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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2025
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____to

Commission File Number: 001-39083

Vir Biotechnology, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**81-2730369**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
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 ☒ No ☐

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

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

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

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

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

As of April 30, 2025, the registrant had 138,238,003 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 ongoing and planned preclinical and clinical studies, the timing and likelihood of regulatory filings and potential approvals for our product candidates, our ability to commercialize our product candidates, the potential benefits of collaborations and in-licensing arrangements, 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 and masked T-cell engager 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 studies may not be indicative of full results or results from later stage or larger scale clinical studies 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, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 273,571	$ 222,947
Short-term investments	517,367	678,051
Restricted cash and cash equivalents, current	88,151	89,385
Equity investments	10,724	4,350
Prepaid expenses and other current assets	42,394	47,725
Total current assets	932,207	1,042,458
Intangible assets, net	8,072	8,120
Goodwill	16,937	16,937
Property and equipment, net	61,681	63,183
Operating lease right-of-use assets	58,559	59,680
Restricted cash and cash equivalents, noncurrent	6,273	6,363
Long-term investments	218,140	190,015
Other assets	5,858	12,057
TOTAL ASSETS	$ 1,307,727	$ 1,398,813
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,725	$ 5,081
Accrued and other liabilities	104,126	85,873
Deferred revenue, current	11,935	12,648
Contingent consideration obligation, current	17,500	16,060
Total current liabilities	137,286	119,662
Operating lease liabilities, noncurrent	88,170	90,139
Contingent consideration obligation, noncurrent	23,640	24,050
Other long-term liabilities	14,812	14,577
TOTAL LIABILITIES	263,908	248,428
Commitments and contingencies (Note 7)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of March 31, 2025 and December 31, 2024; no shares issued and outstanding as of March 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of March 31, 2025 and December 31, 2024; 138,063,698 and 136,959,446 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	14	14
Additional paid-in capital	1,926,529	1,911,872
Accumulated other comprehensive loss	(1,975)	(1,717)
Accumulated deficit	(880,749)	(759,784)
TOTAL STOCKHOLDERS' EQUITY	1,043,819	1,150,385
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,307,727	$ 1,398,813

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,	
	2025	**2024**
Revenues:		
Collaboration revenue	$ (70)	$ (987)
Contract revenue	1,864	52,191
Grant revenue	1,238	5,172
Total revenues	3,032	56,376
Operating expenses:		
Cost of revenue	—	59
Research and development	118,645	100,125
Selling, general and administrative	23,944	36,321
Restructuring, long-lived assets impairment and related charges, net	(10)	(48)
Total operating expenses	142,579	136,457
Loss from operations	(139,547)	(80,081)
Other income:		
Change in fair value of equity investments	6,382	(5,915)
Interest income	12,288	21,283
Other expense, net	(72)	(287)
Total other income	18,598	15,081
Loss before provision for income taxes	(120,949)	(65,000)
Provision for income taxes	(16)	(276)
Net loss	$ (120,965)	$ (65,276)
Net loss per share, basic and diluted	$ (0.88)	$ (0.48)
Weighted-average shares outstanding, basic and diluted	137,468,900	135,280,648

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,	
	2025	**2024**
Net loss	$ (120,965)	$ (65,276)
Other comprehensive loss:		
Unrealized loss on investments	(303)	(1,411)
Pension actuarial gain (loss)	45	(171)
Total other comprehensive loss	(258)	(1,582)
Comprehensive loss	$ (121,223)	$ (66,858)

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

VIR BIOTECHNOLOGY, INC.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2024	136,959,446	$ 14	$ 1,911,872	$ (1,717)	$ (759,784)	$ 1,150,385
Vesting of restricted common stock	1,011,628	—	—	—	—	—
Exercise of stock options	92,624	—	598	—	—	598
Stock-based compensation	—	—	14,059	—	—	14,059
Other comprehensive loss	—	—	—	(258)	—	(258)
Net loss	—	—	—	—	(120,965)	(120,965)
Balance at March 31, 2025	138,063,698	$ 14	$ 1,926,529	$ (1,975)	$ (880,749)	$ 1,043,819

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	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

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,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (120,965)	$ (65,276)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in estimated constraint on profit-sharing amount	—	685
Depreciation and amortization	2,867	4,517
Amortization of premiums on investments, net	4,089	238
Noncash lease expense	1,121	1,447
Change in fair value of equity investments	(6,382)	5,915
Change in estimated fair value of contingent consideration	1,030	1,650
Stock-based compensation	14,059	23,757
Other non-cash items, net	6	(176)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	5,058	1,433
Other assets	6,200	(86)
Accounts payable	(1,415)	735
Accrued liabilities and other long-term liabilities	18,725	(30,003)
Operating lease liabilities	(1,796)	(4,067)
Deferred revenue	(713)	(50,159)
Net cash used in operating activities	(78,116)	(109,390)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of equipment	281	533
Purchases of property and equipment	(1,629)	(1,872)
Purchases of investments	(173,694)	(562,939)
Maturities and sales of investments	301,860	592,698
Net cash provided by investing activities	126,818	28,420
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of principal on financing lease obligation	—	(69)
Proceeds from exercise of stock options	598	221
Net cash provided by financing activities	598	152
Net increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents	49,300	(80,818)
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	318,695	261,292
Cash, cash equivalents and restricted cash and cash equivalents at end of period	$ 367,995	$ 180,474
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH AND CASH EQUIVALENTS TO THE CONDENSED CONSOLIDATED BALANCE SHEETS:		
Cash and cash equivalents	$ 273,571	$ 160,711
Restricted cash and cash equivalents, current	88,151	13,335
Restricted cash and cash equivalents, noncurrent	6,273	6,428
Total cash, cash equivalents and restricted cash and cash equivalents	$ 367,995	$ 180,474

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 Bio or the Company) is a clinical-stage biopharmaceutical company focused on powering the immune system to transform lives by discovering and developing medicines for serious infectious diseases and cancer. Its clinical-stage portfolio includes infectious disease programs for chronic hepatitis delta and chronic hepatitis B infections and multiple dual-masked T-cell engagers (TCEs) across validated targets in solid tumor indications. Vir Bio also has a preclinical portfolio of programs across a range of infectious diseases and oncologic malignancies. Vir Bio has exclusive rights to the PRO-XTEN™ masking platform for oncology and infectious disease. PRO-XTEN™ is a trademark of Amunix Pharmaceuticals, Inc., a Sanofi company.

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 U.S. 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, 2025, no shares have been sold under the Sales Agreement.

As of March 31, 2025, the Company had $1.02 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. The Company also had $94.4 million in restricted cash and cash equivalents as of March 31, 2025.

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. 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, 2025 are not necessarily indicative of the results to be expected for the year ending December 31, 2025, 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, 2024.

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.

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

Segments

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker (CODM) in deciding how to allocate resources and in assessing performance. The Company manages the business activities on a consolidated basis and operates as one reportable segment that constitutes all of the consolidated entity, which is the business of powering the immune system to transform lives by discovering and developing medicines for serious infectious diseases and cancer. Factors used in determining the reportable segment include the nature of the Company's operating activities, the organizational and reporting structure, and the type of information regularly provided to the CODM to allocate resources and evaluate financial performance. The Company's CODM is its Chief Executive Officer.

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, which are carried at 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 primarily includes the $75.0 million milestone payment due upon VIR-5525 achieving "first in human dosing" by 2026, amounts that may need to be refunded to the Gates Foundation and money market funds to secure standby letters of credit and security deposits with financial institutions under lease agreements.

Research and Development Expenses

To date, research and development expenses have related primarily to discovery efforts and preclinical and clinical development of 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. Research and development expenses include expenses related to license and collaboration agreements; contingent consideration from business acquisitions; personnel-related expenses, including salaries, benefits, and stock-based compensation for personnel contributing to research and development activities; expenses incurred under agreements with third-party contract manufacturing organizations, contract research organizations, and consultants; clinical costs, including laboratory supplies and costs related to compliance with regulatory requirements; and other allocated expenses, including expenses for rent, facilities maintenance, and depreciation and amortization.

The Company has acquired and may continue to acquire the rights to develop and commercialize new product candidates from third parties. Upfront payments and research and development milestone payments made in connection with acquired licenses or product rights are expensed as incurred, provided that they do not relate to a regulatory approval milestone or assets acquired in a business combination.

The Company's expense accruals for clinical trials and manufacturing are based on estimates of contracted services provided by third-party vendors not yet billed. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of its outstanding obligations to those third parties as of the period end. The accrual estimates are based on a number of factors, including the Company's knowledge of the research and development programs and clinical manufacturing activities, the status of the programs and activities, invoicing to date, and the provisions in the contracts. The Company obtains information regarding unbilled services directly from these service providers and performs procedures to support its estimates based on its internal understanding of the services provided to date. However, the Company may also be required to estimate these services based on information available to its internal clinical and manufacturing administrative staff if such information is not able to be obtained timely from its service providers.

New Accounting Pronouncement Not Yet Adopted

In December 2023, the Financial Accounting Standards Board (FASB) issued *Accounting Standards Updates (ASU) No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, 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 annual consolidated financial statements and related disclosures.

