenience.

The Company recognized grant revenue related to BARDA of $ 3.3 million and $14.3 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024 and December 31, 2023, the Company had receivables from BARDA of $4.1 million and $7.6 million, respectively, as part of prepaid expenses and other current assets. As of March 31, 2024, $53.3 million of potential future reimbursement remains available under the Amended BARDA Agreement.

5. Collaboration and License Agreements

Collaboration Agreements with GSK

2020 GSK Agreement

In 2020, the Company, Glaxo Wellcome UK Limited and Beecham S.A. entered into a collaboration agreement (the "2020 GSK Agreement"). Subsequently, Beecham S.A. assigned and transferred all its rights, title, interest, and benefit in the 2020 GSK Agreement to GlaxoSmithKline Biologicals S.A. (Glaxo Wellcome UK Limited and GlaxoSmithKline Biologicals S.A., referred to, individually and together, as "GSK"). 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 initially focused on the development and commercialization of 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").

On February 8, 2023, the Company and GSK entered into Amendment No. 2 and Amendment No. 3 to the 2020 GSK Agreement. Pursuant to Amendment No. 2, the Company and GSK agreed to remove the Vaccine Program from the 2020 GSK Agreement, and to wind down and terminate the cost-sharing arrangements and all ongoing activities in relation to the Vaccine Program. As of the effective date of Amendment No. 2, the Vaccine Program had not yet advanced to its predefined development candidate stage. The Company retains the right to progress development of vaccine products directed to SARS-CoV-2 and other coronaviruses independently (including with or for third parties) outside the scope of the 2020 GSK Agreement, subject to the payment of tiered royalties to GSK on net sales of any vaccine products covered by certain GSK intellectual property rights in the low single digits. Pursuant to Amendment No. 3, the Company and GSK agreed to modify the Antibody Program to remove from the collaboration all coronavirus antibodies other than sotrovimab and VIR-7832, and certain variants thereof. Sotrovimab and VIR-7832, and certain variants thereof, remain subject to the terms of the 2020 GSK Agreement, and the Company retains the sole right to progress the development and commercialization of the terminated antibody products independently (including with or for third parties), subject to the payment of tiered royalties to GSK on net sales of such terminated antibody products at percentages ranging from the very low single digits to the mid-single digits, depending on the nature of the antibody product being commercialized.

Subject to an opt-out mechanism, the parties 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, except that GSK has the sole right to develop (including to seek, obtain or maintain regulatory approvals), manufacture and commercialize sotrovimab in and for mainland China, Hong Kong, Macau and Taiwan at GSK's sole cost and expense, and equal sharing of such costs for the functional genomics products.

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.

In May 2021, the U.S. Food and Drug Administration ("FDA") granted an EUA in the United States for sotrovimab, the first collaboration product under the Antibody Program. In April 2022, the FDA excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. As the lead party for all manufacturing and commercialization activities, GSK incurs all of the manufacturing, sales and marketing expenses and is the principal on sales transactions with third parties. As described in Note 2—Summary of Significant Accounting Policies, the Company's accounting policy related to the profit-share is to consider the agreed-upon share of the profit-sharing amounts each quarter and evaluate whether those amounts are subject to potential future adjustments based on the latest available facts and circumstances. As the Company is the agent, the Company recognizes its contractual share of the profit-sharing amounts or royalties (in case of an opt-out) as revenue, based on sales net of various estimated deductions such as rebates, discounts, chargebacks, credits and returns, less cost of sales and allowable expenses (including manufacturing, distribution, medical affairs, selling, and marketing expenses) in the period the sale occurs. Manufacturing costs include inventory revaluation adjustments, lower of cost or market inventory adjustments, inventory write-downs and write-offs, and binding purchase commitments with a third-party manufacturer among other manufacturing costs.

In periods when allowable expenses exceed amounts recognized for net product sales of sotrovimab, negative revenue would be reported in our consolidated statements of operations. The Company's contractual share of the profit-sharing amounts is subject to potential future adjustments to allowable expenses, which represents a form of variable consideration. At each reporting period, the Company evaluates the latest available facts and circumstances to determine whether any portion of profit-sharing amounts should be constrained.

In 2023, GSK reported to the Company certain allowable manufacturing expenses related to excess sotrovimab supply and binding reserved manufacturing capacity not utilized, which the Company had previously reserved as constraint on its cumulative profit-sharing amounts. For the year ended December 31, 2023, the Company paid GSK $341.4 million relating to these manufacturing expenses. GSK may continue to adjust allowable manufacturing expenses for the Company's share of the excess supply write-offs and unused binding manufacturing capacity and report to the Company as cost-sharing amounts in future periods. The Company evaluated the latest available facts and circumstances to update its evaluation of profit-sharing amounts to be constrained. As of March 31, 2024, the Company's share of the remaining estimated manufacturing expenses related to excess sotrovimab supply and binding reserved manufacturing capacity not utilized is $0.7 million. The Company re-assesses these estimates each reporting period.

During the three months ended March 31, 2024 and 2023, the Company recorded profit-sharing amount, profit-sharing amount constrained, and profit-sharing amount previously constrained, released as components of collaboration revenue in the unaudited condensed consolidated statements of operations, as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Profit-sharing amount	$ (287)	$ 7,236
Profit-sharing amount constrained	(700)	—
Profit-sharing amount previously constrained, released	—	39,338
Total collaboration revenue, net	$ (987)	$ 46,574

Costs associated with co-development activities performed under the 2020 GSK Agreement are included in research and development expenses on the unaudited 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 $2.8 million and $7.3 million during the three months ended March 31, 2024 and 2023, respectively.

2021 Expanded GSK Collaboration

In 2021, the Company and GSK entered into a collaboration agreement (the "2021 GSK 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 certain mAbs for the prevention, treatment or prophylaxis of the influenza virus (the "Influenza Program"), excluding VIR-2482 unless GSK exercises its exclusive option to co-develop and commercialize after the Company completes a Phase 2 clinical trial ("VIR-2482 Option"); (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 if selected by GSK prior to March 25, 2024 (the "Selected Pathogens" and such programs, the "Additional Programs").

On February 21, 2024, the Company and GSK entered into a letter agreement (the "Letter Agreement") pursuant to which the Company and GSK agreed to terminate the Influenza Program and GSK's VIR-2482 Option from the 2021 GSK Agreement and to wind down and terminate the cost-sharing arrangements and all ongoing activities in relation to the Influenza Program.

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The parties 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 is 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, the Company granted or will grant GSK certain license rights related to the development, manufacturing and commercialization of products arising from the program. GSK selected RSV as its first pathogen under the Additional Programs in 2022. During the three months ended March 31, 2024, the Company recognized contract revenue of $51.7 million as GSK's rights to select the remaining two additional non-influenza target pathogens expired on March 25, 2024. The Company had no other remaining performance obligations under the 2021 GSK Agreement.

The parties share 50% of all development costs in accordance with the budget for each of the collaboration programs. The parties also share 50% of all profits and losses arising from any collaboration product. Costs associated with co-development activities performed under the 2021 GSK Agreement are included in research and development expenses in the unaudited condensed consolidated statements of operations, with any reimbursement of costs by GSK reflected as a reduction of such expenses. Under the 2021 GSK Agreement, the additional net research and development expenses were not material during the three months ended March 31, 2024 and 2023.

6. Balance Sheet Components

Property and Equipment, net

Property and equipment, net consists of the following (in thousands):

	March 31, 2024	December 31, 2023
Laboratory equipment	$ 43,955	$ 43,728
Computer equipment	2,915	2,783
Furniture and fixtures	2,887	2,887
Leasehold improvements	80,359	80,290
Construction in progress	506	226
Property and equipment, gross	130,622	129,914
Less accumulated depreciation	(38,145)	(33,896)
Total property and equipment, net	$ 92,477	$ 96,018

Depreciation expenses were $4.4 million and $5.5 million for the three months ended March 31, 2024 and 2023, respectively.

Accrued and Other Liabilities

Accrued and other liabilities consist of the following (in thousands):

	March 31, 2024	December 31, 2023
Research and development expenses	$ 27,314	$ 33,129
Payroll and related expenses	17,508	41,322
Operating lease liabilities, current	11,913	12,867
Excess funds payable under grant agreements	7,603	9,202
Other professional and consulting expenses	3,492	3,418
Accrued royalties	1,112	816
Net profit-sharing amount	287	—
Accrued income taxes	146	149
Other accrued expenses	2,885	3,317
Total accrued and other liabilities	$ 72,260	$ 104,220

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Notes to Unaudited Condensed Consolidated Financial Statements

7. Restructuring, Impairment and Other Costs

In December 2023, the Company initiated strategic steps to reduce operating expenses and focus its capital allocation on programs with the highest potential for patient impact and value creation ("Restructuring Plan"). As part of the steps, the R&D facilities in St. Louis, Missouri and Portland, Oregon will be closed in 2024. In addition, approximately 75 net positions, or 12% of the workforce, will be eliminated, which includes reductions from the Company's discontinuation of its innate immunity small molecule group that was initiated in the third quarter of 2023. The Company expects all actions related to the Restructuring Plan to be substantially completed in the third quarter of 2024.

During the year ended December 31, 2023, the Company incurred severance and other employee-related expenses of $ 5.9 million, of which $4.0 million was included in research and development expense and $ 1.9 million was included in selling, general and administrative expense. As of December 31, 2023, the Company recorded $4.5 million as accrued and other liabilities related to restructuring costs. In addition to severance and other employee-related expenses, the Company also recorded one-time non-cash impairment charges and disposal losses on ROU assets, leasehold improvements, and equipment of $7.7 million for the year ended December 31, 2023, primarily related to the consolidation of facilities and disposal of equipment used in the small molecule platform that was discontinued. Of the $7.7 million, $5.6 million was included in research and development expense, and $2.1 million was included in selling, general and administrative expense.

The following table is a summary of restructuring related severance and other employee-related expenses incurred during the three months ended March 31, 2024 and a roll forward of accrued restructuring costs from December 31, 2023 to March 31, 2024 (in thousands).

	Severance and other employee-related expenses
Accrued restructuring charges at December 31, 2023	$ 4,454
Restructuring charges, net	
Research and development	—
Selling, general and administrative	(48)
Total restructuring charges, net	(48)
Cash payment	(2,592)
Accrued restructuring charges at March 31, 2024	$ 1,814
Reconciliation of accrued restructuring charges to the condensed consolidated balance sheets	
Accrued and other liabilities	$ 1,814

For the three months ended March 31, 2024, the Company did not incur material contract termination costs, other associated exit costs, impairment charges, or long-lived assets disposal losses related to restructuring activities. As of March 31, 2024, the Company continues to expect to incur additional restructuring charges of approximately $25 million to $35 million, primarily related to facility closures in the future.

8. Commitments and Contingencies

Manufacturing and Supply Agreements

In the first quarter of 2024, the Company and a third-party contract development manufacturing organization entered into various scopes of work with respect to the manufacturing of tobevibart (the "Tobevibart Agreements"). As of March 31, 2024, the Company had a balance of unpaid commitments of approximately $20 million under the Tobevibart Agreements.

Legal Proceedings

The Company may from time to time be party to claims and legal proceedings that arise in the normal course of its business and that may or may not have, individually or in the aggregate, a material adverse effect on its results of operations, financial condition or liquidity.

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Indemnification

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

9. Related Party Transactions

The Company holds a minority equity interest in Brii Biosciences Offshore Limited through Brii Bio Parent. As of March 31, 2024, one member of the Company's board of directors serves on Brii Bio Parent's board of directors.

10. Stock-Based Awards

The Company has maintained a stock incentive plan for the issuance of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock, other stock awards and performance cash awards, to employees, non-employee directors, and consultants. The Company also has an employee stock purchase plan ("ESPP") for its employees.

