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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

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 1-39083

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, $0.0001 par value	VIR	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant as of June 30, 2024 was approximately $745.6 million based upon the closing price of its Common Stock on June 30, 2024 of $8.90 per share, as reported by The Nasdaq Global Select Market.

The number of shares of the Registrant's Common Stock outstanding as of February 20, 2025 was 137,143,286.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement, or the Proxy Statement, for the Registrant's 2025 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the Registrant's fiscal year ended December 31, 2024.

Auditor PCAOB ID: 42	Auditor: Ernst & Young LLP	Address: San Mateo, California

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K 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 Annual Report on Form 10-K, 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.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties as well as our own estimates of potential market opportunities. All of the market data used in this Annual Report on Form 10-K involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research, and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

PART I

Item 1. Business.

Overview and Strategy

Powering the Immune System to Transform Lives.

Vir Biotechnology, Inc. (including its subsidiaries, referred to as "VirBio," "the Company," "we," "our" or "us") 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.

These diseases represent formidable challenges to human health. Under normal conditions, our immune system is naturally equipped to protect us by identifying and eradicating both cancer cells and viruses. However, these threats have evolved sophisticated mechanisms to evade our immune defenses. When cancer cells or viruses successfully bypass our immune system, they have the potential to cause diseases that may be life-threatening. We are focused on developing therapies that enhance the immune system's ability to overcome these evasion tactics, effectively powering the immune system to combat viruses and fight cancer.

We believe our unified approach of leveraging our deep understanding of immunology to address seemingly disparate threats distinguishes us in the field. Our mission is to develop innovative therapies that can transform patients' lives by addressing areas of high unmet medical need.

Our clinical development pipeline consists of investigational therapies targeting hepatitis delta virus (HDV) and various solid tumors. In hepatitis delta, our phase 3 ECLIPSE registrational program evaluating the combination of tobevibart and elebsiran is scheduled to commence in the first half 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 T-cell engagers (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 are expected to begin in the first half of 2025.

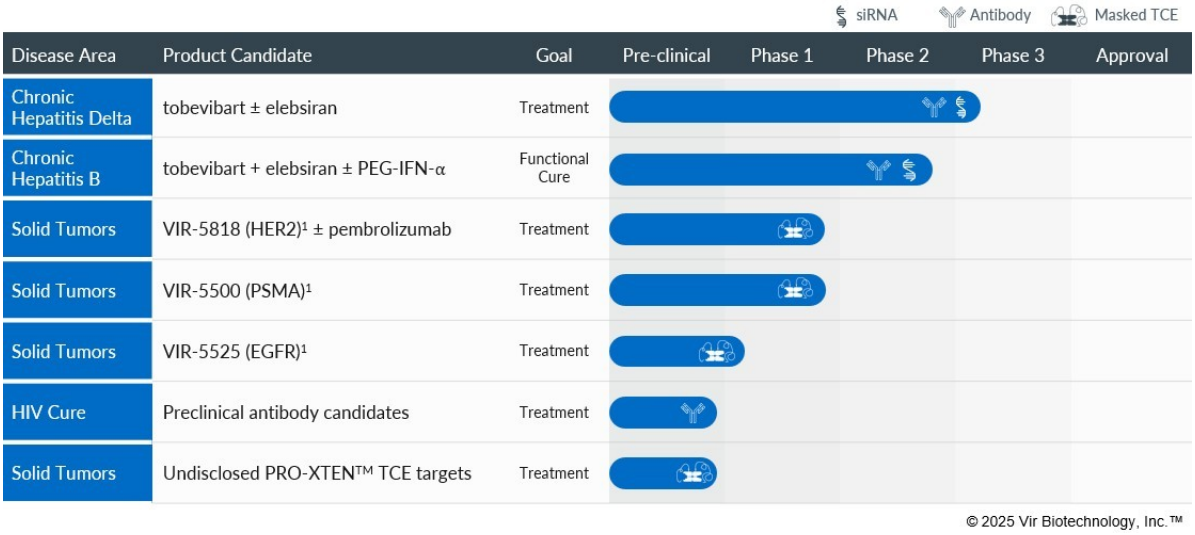
We are also developing therapeutic candidates in hepatitis B virus (HBV), HIV cure, and other solid tumors, leveraging our expertise and platform strengths. Advancement of our HBV program beyond the current MARCH study is contingent upon securing a worldwide (excluding People's Republic of China, Taiwan, Hong Kong and Macau, collectively the "China Territory") development and commercialization partner. Our HIV broadly neutralizing antibodies (bnAbs) are being developed as a potential long-acting treatment or cure in combination with existing or investigational regimens. These research and development efforts are driven by two core technology platforms—an advanced antibody discovery and protein engineering platform, and the exclusive PRO-XTEN™ dual-masked TCE platform (a trademark of Amunix Pharmaceuticals, Inc., a Sanofi company (PRO-XTEN™)), which we in-licensed from Sanofi for worldwide rights in oncology and infectious diseases. These platforms, individually and in combination, enable us to modulate the immune system in innovative ways, harnessing its power to combat viruses and fight cancer. Our antibody platform leverages artificial intelligence and machine learning (collectively referred to as AI) for optimization, while the PRO-XTEN™ platform allows for the development of potentially best-in-class TCEs with improved safety and efficacy profiles across multiple therapeutic areas.

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.

Our Research and Development Pipeline

Millions of people suffer from infectious diseases and cancer, where a key factor is evasion of the innate immune system. Our strategy leverages this commonality to power the immune system to fight back. We use our world-class capabilities in antibody discovery and engineering, coupled with our proprietary AI engine (data AI structure and antibody system, or dAIsY™ system), and the PRO-XTEN™ masking technology, to quickly and effectively discover and optimize potential new medicines.

We have built a strong foundation based on cutting-edge core scientific capabilities and a world-class team of experts who bring deep knowledge and experience to our R&D efforts. This has enabled us to make significant strides in developing treatments for infectious diseases and strategically expand our approach to address critical oncology indications with limited treatment options. Our pipeline includes multiple candidates in clinical development stages for diseases with significant unmet medical need, which is summarized by disease area in the chart below.



[1]: Masked TCEs licensed from Sanofi
HIV: Human Immunodeficiency Virus; PEG-IFN-α: peg-interferon alfa-2a; mAb: monoclonal antibody; siRNA: small interfering RNA; HER2: human epidermal growth factor receptor 2; PSMA: prostate-specific membrane antigen; EGFR: epidermal growth factor receptor. Tobevibart incorporates Xencor's Xtend™ and other Fc technologies.