In November 2024, the FASB issued *ASU No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (ASU 2024-03)*, which requires entities to disclose specific information on the types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses. The guidance is effective for annual periods beginning after December 15, 2026 and interim periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. ASU 2024-03 should be applied on a prospective basis, but retrospective application is permitted. The Company is currently evaluating the impact the adoption of ASU 2024-03 may have on its consolidated financial statements and related disclosures.

Reclassification

Certain reclassifications have been made to prior period amounts on the Company's condensed consolidated statements of operations to conform to the current period presentation and enhance comparability. As a result, certain amounts related to restructuring activities and long-lived assets impairment and disposal gains or losses, previously reflected in *selling, general and administrative*, were reclassified to *restructuring, long-lived assets impairment and related charges, net*. These reclassifications had no impact on previously reported total revenues, total operating expenses, or net loss.

Certain reclassifications have been made to prior period amounts on the Company's condensed consolidated statements of cash flows to conform to the current period presentation and enhance comparability. As a result, certain amounts related to collaboration receivables, previously reflected in *changes in operating assets and liabilities – receivable from collaboration*, were reclassified to *changes in operating assets and liabilities – prepaid assets and other current assets*.

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 that 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 certain financial instruments, including accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities.

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 by level within the fair value hierarchy as of March 31, 2025 and December 31, 2024 (in thousands):

		March 31, 2025			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Money market funds	Level 1	$ 168,828	$ —	$ —	$ 168,828
U.S. government treasuries	Level 2	450,270	406	(10)	450,666
U.S. government agency bonds and discount notes	Level 2	67,991	36	(29)	67,998
Asset-backed securities	Level 2	58,515	177	(1)	58,691
Corporate bonds	Level 2	243,488	538	(3)	244,023
Equity securities	Level 1	N/A	N/A	N/A	10,724
Total financial assets		$ 989,092	$ 1,157	$ (43)	$ 1,000,930
Reconciliation to cash, cash equivalents and investments on condensed consolidated balance sheet					
Minus: Restricted cash equivalents invested in money market funds					(18,957)
Plus: Cash deposits					37,829
Total cash, cash equivalents and investments					$ 1,019,802

		December 31, 2024			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Money market funds	Level 1	$ 146,505	$ —	$ —	$ 146,505
U.S. government treasuries	Level 2	588,794	722	(33)	589,483
U.S. government agency bonds and discount notes	Level 2	38,081	17	(19)	38,079
Asset-back securities	Level 2	51,038	220	(10)	51,248
Corporate bonds	Level 2	252,935	529	(9)	253,455
Equity securities	Level 1	N/A	N/A	N/A	4,350
Total financial assets		$ 1,077,353	$ 1,488	$ (71)	$ 1,083,120
Reconciliation to cash, cash equivalents and investments on condensed consolidated balance sheet					
Minus: Restricted cash equivalents invested in money market funds					(20,281)
Plus: Cash deposits					32,524
Total cash, cash equivalents and investments					$ 1,095,363

Accrued interest receivables 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 receivables amounted to $5.4 million and $5.0 million as of March 31, 2025 and December 31, 2024, respectively. The Company did not write off any accrued interest receivables during the three months ended March 31, 2025 and 2024.

The Company recognized total net unrealized gains of $1.1 million and $1.4 million in accumulated other comprehensive loss as of March 31, 2025 and December 31, 2024, respectively. The gross unrealized losses as of March 31, 2025 were due to changes in interest rates and 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, 2025, no securities have contractual maturities (or weighted average life for asset-backed securities) of longer than two years.

As of March 31, 2025, 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 Stock Exchange of Hong Kong Limited and are considered to be marketable equity securities measured at fair value at each reporting date. As of March 31, 2025, the Company remeasured the equity investment at a fair value of $10.7 million. The Company recognized an unrealized gain of $6.4 million and an unrealized loss of $5.9 million for the three months ended March 31, 2025 and 2024, respectively, as part of other income in the unaudited condensed consolidated statement of operations. For the three months ended March 31, 2025 and 2024, the unrealized gains or losses related to foreign currency translation were not material.

Contingent Consideration

Contingent consideration primarily includes potential milestone payments in connection with the acquisitions of Humabs BioMed SA (Humabs) in 2017. The Company classifies the contingent consideration as Level 3 financial liabilities within the fair value hierarchy as of March 31, 2025 and December 31, 2024. 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.

During the three months ended March 31, 2025, the Company achieved $17.5 million clinical milestone upon the enrollment of the first patient in phase 3 ECLIPSE registrational program for chronic hepatitis delta. As of March 31, 2025, the Company recorded this $17.5 million as contingent consideration obligation, current on its unaudited condensed balance sheets and calculated the estimated fair value of the remaining clinical and regulatory milestones related to tobevibart using the following significant unobservable inputs:

Unobservable input	Value
Discount rates	12.1%
Probability of achievement	67.5%

For the commercial milestones, the Company used a Monte Carlo simulation because of the availability of discrete revenue forecasts. As of March 31, 2025, 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	55.0%
Discount rate	10.0%
Probability of achievement	67.5%

The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. As of March 31, 2025 and December 31, 2024, the estimated fair value of the contingent consideration related to the Humabs acquisition was $41.1 million and $40.1 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, which 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 Obligation
Balance at December 31, 2024	$ 40,110
Changes in fair value	1,030
Balance at March 31, 2025	$ 41,140

4. Grant Agreements

Gates Foundation Grants

The Company has entered into various grant agreements with the Gates Foundation (formerly known as the Bill & Melinda Gates Foundation), under which it is currently 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 Gates Foundation for the Company's breach, failure to progress the funded project, in the event of the Company's change of control, change in the Company's tax status, or significant changes in the Company's leadership that the Gates Foundation reasonably believes may threaten the success of the projects.

Concurrently with the execution of the grant agreement for the vaccinal antibody program, the Company entered into a stock purchase agreement with the Gates Foundation, under which the Gates Foundation 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 Gates Foundation 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 Gates Foundation based on its fair market value on the closing date and determined that the premium paid by the Gates Foundation should be included in the deferred revenue from the vaccinal antibody grant.

In August 2024, the Company announced a strategic realignment that included phasing out certain research programs, which included the HIV vaccine program and the tuberculosis vaccine program funded by Gates Foundation grants. The Company continues to pursue a cure for HIV in collaboration with the Gates Foundation.

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 $1.2 million and $1.9 million for the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025 and December 31, 2024, the Company had deferred revenue of $10.4 million and $11.1 million, respectively. As of March 31, 2025 and December 31, 2024, the Company had $11.2 million and $11.6 million, respectively, within accrued and other liabilities, which may need to be refunded to the Gates Foundation.

5. Collaboration and License Agreements

License Agreement with Sanofi

On September 9, 2024 (Acquisition Date), the Company closed the license agreement with Amunix Pharmaceuticals, Inc., a Sanofi company, previously announced on August 1, 2024 (Sanofi Agreement). The Sanofi Agreement provides the Company with an exclusive worldwide license to use of the proprietary PRO-XTEN™ universal masking technology for oncology and infectious disease,excluding the ophthalmological field, and to three early clinical-stage dual-masked TCEs that all leverage the PRO-XTEN™ universal masking platform within a range of oncology indications.

Under the Sanofi Agreement the Company made an upfront payment to Sanofi in the amount of $100.0 million and placed into escrow a $75.0 million milestone payment due to former shareholders of Amunix Pharmaceuticals, Inc., which is subject to VIR-5525 achieving "first in human dosing" by 2026. The cash paid into escrow is under the control of the Company and is classified as restricted cash and cash equivalents, current in the unaudited condensed consolidated balance sheets. Sanofi will also be eligible to receive up to an additional $323.0 million in future development and regulatory milestone payments, up to an additional $1.49 billion in commercial net sales-based milestone payments, and low single-digit to low double-digit tiered royalties on worldwide net sales. In addition, if, within a two-year period from the execution of the Sanofi Agreement, the Company executes a transaction that gives rise to Vir Bio receiving certain sublicense income related to the licenses obtained from the Sanofi Agreement, Sanofi may be eligible to receive a portion of such income.

Additionally, as part of the Sanofi Agreement, the Company paid $3.7 million to acquire certain lab equipment and cash deposits primarily related to contract manufacturing agreements. Shortly after the closing of the Sanofi Agreement, the Company hired certain former Sanofi personnel. The Company incurred approximately $4.6 million of transaction costs associated with the closing of the Sanofi Agreement. The following table summarizes the aggregate amount paid for the assets acquired by the Company in connection with the Sanofi Agreement as of the Acquisition Date (in thousands):

Upfront	$	100,000
Equipment		1,150
Deposits		2,580
Transaction costs		4,612
Total purchase consideration	$	108,342

The Company accounted for the Sanofi Agreement as an asset acquisition in accordance ASC 805-50 as substantially all of the fair value of the assets acquired is concentrated in a group of similar identifiable assets. The three early clinical stage oncology TCEs use the same universal PRO-XTEN™ masking technology and have similar development timelines, probabilities of risk, and loss of patent exclusivity among other characteristics. ASC 805-50 requires the acquiring entity in an asset acquisition to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes consideration given. The total purchase price was allocated to the acquired assets based on their relative fair values, as of the Acquisition Date as follows (in thousands):

In-process research and development	$	102,836
Property and equipment		1,119
Prepaid expenses and other current assets [(1)]		3,975
Assembled workforce		412
Total purchase consideration	$	108,342

(1) Includes acquired cash deposits primarily related to contract manufacturing agreements.