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 with the following assumptions:

	Three Months Ended March 31,	
	2024	**2023**
Expected term of options (in years)	6.1	6.1
Expected stock price volatility	89.2% - 89.3%	100.7% - 101.2%
Risk-free interest rate	4.3%	3.4% - 4.1%
Expected dividend yield	—	—

The valuation assumptions for stock options were determined as follows:

- *Expected Term* — The expected term represents the period that the stock 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).
- *Expected Volatility* — Expected volatility is determined by using a blended approach of the Company and certain industry peers' historical volatilities.
- *Risk-Free Interest Rate* — The Company based the risk-free interest rate over the expected term of the stock 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.

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Notes to Unaudited Condensed Consolidated Financial Statements

Stock-Based Compensation Expense

Stock-based compensation is recognized on a straight-line basis over the requisite service period, which is generally the vesting period. The following table sets forth the total stock-based compensation expense for all awards granted to employees and non-employees and the ESPP in the unaudited condensed consolidated statements of operations (in thousands):

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 13,606	$ 13,353
Selling, general and administrative	10,151	12,128
Total stock-based compensation	$ 23,757	$ 25,481

11. Net Loss Per Share

Basic net loss per common share is computed by dividing the net loss attributable to Vir by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per common share is computed by dividing the net loss attributable to Vir 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. For periods that the Company was in a net loss position, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential common securities outstanding would have been anti-dilutive.

The following is a calculation of the basic and diluted net loss per share (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2024	2023
Net loss attributable to Vir	$ (65,276)	$ (140,900)
Weighted-average shares outstanding, basic and diluted	135,280,648	133,552,839
Net loss attributable to Vir per share, basic and diluted	$ (0.48)	$ (1.06)

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 March 31,	
	2024	2023
Options issued and outstanding	12,018,822	9,135,760
Restricted shares subject to future vesting	4,521,874	3,032,073
Total	16,540,696	12,167,833

12. Income Taxes

The table below presents our loss before (provision for) benefit from income taxes, (provision for) benefit from income taxes and effective tax rate for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,	
	2024	2023
Loss before (provision for) benefit from income taxes	$ (65,000)	$ (143,188)
(Provision for) benefit from income taxes	$ (276)	$ 2,232
Effective tax rate	(0.4 %)	1.6 %

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The Company is subject to income taxes in the United States and foreign jurisdictions. These foreign jurisdictions have statutory tax rates different from those in the United States. Accordingly, the Company's effective tax rates will vary depending on the relative proportion of foreign to United States income/loss, the utilization of net operating loss and tax credit carry forwards and carrybacks, changes in jurisdictional mix of income and expense, changes in management's assessment of matters such as the ability to realize deferred tax assets, and changes in tax laws.

The provision for income taxes for the three months ended March 31, 2024 was not material. The benefit from income taxes for the three months ended March 31, 2023 was primarily due to a pre-tax loss and the Company's ability to carry back the research and development credit to 2022.

Unrecognized tax benefits were $13.9 million and $13.6 million as of March 31, 2024 and December 31, 2023, respectively, and if recognized, would favorably affect the effective tax rate in future periods.

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, 2023. 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 an immunology company focused on combining cutting-edge technologies to treat and prevent serious infectious diseases and other serious conditions, including viral-associated diseases. At Vir, we have a bold vision – powering the immune system to transform lives. We aim to achieve this in two fundamental ways – first through developing powerful antibody therapeutics and second by generating unique T cell responses in vivo through our T cell-based viral vector platform. Our growth and pursuit of scientific innovation is fueled by our world-class leading monoclonal antibody (mAb) platform that has a proven track record and is further strengthened by our artificial intelligence-led mAb optimization and engineering capabilities.

Our current clinical development pipeline consists of product candidates targeting hepatitis delta virus (HDV), hepatitis B virus (HBV), and human immunodeficiency virus (HIV). The most advanced preclinical candidates in our pipeline include those targeting influenza A and B, coronavirus disease 2019 (COVID-19), respiratory syncytial virus (RSV) and human metapneumovirus (MPV), and human papillomavirus (HPV). We have assembled two technology platforms that modulate the immune system by exploiting critical observations of natural immune processes— a mAb discovery platform and a T cell-based viral vector platform. Additionally, Vir is evaluating a small interfering RNA (siRNA) through a collaboration with Alnylam in our hepatitis clinical trials. We have established our own internal process development, analytical development, manufacturing, supply chain and quality capabilities and work with contract development and manufacturing organizations (CDMOs) to develop, manufacture, test and supply our early- and late-stage product candidates.

We have an industry-leading management team and board of directors with significant immunology and infectious diseases experience, including a proven track record of progressing product candidates from early-stage research through clinical development, and worldwide regulatory approval and commercialization experience. Given the global impact of infectious diseases and other serious conditions, we are committed to providing broad access to our therapeutics.

Significant Developments

Following is a summary of selected significant developments affecting our business that occurred since the filing of our Annual Report on Form 10-K for the year ended December 31, 2023.

Pipeline Programs

Chronic Hepatitis Delta (CHD)

- On March 5, 2024, we announced our Phase 2 chronic hepatitis delta SOLSTICE trial completed enrollment of its current cohorts one month ahead of schedule with over 60 participants enrolled in two additional cohorts.
  - The trial is evaluating the safety, tolerability and efficacy of tobevibart and elebsiran for the treatment of people living with chronic hepatitis delta.
  - One cohort is evaluating the combination of tobevibart and elebsiran given every 4 weeks with a second cohort evaluating tobevibart monotherapy given every 2 weeks.
  - Approximately 50% of participants have compensated cirrhosis.
- We will report data on a subset of SOLSTICE participants in a late breaker poster presentation at the European Association for the Study of the Liver (EASL) Congress 2024. This includes additional 12-week treatment data on approximately 30 participants (~15 per regimen) and 24-week treatment data on approximately 20 participants (~10 per regimen).

- Additional follow-up data for the initial six SOLSTICE trial participants will also be shared at the EASL Congress 2024.
- Complete 24-week treatment data is expected in the fourth quarter of 2024.

Chronic Hepatitis B (CHB)

- Two abstracts have been accepted for poster presentation at the EASL Congress 2024.
- The Phase 2 MARCH Part B trial is fully enrolled with 48-week end of treatment data expected in the fourth quarter of 2024. The trial is evaluating the safety, tolerability and antiviral activity of the combination of tobevibart and elebsiran with and without peginterferon alpha.
- Initial data from the Phase 2 PREVAIL platform trial and its THRIVE/STRIVE sub-protocols is expected in the first half of 2025. These trials are evaluating combinations of tobevibart, elebsiran and/or peginterferon alpha in two patient populations: immune-active but treatment-naïve and inactive carriers.

Human Immunodeficiency Virus (HIV)

- Part A of the Phase 1 trial of VIR-1388, an investigational novel T cell vaccine for the prevention of HIV, is fully enrolled with initial immunogenicity data expected in the second half of 2024.
  - The trial is supported by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, and the Bill & Melinda Gates Foundation, and is being conducted by the HIV Vaccine Trials Network.

Influenza

- On April 4, 2024, we published the full data analysis from the Phase 2 PENINSULA trial evaluating VIR-2482 on medRxiv.

Preclinical Pipeline Candidates

- We are continuing to advance next-generation antibodies using our proprietary platform, which leverages dAIsY™ (**d**ata **AI s**tructure and antibod**y**), our proprietary AI engine, enabling us to bring high-quality drug candidates to the clinic more efficiently.
- We expect the filing of multiple investigational new drug applications within the next 18 months, including:
  - VIR-1949, an investigational therapeutic T cell vaccine based on our human cytomegalovirus (HCMV) vector platform that is designed to treat precancerous lesions caused by the human papillomavirus.
  - VIR-7229, a next-generation COVID monoclonal antibody candidate that has been AI-engineered to have increased potency, breadth and resistance to viral escape. The development of VIR-7229 has been supported in part with federal funds from the Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction Number: 75A50122C00081.
  - VIR-2981, an investigational neuraminidase-targeting monoclonal antibody against both influenza A and B viruses.
  - VIR-8190 and other investigational monoclonal antibodies against respiratory syncytial virus and/or metapneumovirus as part of the collaboration established with GSK in May of 2021.

Corporate Update

- Effective May 3, 2024, Sung Lee, Executive Vice President and Chief Financial Officer will be stepping down from his role to pursue another career opportunity. We have initiated a search for a successor.

Our Collaboration, License and Grant Agreements

We have entered into collaboration, license and grant arrangements with various third parties. For details regarding these and other agreements, see Note 4—Grant Agreements and Note 5—Collaboration and License Agreements to our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, and Note 7—Collaboration and License Agreements to our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission, or SEC, on February 26, 2024.

Components of Operating Results

Revenues

To date, sotrovimab has been granted emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®), and has been supplied in more than 30 countries. Although we have previously recognized revenue from our profit-share related to sotrovimab under our definitive collaboration agreement with GSK executed in June 2020, or the 2020 GSK Agreement, we may continue to incur net operating losses for at least the next several years as the extent of future revenue from the sale of sotrovimab remains uncertain. While we have an EUA from the U.S. Food and Drug Administration, or FDA, for sotrovimab, the FDA has excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. With this EUA revision, sotrovimab is not currently authorized for use in any U.S. region. Although certain countries outside the U.S. continue to maintain access to 500 mg IV while noting that the clinical efficacy is unknown or uncertain against existing and emerging variants, we cannot predict whether other countries will further limit the use of sotrovimab. Due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a Biologics License Application, or BLA, for sotrovimab at this time. In light of these developments, we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future, and we do not expect meaningful collaboration revenue in the future from the sale of sotrovimab for the treatment of COVID-19 even if it were reauthorized by the FDA. In addition, 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.

Collaboration revenue

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 applied to the net sales reported in the period by GSK, net of cost of goods sold and allowable expenses from both GSK and us (e.g., manufacturing, distribution, medical affairs, selling, and marketing expenses). In order to record collaboration revenue, we utilize certain information from our collaboration partner, including actual net product sales and costs incurred for sales activities, and make key judgments based on business updates related to commercial and clinical activities, such as expected commercial demand, commercial supply plan, manufacturing commitments, risks related to expired or obsolete inventories, and risks related to potential product returns or contract terminations. In 2024, we expect a nominal amount of collaboration revenue, if any, from our 2020 GSK Agreement, and we may incur negative collaboration revenue related to costs for ongoing required support efforts that our partner GSK leads.

Constraint on variable consideration

In May 2021, the FDA granted an EUA in the U.S. for sotrovimab. In April 2022, the FDA excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. As the lead party for all manufacturing and commercialization activities, GSK incurs all of the manufacturing, sales and marketing expenses and is the principal on sales transactions with third parties. Our accounting policy related to the profit-share is to consider the agreed-upon share of the profit-sharing amounts each quarter and evaluate whether those amounts are subject to potential future adjustments based on the latest available facts and circumstances, subject to the terms of the 2020 GSK Agreement.

As we are the agent under the 2020 GSK Agreement, we recognize our contractual share of the profit-sharing amounts or royalties (in case of an opt-out) as revenue, based on sales net of various estimated deductions such as rebates, discounts, chargebacks, credits and returns, less cost of sales and allowable expenses (including manufacturing, distribution, medical affairs, selling, and marketing expenses) in the period the sale occurs. Manufacturing costs include inventory revaluation adjustments, lower of cost or market inventory adjustments, inventory write-downs and write-offs, and binding purchase commitments with a third-party manufacturer, among other manufacturing costs. Our contractual share of the profit-sharing amounts is subject to potential future adjustments to allowable expenses, which we account for as a form of variable consideration.