Infectious Diseases

Tobevibart

Molecular Characteristics and Preclinical Data. Tobevibart is an investigational neutralizing monoclonal antibody (mAb) that has been engineered for immune engagement and targets a conserved region on the hepatitis B surface antigen (HBsAg), a protein which is required for the HDV viral life cycle. Tobevibart specifically targets the antigenic loop (AGL) on HBsAg. The AGL helps HBV bind to hepatocytes and subsequently infect these cells. By binding to the AGL, tobevibart is designed to prevent viral entry, which prevents the spread of HDV to uninfected hepatocytes. It has been engineered to neutralize strains from all 10 HBV genotypes. Tobevibart, through a process called opsonization, also helps remove HBV virions and sub-viral particles (SVPs) from the blood.

Tobevibart was identified using our proprietary antibody discovery platform. Tobevibart's proprietary fragment crystallizable (Fc) engineering enhances its ability to engage immune cells, promoting the removal of antibody-virion complexes. Tobevibart also incorporates Xencor's Xtend™ neonatal Fc receptor technology, which extends its half-life.

Tobevibart has the potential to activate the immune system to fight the virus via three different processes. First, due to specialized mutations in the Fc domain, tobevibart has the potential to act as a T-cell vaccine, inducing the production of protective T-cells and promoting immunity. This is based on a mechanism by which tobevibart could capture virions and SVPs, deliver them to dendritic cells and instruct these cells to mature and stimulate T-cells that can then eliminate HBV infected hepatocytes. Second, tobevibart has the potential to act via antibody-dependent cell cytotoxicity (ADCC). In this process, by binding to HBsAg at the cell surface, tobevibart recruits natural killer cells to eliminate infected hepatocytes. The Fc domain of tobevibart has been engineered to promote ADCC. Third, when large quantities of HBV proteins are released into the blood, especially HBsAg, they can be immunosuppressive. Tobevibart has the potential to activate the immune system by reducing the amount of HBsAg in the blood, decreasing the ability of HBV to suppress the immune system and further enabling the natural immune response to the virus.

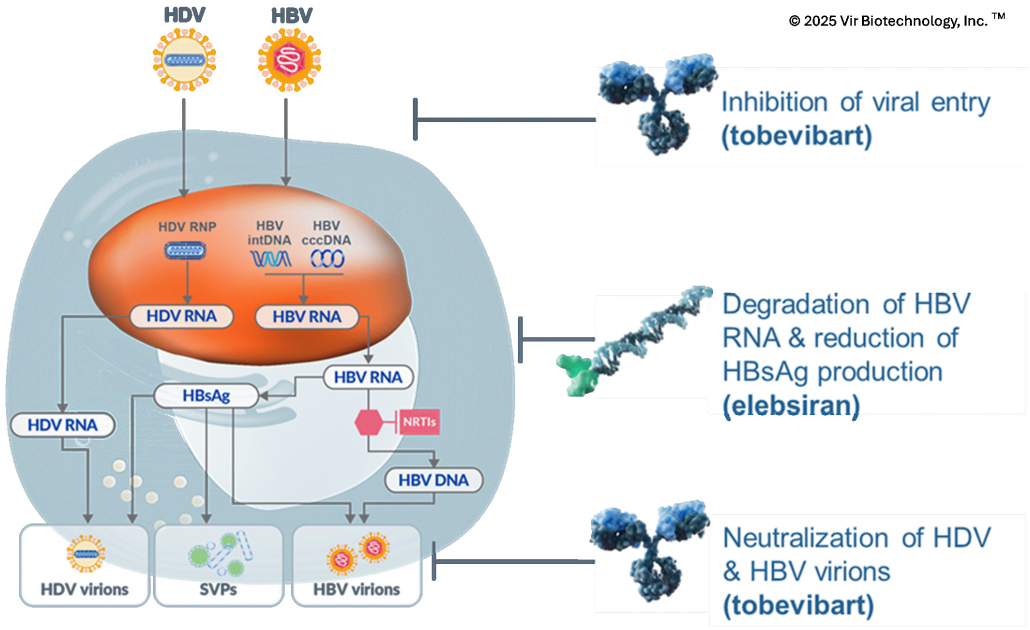
Elebsiran

Molecular Characteristics and Preclinical Data. Elebsiran is an investigational HBV-targeted small interfering RNA (siRNA) that reduces HBsAg. Elebsiran targets a conserved sequence of HBV that allows for predicted activity against 99.7% of the strains of HBV, including all 10 HBV genotypes. Because this conserved sequence falls within a specific region of the X gene of HBV that exists within all four HBV RNA transcripts, elebsiran is designed to degrade each transcript, and consequently decrease the expression of all proteins produced by the virus: X, polymerase, S, and core.

Once inside the infected cell, DNA from the HBV virus can become integrated into human DNA as integrated DNA (intDNA). Because elebsiran targets a region of HBV that is conserved in the large majority of HBV intDNA, this single siRNA is predicted to be able to prevent the production of HBV proteins derived from intDNA, as well as the production of all other HBV proteins from covalently closed circular DNA (cccDNA).

There are at least two potential mechanisms by which the large amount of HBV protein that is transcribed in liver cells can suppress the immune system. The first mechanism is T-cell tolerance and exhaustion by the presentation of intracellular HBV antigens on hepatocytes. The second is the large quantities of HBV proteins that are released into the blood, especially HBsAg, which may also be immunosuppressive. By directly reducing the amount of HBV proteins made, elebsiran has the potential to decrease the ability of HBV to suppress the immune system and enable the natural immune response to the virus. In mice models, siRNAs that are able to reduce HBsAg expression can transform an otherwise ineffective therapeutic HBV vaccine into one that can functionally cure the mice of HBV, suggesting that HBsAg suppression has the ability to enhance the immune response against HBV.

We believe that elebsiran is the only HBV-targeting siRNA currently in development that includes enhanced stabilization chemistry (ESC+) technology and preclinical modeling. Initial clinical data suggest this technology may be able to enhance the safety profile of elebsiran.



Simplified mechanism of action representation of tobevibart and elebsiran.
cccDNA: covalently closed circular DNA, HBsAg: hepatitis B virus surface antigen, HBV: hepatitis B virus, HDV: hepatitis D virus, Int: integrated, NRTI: nucleoside/nucleotide reverse transcriptase inhibitor, RNP: ribonucleoprotein, SVP: subviral particle

Chronic Hepatitis Delta (CHD)

CHD is a chronic, progressive liver disease caused by the HDV, which requires HBV for its replication. This means that hepatitis delta infection cannot occur in the absence of HBV. HDV-HBV coinfection is the most severe form of chronic viral hepatitis. CHD increases the risk of liver cancer and accelerates progression to cirrhosis and liver failure, which often occurs within 5 years of infection. There is no approved CHD treatment in the U.S., and options are limited in the European Union and globally.