The fair value of the IPR&D was estimated using a multi-period excess earnings income approach that discounts expected cash flows to present value by applying a discount rate that represents the estimated rate that market participants would require for the intangible asset. The expected cash flows and related discount rate are significant unobservable inputs categorized within Level 3 of the fair value hierarchy. In accordance with ASC 730, as the three early clinical stage oncology TCEs have not achieved regulatory approval when acquired, the portion of the purchase price allocated to the IPR&D was immediately expensed to research and development expenses as they had no alternative future use. Contingent milestone payments were determined to be within the scope of ASC 450 and will be recognized when the contingency is resolved and the consideration is paid or becomes payable. Any milestone payments made in the future will either be expensed as research and development or capitalized as a developed asset based on when regulatory approval is obtained. The Company will recognize sales-based milestone and royalty payments in cost of sales as revenue from product sales is recognized. The fair value of the assembled workforce was estimated using a replacement cost method. The assembled workforce is classified as intangible assets, net and is amortized over an expected useful life of five years.

Alnylam Pharmaceuticals, Inc.

In October 2017, the Company and Alnylam Pharmaceuticals, Inc. (Alnylam) entered into a collaboration and license agreement (the Alnylam Agreement). Under the Alnylam Agreement, the Company obtained a worldwide, exclusive license to develop, manufacture and commercialize siRNA product candidates, including elebsiran, for all uses and purposes including the treatment of hepatitis B virus (HBV) and hepatitis delta virus (HDV). Under the Alnylam Agreement, the Company also held options to obtain similar licenses to siRNA product candidates for up to four other infectious disease targets selected by Vir Bio, but following an amendment and restatement of the Alnylam Agreement in March 2025 (the Restated Alnylam Agreement), those options (and all rights and obligations related to those infectious disease targets) were terminated. At the same time Alnylam elected to not opt-in to the profit-sharing arrangement with respect to any approved siRNA product candidates, including elebsiran, directed to HBV or HDV. The Company remains solely responsible, at its expense, for conducting all development, manufacture and commercialization activities for elebsiran in HBV and HDV indications, and the Company is required to use commercially reasonable efforts to develop and commercialize elebsiran for the treatment of HBV or HDV in the United States and specified major markets.

In connection with the Restated Alnylam Agreement and Alnylam's election to not opt-in to the profit-sharing arrangement, the Company agreed to pay Alnylam $30.0 million, which was recorded as part of research and development expenses in the Company's unaudited condensed statement of operations for the three months ended March 31, 2025 and as part of accrued and other liabilities on its unaudited condensed balance sheets as of March 31, 2025. After this payment, the remaining amount of the development and regulatory milestones is up to $145.0 million, down from the $175.0 million as previously disclosed in the audited consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2024. Any development and regulatory milestones for an elebsiran product will be payable to Alnylam only once, irrespective of dosage, formulation forms, route of administration or indication. Following commercialization, the Company will be required to pay to Alnylam up to $250.0 million in the aggregate for the first achievement of specified levels of net sales by elebsiran products directed to HBV, whether for the treatment of HBV or HDV. The Company will also be required to pay Alnylam tiered royalties at percentages ranging from the low double-digits to mid-teens on annual net sales of siRNA products directed to HBV, such as elebsiran, whether for the treatment of HBV or HDV, subject to specified reductions and offsets. The royalties are payable on a product-by-product and country-by-country basis until the later of the expiration of all valid claims of specified patents covering such product in such country and 10 years after the first commercial sale of such product in such country. Alnylam is also entitled to receive a portion of any consideration the Company receives as a result of granting a sublicense under the licenses granted to Vir Bio by Alnylam under the Alnylam Agreement.

The term of the Restated Alnylam Agreement will continue, on a product-by-product and country-by-country basis, until expiration of all royalty payment obligations under the Restated Alnylam Agreement. The Company may terminate the Alnylam Agreement on a program-by-program basis or in its entirety for any reason on 90 days' written notice. Either party may terminate the agreement for cause for the other party's uncured material breach on 60 days' written notice (or 30 days' notice for payment breach), or if the other party challenges the validity or enforceability of any patent licensed to it under the Restated Alnylam Agreement on 30 days' notice.

The Company did not incur material expenses during the three months ended March 31, 2024 related to collaboration with Alnylam.

6. Balance Sheet Components

Property and Equipment, net

Property and equipment, net consists of the following (in thousands). Depreciation expenses were $2.8 million and $4.4 million for the three months ended March 31, 2025 and 2024, respectively.

	Useful life (in years)	March 31, 2025	December 31, 2024
Leasehold improvements	8 - 12	$ 53,981	$ 53,992
Laboratory equipment	5	39,426	39,428
Furniture and fixtures	5	2,715	2,696
Computer equipment	3	2,621	2,778
Construction in progress	N/A	1,808	1,074
Property and equipment, gross		100,551	99,968
Less: accumulated depreciation		(38,870)	(36,785)
Total property and equipment, net		$ 61,681	$ 63,183

Accrued and Other Liabilities

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

	March 31, 2025	December 31, 2024
Research and development expenses	$ 67,893	$ 29,225
Payroll and related expenses	11,611	31,165
Excess funds payable under grant agreements	11,177	11,589
Operating lease liabilities, current	7,925	7,752
Other professional and consulting expenses	2,068	2,268
Other accrued expenses	3,452	3,874
Total accrued and other liabilities	$ 104,126	$ 85,873

7. 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 (Tobevibart Agreements). As of March 31, 2025, the Company had unaccrued unpaid commitments of approximately $22 million under the Tobevibart Agreements. In the third 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 elebsiran (Elebsiran Agreements). As of March 31, 2025, the Company had unaccrued unpaid commitments of approximately $8 million under the Elebsiran 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.

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.

8. 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,	
	2025	**2024**
Expected term of options (in years)	6.1	6.1
Expected stock price volatility	89.5% – 89.9%	89.2% – 89.3%
Risk-free interest rate	4.1% – 4.5%	4.3%
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) as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants.

Expected Volatility — The expected volatility is determined by using a blended approach of the Company and its industry peers' historical volatilities.

Risk-Free Interest Rate — The Company determines 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.

VIR BIOTECHNOLOGY, INC.
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,	
	2025	2024
Research and development	$ 7,005	$ 13,606
Selling, general and administrative	7,054	10,151
Total stock-based compensation	$ 14,059	$ 23,757

9. Net Loss Per Share

Basic net loss per common share is computed by dividing the net loss 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 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,	
	2025	2024
Net loss	$ (120,965)	$ (65,276)
Weighted-average shares outstanding, basic and diluted	137,468,900	135,280,648
Net loss per share, basic and diluted	$ (0.88)	$ (0.48)

Securities that could potentially dilute basic net loss per common share in the future that were not included in the computation of diluted net loss per common share because to do so would have been antidilutive for the periods presented were as follows:

	Three Months Ended March 31,	
	2025	2024
Options issued and outstanding	11,080,159	12,018,822
Restricted shares subject to future vesting	6,888,462	4,521,874
Total	17,968,621	16,540,696

10. Income Taxes

The table below presents our loss before provision for income taxes, provision for income taxes and effective tax rate for the three months ended March 31, 2025 and 2024(in thousands):

	Three Months Ended March 31,	
	2025	2024
Loss before provision for income taxes	$ (120,949)	$ (65,000)
Provision for income taxes	$ (16)	$ (276)
Effective tax rate	— %	(0.4 %)

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.

Unrecognized tax benefits were $18.5 million and $17.9 million as of March 31, 2025 and December 31, 2024, respectively, and if recognized, would favorably affect the effective tax rate in future periods.

11. Segment Reporting

The Company manages the business activities on a consolidated basis and operates as one reportable segment that constitutes all of the consolidated entity, which is the business of powering the immune system to transform lives by discovering and developing medicines for serious infectious diseases and cancer. The Company's CODM is its Chief Executive Officer. The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The measure of segment profit or loss is segment net loss that also is reported on the consolidated statements of operations as consolidated net loss. The measure of segment assets is reported on the balance sheet as total consolidated assets. The CODM uses segment net loss to monitor spending, assess performance for the Company and management, evaluate the progress of completing corporate goals, decide how to allocate resources among the Company's clinical and pre-clinical portfolios, and make strategic decisions about business development opportunities.

The segment revenue, segment profit or loss, and significant segment expenses regularly provided to CODM are summarized as follows (in thousands).

	Three Months Ended March 31,	
	2025	2024
Segment revenue	$ 3,032	$ 56,376
Less: Segment expenses [1]		
Cost of revenue	—	59
Research and development		
Contract manufacturing	9,336	9,669
Clinical costs	20,606	11,607
Personnel [2]	33,718	46,190
Licenses, collaborations and contingent consideration	36,591	5,696
Other R&D [3]	18,394	26,963
Selling, general and administrative [2]	23,944	36,321
Restructuring, long-lived assets impairment and related charges, net	(10)	(48)
Plus: Other segment items [4]	18,582	14,805
Segment and consolidated net loss	$ (120,965)	$ (65,276)

[1] Refer to Note 6 Balance Sheet Components for depreciation and amortization expenses included in segment expenses.

[2] Refer to Note 8 Stock-Based Awards for stock-based compensation expenses included in segment expenses.