In 2023, GSK reported to us certain allowable manufacturing expenses related to excess sotrovimab supply and binding reserved manufacturing capacity not utilized, which we had previously reserved as a constraint on our cumulative profit-sharing amounts. GSK may continue to adjust allowable manufacturing expenses for our share of the excess supply write-offs and unused binding manufacturing capacity and report to us as cost-sharing amounts in future periods. We evaluate the latest available facts and circumstances to update our evaluation of whether any portion of profit-sharing amounts should continue to be constrained. We re-assess these estimates at each reporting period. Actual results could materially differ from estimates.

Contract revenue

Contract revenue includes recognition of revenue generated from license rights issued to GSK, from research and development services under third-party contracts, and from a third-party clinical supply agreement.

Grant revenue

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

Operating Expenses

Cost of Revenue

Cost of revenue currently represents royalties earned by third-party licensors on net sales of sotrovimab. 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 all 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 certain contingent consideration obligations arising 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 over time 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.

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 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, our existing collaborators have significant discretion in determining the efforts and resources that they will apply to our collaborations and may not pursue further development and commercialization of products resulting from our collaboration arrangements or may elect to not to continue or renew research and development programs, which would delay the development and may increase the cost of developing our product candidates and may result in a need for additional capital or a suitable replacement collaborator. For those product candidates where there is not a current collaboration arrangement in place, 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 will 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;
- enrollment and retention of patients in trials in countries disrupted by geopolitical events, including civil or political unrest;
- 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 certain contingent consideration obligations arising from business acquisitions. Personnel-related expenses consist of salaries, benefits and stock-based compensation.

We expect our selling, general and administrative expenses to increase in absolute dollars over time as we continue to support our research and development activities, and commercialization activities for any of our product candidates, if approved, and to grow our business.

Change in Fair Value of Equity Investments

Change in fair value of equity investments consists of the remeasurement of our investment in Brii Biosciences Limited's, or Brii Bio Parent, 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 Expense, Net

Other expense, net consists of gains and losses from foreign currency transactions and the remeasurement of our contingent consideration obligation.

(Provision for) Benefit from Income Taxes

(Provision for) benefit from income taxes consists primarily of income taxes on our domestic and foreign operations.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest consists of net loss attributable to the noncontrolling interest owners of Encentrio Therapeutics, Inc., our subsidiary, during the three months ended March 31, 2023.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table summarizes our results of operations for the periods presented (in thousands):

	Three Months Ended March 31,		
	2024	2023	Change
Revenues:			
Collaboration revenue	$ (987)	$ 46,574	$ (47,561)
Contract revenue	52,191	138	52,053
Grant revenue	5,172	16,245	(11,073)
Total revenues	56,376	62,957	(6,581)
Operating expenses:			
Cost of revenue	59	1,907	(1,848)
Research and development	100,125	157,643	(57,518)
Selling, general and administrative	36,273	46,778	(10,505)
Total operating expenses	136,457	206,328	(69,871)
Loss from operations	(80,081)	(143,371)	63,290
Other income:			
Change in fair value of equity investments	(5,915)	(13,103)	7,188
Interest income	21,283	21,307	(24)
Other expense, net	(287)	(8,021)	7,734
Total other income	15,081	183	14,898
Loss before (provision for) benefit from income taxes	(65,000)	(143,188)	78,188
(Provision for) benefit from income taxes	(276)	2,232	(2,508)
Net loss	(65,276)	(140,956)	75,680
Net loss attributable to noncontrolling interest	—	(56)	56
Net loss attributable to Vir	$ (65,276)	$ (140,900)	$ 75,624

Revenues

The decrease in collaboration revenue for the three months ended March 31, 2024 compared to the same period in 2023 was primarily due to lower revenues from the release of profit-sharing amount previously constrained and from the sales of sotrovimab under the 2020 GSK Agreement. The negative collaboration revenue for the three months ended March 31, 2024 consisted of $0.3 million profit-sharing loss from the sale of sotrovimab and $0.7 million profit-sharing amount constrained.

The increase in contract revenue for the three months ended March 31, 2024 compared to the same period in 2023 was primarily due to $51.7 million of deferred revenue recognized during the three months ended March 31, 2024 as GSK's rights to select up to two additional non-influenza target pathogens under the 2021 GSK Agreement expired on March 25, 2024.

The decrease in grant revenue for the three months ended March 31, 2024 compared to the same period in 2023 was primarily due to lower revenue recognized in accordance with our agreement with BARDA.

Cost of Revenue

The decrease in cost of revenue for the three months ended March 31, 2024 compared to the same period in 2023 was primarily due to lower third-party royalties owed based on the sales of sotrovimab under the 2020 GSK Agreement.

Research and Development Expenses

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

	Three Months Ended March 31,		
	2024	2023	Change
Licenses, collaborations and contingent consideration	$ 5,696	$ 7,746	$ (2,050)
Personnel	46,190	43,944	2,246
Contract manufacturing	9,669	37,553	(27,884)
Clinical costs	11,607	39,838	(28,231)
Other	26,963	28,562	(1,599)
Total research and development expenses	$ 100,125	$ 157,643	$ (57,518)

The decrease in research and development expenses for the three months ended March 31, 2024 compared to the same period in 2023 was primarily due to lower clinical costs and contract manufacturing costs associated with the wind down of the Company's Phase 2PENINSULA trial evaluating VIR-2482.

Selling, General and Administrative Expenses

The decrease in selling, general and administrative expenses for the three months ended March 31, 2024 compared to the same period in 2023 was primarily due to cost saving initiatives implemented during the second half of 2023.

Change in Fair Value of Equity Investments

Our investment consisted solely of shares of Brii Bio Parent is a marketable equity investment and remeasured to fair value at each reporting period. For the three months ended March 31, 2024, we recognized an unrealized loss of $5.9 million due to the change in fair value, compared to an unrealized loss of $13.1 million for the same period in 2023.

Interest Income

The decrease in interest income for the three months ended March 31, 2024 compared to the same period in 2023 was not material.

Other Expense, Net

The decrease in other expense, net for the three months ended March 31, 2024 compared to the same period in 2023 was primarily due to a decrease in foreign exchange measurement loss related to the accrued liability recognized in connection with the profit-sharing amount constrained under the 2020 GSK Agreement.

(Provision for) Benefit from Income Taxes

The provision for income taxes for the three months ended March 31, 2024 was not material. The benefit from income taxes for the three months ended March 31, 2023 was primarily due to a pre-tax loss and the Company's ability to carry back the research and development credit to 2022.

Liquidity, Capital Resources and Capital Requirements

Sources of Liquidity

To date, we have financed our operations primarily through sales of our common stock from our initial public offering and subsequent follow-on offering, sales of our convertible preferred securities, and payments received under our grant and collaboration agreements. As of March 31, 2024, we had $1.51 billion in cash, cash equivalents, and investments. As of March 31, 2024, we had accumulated deficit of $303.1 million. We entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or TD Cowen, in November 2023 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 TD Cowen, acting as sales agent or principal. The shares will be offered and sold under the shelf registration statement on Form S-3 and a related prospectus that we filed with the SEC on November 3, 2023. We will pay TD 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 TD Cowen with customary indemnification and contribution rights. As of March 31, 2024, no shares have been sold under the Sales Agreement.

Funding Requirements and Conditions

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 clinical trials, and to a lesser extent, selling, general and administrative expenditures.

We have not obtained regulatory approval for any product candidates other than sotrovimab, 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 may continue to incur net losses for the foreseeable future. Based upon our current operating plan, we believe that our existing cash, cash equivalents and investments as of March 31, 2024 as noted above will enable us to fund our operations for at least the next 12 months from the filing date of 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 raise additional capital to complete the development and commercialization of our product candidates and fund certain of our existing manufacturing and other commitments. We expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. 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. See the sections titled “Risk Factors—Risks Related to Our Financial Position and Capital Needs—Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates” and “Risk Factors—Risks Related to Our Financial Position and Capital Needs—We may 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” for a description of the risks that may be associated with any future capital raises.

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. See the section titled “Risk Factors—Risks Related to Our Financial Position and Capital Needs” for a description of certain risks that will affect our future capital requirements.

We have various operating lease arrangements for office and laboratory spaces located in California, Oregon, Missouri and Switzerland with contractual lease periods expiring between 2024 and 2034. As of March 31, 2024, we expect to make total lease payments of $152.1 million through 2034.

To date, we have entered into collaboration, license and acquisition agreements where the payment obligations are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones, and we are required to make royalty payments in connection with the sale of products developed under those agreements. For additional information regarding these agreements, including our payment obligations thereunder, see Note 5—Collaboration and License Agreements to our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, and Note 7—Collaboration and License Agreements to our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024. For information related to our future commitments under our facilities and manufacturing agreements. see Note 10—Commitments and Contingencies to our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024.

In the first quarter of 2024, the Company and a third-party contract development manufacturing organization entered into various scopes of work with respect to the manufacturing of tobevibart (the Tobevibart Agreements). As of March 31, 2024, the Company had a balance of unpaid commitments of approximately $20 million under the Tobevibart Agreements.

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2024	**2023**
Net cash (used in) provided by:		
Operating activities	$ (109,390)	$ (125,782)
Investing activities	28,420	98,079
Financing activities	152	2,344
Net decrease in cash, cash equivalents and restricted cash and cash equivalents	$ (80,818)	$ (25,359)

Operating Activities

Cash used in operating activities is derived by adjusting our net loss for non-cash items and changes in operating assets and liabilities. Cash used in operating activities during the three months ended March 31, 2024 decreased compared to the same period in 2023 primarily due to lower clinical development and contract manufacturing activities related to the wind down of the Phase 2 PENINSULA trial evaluating VIR-2482, lower payments for third-party royalties based on the sales of sotrovimab under the 2020 GSK Agreement, and higher interest receipts, partially offset by lower receipts for grant and collaboration revenues.

Investing Activities

Cash provided by investing activities during the three months ended March 31, 2024 decreased compared to the same period in 2023 primarily due to lower proceeds from investments maturities and sales net of investments purchases.

Financing Activities

Cash provided by financing activities during the three months ended March 31, 2024 decreased compared to the same period in 2023 primarily due to lower proceeds from the exercises of stock options.

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 three months ended March 31, 2024, as compared with those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024.

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 $180.5 million as of March 31, 2024, which primarily consisted of money market funds. We also had short-term and long-term investments of $1.3 billion as of March 31, 2024. 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 treasuries, U.S. government agency bonds and discount notes, and securities issued by institutions with investment-grade credit ratings mature prior to our expected need for liquidity, we believe that our exposure to interest rate risk is not significant, and one percent 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 March 31, 2024.

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 our collaboration with GSK and consequently the Swiss Franc, Australian dollar and British pound. Transaction gains and losses are included in other expense, net on the unaudited condensed consolidated statements of operations and were not material for the three months ended March 31, 2024 and 2023.

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 unaudited condensed consolidated statements of operations. The fair value of these equity securities was approximately $3.9 million as of March 31, 2024. 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 price of these equity securities would increase or decrease their fair value as of March 31, 2024 by approximately $0.4 million.

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 the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. 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 have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our fiscal quarter ended March 31, 2024, that have 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 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 Quarterly Report on Form 10-Q 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.

Risk Factors Summary

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 net losses and anticipate that we will continue to incur net losses in the foreseeable future.
- We do not expect meaningful future revenue from the sale of sotrovimab for the treatment of COVID-19, even if it were reauthorized by the FDA. If the FDA were to revise or revoke our EUA, our business could be adversely impacted.
- 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 may 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.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.
- Our future success is substantially dependent on the successful clinical development, regulatory approval and commercialization of our product candidates in a timely manner. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate product revenue will be adversely affected.
- 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.
- 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 marketing authorizations. We have and may continue to commit substantial financial resources with respect to clinical trials that may not be successful, and we may not be able to recoup those investments.
- 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.
- 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 spend significant additional capital or that we relinquish rights to and control over the development and commercialization of our product candidates.