VirBio is working to develop a chronic suppressive therapy to help address this significant unmet medical need, based on a combination of our investigational antibody, tobevibart, and a siRNA, elebsiran.

Tobevibart + elebsiran for CHD

Phase 2 Trial of tobevibart, both alone and in combination with elebsiran in hepatitis delta. SOLSTICE is a Phase 2 study to evaluate the safety, tolerability, and efficacy of tobevibart, alone or in combination with elebsiran, in people with CHD. This Phase 2 study is a multi-center, open-label, randomized study. Primary endpoints include proportion of participants with protocol defined virologic endpoint (defined as HDV RNA equal or greater than 2 $\log_{10}$ decrease from baseline or below limit of detection) up to week 24, alanine aminotransferase (ALT) normalization (defined as ALT below upper limit of normal) up to week 24, and treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs) up to 118 weeks. Secondary endpoints include proportion of participants with undetectable HDV RNA and different timepoints up to 192 weeks. Clinical trial participants have been randomized to receive tobevibart 300 mg monotherapy every two weeks (n=33) or a combination of tobevibart 300 mg and elebsiran 200 mg every four weeks (combination *de novo* arm, n=32). In addition, the participants from previous tobevibart or elebsiran monotherapy cohorts could rollover to receive the combination of tobevibart 300 mg and elebsiran 200 mg every four weeks (combination *rollover*, n=13). The latest data from the ongoing clinical trial was presented in an oral session at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting®, in San Diego, CA, in November 2024. The data included rates of virologic suppression and ALT normalization evaluated at Week 24, and Weeks 36, 48 and 60 in those participants that had reached each timepoint. The trial assesses the combined endpoint of HDV RNA decrease ≥ 2 $\log_{10}$ compared to baseline or HDV RNA below LOD and ALT normalization, which is the current combined endpoint used for regulatory approval. At the same time, HDV RNA below the lower limit of quantification (< LLOQ), target not detected (HDV RNA TND) and the composite endpoint of HDV RNA TND and ALT normalization is also being monitored to assess efficacy.

100% of participants across combination arms achieved an HDV RNA ≥ 2 $\log_{10}$ decrease or below LOD at Week 24, and this rate was sustained over time in all participants at Weeks 36 (22/22) and those in the combination *rollover* cohort that reached Week 60 (5/5). HDV RNA TND was achieved in 41% (13/32) of participants across combination arms at Week 24 and this rose to 64% (14/22) at Week 36. By week 60, this had risen further with 80% (4/5) of participants in the combination *rollover* cohort having achieved no detectable viral RNA.

ALT decreased in most participants between Day 1 and Week 24 and normalized in 47% (15/32) of participants in the combination *de novo* cohort and 56% (5/9) in the combination *rollover* cohort by Week 24. These rates were sustained at Week 36.

The protocol defined combined endpoint of HDV RNA decrease ≥ 2 $\log_{10}$ compared to baseline or HDV RNA below LOD and ALT normalization at Week 24 was observed in 47% (15/32) of participants in the combination *de novo* arm. The more stringent composite endpoint of HDV RNA TND and ALT normalization was achieved in 19% (6/32) of participants in the combination *de novo* arm at Week 24, which increased to 27% (6/22) by Week 36. This trend was reflected in the combination *rollover* cohort in which 33% (3/9) of participants achieved this endpoint at Week 24 and 40% (2/5) at Week 60. Rates of HDV RNA suppression and ALT normalization were similar between non-cirrhotic and cirrhotic participants across combination arms.

The safety profile of tobevibart and elebsiran is consistent with previous studies. TEAEs were generally mild or moderate and transient across all treatment groups, with influenza-like symptoms being the most common event. No ALT flares were observed. There were no study-related discontinuations in the combination arms, and no treatment-related SAEs were reported.

A Phase 3 registrational clinical program, ECLIPSE, which will evaluate the tobevibart and elebsiran combination in people living with CHD, is expected to commence in the first half of 2025. The trial will include three randomized, controlled trials designed to evaluate the combination therapy in comparison to deferred treatment or bulevirtide. All studies will enroll both cirrhotic and non-cirrhotic participants.

The combination of tobevibart and elebsiran have now been recognized by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for their potential to address the critical unmet need in CHD. In June 2024, the combination received Fast Track designation from the FDA, which was followed by Breakthrough Therapy designation in December 2024. In addition, the combination received a Priority Medicines (PRIME) designation from the EMA, and orphan drug designation from the European Commission (EC), each in December 2024.

Chronic Hepatitis B (CHB)

CHB is a long-lasting, inflammatory liver disease caused by the HBV. The World Health Organization estimates that 254 million people live with CHB, and an estimated 1.1 million yearly deaths are associated with the disease. Complications from CHB may include liver cirrhosis, liver failure and liver cancer.

The rate of functional cure (lifelong control of the virus after a finite duration of treatment) with current approved treatments is 3%-7%. Alternatively, suppressive therapy with daily nucleotide/nucleoside transcriptase inhibitors (NRTIs) is commonly used, and CHB patients often require a lifetime of therapy, and NRTIs reduce but do not eliminate the risk of further progression and developing end-stage liver disease complications such as cirrhosis or cancer.

We are pursuing a functional cure for CHB based on a combination regimen of tobevibart and elebsiran with or without pegylated interferon alpha (PEG-IFNα).

Tobevibart + elebsiran ± PEG-IFNα for CHB

Phase 2 Trial of tobevibart in combination with elebsiran alone (doublet regimen) or in combination with PEG-IFNα (triplet regimen). In July 2021 we initiated the MARCH two-part study to evaluate the combination of tobevibart and elebsiran in virally suppressed HBV patients. MARCH Part A evaluated short treatment courses of tobevibart and elebsiran to rapidly evaluate safety, pharmacokinetics and HBsAg suppression when tobevibart is given weekly concomitantly with or after pre-treatment with elebsiran. Results from MARCH Part A in 2022 showed that the combination of tobevibart and elebsiran resulted in an approximate 3 $\log_{10}$ IU/mL decline in HBsAg with no safety signals. In November 2022, we announced end of treatment data for all MARCH Part A that the combination of tobevibart and elebsiran achieved mean HBsAg reductions >2.7 $\log_{10}$ IU/mL in all cohorts, absolute HBsAg levels <10 IU/mL were achieved in most participants, and no safety signals. Follow-up data after end of treatment showed rebounds in HBsAg levels over time.