[3] Other research and development expenses primarily includes non-personnel research expenses, allocated facility and IT expenses, IPR&D impairment, and depreciation expenses.

[4] Other segment items include change in fair value of equity investments, interest income, other expense, net, and provision for income taxes, all of which were presented on the condensed consolidated statements of operations.

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

The following table summarizes segment revenues by geographic area (in thousands). The revenues attributed to foreign customers primarily include collaboration and contract revenues recognized under the Company's collaboration agreements with GSK, contract revenue generated from clinical supplies provided to foreign companies, and license revenue from the Company's collaboration with Brii Bio.

	Three Months Ended March 31,	
Segment revenues attributed to:	**2025**	**2024**
U.S. customers	$ 1,238	$ 5,172
Foreign customers		
GSK	(70)	50,694
Other	1,864	510
Total segment and consolidated revenue	$ 3,032	$ 56,376

The Company's long-lived assets are primarily located in the U.S.

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, 2024. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to the "Company", "Vir Bio," "we," "us" and "our" refer to Vir Biotechnology, Inc. and its consolidated subsidiaries.

Overview

We are a clinical-stage biopharmaceutical company focused on powering the immune system to transform lives by discovering and developing medicines for serious infectious diseases and cancer.. Our clinical-stage portfolio includes infectious disease programs for Chronic Hepatitis Delta (CHD) and Chronic Hepatitis B (CHB) infections and multiple dual-masked T-cell engagers (TCEs) across validated targets in solid tumor indications. We also has a preclinical portfolio of programs across a range of infectious diseases and oncologic malignancies.

Our clinical development pipeline consists of investigational therapies targeting hepatitis delta virus (HDV) and various solid tumors. In HDV, we enrolled the first patient in our phase 3 ECLIPSE registrational program in the first quarter of 2025. Should the ECLIPSE program yield positive results that support regulatory approval and subsequent commercial launch, we believe the combination has the potential to be a new standard of care for hepatitis delta patients, for whom approved treatment options are either limited or unavailable. In oncology, we are advancing phase 1 clinical studies for our dual-masked TCEs: VIR-5818 in patients with HER2-expressing tumors and VIR-5500 in patients with PSMA-expressing metastatic castration-resistant prostate cancer (mCRPC). We are also advancing our third TCE program,VIR-5525, in patients with EGFR-expressing tumors, with phase 1 clinical studies expected to begin in the second quarter of 2025. We are also developing therapeutic candidates in hepatitis B, HIV cure, and other solid tumors, leveraging our expertise and platform strengths.

We have an industry-leading management team and board of directors with significant immunology, infectious diseases, and oncology 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 cancer, we are committed to developing transformative therapies that can make a meaningful difference in patients' lives.

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 period ended December 31, 2024. For additional developments or for a more comprehensive discussion of certain developments below, see our Annual Report on Form 10-K for the year ended December 31, 2024.

Chronic Hepatitis Delta (CHD)

- ECLIPSE 1, the first Phase 3 trial of our registrational program in CHD enrolled its first patient in March 2025 and is progressing as planned. The clinical trial will assess the efficacy and safety of tobevibart and elebsiran compared to deferred treatment in regions such as the U.S. where bulevirtide is not available or other regions where its access is limited.
- We are advancing plans for the initiation of ECLIPSE 2, a Phase 3 trial that will evaluate the efficacy and safety of switching to tobevibart and elebsiran in people with CHD who have not achieved viral suppression with bulevirtide therapy.
- We plan to share Phase 2 SOLSTICE subgroup analysis data in CHD in a poster presentation at the European Association for the Study of the Liver (EASL) Congress 2025. The poster was selected by EASL to be highlighted during the poster tour on May 8, 2025.
- Tobevibart and elebsiran combination therapy is supported by multiple U.S. and EU regulatory designations, including U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation, U.S. FDA Fast Track designation, European Priority Medicines (PRIME) designation and European Orphan Drug designation, signifying the significant unmet need in CHD.

Solid Tumors

- VIR-5818, the only dual-masked HER2-targeting TCE in clinical trials, continues to advance through dose escalation as a monotherapy, and in combination with pembrolizumab, in multiple tumor types, including metastatic breast cancer and metastatic colorectal cancer.
    - In early Phase 1 data reported in January 2025, VIR-5818 showed tumor shrinkage across various tumor types in 50% (10/20) of participants receiving doses ≥400 µg/kg, with confirmed partial responses in 33% (2/6) of participants with HER2-positive colorectal cancer (CRC).
- VIR-5500, the only dual-masked PSMA-targeting TCE in clinical trials, continues to advance through dose escalation aiming to further optimize dosing and efficacy.
    - In early Phase 1 data reported in January 2025, VIR-5500 showed PSA reductions in 100% (12/12) of metastatic castration resistant prostate cancer (mCRPC) patients after an initial dose ≥120 µg/kg. PSA_{50} response was confirmed in 58% (7/12) of participants.
- Early Phase 1 data for VIR-5818 and VIR-5500 reported in January 2025 showed promising safety profiles for both clinical candidates, with maximum tolerated dose not yet reached, no dose-limiting cytokine release syndrome (CRS) observed and no CRS greater than grade 2 reported.
- Initial clinical data demonstrate the PRO-XTEN™ masking technology's potential to minimize systemic toxicity while enabling selective killing of cancer cells in the tumor microenvironment, minimizing CRS and expanding the therapeutic index compared to traditional therapeutic approaches. PRO-XTEN™ is a trademark of Amunix Pharmaceuticals, Inc., a Sanofi company.
- We plan to initiate a Phase 1 study of VIR-5525, our PRO-XTEN™ dual-masked EGFR-targeting TCE, in the second quarter of 2025, to evaluate its potential across a number of solid tumor indications.

Chronic Hepatitis B (CHB)

- We will present functional cure data from the 24-week follow-up of the MARCH Part B Phase 2 clinical study evaluating combinations of tobevibart and elebsiran, alone, or in combination with pegylated interferon alfa (PEG-IFNα) at the EASL Congress 2025 on May 9, 2025.
- Future advancement in CHB by us will be contingent on securing a worldwide development and commercialization partner outside China Territory (People's Republic of China, Hong Kong, Taiwan, and Macau).

Preclinical Pipeline Candidates

- We continue to progress multiple undisclosed PRO-XTEN™ dual-masked TCEs against clinically validated targets with potential applications across a number of solid tumors. These preclinical candidates integrate the PRO-XTEN™ masking technology with novel TCEs discovered and engineered using Vir Biotechnology's antibody discovery platform and our proprietary dAIsY™ (**d**ata **AI s**tructure and antibod**y**) AI engine.
- We have advanced a broadly neutralizing antibody to development candidate status in our HIV cure program in collaboration with the Gates Foundation.

Corporate Update

- In January 2025, we announced positive initial Phase 1 dose escalation data for two of our PRO-XTEN™ dual-masked TCEs.
- During the quarter, Vir Biotechnology and Alnylam Pharmaceuticals, Inc. (Alnylam) amended and restated their collaboration agreement (Restated Alnylam Agreement), with Alnylam electing not to opt-in to its profit-sharing option for elebsiran in CHB and CHD indications. The amended agreement provides us with the flexibility to pursue commercialization partners in markets outside the U.S.

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 6—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, 2024.

Components of Operating Results

Revenues

Other than sotrovimab, we have not obtained regulatory approval for our 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. In December 2024, the FDA revoked EUA granted to sotrovimab in May 2021. 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. We do not expect meaningful collaboration revenue in the future from the sale of sotrovimab for the treatment of COVID-19.

Our revenues consist of the following:

Collaboration revenue includes recognition of our profit-share from the sales of sotrovimab pursuant to our 2020 collaboration agreement with GlaxoSmithKline plc (together with its affiliates, GSK, and 2020 GSK Agreement). 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 the agent, we recognize our contractual share (72.5%) of the profit-sharing amounts 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.

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. 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 previous years, GSK reported to us certain adjustments to allowable manufacturing expenses, which we had previously reserved as a constraint on our cumulative profit-sharing amounts. GSK may continue to adjust allowable manufacturing expenses in future periods. We evaluate the latest available facts and circumstances at each reporting period to re-assess whether any portion of profit-sharing amounts should continue to be constrained. Actual results could materially differ from estimates.

In 2025, 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.

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 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 (CROs), 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 and clinical studies 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.

In addition, under our some of our license agreements , we may incur additional clinical, and regulatory milestone payments based on the development progress of certain clinical programs. We may also be required to pay commercial milestone payments and royalties in the event of a successful product launch and our receipt of commercial revenues. Therefore, we are unable to predict the timing or the final cost to complete our clinical programs or validation of our manufacturing and supply processes and delays may occur due to numerous factors. Factors that could cause or contribute to delays or additional costs include, but are not limited to, those discussed in the “Risk Factors” section of this Quarterly Report.

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 and clinical studies, regulatory developments, our ongoing assessments as to each product candidate’s commercial potential. 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 studies required for approval;
- the number of sites included in the studies;
- enrollment and retention of patients in studies 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 studies;
- 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 studies 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. In the long-term as we advance our research and development programs toward potential commercialization, we expect our selling, general, and administrative expenses to increase in absolute dollars to support commercialization activities and related expansion in research and development activities.

Restructuring, long-lived asset impairment and related charges

Restructuring, long-lived asset impairment and related charges consist primarily of charges incurred in connection with our cost saving initiatives implemented in 2024 and 2023.