- The deployment of artificial intelligence in our, or our collaborators', efforts to discover and develop next-generation antibodies or other investigational products, could adversely affect our business, reputation, or financial results.
- Even if any of our product candidates receive marketing approval, they may fail to achieve adoption by physicians, patients, third-party payors or others in the medical community necessary for commercial success.
- We rely on third parties to produce clinical and commercial supplies of our product candidates.
- 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.
- 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.
- 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.
- 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 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 have experienced significant growth in our organization in recent years and expect to continue to expand, and we may experience difficulties in managing this growth, which could disrupt our operations.
- 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.
- 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.

Risks Related to Our Financial Position and Capital Needs

We have incurred net losses and anticipate that we will continue to incur net losses in the foreseeable future.

Although we recorded net income for the years ended December 31, 2022, and 2021, we have otherwise incurred net losses since inception in April 2016. We had net loss of $65.3 million and net loss of $141.0 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $303.1 million.

We expect to continue to incur significant expenses and will continue to incur net losses in 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.

It could be several years, if ever, before we are able to commercialize any of our product candidates. Any net losses we incur may fluctuate significantly from quarter to quarter and year to year. To become 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 and 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 not be able to continue to generate revenue that is sufficient to offset our expenses and maintain 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 if we will be able to return to 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.

Our failure to return to being 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.

We do not expect meaningful future revenue from the sale of sotrovimab for the treatment of COVID-19, even if it were reauthorized by the FDA. If the FDA were to revise or revoke our EUA, our business could be adversely impacted.

In May 2021, we, along with our partner GSK, received an Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, for the sale of sotrovimab for the treatment of COVID-19. In March and April 2022, the FDA amended the EUA fact sheet to exclude sotrovimab use in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information, including variant susceptibility to these drugs and regional variant frequency. With this EUA revision, sotrovimab is not currently authorized for use in any U.S. region, and we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future. In addition, there can be no assurance with respect to how long the EUA will remain in effect or whether the EUA will be further revised or revoked by the FDA following the termination of the underlying public health emergency declaration on May 11, 2023 or for other reasons. Furthermore, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and Glaxo Wellcome UK Limited and GlaxoSmithKline Biologicals S.A. (individually and collectively referred to as GSK) do not plan to file a Biologics License Application, or BLA, for sotrovimab at this time.

In May 2021, we and our partner GSK also received a positive scientific opinion from the Committee for Human Medicinal Products, or CHMP, in the European Union, or EU, for sotrovimab and to date, sotrovimab has obtained emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®) for early treatment of COVID-19, and has been supplied in more than 30 countries. However, foreign regulatory authorities may impose similar limitations to the FDA on the use of sotrovimab in jurisdictions where sotrovimab has been granted EUA, temporary authorization or marketing approval. For example, although certain countries outside the U.S. continue to maintain access to 500 mg IV while noting that the clinical efficacy is unknown or uncertain against existing and emerging Omicron variants, we cannot predict whether other countries will further limit the use of sotrovimab.

Furthermore, based on the evolving COVID-19 landscape and our expectations for future sales in light of these factors, there are no assurances that we will secure future supply commitments from governments. In addition, COVID-19 treatment standards are susceptible to rapid changes in epidemiology and the emergence of new variants or subvariants, which may render sotrovimab inferior or obsolete in the future.

In addition, there can be no assurance with respect to how long the EUA will remain in effect or whether the EUA will be further revised or revoked by the FDA following the termination of the underlying public health emergency declaration on May 11, 2023, or for other reasons. Any such revision or revocation of our EUA by the FDA could adversely impact our business in a variety of ways, including having to absorb related manufacturing and overhead costs as well as potential inventory write-offs. Furthermore, if we or our collaborators experience inventory revaluation adjustments, lower of cost or market inventory adjustments, and excess inventory, it may be necessary to write down or write-off inventory or incur an impairment charge with respect to the facility where such product is manufactured, which could adversely affect our operating results. For example, during the year ended December 31, 2023, we released approximately $35.7 million of constraint related to sotrovimab due to changes in estimated allowable manufacturing expenses as agreed to with GSK.

Due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA for sotrovimab at this time. Furthermore, foreign regulatory authorities may impose similar limitations to the FDA on the use of sotrovimab in jurisdictions where sotrovimab has been granted EUA, temporary authorization or marketing approval. Although certain countries outside the U.S. continue to maintain access to 500 mg IV while noting that the clinical efficacy is unknown or uncertain against existing and emerging Omicron variants, we cannot predict whether other countries will limit the use of sotrovimab.

Even if we were to file a BLA or marketing applications in other jurisdictions, it is possible that the FDA and other regulatory authorities may not grant sotrovimab full marketing approval for the treatment of COVID-19, or that any such marketing approvals, if granted, may have similar or other significant limitations on its use. If the FDA does not reauthorize the use of sotrovimab in the U.S., and/or if countries outside of the U.S. continue to limit its use, we may be unable to sell sotrovimab in or outside of the U.S.

The FDA may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect public health or safety. An EUA may also be terminated upon a declaration by the Secretary of HHS that the public health emergency has ended. The public health emergency declarations related to COVID-19 ended on May 11, 2023.

At this point, it is unclear how, if at all, these developments will impact our EUA. We, therefore, cannot predict how long our EUA will remain in effect, and we may not receive advance notice from the FDA regarding revocation of our EUA. If our EUA is terminated or revoked, sotrovimab cannot be reauthorized by the FDA in the U.S. unless and until we have obtained FDA approval of a BLA for the product. 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.

For all of these reasons, we do not currently expect meaningful future revenue from sotrovimab for the treatment of COVID-19.

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 company founded in April 2016 and our operations to date have been largely focused on identifying, researching and conducting preclinical and clinical activities of our product candidates, acquiring and developing our technology platforms and product candidates, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio.

As an organization, beyond sotrovimab for COVID-19, we have not yet demonstrated an ability to successfully manufacture a BLA-approved, commercial-scale product or conduct sales and marketing activities necessary for successful commercialization. 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 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 may 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 March 31, 2024, we had cash, cash equivalents and investments of $1.51 billion. Based upon our current operating plan, we believe that the $1.51 billion as of March 31, 2024 will fund our current operating plans for at least the next 12 months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional financing to fund our long-term operations sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future revenue and expenses given the dynamic and rapidly evolving nature of our business. We may 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. Other unanticipated costs may also arise. Because the design and outcome of our clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of our product candidates or any future product candidates that we develop.

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 opt-in mechanisms contained in, 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 product candidates for which we receive marketing approval;

- the amount of revenue received from commercial sales of 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.

General economic conditions, both inside and outside the U.S., including heightened inflation, capital market volatility, interest rate and currency rate fluctuations, and economic slowdown or recession, including the evolution of new and existing variants of COVID-19, and geopolitical events, including civil or political unrest (such as the ongoing war between Israel and Hamas and Ukraine and Russia), have 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.

In addition, market volatility, high levels of inflation and interest rate fluctuations may increase our cost of financing or restrict our access to potential sources of future liquidity. 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 marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, 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, strategic alliances or licensing arrangements, 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.

Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or nonperformance by financial institutions, could adversely affect our business, financial condition or results of operations.

We hold our cash, cash equivalents and investments that we use to meet our working capital and operating expense needs in accounts at multiple financial institutions. The balance held in these accounts typically exceeds the Federal Deposit Insurance Corporation, or FDIC, standard deposit insurance limit of $250,000. Should events, including limited liquidity, defaults, nonperformance or other adverse developments, occur with respect to the banks or other financial institutions that hold our funds, or that affect financial institutions or the financial services industry generally, or concerns or rumors arise about any events of these kinds or other similar risks, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations.

For example, in March 2023 Silicon Valley Bank, or SVB, and Signature Bank were each closed by state regulators and the FDIC was appointed receiver for each bank. Prior to such events, we held cash deposits at SVB in excess of government insured limits. The FDIC created successor bridge banks and all deposits of SVB and Signature Bank were transferred to bridge banks under a systemic risk exception approved by the United States Department of the Treasury, the Federal Reserve and the FDIC. If financial institutions in which we hold funds for working capital and operating expenses were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on terms favorable to us, or at all, and could have a material adverse effect on our liquidity, our business, financial condition or results of operations.

Risks Related to Development and Commercialization

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

We have invested a significant portion of our time and financial resources in the development of our product candidates and have initiated clinical trials for multiple product candidates. Our business is dependent on our ability to successfully complete development of, obtain regulatory approval for, and successfully commercialize our 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. 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 or other regulatory authorities 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.

For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other “pivotal study” of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, actions plans must include the sponsor’s goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on diversity action plans. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

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. As a company, we have no prior experience in these areas. 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, strategic alliances, 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.

Furthermore, we intend to seek approval to market our product candidates outside of the U.S., and may also do so for future product candidates. If we market approved products outside of the U.S., we expect that we will be subject to additional risks in commercialization. As a company, 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.

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 elebsiran and tobevibart for the functional cure of hepatitis B virus, or HBV, and for the chronic treatment of hepatitis delta virus, or HDV. Each of these product candidates has the potential to stimulate an effective immune response and 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 have an ongoing Phase 2 clinical trial that combines elebsiran with pegylated interferon-alpha and a Phase 2 clinical trial that combines elebsiran with tobevibart. We are also evaluating additional combinations with other immunotherapy agents and direct acting antiviral agents. We also have a Phase 2 clinical trial evaluating elebsiran and tobevibart as a monotherapy or in combination for the treatment of chronic HDV. 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 comparable foreign regulatory authorities 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. For example, the other therapies may lead to toxicities that are improperly attributed to our product candidates or the combination of our product candidates with other therapies may result in toxicities that the product candidate or other therapy does not produce when used alone. 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 comparable foreign regulatory authorities. 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 comparable foreign regulatory authorities 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. We have and may continue to commit substantial financial resources with respect to clinical trials that may not be successful, and may not be able to recoup those investments.

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. We have and may continue to commit substantial financial resources with respect to clinical trials that may not be successful, and we may not be able to recoup those investments.

For example, in July 2023, we announced that our Phase 2 clinical trial of VIR-2482 for the prevention of symptomatic influenza A illness did not meet primary or secondary efficacy endpoints. We committed substantial financial resources and made substantial capital commitments with third party contract development manufacturing organizations, or CDMOs, with respect to raw materials and manufacturing in connection with VIR-2482.

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.

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 inherently uncertain as to outcome. We do not know whether our planned clinical trials will begin or enroll on time, will be conducted as planned, will need to be redesigned or will be completed on schedule, if at all. For example, the availability of superior or competitive therapies coupled with changing standards of care could limit our ability to perform placebo-controlled trials and/or require us to enroll a larger number of subjects to address competing treatments. A failure or significant delay 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 may be greater than anticipated or may 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, will be conducted as planned, will need to be restructured or will be completed on schedule, if at all. For example, enrollment and retention of patients in clinical trials could be disrupted by geopolitical events, including civil or political unrest, terrorism, insurrection or war (such as the ongoing war between Israel and Hamas and Ukraine and Russia), man-made or natural disasters, or public health pandemics or epidemics or other business interruptions, including the COVID-19 pandemic and future outbreaks of the disease.

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 cytomegalovirus, or CMV, vector technologies. 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 CMV, 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. Also, because our HCMV-vector technology is novel, regulatory agencies may lack experience with product candidates such as VIR-1388, which may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. In addition, our HCMV-vector technology utilizes live-attenuated, genetically-modified organisms for which the FDA, the European Medicines Agency, or 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 place a full or partial hold on 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 IND applications or clinical trial applications, 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.

Our inability to bring a product to market or a significant delay in the expected approval and related launch date of a new product for any of the reasons discussed above could have a negative effect on our stock price and related market capitalization and could result in a significant impairment of goodwill, other intangible assets and long-lived assets.