MARCH Part B includes cohorts treated for 24- and 48-weeks with monthly doses of tobevibart plus elebsiran with and without PEG-INF-α. In November 2024, we presented 48-week end-of-treatment data from MARCH Part B that evaluated the combination of tobevibart and elebsiran alone or with IFN-α (doublet and triplet regimens, respectively) in an oral session at the AASLD The Liver Meeting®, in San Diego, CA. This analysis included data from 51 participants in the doublet regimen arm and 27 participants in the triplet regimen arm at the end of treatment. The study demonstrated promising rates of HBsAg loss (seroclearance, defined as HBsAg below the lower limit of quantification) in participants with low baseline HBsAg (<1000 IU/mL) in both combination regimens. The efficacy and safety profile support continued development to evaluate the potential to achieve a functional cure. The doublet and triplet regimens resulted in HBsAg loss at the end of treatment in 39% (7/18) and 46% (5/11) of participants with baseline HBsAg<1,000 IU/mL, respectively. The proportion of participants with varying baseline HBsAg levels who achieved HBsAg loss at end of treatment was 16% (8/51) for the doublet and 22% (6/27) for the triplet regimen. The doublet regimen resulted in 50% (4/8) of participants who had achieved HBsAg loss also achieving anti–hepatitis B surface antibody (anti-HBs) seroconversion. All participants with HBsAg loss at the end of treatment who received the triplet regimen achieved anti-HBs seroconversion (100%, 6/6). Participants with HBsAg seroclearance at end of treatment who meet eligibility criteria will discontinue treatment. Functional cure assessment will occur 24 weeks after treatment discontinuation. Functional cure data is expected in the first half of 2025.

The Phase 2 PREVAIL platform trial evaluating the efficacy and safety of tobevibart and elebsiran in participants with CHB is ongoing. This trial is designed to evaluate combinations of tobevibart, elebsiran and/or PEG-IFNα in two patient populations: immune-active but treatment-naïve and inactive carriers.

Elebsiran is also being evaluated in additional Phase 2 clinical trials with collaborators. Brii Biosciences Offshore Limited (“Brii Bio”) is the sponsor for the Phase 2 trial of elebsiran in combination with BRII-179, an investigational therapeutic vaccine, for the treatment of chronic HBV infection. As described in further detail below under the heading “Our Collaboration, License and Grant Agreements,” we granted Brii Bio an option to obtain exclusive rights to develop and commercialize elebsiran and tobevibart in the China Territory, for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection, or the Field of Use.

Oncology

One in five people worldwide develop cancer during their lifetime, and although tremendous strides have been made in cancer prevention and treatment, cancer still remains the second-leading cause of death globally and remains the leading or second-leading cause of premature death (before age 70 years) in 112 countries.

While major advances have been made in immunotherapies for hematologic malignancies, a large unmet need remains for novel and tolerable therapeutics for patients with solid tumors. TCEs are potent anti-tumor agents that direct the immune system, specifically T-cells, to attack cancer cells. VirBio's bi-specific TCE is comprised of two antibody fragments: a tumor-associated antigen (TAA) binding domain and a CD3 binding domain. They are designed to simultaneously recruit T-cells and TAA expressing cancer cells, directing the cytotoxic activity of T-cells against the tumor. However, if the antigen is also expressed on healthy cells, bi-specific TCEs can similarly bind to TAAs present in non-cancerous cells or healthy tissue, driving on-target, off-tumor toxicity, including cytokine release syndrome (CRS), thus limiting the potential therapeutic index of TCEs.

Masking of TCEs is a strategy designed to circumvent these limitations. This technology specifically leverages overactivity of proteases in the tumor microenvironment (whereas proteases are tightly regulated by protease inhibitors elsewhere in the body). By attaching masks joined by protease cleavable linkers to the TCE, VirBio's TCEs are designed to remain inactive until they reach the tumor microenvironment. Once in the tumor microenvironment, tumor-specific proteases can cleave off the mask and release the unmasked TCE, which can bind to both T-cell and tumor cells expressing the TAA, and lead to killing of cancer cells. By limiting the unmasking of the TCEs to the tumor microenvironment, we aim to limit the toxicity of these agents in the periphery and potentially increase their safety and efficacy.

We are currently advancing three clinical-stage dual-masked TCEs, VIR-5818 (phase 1), VIR-5500 (phase 1), and VIR-5525 (IND cleared, initiating phase 1), that leverage the PRO-XTEN™ masking technology with TCEs targeting CD3 on T-cells, and HER2, PSMA and EGFR, respectively, on tumor cells.

VIR-5818 ± pembrolizumab for the treatment of HER2-positive solid tumors

Molecular Characteristics and Preclinical Data. While the role of HER2 in breast and gastric cancer has been well established for many years, only recently has there been a recognition of the importance of HER2 in other disease types, in particular as a resistance biomarker to other signaling pathways such as EGFR. With more patients undergoing biopsies after progression from prior therapies, and the advance of more routine molecular genotyping, numerous aberrations in HER2 have been discovered. Collectively, HER2+ tumors (IHC 3+ or in situ hybridization [ISH]+) and solid tumors with activating HER2 mutations represent a large unmet need. VIR-5818, with its novel mode of action and potential for large safety margins due to masking, may be an important treatment option that can extend survival and provide cancer immunity to these tumors.

VIR-5818 is a HER2-targeted, conditionally activated masked TCE designed to exploit dysregulated protease activity in tumors while sparing healthy tissues in which there is minimal protease activity, thus broadening the safety margin and therapeutic index. The core consists of two, tandem, single-chain variable fragments (scFvs) targeting CD3 and HER2 that are flanked by two unstructured polypeptide masks (XTEN™) that sterically reduce target engagement in normal tissues and extend half-life. Protease cleavage sites at the base of the XTEN™ masks enable proteolytic activation of fully masked TCE in the tumor microenvironment, unleashing a small, highly potent, unmasked TCE, which is able to redirect cytotoxic T-cells to kill target-expressing tumor cells. The potent, unmasked form (uTCE) of VIR-5818, also has a much shorter half-life to potentially increase the therapeutic index if the activated form should leak back into circulation. In healthy tissues, in which protease activity is tightly regulated, VIR-5818 should remain predominantly masked and as an intact prodrug. Additional information is available in "Our Technology Platforms" section.