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 investment management expenses.

Provision for Income Taxes

Provision for income taxes consists primarily of income taxes on our domestic and foreign operations.

Results of Operations

Comparison of the Three Months Ended March 31, 2025 and 2024

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

	Three Months Ended March 31,		
	2025	**2024**	**Change**
Revenues:			
Collaboration revenue	$ (70)	$ (987)	$ 917
Contract revenue	1,864	52,191	(50,327)
Grant revenue	1,238	5,172	(3,934)
Total revenues	3,032	56,376	(53,344)
Operating expenses:			
Cost of revenue	—	59	(59)
Research and development	118,645	100,125	18,520
Selling, general and administrative	23,944	36,321	(12,377)
Restructuring, long-lived assets impairment and related charges, net	(10)	(48)	38
Total operating expenses	142,579	136,457	6,122
Loss from operations	(139,547)	(80,081)	(59,466)
Other income:			
Change in fair value of equity investments	6,382	(5,915)	12,297
Interest income	12,288	21,283	(8,995)
Other expense, net	(72)	(287)	215
Total other income	18,598	15,081	3,517
Loss before provision for income taxes	(120,949)	(65,000)	(55,949)
Provision for income taxes	(16)	(276)	260
Net loss	$ (120,965)	$ (65,276)	$ (55,689)

Revenues

The change in collaboration revenue for the three months ended March 31, 2025 compared to the same period in 2024 was nominal.

The decrease in contract revenue for the three months ended March 31, 2025 compared to the same period in 2024 was primarily due to $51.7 million of deferred revenue recognized during the first quarter of 2024 when GSK's rights to select up to two additional non-influenza target pathogens expired on March 25, 2024.

The decrease in grant revenue for the three months ended March 31, 2025 compared to the same periods in 2024 was primarily due to lower revenue recognized in accordance with our agreement with BARDA and the Gates Foundation. We terminated our agreement with BARDA on December 31, 2024.

The decrease in cost of revenue for the three months ended March 31, 2025 compared to the same period in 2024 was nominal.

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,		
	2025	2024	Change
Contract manufacturing	$ 9,336	$ 9,669	$ (333)
Clinical costs	20,606	11,607	8,999
Personnel	33,718	46,190	(12,472)
Licenses, collaborations and contingent consideration	36,591	5,696	30,895
Other	18,394	26,963	(8,569)
Total research and development expenses	$ 118,645	$ 100,125	$ 18,520

The increase in research and development expenses for the three months ended March 31, 2025 compared to the same period in 2024 was primarily due to:

- higher *license, collaborations and contingent consideration expenses* related to a $30.0 million expense (paid in April 2025) in connection with signing the Restated Alnylam Agreement and milestone payments due upon the enrollment of the first patient in phase 3 ECLIPSE registrational program for CHD. As part of the Restated Alnylam Agreement, Alnylam had elected to not opt-in to the profit-sharing arrangement for elebsiran, resulting in a milestone and royalty-based structure rather than a profit-sharing model. We are solely responsible for the development, manufacturing, and commercialization activities associated with elebsiran;
- higher *clinical cost* due to the initiation of our phase 3 ECLIPSE registrational program and newer oncology programs;

partially offset by:

- lower *contract manufacturing expenses* related to our de-prioritized programs partially offset by activities associated with our newer oncology programs;
- lower *personnel expenses* associated with headcount reductions; and
- lower *other R&D expenses* related to de-prioritized R&D programs and other ongoing cost savings, including the closing of our St. Louis, Missouri and Portland, Oregon sites.

Selling, General and Administrative Expenses

The decrease in selling, general and administrative expenses for the three months ended March 31, 2025 compared to the same periods in 2024 was primarily due to ongoing cost saving realized through headcount reductions and other initiatives.

Restructuring, long-lived assets impairment and related charges

The decrease in restructuring, long-lived assets impairment and related charges for the three months ended March 31, 2025 compared to the same period in 2024 was nominal. Our restructuring plans implemented in prior years were substantially completed by the end of 2024.

Change in Fair Value of Equity Investments

Our equity investment consisted solely of shares of Brii Bio Parent, which is a marketable equity investment and remeasured to fair value at each reporting period. For the three months ended March 31, 2025, we recognized an unrealized gain of $6.4 million due to the change in fair value, compared to an unrealized loss of $5.9 million for the same period in 2024.

Interest Income

The decrease in interest income for the three months ended March 31, 2025 compared to the same periods in 2024 was primarily due to lower balances of cash, cash equivalents, and investments.

Other Expense, Net

The change in other expense, net for the three months ended March 31, 2025 compared to the same period in 2024 was nominal.

Provision for Income Taxes

The decrease in the provision for income taxes for the three months ended March 31, 2025 compared to the same periods in 2024 was nominal.

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, 2025, we had $1.02 billion in cash, cash equivalents, and investments and $94.4 million in restricted cash and cash equivalents, which included the $75.0 million subject to VIR-5525 achieving "first in human dosing" by 2026. As of March 31, 2025, our accumulated deficit was $880.7 million. In November 2023, we 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 shelf registration statement on Form S-3 and a related prospectus that we filed with the U.S. Securities and Exchange Commission (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, 2025, no shares have been issued 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.

In December 2024, the FDA revoked EUA granted to sotrovimab in May 2021. 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, 2025 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 research and 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.

Our primary operating lease arrangements are for office and laboratory spaces located in California and Switzerland with contractual lease periods expiring between 2033 and 2035. As of March 31, 2025, we expect to make total lease payments of approximately $120.5 million through 2035.

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 6—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, 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, 2024.

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 presented (in thousands):

	Three Months Ended March 31,	
	2025	**2024**
Net cash (used in) provided by:		
Operating activities	$ (78,116)	$ (109,390)
Investing activities	126,818	28,420
Financing activities	598	152
Net increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents	$ 49,300	$ (80,818)

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, 2025 decreased compared to the same period in 2024 primarily due to ongoing cost saving realized through headcount reductions, the closing of our St. Louis, Missouri and Portland, Oregon sites and de-prioritized R&D programs.

Investing Activities

Cash provided by investing activities during the three months ended March 31, 2025 increased compared to the same period in 2024 primarily due to higher cash provided by maturities and sales of investment, net of investment purchases. Cash provided by investing activities during three months ended March 31, 2025 was primarily due to $301.9 million in proceeds received from investments that matured or sold during the year, partially offset by purchases of investments of $173.7 million. Cash provided by investing activities during three months ended March 31, 2024 was primarily due to $592.7 million in proceeds received from investments that matured or sold during the period, partially offset by purchases of investments of $562.9 million.

Financing Activities

The change in cash provided by financing activities during the three months ended March 31, 2025 compared to the same period in 2024 was nominal.

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. For more details on our critical accounting policies, refer to Note 2 *Summary of Significant Accounting Policies* to our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2024.

There have been no significant changes in our critical accounting policies during the three months ended March 31, 2025, as compared with those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 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 $368.0 million as of March 31, 2025, which primarily consisted of deposits in checking and sweep accounts at financial institutions and money market funds. We also had short-term and long-term investments of $735.5 million as of March 31, 2025. 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 consist of 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, 2025.

Foreign Currency

The majority of our transactions occur in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar. 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 Euro, Swiss Franc and Australian dollar. 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, 2025 and 2024.

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 $10.7 million as of March 31, 2025. 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, 2025 by approximately $1.1 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 has 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 was accumulated and communicated to our management, including our Chief Executive Officer and our 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, 2025, 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.
- Our limited commercialization 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 research and 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 successfully develop the additional product candidates we identify or replicate our approach for other diseases.
- We are developing, and in the future may develop, product candidates in combination with other therapies, which exposes us to additional risks.
- Success in preclinical studies or early-stage clinical studies may not be indicative of results in future clinical studies and we cannot assure you that any ongoing, planned or future clinical studies 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 studies that may not be successful, and we may not be able to recoup those investments.
- Interim, "top line" and preliminary data from our clinical studies 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.

- Although the combination of tobevibart and elebsiran has received Fast Track and Breakthrough Therapy designation from the FDA, as well as PRIME designation from the EMA and European orphan drug designation, in each case for the treatment of CHD, there can be no assurance that any of our product candidates that receive such designations in the U.S. or similar designations in any other regulatory jurisdictions will maintain such designations or receive regulatory approval any sooner than other product candidates that do not have such designations, or at all.
- Clinical product development involves a lengthy and expensive process. We may incur additional costs and encounter substantial delays or difficulties in our clinical studies.
- Enrollment and retention of patients in clinical studies is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control.
- 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.
- 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 may 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 (AI) 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, and furthermore our competitors may be able to utilize such technologies more effectively than we can.
- 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 supplies of our product candidates. There could be delays or supply shortages beyond our control limiting our access to clinical supplies.
- We rely on third parties to conduct, supervise and monitor our preclinical and clinical studies, 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.
- 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 could be harmed.
- Our success depends on our ability to manage our growth.
- 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 losses of $121.0 million and $65.3 million for the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025, we had an accumulated deficit of $880.7 million.

We expect to continue to incur significant expenses and net losses in the foreseeable future as we develop our product candidates and technology platforms.

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 based on operating expenses and other factors. 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 and clinical studies 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, and we may never attain a level of commercial success that will generate sufficient revenue 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 in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical studies 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.