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. In particular, clinical trials for prophylaxis are impacted by many factors including competing therapies that 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 depend on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data, changing standards of care, 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. The enrollment and retention of patients in our clinical trials may be disrupted or delayed as a result of, for example, regulatory feedback, clinicians' and patients' perceptions as to the potential advantages of therapies in development in relation to other available therapies, including products that have been recently authorized under EUAs or approved and licensed through NDAs and BLAs. In addition, enrollment and retention of patients in clinical trials could be disrupted by geopolitical events, including civil or political unrest, terrorism, insurrection or war (such as the ongoing war between Israel and Hamas and Ukraine and Russia), 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 contract research organizations, or CROs, and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to ensure their actual performance.

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

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

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

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 spend significant additional capital or 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. 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 Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024.

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 and other serious conditions. 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. We are likely to face significant competition in seeking appropriate strategic collaborators, strategic collaborations and licenses can be complicated and we may not be able to negotiate strategic collaborations on acceptable terms, or at all. If we are unable to enter into new strategic collaborations or licenses related to our product candidates in certain geographies for certain indications, we may not be able to develop and commercialize certain of our product candidates which would harm our business prospects, financial condition and results of operations.

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

- 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 dosages or indications, or design clinical trials, in a way that may be less successful than if we were doing so or in a way that may differ from our strategy, which could negatively impact our development, manufacturing and commercialization of the same or a similar product candidate;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement due to development programs based on data readouts, changes in their strategic focus as a result of an acquisition of competitive products or other internal pipeline advancements, availability of funding or other external factors, that diverts resources or creates competing priorities;
- 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 not exercise their opt-in rights, which may delay the development, may increase the cost of developing our product candidates and result in a need for additional capital to pursue further development or commercialization of the applicable 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.

The deployment of artificial intelligence in our, or our collaborators', efforts to discover, develop, and engineer next-generation antibodies or other investigational products, could adversely affect our business, reputation, or financial results.

We integrate artificial intelligence and machine learning, or AI, in our efforts to develop and engineer next-generation antibodies, and we might utilize AI in the future in connection with drug discovery activities. AI may be difficult to deploy successfully due to operational and technical issues inherent in such methods. In particular, AI algorithms might utilize machine learning and predictive analytics which may lead to flawed, biased or inaccurate results, which could lead to ineffective product or target candidates and exposure to competitive and reputational harm. In addition, perceived or actual technical, legal, compliance, privacy, security, ethical or other issues relating to the use of AI may cause regulators' or the public's confidence in AI to be undermined, which could impede our ability to develop products using AI. In addition, any latency, disruption, or failure in our AI operations or infrastructure could result in failures, delays or errors in our discovery and development of next-generation antibodies or other investigational products. Developing, testing and deploying resource-intensive AI systems may also require additional investment and increase our costs, and there is no guarantee that our investment in such systems will lead to more effective or efficient discovery or development of antibodies or other investigational products, or lead to eventual regulatory approval or commercialization of any new products.

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 and other serious conditions. 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. 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 we do.

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.

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.

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, and 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 acquiring third-party contract manufacturing capacity and raw materials, 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.

Our success is also subject to the risk of current and future disruptive technologies, such as AI. The failure to successfully develop and apply AI may impact our ability to increase the efficiency of, and reduce costs associated with, the discovery and development of next-generation antibodies and other investigational products, and to eventually receive regulatory approval for, and commercialize, new products. If our competitors are able to more effectively utilize any such new technologies, including but not limited to those that may involve AI or be created using AI, to discover, develop and commercialize products that compete with any of our investigational or commercial products, such technologies could adversely impact our ability to compete and could adversely affect our business, operating results, or financial condition.

As a result of these factors, our competitors may achieve patent protection or obtain regulatory approval or authorization 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 Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024.

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

Even if any of our product candidates receive marketing approval, they may fail to achieve adoption 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;
- acceptance in the medical and patient communities of our product candidates as a safe and effective treatments;
- 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 products' safety profile; 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 and potential enforcement actions.

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, continuing regulatory review and review by other government agencies and third parties. 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 or authorized 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 comparable foreign 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 or monetary penalties, among other actions. The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we market our medicines for uses other than their respective approved indications, we may be subject to DOJ-led enforcement actions for off-label marketing. Violations of the Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws, which violations may result in the imposition of significant administrative, civil and criminal penalties. 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. For additional information regarding regulatory approval and ongoing regulatory oversight, see the section titled "Business—Government Regulation and Product Approval" in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024.

Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval outside of 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 of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. 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 of 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.

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. In addition, our insurance policies may be inadequate and potentially expose us to unrecoverable risks.

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. Furthermore, 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

Any biologic 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, biologic product candidates are subject to approval and licensure 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 Regulatory Exclusivity” in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024. If competitors are able to obtain marketing approval for biosimilars referencing our licensed biologic products after the expiration of applicable periods of regulatory exclusivity, our 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. In addition, the extent to which any regulatory exclusivity may apply to competing products authorized under an EUA is unclear and may not apply.

For additional information regarding competition, see the section titled “Business—Competition” in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024.

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 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 impact the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any product candidates, if approved. For additional information regarding these laws, see the section titled “Business—Government Regulation and Product Approval” in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024. Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely continue to be costly. 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.

If we obtain regulatory approval in the United States, coverage and adequate reimbursement may not be available for any product candidates that we commercialize, which could make it difficult for us to sell profitably.

Even if we obtain regulatory approval in the United States, market acceptance and sales of any product candidates that we commercialize 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 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. The position on a payor’s list of covered drugs and biological products, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. In addition, because certain of our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used.

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

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

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future product candidates or additional pricing pressures. For example, in August 2022, the Inflation Reduction Act, or IRA, was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B, to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

While it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition. For additional information regarding other healthcare legislative reform measures, see the section titled “Business—Government Regulation and Product Approval—Healthcare Reform” in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024.

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

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

We are subject to 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, collaborators 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, reputation, financial condition, results of operations and prospects.

Risks Related to Our Dependence on Third Parties

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

We are currently conducting process development and manufacturing material for product candidates of three different therapeutic modalities: mAbs, HCMV-based vaccines and siRNAs. Except for limited early-clinical phase process, analytical and formulation development, cell line development, small-scale non-GMP manufacturing for preclinical studies, and quality control testing capabilities in certain of our facilities that is either established or is currently being built, we do not own or operate facilities for full process development or product manufacturing, storage and distribution, or testing. We are dependent on third parties, including strategic collaborators and contract development and manufacturing organizations, or CDMOs, to develop the manufacturing process and manufacture the clinical supplies of our current and any future product candidates. We have established relationships with multiple third parties that have developed the manufacturing processes and produced material to support our preclinical, Phase 1, 2, and 3 clinical trials. 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, 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 third party manufacturers to develop and manufacture our product candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after we submit our EUA, NDA or BLA to the FDA or foreign marketing application to the appropriate regulatory authority. We do not control the manufacturing process of, and are completely dependent on, our third party manufacturers for compliance with cGMP requirements. If our third party 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 third party manufacturers to maintain adequate quality control, quality assurance, qualified personnel or oversight of their subcontractors. If the FDA or a comparable foreign regulatory authority does not approve our third party's 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 have sufficient manufacturing capacity to meet demand for our product candidates, meet our working assumptions of manufacturing titer and yield per batch of our product candidates or consistently manufacture product meeting our quality requirements. Any shortfall in manufacturing capacity or reduction in anticipated manufacturing titer, yield per batch or batch success rates 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 strategic collaborators and foreign suppliers and CDMOs, and will likely continue to rely on strategic collaborators and foreign suppliers and manufacturers in the future. Foreign third party suppliers and manufacturers, and third party suppliers and manufacturers operating in foreign countries, 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 or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies.

For example, the biopharmaceutical industry 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 strategic collaborators, third-party suppliers and manufacturers operating in China which could have an adverse effect on our business, financial condition, results of operations and prospects. Evolving changes in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the U.K., could also negatively impact our ability to manufacture or supply 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. For example, on February 12, 2024, a group of bipartisan U.S. lawmakers sent a letter to Commerce Secretary Gina Raimondo, Treasury Secretary Janet Yellen, and Defense Secretary Lloyd Austin calling on them to investigate Chinese biotech company WuXi AppTec and its subsidiary, WuXi Biologics, one of our CDMOs, citing ties to the Chinese military, the Chinese Communist Party, and potential threats to U.S. intellectual property and national security, and requesting that U.S. agencies consider adding the companies to the U.S. Department of Defense's Chinese Military Companies List (1260H list), the Department of Commerce's Bureau of Industry and Security Entity List, and the Department of Treasury's Non-SDN Chinese Military-Industrial Complex Companies List. Additionally, the U.S. House of Representatives recently introduced the "BIOSECURE Act" (H.R. 7085) and the Senate has advanced a substantially similar bill (S. 3558), which legislation, if passed and enacted into law, would have the potential to restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies "of concern", including WuXi Biologics, or risk losing the ability to contract with, or otherwise receive funding from, the U.S. government.

Further, our reliance on third-party suppliers and manufacturers entails risks to which we would not be exposed or that may be reduced if we conducted process development or 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 or excess raw materials 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 process development, manufacturing, technology transfers, manufacturing procedures and other logistical support requirements appropriately or on a timely basis;
- inability to negotiate development and manufacturing agreements with third parties under commercially reasonable terms, if at all;
- greater costs and competition for access to an increasingly smaller pool of third-party manufacturers as a result of consolidation in the contract manufacturing industry;
- breach, termination or nonrenewal of development and 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 raw materials or components;
- lack of qualified backup suppliers for those raw materials or 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 parties in the manufacturing process for our product candidates;
- price increases or decreased availability of product raw materials or components;
- disruptions to operations of our third-party suppliers and manufacturers by conditions unrelated to our business or operations, including supply chain issues, capacity constraints, transportation and labor disruptions, global competition for resources, the bankruptcy of the manufacturer and/or general economic conditions, heightened inflation, interest rate and currency rate fluctuations, and economic slowdown or recession;

- disruptions caused by geopolitical events, including civil or political unrest, terrorism, insurrection or war (such as the ongoing war between Ukraine and Russia, and between Israel and Hamas), man-made or natural disasters or public health pandemics or epidemics, including, for example, the COVID-19 pandemic; and
- carrier disruptions or increased costs that are beyond our control, including increases in material, labor or other manufacturing-related costs or higher supply chain logistics costs.

We may be unable to obtain product raw materials or components for an indeterminate period of time if any of our third-party suppliers and manufacturers were to cease or interrupt production or otherwise fail to supply these materials or components to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier or manufacturer, failure by the supplier or manufacturer to comply with cGMP, facility outages (including due to contamination), business interruptions, or labor shortages or disputes. Suppliers and manufacturers may extend lead times, limit supplies, change manufacturing schedules, increase prices, or require significant upfront fees due to capacity and material supply constraints or other factors beyond our control. For example, recent increased demand for GLP-1 therapeutics could result in increased competition for our third-party manufacturers' services and limited capacity, which could limit our access to, and increase our costs for, manufacturing production and potentially harm our business and results of operations. We cannot be sure that single source suppliers for our product raw materials or 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 our product raw materials or components for our intended purpose. In addition, the lead time needed to establish a relationship with a new raw material or component supplier or manufacturer can be lengthy and we may experience delays in meeting demand in the event we must switch to a new supplier or manufacturer. The time and effort to qualify a new supplier or manufacturer could result in manufacturing delays, additional costs, diversion of resources or reduced manufacturing capacity or yields, any of which would negatively impact our operating results.