In preclinical (*in vitro*) studies, binding affinities of VIR-5818 were found to be similar between human and cynomolgus monkey HER2 and CD3, thus cynomolgus monkeys are a relevant species for toxicology studies. GLP NHP toxicology studies have demonstrated minimal toxicities with a NOAEL at the top dose evaluated of 6mg/kg. Unmasked VIR-5818 had single digit pM potent cytotoxicity to HER-2 expressing tumor cells, but significantly less cytotoxic to HER-2 expressing cardiomyocytes, requiring >1uM, thus demonstrating the potential wide therapeutic index compared to normal tissue and showing the need for dysregulated proteases (only found in tumor cells) for unmasking and eventual cell killing.

Phase 1 Trial of VIR-5818 ± pembrolizumab. VIR-5818 is being evaluated in a Phase 1 clinical trial designed to study its safety and pharmacokinetics alone, and in combination with pembrolizumab, in participants with a variety of HER2-expressing cancers, including breast and colorectal cancer (CRC). As of November 2024, the study had enrolled 79 heterogeneous and heavily pretreated participants in monotherapy cohorts, and we presented early safety and efficacy data from the monotherapy cohort at an investor event on January 8, 2025.

Early efficacy data showed that 50% (10/20) of participants receiving VIR-5818 doses ≥400 µg/kg experienced dose-dependent tumor shrinkage across multiple HER2-positive tumor types at either QW or Q3W dosing schedule after an initial step-up dosing in Cycle 1. This includes participants who had received up to 9 prior lines of therapy. Strong anti-tumor activity was observed in a subset of participants with HER2-positive CRC who have exhausted standard of care. In this subset, confirmed partial responses (cPRs) were seen in 33% (2/6) of participants at early doses, and one patient continued in cPR for more than 18 months as of the data cut-off in November 2024. All the HER2-positive CRC tumors were also MSS (Microsatellite Stable) which traditionally are unresponsive to immunotherapies..

Preliminary safety data demonstrated that VIR-5818 was generally well-tolerated, with minimal grade 1 or 2 CRS (20% and 10%, respectively) and no grade 3 or greater CRS observed in any of the 79 participants across doses up to 1 mg/kg. Most TEAEs were low grade, reversible and manageable. The maximum tolerated dose (MTD) has not yet been reached. Preliminary pharmacokinetics and safety data indicate low systemic unmasking of the TCE, suggesting tumor-specific activation. Dual masking results in a half-life of approximately 6 days, which may enable a less frequent dosing regimen. As a result, VirBio is currently evaluating a Q3W dosing regimen. Dose escalation is ongoing, and the MTD has of VIR-5818 has not yet been reached.

VIR-5500 for the treatment of metastatic castration-resistant prostate cancer

Molecular Characteristics and Preclinical Data. Similar to VIR-5818, VIR-5500 is a protease-activated, bispecific dual-masked TCE, designed to exploit the dysregulated protease activity in tumors relative to healthy tissues, thus expanding the safety margin and therapeutic index. The VIR-5500 core consists of a VHH (single-variable domain on a heavy chain) domain targeting PSMA and an scFv-targeting CD3. The core is flanked by 2 unstructured polypeptide masks (XTEN™ masks) that sterically reduce target engagement in healthy tissue and extend the half-life of the protein. Protease cleavage sites at the base of the XTEN™ masks enable proteolytic activation of unmasked protein in the tumor microenvironment, unleashing a small, highly potent unmasked TCE, designed to redirect cytotoxic T-cells to kill PSMA-expressing tumor cells. In healthy tissues, in which protease activity is minimal due to tight regulation, VIR-5500 should remain predominantly inactive.

Phase 1 Trial of VIR-5500. VIR-5500 is being evaluated in a Phase 1 clinical trial designed to assess its safety, pharmacokinetics, and preliminary efficacy in participants with mCRPC. As of November 2024, the study had enrolled 18 participants with significant disease burden who have received 3 to 6 prior lines of therapy, and we presented early safety and efficacy data from the ongoing dose escalation trial at an investor event on January 8, 2025.

PSA reductions were observed in 100% (12/12) of participants after an initial dose ≥120 µg/kg. PSA50 response was confirmed in 58% (7/12) of participants receiving a first dose ≥120 µg/kg. Preliminary data show no dose-limiting toxicities observed up to 1000 µg/kg without the use of prophylactic corticosteroids or anti-IL6 antibodies. Safety findings showed minimal grade 1 or 2 CRS (17% and 11%, respectively) and no grade 3 or greater CRS at any dose. Most TEAEs were low grade. No hearing loss has been reported, suggesting safety benefits of dual masking in preventing on-target, off-tumor toxicities. Dose escalation is ongoing, and the MTD for VIR-5500 has not yet been reached. Preliminary pharmacokinetics and safety data indicate tumor-specific activation with minimal unmasking outside the tumor. The dual-masked TCE shows a preliminary half-life of 8-10 days, potentially enabling a Q3W dosing regimen, which is currently being evaluated. The safety and tolerability profile observed for VIR-5500 in ongoing dose escalation, together with the observed signs of early anti-tumor activity at low doses, may enable a wide therapeutic index.

VIR-5525

The Epidermal Growth Factor Receptor (EGFR) is a clinically validated target, well-known to play a key role in cancer. This molecule is over-expressed in a variety of solid tumors, such as colorectal, squamous cell carcinoma of the head and neck, non-small cell lung cancer, and renal cell carcinoma, making it an attractive target for targeted cancer therapy.

We are advancing VIR-5525, an investigational dual-masked TCE that combines a bispecific EGFR and CD3 binding TCE with the PRO-XTEN™ masking technology. This technology is designed to keep the TCEs inactive until they reach the tumor microenvironment, where tumor-specific proteases can cleave off the mask and activate the TCEs leading to killing of cancer cells. By driving the activity exclusively tin the tumor microenvironment, we aim to increase efficacy and tolerability while limiting toxicity. The FDA has cleared the IND for VIR-5525, and a Phase 1 clinical study is expected to begin enrollment in the first half of 2025.

Undisclosed PRO-XTEN™ TCE Targets:

We are advancing multiple undisclosed dual-masked TCEs targeting clinically validated targets with potential applications across a variety of solid tumors. These preclinical candidates leverage the PRO-XTEN™ masking technology with novel TCE fragments discovered and engineered using our antibody discovery platform.

HIV cure

Despite major advances in HIV treatment, most persons living with HIV must take daily antiretroviral medications for viral control. HIV bnAbs are a novel modality that have shown promise for controlling virus without daily antiretroviral medications. Furthermore, in rare individuals, HIV bnAb treatment has induced a state of sustained viral control off all therapy, effectively achieving a functional cure.