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

Since our founding in April 2016, our operations 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 new drug application (NDA)- or biologics licensing application (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 history of commercialization. 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 research and development programs or other operations.

As of March 31, 2025, we had cash, cash equivalents and investments of $1.02 billion. Based upon our current operating plan, we believe that this amount 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 studies 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, if approved, 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 clinical trial financing and other collaborations, strategic alliances and licensing arrangements with other companies, 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 and clinical studies of our product candidates;

- the scope, progress, results and costs of preclinical development, laboratory testing and clinical studies of other potential 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 reviews 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 capital market volatility, interest rate and currency rate fluctuations, and economic slowdown or recession, as well as geopolitical events, including civil or political unrest, terrorism, insurrection or war (such as the ongoing conflicts in the Middle East and Eastern Europe), and also investor concerns regarding the U.S. or international financial systems, have in the past resulted in, and may in the future cause, a significant disruption of financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital or increased costs of financing through higher interest rates or costs or tighter financial and operating covenants, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments.

Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether terminate our research and development programs or commercialization efforts, which may adversely affect our business, financial condition, results of operations and prospects. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

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 research and product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

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.

In December 2024, the FDA revoked the emergency use authorization (EUA) that we and GSK had received in May 2021 for the sale of sotrovimab to treat COVID-19. Even prior to the FDA's revocation of our EUA, sotrovimab had not been authorized for use in any U.S. region for the treatment of COVID-19 since the FDA's exclusionary revisions to our EUA in March and April 2022. Due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA.

While sotrovimab still maintains emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®) for early treatment of COVID-19 in certain territories outside of the United States, we did not earn meaningful revenue from sales of sotrovimab during the most recent fiscal year ended December 31, 2024. Moreover, 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 other marketing approval, which could further reduce revenue. For example, although certain countries outside the United States. 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. There are no assurances that we will secure future supply commitments from governments for sotrovimab, or that sotrovimab will be effective against any new COVID-19 variants or subvariants.

Even if we and GSK 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.

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

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, in-licensing and acquisition of our product candidates and have initiated clinical studies for multiple product candidates. Accordingly, our business is dependent on our ability to successfully complete clinical 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 studies 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-designed registrational clinical studies, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidate is safe and effective to treat its intended indications. Results from preclinical studies 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 comparable foreign regulatory authorities may also require us to conduct additional preclinical or clinical studies for our product candidates, either prior to or post-approval, or may object to elements of our clinical development program and require us to alter them.

Even if we eventually complete clinical testing and receive approval of an NDA, BLA or foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authorities may grant an approval or other marketing authorization that is contingent on the performance of costly additional clinical studies, including post-marketing clinical trials. Furthermore, these authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates.

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, experience disruptions or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain applicable regulatory approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Furthermore, even if we obtain regulatory approval for our product candidates, we may still need to develop a commercial organization, establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors, including government health administration authorities. 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 successfully develop the additional product candidates we identify or replicate our approach for other diseases.

A core element of our business strategy is to successfully develop 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. Even when we are successful in identifying and acquiring or in-licensing potential product candidates, such as our license to three clinical-stage TCEs from Sanofi, our efforts may 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 developing additional product candidates or are unable to do so, or if the product candidates that we identify and acquire or in-license do not meet our expectations or fail to result in viable products, 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, product candidates in combination with other therapies, which exposes us to additional risks.

We are pursuing a functional cure of CHB based on a combination regimen of tobevibart and elebsiran, with or without PEG-IFNα, as well as developing the combination of tobevibart and elebsiran as a treatment for CHD. Each of these product candidates has demonstrated direct antiviral activity and the potential to stimulate an effective immune response. We believe that a functional cure for CHB will require an effective immune response, in addition to antiviral activity, based on the latest functional cure data and on the observation that severe immunosuppression can reactivate CHB. Accordingly, a combination therapy that includes both of these components may be needed to achieve a functional cure. For CHB, we have ongoing Phase 2 clinical trials evaluating the combination of tobevibart and elebsiran, with or without PEG-IFNα, and we are also evaluating additional combinations with other immunotherapy agents and direct-acting antiviral agents. For CHD, we have an ongoing Phase 2 clinical trial evaluating tobevibart as a monotherapy or in combination with elebsiran, and we have a planned registrational trial program that will further evaluate the doublet combination.

In our early-stage oncology programs, we are evaluating VIR-5818 in combination with pembrolizumab in a Phase 1 basket study in multiple tumor types, including metastatic breast cancer and metastatic CRC. The inclusion of critically ill patients in our oncology clinical studies may result in serious adverse medical events, including death, due to other therapies or medications that such patients may be using or in combination with our product candidates. 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 approvals that will facilitate the successful commercialization of our product candidates.

Success in preclinical studies or early-stage clinical studies may not be indicative of results in future clinical studies and we cannot assure you that any ongoing, planned or future clinical studies 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 studies that may not be successful, and we may not be able to recoup those investments.

Success in preclinical testing and early-stage clinical studies does not ensure that later clinical studies will generate similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Certain of our clinical programs have not yielded positive results in late-stage studies (such as our Phase 2 clinical study of VIR-2482 for the prevention of symptomatic influenza A illness, which did not meet primary or secondary efficacy endpoints, as announced in July 2023), and our product candidates currently under development may similarly fail to meet efficacy endpoints or otherwise show the desired characteristics in clinical development sufficient to obtain regulatory approval, despite positive results in preclinical studies or having successfully advanced through early-stage clinical studies. We have and may continue to commit substantial financial resources with respect to clinical studies that may not be successful, and we may not be able to recoup those investments.

If we are unable to design and execute a clinical trial to support regulatory approval, we will suffer setbacks that could negatively impact our business, financial condition, results of operations and prospects. Moreover, our inability to bring a product to market or a significant delay in the expected approval and related launch date of a new product could have a negative effect on our stock price and related market capitalization, which could result in a significant impairment of goodwill, other intangible assets and long-lived assets.

Interim, "top-line" and preliminary data from our clinical studies 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 studies. Interim data from clinical studies 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.

Although the combination of tobevibart and elebsiran has received Fast Track and Breakthrough Therapy designation from the FDA, as well as PRIME designation from the EMA and European orphan drug designation, in each case for the treatment of CHD, there can be no assurance that any of our product candidates that receive such designations in the U.S. or similar designations in any other regulatory jurisdictions will maintain such designations or receive regulatory approval any sooner than other product candidates that do not have such designations, or at all.

In June 2024 and December 2024, we announced that the FDA granted Fast Track designation and Breakthrough Therapy designation, respectively, for the combination of tobevibart and elebsiran for the treatment of CHD. In addition, the combination received PRIME designation from the EMA and European orphan drug designation in December 2024 for the same indication. We can provide no assurances that the combination of tobevibart and elebsiran or any of our other product candidates that receive Fast Track, Breakthrough Therapy, Priority Review or similar designations in the U.S., EU or in any other regulatory jurisdictions will receive regulatory approval any sooner than other product candidates that do not have such designations, or at all. The FDA, EMA or other foreign regulatory authorities may also withdraw or revoke any such designation, or elect to treat designated candidates in a manner different from what was originally indicated, if determined that any such product candidates that receive such designations no longer meet the relevant criteria. Failure to realize the potential benefits of any of these designations could materially and adversely affect our business, financial condition, cash flows and results of operations. For additional information, see the sections titled "Government Regulation and Product Approval—Expedited Development and Review Programs" and "Government Regulation and Product Approval—Foreign Regulation" in "Part I, Item 1. Business" in our Annual Report on Form 10-K for the year ended December 31, 2024.

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

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical studies 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 studies 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.

A failure or significant delay of one or more clinical studies can occur at any stage of testing. For example, during initial dose escalation studies, we, the FDA or comparable foreign regulatory authorities have in the past and may in the future impose restrictions relating to chemistry, manufacturing and control (CMC) standards, and such restrictions could then delay or limit our evaluation of a product candidate and its subsequent advancement to late-stage studies. Also, the availability of superior or competitive therapies coupled with changing standards of care could limit our ability to perform placebo-controlled studies and/or require us to enroll a larger number of subjects to address competing treatments. 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 and clinical studies have nonetheless failed to obtain marketing approval of their products. Any of these or other unforeseen events that we may experience prior to, during, or as a result of clinical studies could delay or prevent us from receiving marketing approval and ultimately commercializing 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 studies 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 required to perform additional clinical studies 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 (REMS);
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be subject to lawsuits, investigations or other legal or regulatory proceedings; or
- experience damage to our reputation.

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. 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.

Enrollment and retention of patients in clinical studies 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 studies is critical to our success. In particular, clinical studies for prophylaxis are impacted by many factors including competing therapies that tend to require enrollment of a larger number of subjects than clinical studies for treatments. We may encounter difficulties in enrolling patients in our clinical studies, 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 studies. Patient enrollment and retention in clinical studies 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 studies of competing therapies for the same indication, the proximity of patients to clinical trial sites and the eligibility criteria for the trial. The enrollment and retention of patients in our clinical studies 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 studies could be disrupted by geopolitical events, including civil or political unrest, terrorism, insurrection or war (such as the ongoing conflicts in the Middle East and Eastern Europe), as well as man-made or natural disasters, public health pandemics or epidemics or other business interruptions.