Furthermore, there are a limited number of suppliers and manufacturers that supply synthetic siRNAs. We currently rely on a limited number of third party suppliers and CDMOs for our supply of synthetic siRNAs. There are risks inherent in pharmaceutical manufacturing that could affect the ability of our CDMOs to meet our delivery time requirements or provide adequate amounts of synthetic siRNAs to meet our needs. Included in these risks are potential extended lead times, delays or shortages of raw materials and components, 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 cGMP requirements, 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 supply requirements, we may need to secure alternative suppliers of synthetic siRNAs and/or key raw materials and components, and such alternative third party 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. Further, alternative suppliers would require filing and regulatory approvals.

In addition, third party 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 that some vectors have a restricted growth phenotype in cells that reduces yields during manufacturing. To address these challenges, we have made significant 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 a CDMO specializing in live vaccine manufacturing. However, the existing process will require additional process development and scale-up for later stages of clinical development and commercial supply. To fulfill our HCMV supply requirements, we may need to secure alternative suppliers and manufacturers viral vector products and/or key raw materials and components, and such alternative suppliers and manufacturers may not have the manufacturing experience or capacity required for HCMV-based vaccine manufacturing, or we may be unable to enter into agreements with them on reasonable terms and in a timely manner.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize, manufacture or supply 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. Any such recall, seizure or suspension could adversely impact our business in a variety of ways, including having to absorb related manufacturing and overhead costs as well as potential inventory write-offs.

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 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 addition, the Chinese government took certain actions, including tariffs, which affect certain products manufactured in the U.S.

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. Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may affect the demand for our product candidates, the competitive position of our product candidates, and import or export of raw materials and product used in our drug development and clinical manufacturing activities, particularly with respect to raw materials and product that we import from China, including pursuant to our development and 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 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. For example, on February 12, 2024, a group of bipartisan U.S. lawmakers sent a letter to Commerce Secretary Gina Raimondo, Treasury Secretary Janet Yellen, and Defense Secretary Lloyd Austin calling on them to investigate Chinese biotech company WuXi AppTec and its subsidiary, WuXi Biologics, one of our CDMOs, citing ties to the Chinese military, the Chinese Communist Party, and potential threats to U.S. intellectual property and national security, and requesting that U.S. agencies consider adding the companies to the U.S. Department of Defense's Chinese Military Companies List (1260H list), the Department of Commerce's Bureau of Industry and Security Entity List, and the Department of Treasury's Non-SDN Chinese Military-Industrial Complex Companies List. Additionally, the U.S. House of Representatives recently introduced the "BIOSECURE Act" (H.R. 7085) and the Senate has advanced a substantially similar bill (S. 3558), which legislation, if passed and enacted into law, would have the potential to restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies "of concern", including WuXi Biologics, or risk losing the ability to contract with, or otherwise receive funding from, the U.S. government.

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 the activities of our third-party manufacturers and suppliers 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, collection, and appropriate 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 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 GLP-compliant and GCP-compliant pre-clinical and 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 we license siRNA technology from Alnylam Pharmaceuticals, Inc. 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 and other serious conditions. 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 claims of our patent applications or issued patents.

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 or patents 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 term, 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 of 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, or could result in licensees seeking release from their license agreements.

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 of 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, including as a result of geopolitical events such as civil or political unrest (including the ongoing war between Ukraine and Russia and recent events in Israel), 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 or out-licensed by us, any of the foregoing could expose us to liability to the applicable patent owner or licensee, respectively.

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 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, which could adversely affect our business and results of operations.

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

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 sotrovimab and other 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. The outcome following legal assertions of invalidity and unenforceability is unpredictable. 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.

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 competing.

Issued patents may be challenged by third parties in the courts or patent offices in various countries throughout the world. Invalidation proceedings may result in patent claims being narrowed, invalidated or held unenforceable. Uncertainties regarding the outcome of such proceedings, as well as any resulting losses of patent protection, could harm our business.

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. Some countries do not enforce patents related to medical treatments, or limit enforceability in the case of a public emergency. 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.

On June 17, 2022, the WTO adopted a Ministerial Decision to waive certain intellectual property rights for COVID-19 vaccines. The waiver allows certain developing countries to permit the manufacture and use of COVID-19 vaccines without the consent of the patent holder(s) to the extent necessary to address the COVID-19 pandemic. The waiver is in effect initially for five years from the date of the Ministerial Decision and will be reviewed annually. The WTO is considering whether to extend the waiver to diagnostics and therapeutics. The WTO may consider additional waivers, the ultimate timing and scope of which, if approved, are unknown. The scope and timing of such extensions and/or additional waivers 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 covering COVID-19 treatments or prophylactics, such as sotrovimab and VIR-7229, is approved, our ability to successfully commercialize our COVID-19 product candidates and protect our related technology could be adversely affected.

The current waiver is the result of public health concerns from the COVID-19 pandemic and an effort to make vaccines more widely available worldwide. This waiver 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, or to waivers for treatments or prophylactics in addition to vaccines. Given that our business is focused on treating and preventing infectious diseases and other serious conditions, 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 intellectual property 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 collaborations 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. 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 of 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. Additionally, the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our work-from-home policies for most of our employees, which provides our employees the choice of working full time in the office, a hybrid approach, or full-time remote. A remote working environment may be less secure and more susceptible to hacking attacks. 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 in certain jurisdictions, as in currently pending oppositions filed against EU-wide registration of our VIR Pharmaceuticals house mark and logo by Industria Quimica y Farmaceutica Vir. S.A., a Spanish company which claims exclusive rights in the term VIR in Spain and Portugal. We also have a pending opposition of the Vir logo in Turkey by Ulkar Kimya Sanayii Ve Ticaret Anonim Şirketi, a Turkish company which claims exclusive rights in the term VIR in Turkey. Third parties may also challenge our use of our 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 an amended and restated letter agreement with the Bill & Melinda Gates Foundation, or the Gates Agreement, in January 2022, which amends and restates the letter agreement with the Bill & Melinda Gates Foundation that we entered into in December 2016. In connection with the Gates Agreement, the Bill & Melinda Gates Foundation purchased $20.0 million of shares of our convertible preferred stock which converted to shares of our common stock after our initial public offering and purchased $40.0 million of shares of our common 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—Amended and Restated Letter Agreement with the Bill & Melinda Gates Foundation" in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 26, 2024.

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 or (2) the fair market value, which amount may increase in the event of 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, vaccinal antibody 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. 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.

We have announced several leadership changes over the past year, including a Chief Executive Officer transition in January 2023 that became effective April 3, 2023. Management transitions may create uncertainty and involve a diversion of resources and management attention, be disruptive to our daily operations or impact public or market perception, any of which could negatively impact our ability to operate effectively or execute our strategies.

Recruiting, integrating 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. 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. Macroeconomic conditions, specifically labor shortages, increased competition for employees and wage inflation, could also have a material impact on our ability to attract and retain talent, our turnover rate and the cost of operating our business. 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 Part I, 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. 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.

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 have experienced significant growth in our organization in recent years and expect to continue to expand, and we may experience difficulties in managing this growth, which could disrupt our operations.

We have experienced significant growth in the number of our employees and the scope of our operations in recent years at both our sites and remote locations, particularly in the areas of research, development and regulatory affairs, and we expect to continue to experience growth as the clinical development of our product candidates progresses. In addition, if any of our product candidates receives marketing approval, we will need to build out our sales and marketing capabilities, either on our own or with others. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, improve our facilities, and continue to recruit and train additional qualified personnel. As a result of the global pandemic resulting from COVID-19, the majority of our workforce began working from home in March 2020. In April 2022, we reopened our offices to allow employees to return to work, and we now have employees working full-time in the office, a hybrid approach, or full-time remote. 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. 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 joined during the global pandemic or otherwise joined us as remote workers. 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 COVID-19 pandemic), geopolitical events, including civil or political unrest in any of our business locations, terrorism, insurrection or war (such as the ongoing war between Israel and Hamas and Ukraine and Russia), 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 geopolitical events, 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 public health outbreaks, pandemics or epidemics, including the COVID-19 pandemic and future pandemics.

Our business could be materially adversely affected by the effects of public health outbreaks, pandemics or epidemics, including the COVID-19 pandemic, the evolution of new and existing variants or subvariants of COVID-19 that are resistant to existing treatments or vaccinations and any future pandemics.

Public health outbreaks, pandemics or epidemics pose the risk that we or our employees, contractors, suppliers, CDMOs or other partners may be prevented from conducting business activities for an indefinite period of time due to spread of the disease, or due to shutdowns that may be requested or mandated by federal, state and local governmental authorities. Business disruptions could include restrictions on our ability to travel, quarantine orders, temporary closures of our facilities or the facilities of our contractors, suppliers, CDMOs and other partners and other restrictions by governments to reduce the spread of the disease. The effects of these business disruptions may negatively impact productivity, limit our ability to obtain sufficient materials, raise the cost of materials (or otherwise disrupt our supply chain) and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of such business disruptions.

For example, our clinical trials were affected by the COVID-19 pandemic. Site initiation and patient enrollment were delayed due to prioritization of hospital resources toward the COVID-19 pandemic, and, if there are future quarantines which impede patient movement or interrupt healthcare services, some patients may not be able or willing to comply with clinical trial protocols. 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, was delayed or disrupted, which had adversely impacted our clinical trial operations. The public health emergency declarations related to COVID-19 ended on May 11, 2023. In addition, the FDA ended 22 COVID-19-related policies when the public health emergency ended on May 11, 2023, and the FDA allowed 22 related-policies to continue for 180 days. The FDA plans to retain 24 COVID-19-related policies with appropriate changes and four policies whose duration is not tied to the end of the public health emergency. However, at this point, it is unclear how, if at all, these developments will impact our efforts to develop and commercialize our product candidates.

We continue to monitor our operations and applicable government recommendations, and we have made lasting modifications to our normal operations because of the COVID-19 pandemic. We now have employees working full time in the office, a hybrid approach, or full-time remote. As a result, we expect to continue to be subject to the challenges and risks of having a remote workforce, as well as new challenges and risks from operating with a hybrid workforce. For example, our employees are accessing our servers remotely through home or other networks to perform their job responsibilities. Such security systems may be less secure than those used in our offices, which may subject us to increased security risks, including cybersecurity-related events, and expose us to risks of data or financial loss and associated disruptions to our business operations. Additionally, employees who access company data and systems remotely may not have access to technology that is as robust as that in our offices, which could place additional pressure on our user infrastructure and third parties that are not easily mitigated. We may also be exposed to risks associated with the locations of remote employees, including compliance with local laws and regulations or exposure to compromised internet infrastructure. Allowing our employees to work remotely may create intellectual property risk if employees create intellectual property on our behalf while residing in a jurisdiction with unenforced or uncertain intellectual property laws. Further, if employees fail to inform us of changes in their work location, we may be exposed to additional risks without our knowledge.

Additionally, operating our business with both remote and in-person workers could have a negative impact on our corporate culture, decrease the ability of our workforce to collaborate and communicate effectively, decrease innovation and productivity, or negatively affect workforce morale. If we are unable to manage cybersecurity and other risks of a flexible-first workforce model, and maintain our corporate culture and workforce morale, our business could be harmed or otherwise adversely impacted.

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, ransomware attacks, user error or malfeasance, data corruption, cyber-based attacks, natural disasters, public health pandemics or epidemics, geopolitical events, including civil or political unrest, 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 experienced minor or inconsequential security breaches of our information technology systems, such as through attempted 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. For example, attackers have used artificial intelligence and machine learning to launch more automated, targeted and coordinated attacks against targets. 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, 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 detect (including performing required forensics), mitigate 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, security breaches 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.

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. In addition, the U.S. Securities and Exchange Commission adopted rules in 2023 requiring us to publicly disclose certain cybersecurity incidents. Such notices could 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. 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 are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to local, state, federal and international data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, EU and the U.K. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Additionally, our use of AI and machine learning may be subject to laws and evolving regulations regarding the use of AI or machine learning, controlling for data bias, and anti-discrimination. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, we could face civil and criminal penalties.