With the support of the Gates Foundation, we are developing a unique and innovative HIV bnAb therapeutic. We are selecting and engineering HIV bnAbs (including using dAIsY™) for exceptional breadth and potency to combat both the diversity of HIV strains worldwide and the ability of the virus to escape from therapeutic intervention. In addition, we are modifying these bnAbs with our Fc engineering technology to enhance their half-life, effector functions, and engagement with the patient's immune system. We believe the resulting therapeutic can make an important impact on the lives of people living with HIV.

Our Technology Platforms

Vir Biotechnology, Inc. has built a strong foundation based on cutting-edge core scientific capabilities and a team of experts who bring deep knowledge and experience to our R&D efforts. This has enabled us to make significant strides in infectious disease, and strategically expand our focus to address critical unmet needs in oncology.

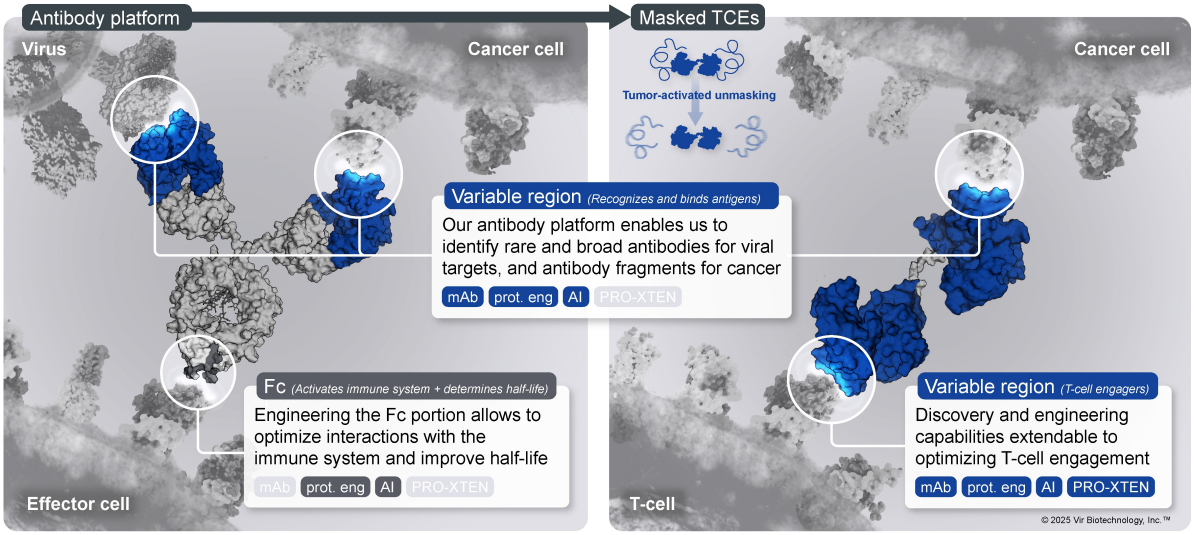
Platforms for the Creation of Transformative Medicines

Millions of people suffer from infectious diseases and cancer, both of which result in chronic disease by evading the immune system.We have purposefully assembled a portfolio of technology platforms that we believe will, individually or in combination, allow us to modulate the immune system in innovative ways, harnessing its power to combat viruses and fight cancer.

Our R&D engine is propelled by two core technology platforms:

1. **Antibody Platform:** We continue to leverage our expertise in antibody discovery and development, enhanced by machine learning and artificial intelligence. Using strategies such as our dAIsY™ system, we can engineer our candidates to optimize key biological and biophysical properties, such as half-life and developability. This discovery platform is utilized to generate antibodies that can be further developed into therapeutic molecules, including the generation of dual-masked TCEs against novel tumor targets.
2. **PRO-XTEN™ Masking Platform:** Exclusively in-licensed from Sanofi in 2024, this platform enables the development of potentially best-in-class masked TCEs for solid tumors. The dual-masking approach is designed to enhance tumor specificity while minimizing off-target effects, potentially improving both efficacy and safety. This technology could make our future medicines more specific, effective, and tolerable by ensuring they act only where needed, reducing damage to healthy cells and tissue. Initial Phase 1 data has provided clinical proof of concept for this approach across multiple tumor types.

These platforms are complemented by our internal capabilities in process development, analytical development, manufacturing, and quality control. We also maintain strategic partnerships with contract development and manufacturing organizations (CDMOs) to support our clinical programs. This combination of cutting-edge technologies, artificial intelligence-driven optimization, and deep immunological expertise positions us to create potentially transformative medicines for some of the more challenging diseases facing humanity today.



mAb: monoclonal antibody platform; prot. eng: protein engineering capabilities; AI: artificial intelligence

Antibody Platform

Overview

We have developed cutting-edge platforms to identify and enhance rare, potent monoclonal antibodies (mAbs) using AI-enabled protein engineering for the treatment of infectious diseases and cancer. Our platforms leverage the efficient interrogation of memory B cells from two primary sources: convalescent human patients and transgenic mice expressing human- immunoglobulin G (IgG) following immunization. This approach enables the selection of highly potent antibodies with unique characteristics that can be further developed into therapeutic molecules, including dual-masked TCEs targeting novel TAA.

Our platform has been successfully applied to identify mAbs for multiple pathogens including SARS-CoV-2, HBV, HDV, Ebola virus, and HIV. Noteworthy achievements include:

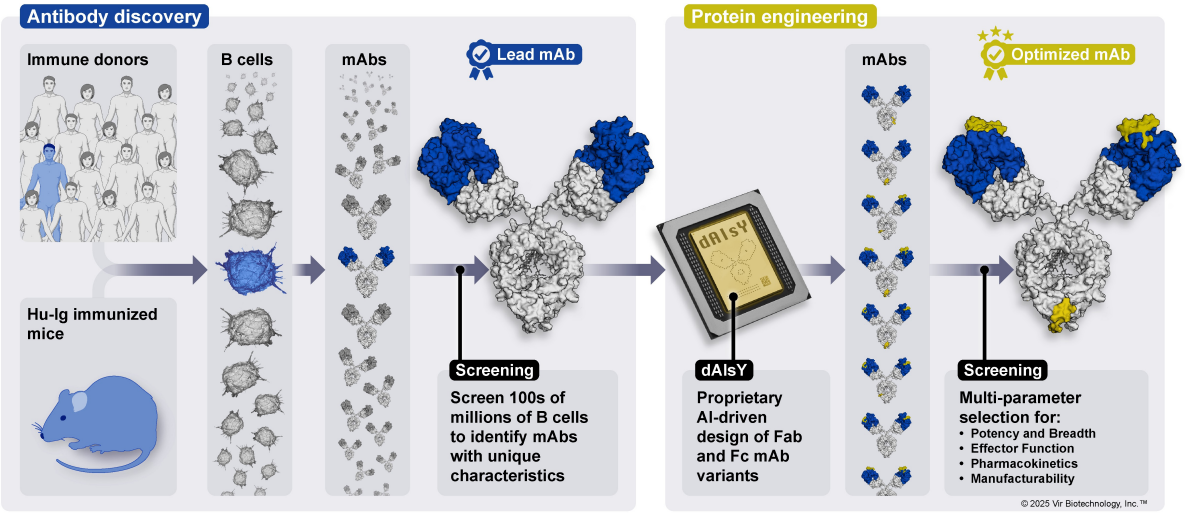
- Sotrovimab (Xevudy®): Anti-SARS-CoV-2 mAb, granted Emergency Use Authorization (EUA) or marketing authorization in multiple regions.
- Ansuvimab (Ebanga™): Anti-Ebola virus mAb developed in collaboration with the NIH and marketed by Ridgeback Biotherapeutics LP.

Our Approach

MAbs function through various mechanisms including pathogen neutralization, target cell lysis (infected or tumor cells), and immunomodulation. Our approach combines rapid, high-throughput isolation of rare and highly potent fully human mAbs from cell culture-based libraries of clonal B lymphocytes.

Our proprietary antibody screening technology enables the screening of antibodies from hundreds of millions of B cells derived from either convalescent individuals or human-Ig immunized mice. This screening identifies rare and potent mAbs capable of binding highly conserved antigens, neutralizing multiple pathogens, or selectively targeting host proteins, including tumor antigens or antigens involved in the modulation of anti-tumor immune responses.

These fully human antibodies can be refined using our proprietary AI-driven protein engineering technology, dAIsY™, enhancing their potency, resistance, pharmacokinetics, as well as their manufacturability. This involves optimizing the antigen-binding fragment (Fab) regions to improve efficacy, potency, and manufacturability, as well as the Fc region to fine-tune the antibody's half-life and to enhance its ability to engage effector functions of the immune system. In this context, we have developed a set of novel and proprietary Fc mutations that have the potential to enhance the anti-tumor efficacy of antibodies.



Hu-Ig = humanized immunoglobulin

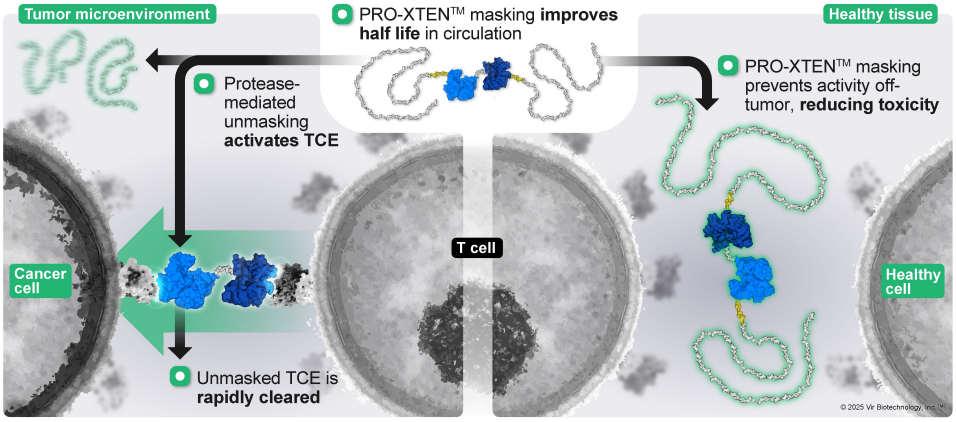
PRO-XTEN™ Masking Platform

Overview

The PRO-XTEN™ masking technology exploits the high protease activity of the tumor microenvironment to specifically release the active form of a drug via release of the mask only in tumor tissues. It can be applied to a variety of molecules such as TCEs, cytokines, or other molecules to broaden the therapeutic index for patients. The preferential release of the drug in the tumor microenvironment is designed to minimize on-target, off-tissue toxicity. The XTEN™ masks are designed to extend the half-life resulting in more convenient dosing regimens for patients and clinicians. This masking approach could be key to pursuing validated oncology targets typically associated with therapies of high toxicity, ultimately offering an opportunity to potentially increase the therapeutic index of drug candidates and deliver more efficacious and safer options for patients.

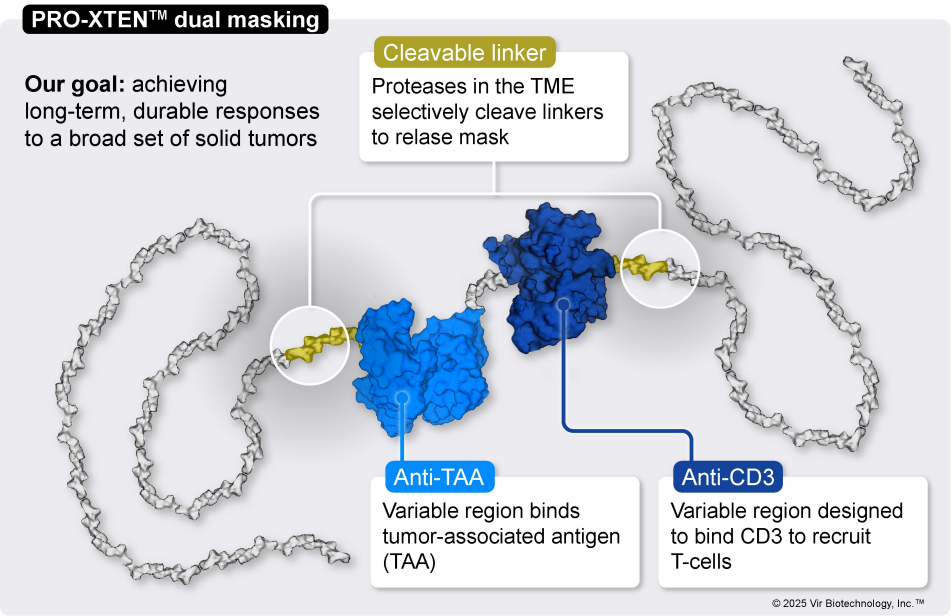
Our Approach

We are currently investigating the PRO-XTEN™ technology in conjunction with TCEs. These are powerful anti-tumor agents that direct the immune system, specifically T-cells, to destroy cancer cells. The PRO-XTEN™ masking technology is designed to keep the TCEs inactive (or masked) until they reach the tumor microenvironment, where tumor-specific proteases cleave off the masks and activate the TCEs leading to killing of cancer cells. By driving the activity exclusively to the tumor microenvironment, we aim to circumvent the traditionally high toxicity associated with TCEs and increase their efficacy and tolerability.