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 (CROs) and clinical trial sites to ensure proper and timely conduct of our future clinical studies and, while we intend to enter into agreements governing their services, we will be limited in our ability to ensure their actual performance which may result in rejection of the data generated at particular clinical trial sites or delays in the completion of our future clinical studies.

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 studies, 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 studies 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 studies, 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 studies, as well as conditions that did not occur or went undetected in previous studies, will be reported by subjects or patients. Many times, side effects are only detectable after investigational products are tested in large-scale pivotal studies 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 may 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 and in-license certain product candidates. These agreements contain obligations that require us to make substantial payments in the event certain milestone events are achieved.

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, cancer 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, and in addition such strategic collaborations, licenses and similar arrangements can be complex. We have in the past and may in the future need to renegotiate such arrangements from time to time, and we may not be able to negotiate these arrangements on acceptable terms, or at all. If we are unable to enter into new strategic collaborations or licenses related to our current or potential product candidates in certain geographies for certain indications, or if we are unable to maintain our current strategic collaborations or license on acceptable terms, 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 or pay regulatory or commercial milestone payments, which may make it difficult to predict the final cost to complete the related clinical programs or commercialize a product candidate;
- we may, during any transition period with respect to in-licensed clinical programs, be reliant on licensors to continue serving as regulatory sponsors (and executing all appropriate sponsorship responsibilities or delegations of such responsibilities) until a complete transition of sponsorship can be made
- 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 studies, 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, or may allege such claims against us; and
- strategic collaborators could terminate the arrangement or not exercise their opt-in rights, which may delay the development or 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.

If these or other risks from our current or potential future strategic collaborations and licenses occur, our business, financial condition, results of operations or prospects could be harmed.

The deployment of AI 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, and furthermore our competitors may be able to utilize such technologies more effectively than we can.

We integrate 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, 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, cancer 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 studies may change the estimated incidence or prevalence of the diseases we are targeting. 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. 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.

Regulatory incentives to develop products for treatment of infectious diseases 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.

Compared to us, 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 ultimately marketing and obtaining reimbursement approved products. The licensing or acquisition of third-party intellectual property rights is a competitive area as well, and more established companies may have greater success in pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. 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 studies, as well as acquiring technologies that are complementary to or necessary for our programs. Smaller or earlier-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 amongst our competitors.

If our competitors are able to utilize new technologies more effectively (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 product candidates or potential commercial products, such technologies could adversely impact our ability to compete..

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 could result in our competitors establishing a strong market position before we are able to enter the market. Our competitors may also develop therapies that are safer, more effective, have fewer or less severe side effects, are more convenient, more widely accepted or less expensive than ours, and may also be more successful than we are in manufacturing, marketing or obtaining reimbursement 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 "Competition" in "Part I, Item 1. Business" in our Annual Report on Form 10-K for the year ended December 31, 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 products for sale at competitive prices;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, as well as patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement;
- the products' safety profile including as compared to alternative treatments and therapies; 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 studies, 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 GMP, 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 or untitled letters to product seizures or significant fines or monetary penalties, among other actions. The FDA and other agencies, including the U.S. Department of Justice (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 FDCA 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 "Government Regulation and Product Approval" in "Part I, Item 1. Business" in our Annual Report on Form 10-K for the year ended December 31, 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 studies 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 or clinical studies. 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.

In particular, obtaining approval for our product candidates in the EU from the EC 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 studies 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 additional 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. Adverse public attitudes may adversely impact our ability to enroll clinical studies. 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 studies 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. For example, 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. Adverse events in our preclinical or clinical studies 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 studies 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 in the future. 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 high cost and/or limited availability.

Risks Related to Regulatory Compliance

Any product candidates for which we intend to seek approval may face competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize any product candidate faster than our competitors, such product candidates may face competition from biosimilar or generic products. For example, in the United States, biologic product candidates are subject to approval and licensure under the BLA pathway, and small molecules, such as our siRNA product elebsiran, are subject to approval and licensure under the NDA pathway. The Biologics Price Competition and Innovation Act of 2009 creates an abbreviated pathway for the approval of biosimilar and interchangeable biologic products following the approval of an original BLA. The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) creates a similar pathway for seeking approval of a generic version of an approved, small molecule innovator drug product. For additional information regarding biosimilars and exclusivity, see the section titled "Government Regulation and Product Approval—Biosimilars and Regulatory Exclusivity" in "Part I, Item 1. Business" in our Annual Report on Form 10-K for the year ended December 31, 2024.

If competitors are able to obtain marketing approval for generics or biosimilars referencing our licensed small molecule or biologic products after the expiration of applicable periods of regulatory exclusivity, our products may become subject to competition from such generics or 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.

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 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 "Government Regulation and Product Approval" in "Part I, Item 1. Business" in our Annual Report on Form 10-K for the year ended December 31, 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. 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, 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.

While it is currently unclear how certain new measures, including the drug pricing provisions of the IRA, will ultimately 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. In addition, it is unclear whether the new Trump Administration will reverse or modify any existing regulatory requirements, pursue new reform initiatives or otherwise influence the overall healthcare regulatory environment, and even if proposed, whether such changes or modifications would be implemented or withstand potential litigation. For additional information regarding other healthcare legislative reform measures, see the sections titled "Government Regulation and Product Approval—Healthcare Reform" and "Government Regulation and Product Approval—Pharmaceutical Prices" in "Part I, Item 1. Business" in our Annual Report on Form 10-K for the year ended December 31, 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 supplies of our product candidates. There could be delays or supply shortages beyond our control limiting our access to clinical supplies.

We are currently conducting process development and manufacturing material for product candidates of three different therapeutic modalities: monoclonal antibodies, siRNAs and TCEs. Except for limited 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 are either established or are currently being built, we do not own or operate facilities for large-scale 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 (CDMOs), to develop large-scale manufacturing processes and manufacture clinical supplies of our current and any future product candidates. We have established relationships with multiple third parties where we have established large-scale manufacturing processes and produced material to support our preclinical and Phase 1, 2, and 3 clinical studies. We do not yet have sufficient information for reliable cost estimates for the commercial manufacturing of our future product candidates. Certain of our product candidates may have to compete with existing and future products 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 CDMOs 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 NDA or BLA to the FDA or foreign marketing application to the appropriate regulatory authority. We do not control the day-to-day operations of, and are completely dependent on, our CDMOs for compliance with cGMP requirements. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other health authorities, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have limited control over the ability of our CDMOs 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 CDMOs' facilities for 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 the timing 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 CDMO could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates.

We also intend to rely on CDMOs to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization. There is, however, no assurance that our CDMOs 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 third-party suppliers and CDMOs that operate outside the United States and will likely continue to rely on these organizations in the future. Such third-party suppliers and CDMOs may be subject to trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement 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 CDMOs 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 studies or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs.

Further, our reliance on third-party suppliers and CDMOs 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;
- the commitment of 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 CDMOs 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 potential CDMO 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 raw materials or components and the 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 CDMO 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 supplier or CDMO and/or general economic conditions, 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 conflicts in the Middle East and Eastern Europe), as well as man-made or natural disasters, or public health pandemics or epidemics; 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 CDMOs 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 CDMO, failure by the supplier or CDMO to comply with cGMP, facility outages (including due to contamination), business interruptions, or labor shortages or disputes. Suppliers and CDMOs 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 CDMOs' 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 CDMO can be lengthy and we may experience delays in meeting demand in the event we must switch to a new supplier or CDMO. The time and effort to technology transfer to a new CDMO or qualify a new supplier or CDMO 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, we currently rely on a limited number of third party suppliers and CDMOs that are able to meet our supply requirements for 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 studies 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.

Changes in U.S. and international trade policies 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. For example, President Trump has imposed or signaled to impose a series of tariffs on certain products manufactured outside the United States, including pharmaceutical products and raw materials and components for pharmaceutical products, and it is unknown whether and to what extent additional 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, clinical manufacturing and future commercial activities. 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 ongoing trade tensions, such changes could have an adverse effect on our business, financial condition and results of operations.

Our business involves the use of hazardous materials and we and our third-party suppliers and CDMOs 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 third-party suppliers and CDMOs 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 CDMOs' 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 CDMOs 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 and clinical studies, 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 and clinical studies, and we expect to have limited influence over their actual performance. We also rely on CROs to monitor and manage data for our clinical programs, as well as the execution of future preclinical and clinical studies. While we expect to control only certain aspects of our CROs' activities, we will nevertheless be responsible for ensuring that each of our preclinical and clinical studies 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 Good Laboratory Practice (GLP) and Good Clinical Practice (GCP), 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 GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct GLP-compliant and GCP-compliant preclinical and clinical studies, we remain responsible for ensuring that each of our GLP preclinical and clinical studies is conducted in accordance with its investigational plan and protocol and applicable laws and regulations. If we or our CROs fail to comply with GCP, the clinical data generated in our clinical studies may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical studies 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 studies, which would delay the regulatory approval process.

Our reliance on third parties to conduct clinical studies will result in less direct control over the management of data developed through clinical studies 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 studies 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.

In addition, principal investigators for our clinical studies 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 we license the PRO-XTEN™ platform from Sanofi and the siRNA technology from Alnylam. We have also developed certain product candidates using intellectual property licensed from third parties or in-licensed certain product candidates 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. We could also be subject to expensive litigation which would detract us from our core business of researching and developing 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.