At least twelve states in the U.S., including California, have passed comprehensive privacy laws. These laws are either in effect or will go into effect sometime before the end of 2026. These laws create obligations related to the processing of personal information, as well as special obligations for the processing of “sensitive” data (which includes health data in some cases). There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond, including New York and New Jersey. Congress has also been debating passing a federal privacy law. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our collaboration partners’ or service providers’ privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures, reckless and/or negligent conduct or unauthorized activities that violates (i) the laws and regulations of FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad, (iv) laws that require the true, complete and accurate reporting of financial information or data and (v) insider trading laws that restrict the buying and selling of shares of our common stock while in possession of material non-public information. 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. 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. In addition, during the course of our operations, our directors, executives and employees may have access to material non-public information regarding our business, our results of operations or potential transactions we are considering. We may not be able to prevent a director, executive or employee from violating our insider trading policies and trading, or "tipping" others who might trade, in our securities or the securities of other companies on the basis of, or while having access to, material non-public information. If a director, executive or employee were to be investigated, or an enforcement action were to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price.

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.

As of December 31, 2023, we had net operating loss carryforwards of $487.0 million for federal tax purposes and $415.4 million for state tax purposes. If not utilized, federal carryforwards will begin expiring in 2036 and state carryforwards will begin expiring in 2031. Our ability to use our federal and state NOLs to offset potential future taxable income is dependent upon our generation of future taxable income before any expiration dates of the NOLs, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures currently and requires taxpayers to capitalize and amortize them over five or fifteen years pursuant to Section 174 of the Internal Revenue Code of 1986, as amended, or the Code. Although Congress is considering legislation that could repeal such requirement or defer the amortization requirement to later years, it is not certain that the provision will be repealed or otherwise modified. If the requirement is not modified, it will continue to reduce our anticipated net operating losses over the next several years.

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. Factors that may cause fluctuations in our financial condition and results of operations include, without limitation, those listed elsewhere in this "Risk Factors" section and those listed below:

- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which will change from time to time;
- the cost of manufacturing our product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of preclinical studies and clinical trials for our product candidates;
- the need to conduct unanticipated clinical trials or clinical trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with our product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of our product candidates;
- the level of demand for any of our product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with our product candidates;
- our ability to commercialize our product candidates, if approved, inside and outside of the U.S., either independently or working with third parties;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic and political environment both inside and outside the U.S., including heightened inflation, capital market volatility, interest rate and currency rate fluctuations, and economic slowdown or recession.

In addition, our collaboration revenue and certain assets and liabilities are subject to foreign currency exchange rate fluctuations due to the global nature of our operations. As a result, currency fluctuations among our reporting currency, the U.S. dollar, and other currencies in which we do business will affect our operating results, often in unpredictable ways. Currency exchange rates have been especially volatile in the recent past, and these currency fluctuations have affected, and may continue to affect, our assets and liabilities denominated in foreign currency. We are also 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. For additional information, see Part I, 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, or Nasdaq, through April 26, 2024, the closing price of our stock ranged from $7.63 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 COVID-19 pandemic, for example, negatively affected some sectors of the stock market and investor sentiment and resulted in significant volatility. In addition, economic trends and other external factors including, but not limited to, heightened inflation, interest rate and currency rate fluctuations, economic slowdown or recession, capital markets volatility, foreign market trends, national crisis, and disasters, may impact the market price of our common stock and result in 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.

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 research, development, manufacturing, regulatory and commercialization efforts with respect to any of our product candidates or information regarding such efforts by competitors with respect to their potential therapies, may also 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 in the foreseeable future.

We have incurred and we will continue to 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 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.

Stockholder activism, the current political environment and the current high level of U.S. government intervention and regulatory reform may also lead to substantial new regulations and disclosure obligations, which may in turn lead to additional compliance costs and impact the manner in which we operate our business in ways we do not currently anticipate. Our management and other personnel will need to devote a substantial amount of time to comply with these requirements. Moreover, these requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements.

If we fail to develop or 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 us and the trading price of our common stock may decline.

Effective internal control over financial reporting are necessary for us to provide reliable financial reports and effectively prevent fraud and operate successfully as a public company. 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 our internal control over financial reporting is not effective, 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 could also restrict our future access to the capital markets.

A material weakness in internal control over financial reporting has in the past and could in the future lead to deficiencies in the preparation of financial statements. Deficiencies in the preparation of financial statements, could lead to litigation claims against us. The defense of any such claims may cause the diversion of management’s attention and resources, and we may be required to pay damages if any such claims or proceedings are not resolved in our favor. Any litigation, even if resolved in our favor, could cause us to incur significant legal and other expenses. Such events could also affect our ability to raise capital to fund future business initiatives.

Pursuant to Section 404 of the Sarbanes-Oxley Act, 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. 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 Securities Exchange Act of 1934, as amended, or 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.

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 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, as updated by our Amended and Restated Bylaws filed herewith as Exhibit 3.2.

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 Delaware General Corporation Law, 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, 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, Use of Proceeds, and Issuer Purchases of Equity Securities.

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Director and Officer Trading Arrangements

A portion of the compensation of the Company's directors and officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) is in the form of equity awards and, from time to time, directors and officers may engage in open-market transactions with respect to the securities acquired pursuant to such equity awards or other Company securities, including to satisfy tax withholding obligations when equity awards vest or are exercised, and for diversification or other personal reasons.

Transactions in Company securities by directors and officers are required to be made in accordance with the Company's insider trading policy, which requires that the transactions be in accordance with applicable U.S. federal securities laws that prohibit trading while in possession of material nonpublic information. Rule 10b5-1 under the Exchange Act provides an affirmative defense that enables directors and officers to prearrange transactions in the Company's securities in a manner that avoids concerns about initiating transactions while in possession of material nonpublic information.

During the quarterly period covered by this report, none of our directors or officers entered into or terminated a Rule 10b5-1 trading arrangement or adopted or terminated a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) except as follows:

On February 29, 2024, for estate and financial planning reasons, Vicki Sato, Ph.D., the Chair of our Board of Directors , adopted a Rule 10b5-1 trading plan for the sale of our common stock that is intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5-1(c) (the "Sato Trading Plan"). The Sato Trading Plan provides for potential trading activity from July 1, 2024, through June 30, 2025, with two monthly limit orders covering up to an aggregate of 263,040 shares of our common stock, which represents approximately 20% of the aggregate shares of Company common stock she currently holds. Dr. Sato has held the shares subject to the Sato Trading Plan for over 7 years from the date she acquired them on January 7, 2017. Under the Company's 10b5-1 plan guidelines, Dr. Sato is prohibited from selling more than 50,000 shares in a single trading day. Each contemplated limit order will remain open for one month, and each open limit order will cancel at the end of that same month if the stock market price of our common stock does not reach the various limit prices specified in the Sato Trading Plan. Even if all the shares subject to the Sato Trading Plan are sold pursuant to such plan, Dr. Sato would still remain in compliance with the Company's applicable equity ownership guidelines. The Sato Trading plan will expire upon the earlier of (i) the date all sales contemplated by the Sato Trading Plan have been executed, or (ii) June 30, 2025.

On January 31, 2024, Ann (Aine) Hanly, Ph.D., our Executive Vice President and Chief Technology Officer, adopted a Rule 10b5-1 trading plan for the sale of our common stock that is intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5-1(c) (the "Hanly Trading Plan"). The Hanly Trading Plan provides for two limit order same day sales of vested stock options. Pursuant to these two orders, an aggregate of 22,518 shares of our common stock may be exercised and sold into the market. Under the Company's 10b5-1 plan guidelines, Dr. Hanly is prohibited from selling more than 50,000 shares in a single trading day. Even if all the shares subject to the Hanly Trading Plan are sold pursuant to such plan, Dr. Hanly would still remain in compliance with the Company's applicable equity ownership guidelines. The Hanly Trading Plan will expire upon the earlier of (i) the date all sales contemplated by the Hanly Trading Plan have been executed, or (ii) January 29, 2025.

On February 22, 2024, the Company issued restricted stock units ("RSUs") subject to mandatory sell-to-cover tax withholding arrangements to the following officers of the Company:

- Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer;
- Sung Lee, Executive Vice President and Chief Financial Officer; and
- Ann (Aine) Hanly, Ph.D., Executive Vice President and Chief Technology Officer.

Additionally, on January 22, 2024, March 1, 2024, March 2, 2024 and March 5, 2024 (each, an applicable "Adoption Date"), respectively, each of Ann (Aine) Hanly, Ph.D., our Executive Vice President and Chief Technology Officer, Sung Lee, our Executive Vice President and Chief Financial Officer, Marianne De Backer, M.Sc., Ph.D., MBA, our Chief Executive Officer, and Phillip Pang, M.D., Ph.D., our former Executive Vice President and Chief Medical Officer, entered into a 10b5-1 trading arrangement that is intended to qualify as an "eligible sell-to-cover transaction" (as described in Rule 10b5-1(c)(1)(ii)(D)(3) of the Exchange Act) with respect to certain RSUs (the "Sell-to-Cover Instructions"). Each of the Sell-to-Cover-Instructions provides for the automatic sale of shares of our common stock that would otherwise be issuable on each settlement of RSUs in amount necessary to satisfy the Company's applicable tax withholding obligation, which is based on the fair market value of the shares of the Company's common stock subject to the RSUs that are settled on each applicable vesting date. The proceeds of any such sale will be delivered to us in satisfaction of such tax withholding obligations. Each of the Sell-to-Cover Instructions are subject to applicable "cooling-off periods", consistent with Rule 10b5-1(c)(1)(ii)(B) of the Exchange Act. Each of Drs. De Backer's, Hanly's and Pang's and Mr. Lee's Sell-to-Cover Instructions apply with respect to the first award of RSUs granted on or after their respective hire dates and any RSUs that may, from time to time following such date, be granted to them by the Company, other than any future granted RSUs which by the terms of the applicable award agreement require the Company to withhold shares to satisfy tax withholding obligations in connection with the vesting and settlement of such RSUs, and therefore do not permit sell-to-cover transactions. Drs. Hanly's and Pang's Sell-to-Cover-Instructions further apply to any outstanding RSUs that were granted to them by the Company prior to the applicable Adoption Dates of their respective Sell-to-Cover Instructions that (i) are not subject to any prior automatic sale or sell-to-cover instruction and (ii) for which the next vesting date is after the applicable cooling-off period, other than any previously granted RSUs which by the terms of the applicable award agreement require the Company to withhold shares to satisfy tax withholding obligations in connection with the vesting and settlement of such RSUs, and therefore do not permit sell-to-cover transactions. The number of shares that will be sold under these RSU sell-to-cover tax withholding arrangements is not currently determinable as the number will vary based on the extent to which vesting conditions are satisfied and the market price of our common stock at the time of settlement.

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 3.1 to the Company's Current Report on Form 8-K (File No. 001-39083), filed with the SEC on March 8, 2023).
10.1†	Letter Agreement between the Company and Glaxo Wellcome UK Limited, dated February 21, 2024.
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 amended, 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 amended, 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).

† Certain portions of this exhibit (indicated by "[***]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

* 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: May 3, 2024 By: /s/ **Marianne De Backer**

Marianne De Backer, M.Sc., Ph.D., MBA
Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 3, 2024 By: /s/ **Sung Lee**

Sung Lee
Executive Vice President and Chief Financial Officer
(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, Marianne De Backer, M.Sc., Ph.D., MBA, 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: May 3, 2024

/s/ **Marianne De Backer**

Marianne De Backer, M.Sc., Ph.D., MBA
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, Sung Lee, 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: May 3, 2024

/s/ **Sung Lee**

Sung Lee
Executive Vice President and Chief Financial Officer
(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 Rules 13a-14(b) and 15d-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), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer and Director of Vir Biotechnology, Inc. (the "Company"), and Sung Lee, Executive Vice President and Chief Financial Officer 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 March 31, 2024, 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 3rd day of May 2024.