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.

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. 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. 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 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. 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.

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. 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. 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 U.S. Patent and Trademark Office (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, or if our patent rights become limited, including as a result of geopolitical events (such as the Russian Federation's recent limitations on patents originating from certain countries that have supported Ukraine, including the United States), 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 studies 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 accordingly they 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 studies 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. 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, inter partes review before the USPTO, or as counterclaims in litigation initiated by us. 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 and any such license could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all, including because companies that perceive us to be a competitor may be unwilling to assign or licenses rights to use, and if such an instance arises, our ability to commercialize our product candidates may be impaired or delayed, or we may have to abandon development of the related program or product candidate, 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. 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. 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. 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. 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 biopharmaceutical 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 because 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 in order to determine the ownership of what we regard as our intellectual property.

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 to the same degree as in the United States, 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 outside the United States, 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 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.

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 utilization of remote working environments for certain employees, which 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 a currently pending opposition filed against the Portuguese 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. 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 potential exercise by the 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.

In January 2022, we entered into an amended and restated letter agreement with the Gates Foundation (formerly known as the Bill & Melinda Gates Foundation, and the agreement, the Gates Agreement), which amended and restated the original letter agreement with the Gates Foundation that we entered into in December 2016. In connection with the Gates Agreement, the Gates Foundation purchased an aggregate of $20.0 million of shares of our convertible preferred stock (which later converted to shares of our common stock after our initial public offering) and purchased $40.0 million of shares of our common stock in January 2022. We are obligated to use the proceeds of the 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 "Our Collaboration, License and Grant Agreements—Amended and Restated Letter Agreement with the Gates Foundation" in "Part I, Item 1. Business" in our Annual Report on Form 10-K for the year ended December 31, 2024.

If we fail to comply with (i) our obligations to use the proceeds of the Gates Foundation's investment for the purposes set forth in the Gates Agreement (and described in our filings with the SEC) 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 Gates Foundation under the Gates Agreement, at the Gates Foundation's request, at a price equal to the greater of (a) the original purchase price or (b) 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 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 Gates Foundation's charitable purpose.

The exercise by the 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 could be harmed.

We are highly dependent on our management, clinical and scientific 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 recently announced several leadership changes, including a new Chief Medical Officer and Chief Financial Officer in 2024. 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. Competition is intense for these skilled employee candidates, and we may be unable to retain or recruit such personnel with the expertise or experience necessary to achieve our business objectives, and such efforts may be further undermined by restructurings, changing office policies and other initiatives we may undertake improve operational efficiencies and operating costs, as well as shifting dynamics in the biotechnology labor market. 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.

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 in "Part I, Item 3. Quantitative and Qualitative Disclosures About Market Risk" in this Quarterly Report on Form 10-Q.

For example, we acquired numerous biotechnology companies between 2016 and 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.

Our success depends on our ability to manage our growth.

We have in the past experienced, and expect to continue to experience, growth in the scope of our operations, particularly in the areas of research, development and regulatory affairs. 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 any 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. 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 any further expansion of our operations, recruit and train additional qualified personnel, or succeed at effectively integrating employees into our operations. 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, clinical trial sites, 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, geopolitical events, including civil or political unrest in any of our business locations, terrorism, insurrection or war (such as the ongoing conflicts in the Middle East and Eastern Europe), as well as other 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 such geopolitical events, 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.

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 AI 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, investigate (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 SEC adopted rules in 2023 requiring us to publicly disclose certain cybersecurity incidents. Such notices may be costly and could harm our reputation and our ability to compete, and our ultimate disclosure or 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 and the third parties with whom we work 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 by us or the third parties with whom we work to comply with such requirements could subject us to significant fines and penalties, investigations and/or reputational harm, which may have a material adverse effect on our business, financial condition or results of operations.

We and the third parties with whom we work 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, 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 by us or any of the third parties with whom we work to comply with any of these laws and regulations could result in investigations or 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, and claims that we failed to comply with privacy laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, result in adverse publicity and have a material adverse effect on our business, financial condition and results of operations.

Numerous states in the U.S., including California where our headquarters is located, have passed comprehensive privacy laws and other states are considering passing such laws. 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). At the federal level, the Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA) imposes specific requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Congress has also considered 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 EEA, and the processing of personal data that takes place in the EEA, is regulated by the EU General Data Protection Regulation 2016/279 (GDPR), 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 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. The U.K. and Switzerland, as well as other countries outside of Europe, have adopted privacy and data security laws that are comparable to the GDPR.

In addition, we may be unable to transfer personal data from EEA countries and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Although there are various mechanisms that may be used in some cases to lawfully transfer personal data to the United States or other countries, these mechanisms are subject to legal challenges and may not be available to us. An inability or material limitation on our ability to transfer personal data to the United States or other countries could materially impact our business operations.

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. Any failure to comply with U.S. federal and state and international laws and regulations regarding data privacy would expose us to risk of enforcement actions taken by data protection authorities, and with them the potential for significant penalties if we are found to be non-compliant. Similarly, such failures could result in government-imposed orders requiring that we change our practices, private lawsuits asserting claims for damages or other liabilities, and potentially 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, insider trading laws, or contractual obligations.

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, (v) insider trading laws that restrict the buying and selling of shares of securities while in possession of material non-public information, (vi) federal and state data privacy laws and regulations and (vii) contractual obligations of Vir Bio or such parties. 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 studies, creating fraudulent data in our preclinical or clinical studies or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation.

It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these contractual provisions, laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud, violations 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, 2024, we had net operating loss carryforwards of $645.3 million for federal tax purposes and $450.2 million for state tax purposes. If not utilized, federal carryforwards will begin expiring in 2036 and state carryforwards will begin expiring in 2037. 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.

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" in this Quarterly Report on Form 10-Q.

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. Accordingly, 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. Investor concerns regarding financial systems and general economic conditions, both inside and outside the U.S., including capital markets volatility, interest rate and currency rate fluctuations, and economic slowdown or recession, as well as geopolitical events, man-made or natural disasters, or public health pandemics or epidemics, 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 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 may be influenced by research and reports that industry or financial analysts publish about us, our business or the potential markets for our products or product candidates. 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 (including changes in analyst recommendations or price targets for our stock), or if the clinical studies and operating results fail to meet the expectations of analysts, our stock could decline. In addition, 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 are subject to the reporting requirements of the Exchange Act, the listing standards of Nasdaq, the Sarbanes-Oxley Act and other applicable securities rules and regulations. We have incurred and will continue to incur significant legal, accounting, investor relations and other expenses to comply with these rules and regulations.

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.

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 amended and restated 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.

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 (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. 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 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 22, 2025, the Company issued restricted stock units (RSUs) subject to mandatory sell-to-cover tax withholding arrangements intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5-1(c) to the following officers of the Company:

- Marianne De Backer, M.Sc., Ph.D., MBA, our Chief Executive Officer;
- Vanina de Verneuil, J.D., our Executive Vice President, General Counsel, and Secretary;
- Mark Eisner, M.D., M.P.H., our Executive Vice President and Chief Medical Officer;
- Jason O'Byrne, MBA, our Executive Vice President and Chief Financial Officer; and
- Brent Sabatini, CPA, MBA, our Senior Vice President and Chief Accounting Officer.

On March 27, 2025, 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 sale activity from July 1, 2025 through June 30, 2026, with monthly market orders covering up to an aggregate of 264,000 shares of our common stock (the Sato Shares). The Sato Shares represent approximately 20% of the Company shares she holds currently. Dr. Sato has held the Sato Shares for over 7 years from the date she acquired them on January 7, 2017. The Sato Trading Plan also provides for potential sale activity from July 1, 2025 through June 30, 2026, with limit orders covering up to an aggregate of 82,377 shares of our common stock subject to vested stock options (the Sato Options). The Sato Options to potentially be exercised and sold represent approximately 41% of the in-the-money vested stock options held by Dr. Sato. 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, 2026. Each limit order contemplated by the Sato Trading Plan will remain open until the expiration of the plan on June 30, 2026, if not executed sooner. Under the Company's 10b5-1 plan guidelines, Dr. Sato is prohibited from selling more than 50,000 shares in a single trading day. Dr. Sato will remain in compliance with the Company's equity ownership guidelines if the Sato Shares and Sato Options are sold under the Sato Trading Plan.

Item 6. Exhibits.

(a) Exhibits.

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit Reference	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of the Company	8-K	001-39083	3.1	10/16/2019	
3.2	Amended and Restated Bylaws of the Company	8-K	001-39083	3.1	03/08/2023	
10.1+	Vir Biotechnology, Inc. Discretionary Bonus Plan	10-K	001-39083	10.9	02/27/2025	
10.2†	Amended and Restated Collaboration and License Agreement by and among Vir Biotechnology, Inc. and Alnylam Pharmaceuticals, Inc. dated as of March 7, 2025					X
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.					X
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.					X
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.					X
101.INS	Inline XBRL Instance Document the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).					

+ Indicates a management contract or compensatory plan or arrangement.

† 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 hereunto duly authorized.

VIR BIOTECHNOLOGY, INC.

Date: May 7, 2025 By: /s/ **Marianne De Backer**

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

Date: May 7, 2025 By: **/s/ Jason O'Byrne**

Jason O'Byrne, MBA
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)