/s/ **Marianne De Backer**	/s/ **Sung Lee**
Marianne De Backer, M.Sc., Ph.D., MBA	**Sung Lee**
Chief Executive Officer and Director	**Executive Vice President and Chief Financial Officer**
(Principal Executive Officer)	***(Principal Financial and Accounting Officer)***

This certification accompanies the Form 10-Q to which it relates and 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.

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT VIR BIOTECHNOLOGY, INC. TREATS AS PRIVATE OR CONFIDENTIAL.

February 21, 2024

Glaxo Wellcome UK Limited
980 Great West Road, Brentford, Middlesex, TW8 9GS
Attn: SVP & Head R&D Business Development

Re: Termination of Influenza Program under the Definitive Collaboration Agreement between Glaxo Wellcome UK Limited ("**GSK**") and Vir Biotechnology, Inc. ("**Vir**"), dated May 18, 2021 (the "**Agreement**")

Dear GSK Business Development:

As you know, the Parties have mutually agreed to terminate the Influenza Program pursuant to Section 16.2 of the Agreement as per the terms set forth in this letter agreement (this "**Letter Agreement**"). Such termination will be effective on February 21, 2024 (the "**Influenza Program Termination Date**").

The Parties wish to set forth certain clarifications and amendments with respect to the Parties' rights and obligations under the Agreement with respect to the Influenza Program and with respect to the Parties' remaining activities and obligations under the Agreement. Capitalized terms used but not defined in this Letter Agreement will have the meanings provided in the Agreement.

Intending to be legally bound, the Parties hereby agree as follows:

From and after the Influenza Program Termination Date:

1. Section 2.4.1 (Influenza Program) of the Agreement shall terminate and be of no further force or effect as of the Influenza Program Termination Date. Except as expressly set forth in this Letter Agreement, Vir shall have no further obligations to GSK with respect to VIR-2482XX2 or VIR-2981 (the "**Existing Terminated Influenza Products**") or any Vir Improved Terminated Influenza Products (as defined below), and shall have the right to further Develop and Commercialize any such Existing Terminated Influenza Product or Vir Improved Terminated Influenza Product independently, alone or via an Affiliate or with a Third Party without restriction. "**Vir Improved Terminated Influenza Product(s)**" means any (a) Variants or derivatives of any Existing Terminated Influenza Products created, discovered, conceived or reduced to practice after the Influenza Program Termination Date, (b) any modifications or improvements to any Existing Terminated Influenza Products made after the Influenza Program Termination Date including, without limitation those related to (i) affinity maturation, (ii) alternative delivery, (iii) antibody format, (iv) formulation, (v) Fc modifications and/or (vi) combination. For clarity, Vir Improved Terminated Influenza Products exclude the Existing Terminated Influenza Products.
2. Sections 7.6.4(a) and 7.6.4(b) of the Agreement shall apply to the Existing Terminated Influenza Products as if they were Vir Sole Development Products. Section 7.6.4(c) shall apply, provided that if Vir subsequently elects to wind down and cease Development of any Existing Terminated Influenza Products, Vir shall be solely responsible for the costs of such wind-down, and the last sentence of Section 7.6.4(c) shall not apply. Sections 7.6.4(d) and 7.6.4(e) shall terminate effective as of the Influenza Program Termination Date.

3. Section 4.2 (GSK's Option to VIR-2482) and Section 4.3 (VIR-2482XX2 and other Vir Influenza mAbs) shall terminate and be of no further force or effect as of the Influenza Program Termination Date. Except as expressly set forth in this Letter Agreement, Vir shall have no further obligations to GSK with respect to VIR-2482. Vir shall have the right to further Develop and Commercialize VIR-2482, the Existing Terminated Influenza Products and the Vir Improved Terminated Influenza Products independently, alone or via an Affiliate or with a Third Party. With the exception of VIR-2482, Vir shall use and shall ensure that any third party uses (in the event that Vir out licenses or divests such products) Commercially Reasonable Efforts to commercialize any such product(s) in the Major Markets.

4. GSK will be deemed to have timely exercised an Opt-Out Option in accordance with Section 7.6.3 of the Agreement with respect to the Existing Terminated Influenza Products, at the following Opt-Out Points:

   (a) VIR-2482XX2: The VIR-2482XX2 Program is also known by the Parties as VIR-2372. All references to VIR-2372 in any materials, documentation, information or data arising from the activities under the Agreement that refer to VIR-2372 shall be deemed to be references to VIR-2482XX2. GSK shall be deemed to have exercised its Opt-Out Option for VIR-2482XX2 (the "**Terminated 2482XX2 Product**") in accordance with the First In Human Opt-Out Point royalty rate, subject to paragraph 6 of this Letter Agreement; and

   (b) VIR-2981: GSK shall be deemed to have exercised its Opt-Out Option for VIR-2981 (the "**Terminated 2981 Product**") in accordance with the First In Human Opt-Out Point royalty rate, subject to paragraph 6 of this Letter Agreement.

5. Notwithstanding anything to the contrary in Section 17.3.2 or Schedule 11.8.2, Vir shall pay to GSK royalties on Net Sales of any Existing Terminated Influenza Products or Vir Improved Terminated Influenza Products at the rates set forth in the table below, regardless of whether Vir has outlicensed or divested such products:

Annual Net Sales in a Calendar Year	Existing Terminated Influenza Product – Vir-2372 Product*	Vir Improved Terminated Influenza Product - Vir-2372 Product*	Existing Terminated Influenza Product - Vir-2981 Product*	Vir Improved Terminated Influenza Product - Vir-2981 Product*
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

- * [***].

Section 11.8 of the Agreement shall survive termination of the Influenza Program with respect to all Existing Terminated Influenza Products and Vir Improved Terminated Influenza Products, based on the Opt-Out Points set forth above.

6. The Parties acknowledge and agree that prior to the Influenza Program Termination Date, GSK has Manufactured ([***]) certain quantities of VIR-2482XX2 (the "**2482XX2 Material**"), which is currently in storage at a [***]. GSK shall transfer ([***]) to Vir (a) all 2482XX2 Material, (b) all right, title and interest in and to the 2482XX2 Material, and (c) all documentation and materials relating to the 2482XX2 Material and necessary to enable Vir's IND submission and subsequent clinical studies related to2482XX2, each (a) – (c) at Vir's reasonable expense. The Parties shall mutually agree the timing and contractual requirements for the transfer of the 2482XX2 Material, which shall be effected no later than ninety (90 days) from the Influenza Program Termination Date. GSK agrees to (i) [***] enable transfer of ownership of materials, data, assays, and all necessary documentation to support successful IND submission to Vir and (ii) provide Vir with a memo confirming such transfer.

7. Section 7.6.3(c)(i) of the Agreement shall not apply to non-cancelable Manufacturing Costs incurred prior to the Influenza Program Termination Date for the Existing Terminated Influenza Products, including the costs associated with the Manufacture and supply of VIR-2981 (but shall apply to the allocation of all other Development Costs and Manufacturing Costs actually incurred prior to the Influenza Program Termination Date), and instead Vir shall be solely responsible for all non-cancelable and future Manufacturing Costs for Development and Commercialization of VIR-2981. In addition, and as partial consideration for Vir bearing the non-cancelable Manufacturing costs for VIR-2981, the royalty applicable to Vir's Commercialization of VIR-2981 shall be reduced by [***] at each Net Sales tier in the table set forth in Schedule 11.8.2 ([***]) as per the table above in paragraph 6 of this Letter Agreement.

8. The Parties acknowledge and agree that the Manufacture and supply of VIR-2981 for the conduct of pre-clinical activities (including IND-enabling studies) and clinical development activities contemplated under the applicable Influenza Development Plan (the "**2981 Activities**") is a commitment incurred by the Parties prior to the Influenza Program Termination Date, and further agreed under the Letter Agreement. Notwithstanding the foregoing, the costs of such clinical supply of VIR-2981 shall not be shared by the Parties, and GSK shall (a) Manufacture and supply to Vir, at Vir's sole expense, quantities of VIR-2981 for the 2981 Activities, and (b) provide Vir with all reports, data, batch records and other materials relating to such Manufacture that are necessary or reasonably useful in connection with Vir's preparation and filing of the IND for VIR-2981. The details of each party's obligations under this paragraph 9 shall be mutually agreed by the parties [***]

9. GSK shall perform a technology transfer to Vir (or its Affiliates or any Third Party contract manufacturer designated by Vir) of the Manufacturing process and all Know-How Controlled by GSK or its Affiliates (including, as applicable, any licenses) that are necessary for the ongoing Manufacture, and Development of each Existing Terminated Influenza Product (including the transfer of any other know-how as agreed by the parties in good faith), the details of which will be included in the [***]. Within forty five (45) days following the date of this Letter Agreement, the Parties shall [***], which would provide for, without limitation, (a) the transfer or transition by GSK to Vir of Manufacturing Know-How related to each Existing Terminated Influenza Product and access to proprietary GSK or Third Party media and feeds, certain cell lines, assays, media and feeds, in all cases that are that are necessary for the Manufacture and Development, of the Existing Terminated Influenza Products following the Influenza Program Termination Date (including the transfer of any other know-how as agreed by the parties in good faith), and (b) reasonable assistance to be provided by GSK, at Vir's sole expense (including reasonable FTE Costs and out of pocket costs associated therewith).

10. Vir shall be solely responsible for all Existing Third Party Payment Obligations applicable to the Existing Terminated Influenza Products and the Vir Improved Terminated Influenza Products pursuant to Section 11.9.1 of the Agreement following the Influenza Program Termination Date. Section 11.9.4 shall survive termination of the Influenza Program and shall continue to apply to the Existing Terminated Influenza Products and the Vir Improved Terminated Influenza Products.

11. The licenses granted to Vir by GSK pursuant to Section 12.2.2 for Vir Sole Development Products shall apply,*mutatis mutandis*, to all Existing Terminated Influenza Products and Vir Improved Terminated Influenza Products arising from the Influenza Program, including VIR-2482,. Section 12.3 shall survive the termination of the Influenza Program with respect to each Existing Terminated Influenza Product and each Vir Improved Terminated Influenza Product, if and to the extent Vir elects not to continue the Development or Commercialization of any Existing Terminated Influenza Product and/or any Vir Improved Terminated Influenza Product following the Influenza Program Termination Date.

12. Within thirty (30) days after the Influenza Program Termination Date, or a timeframe otherwise mutually agreed by the Parties, GSK will return to Vir, or destroy, at Vir's direction, all Confidential Information of Vir (including all copies thereof) related to the Influenza Program, except (a) as otherwise provided in Section 18.4 (Return of Confidential Information) of the Agreement or (b) as is necessary for GSK to perform its obligations under this Letter Agreement [***].

13. Except as set forth in this Letter Agreement, termination of the Influenza Program shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination of the Influenza Program. All provisions of the Agreement not surviving in accordance with this Letter Agreement shall terminate, with respect to the Influenza Program and all Existing Terminated Influenza Products upon the Influenza Program Termination Date and shall be of no further force and effect. The Agreement shall remain in full force and effect in accordance with and subject to the terms and conditions on an unamended basis with respect to all unaffected Collaboration Programs and Collaboration Products of this Agreement, as set forth in Section 17.4.3 of the Agreement.

Please confirm GSK's understanding of and agreement to the foregoing by signing this Letter Agreement below and returning a signed copy to me at your earliest convenience.

Sincerely,

/s/ Marianne De Backer

Chief Executive Officer

Vir Biotechnology, Inc.

Acknowledged and agreed to by:

Glaxo Wellcome UK Limited.

By: /s/ Darren Barnett

Name: Darren Barnett

Title: Authorised Signatory, representing Glaxo Group Limited, Corporate Director