TCE: T-Cell Engager

Our dual-masked TCEs are single protein polypeptides with three key functions, a bi-specific TCE at their core, two universal PRO-XTEN™ masks, which are connected to the TCE component by protease-cleavable linkers. The bi-specific TCE is comprised of two antibody fragments: a TAA binding domain and a CD3 binding domain. Upon unmasking, they are designed to simultaneously recruit T-cells to cells expressing the target TAA, preferentially cancer cells, directing the cytotoxic activity of T-cells against the tumor. Our discovery and antibody engineering capabilities are extendable to optimizing TAA and T-cell engagement component and identifying novel TCE fragments for additional targets, not only in oncology but also in infectious disease. The protease-activated linkers that are part of PRO-XTEN™ were discovered by applying a combination of in vitro and in vivo experiments together with a genetic algorithm for sequence optimization.



TME: tumor microenvironment; TCE: T-Cell Engager; CD3: cluster of differentiation 3; TAA: tumor associated antigen; CRS: cytokine release syndrome; Q3W: once every 3 weeks

Our Collaboration, License and Grant Agreements

License Agreement with Sanofi

On September 9, 2024, we closed a license agreement with Amunix Pharmaceuticals, a Sanofi company, previously announced on August 1, 2024 (the Sanofi Agreement), pursuant to which we obtained an exclusive (as to Sanofi and its affiliates), worldwide, royalty-bearing, sublicensable (through multiple tiers), transferable license to research, develop, manufacture, commercialize and otherwise exploit: (i) three clinical-stage masked TCEs of Sanofi, for all therapeutic, prophylactic, palliative, and diagnostic uses, excluding the ophthalmological field, and (ii) the PRO-XTEN™ universal masking technology for oncology and infectious disease, excluding the ophthalmological field. As part of the closing of the Sanofi Agreement, we made an upfront payment to Sanofi in the amount of $100.0 million and transferred $75.0 million to an escrow account that is due to former shareholders of Amunix Pharmaceuticals, Inc. upon VIR-5525 achieving "first in human dosing" by 2026. 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, we execute a transaction that gives rise to VirBio receiving certain sublicense income related to the licenses obtained from the Sanofi Agreement, Sanofi may be eligible to receive a portion of such income.

The Sanofi Agreement will remain in force, on a product-by-product and country-by-country basis, until the expiration of all royalty payment obligations. We may terminate the Sanofi Agreement in its entirety, or on a target-by-target basis, for convenience upon 120 days' written notice if there have been no commercial sales of such target or upon 12 months written notice after the first commercial sale of such target as long as such termination is after December 31, 2026.

Collaboration Agreements with GSK

2020 Collaboration Agreement with GSK

In June 2020, we entered into a definitive collaboration agreement with GSK (the 2020 GSK Agreement), pursuant to which we agreed to collaborate to research, develop and commercialize products for the prevention, treatment and prophylaxis of diseases caused by SARS-CoV-2, the virus that causes COVID-19, and potentially other coronaviruses. The collaboration initially focused on the development and commercialization of three types of collaboration products under three programs: (1) antibodies targeting SARS-CoV-2, and potentially other coronaviruses (the Antibody Program); (2) vaccines targeting SARS-CoV-2, and potentially other coronaviruses (the Vaccine Program); and (3) products based on genome-wide CRISPR screening of host targets expressed in connection with exposure to SARS-CoV-2, and potentially other coronaviruses (the Functional Genomics Program). The antibody under the Antibody Program is sotrovimab, developed and commercialized for the treatment and prophylaxis of COVID-19.

In connection with the 2020 GSK Agreement, we also entered into a stock purchase agreement in April 2020, pursuant to which we issued 6,626,027 shares of our common stock to Glaxo Group Limited, an affiliate of GSK (GGL), at a price per share of $37.73 and an aggregate purchase price of approximately $250.0 million.

In February 2023, we and GSK entered into two amendments to the 2020 GSK Agreement. Pursuant to the amendments, we and GSK agreed to remove the Vaccine Program from the 2020 GSK Agreement and to wind down and terminate the cost-sharing arrangements and all ongoing activities in relation to the Vaccine Program. As of the effective date of amendments, the Vaccine Program had not yet advanced to its predefined development candidate stage. We retained the right to progress development of vaccine products directed to SARS-CoV-2 and other coronaviruses independently (including with or for third parties) outside the scope of the 2020 GSK Agreement, subject to the payment of tiered royalties to GSK on net sales of any vaccine products covered by certain GSK intellectual property rights in the low single digits. In addition, we and GSK agreed to modify the Antibody Program to remove from the collaboration all coronavirus antibodies other than sotrovimab and VIR-7832, and certain variants thereof, which remained subject to the terms of the 2020 GSK Agreement. We retained the sole right to progress the development and commercialization of the terminated antibody products independently (including with or for third parties), subject to the payment of tiered royalties to GSK on net sales of such terminated antibody products at percentages ranging from the very low single digits to the mid-single digits, depending on the nature of the antibody product being commercialized.

Subject to an opt-out mechanism, the parties share all development costs, manufacturing costs, and costs and expenses for the commercialization of the collaboration products, with us bearing 72.5% of such costs for sotrovimab, except that GSK has the sole right to develop (including to seek, obtain or maintain regulatory approvals), manufacture and commercialize sotrovimab in and for mainland China, Hong Kong, Macau and Taiwan at GSK's sole cost and expense. 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.

The 2020 GSK Agreement will remain in effect with respect to sotrovimab for as long as it is being commercialized by the lead party. Either party has the right to terminate the 2020 GSK Agreement in the case of the insolvency of the other party, an uncured material breach of the other party with respect to a collaboration program or collaboration product, or as mutually agreed by the parties.

In May 2021, the FDA granted an EUA in the United States for sotrovimab, for the early treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and at high risk for progression to severe COVID-19, including hospitalization or death. In December 2021, the EC granted marketing authorization to Xevudy® (sotrovimab) in the EU for the treatment of adults and adolescents at increased risk of progressing to severe COVID-19. In April 2022, the FDA excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain variants, and in December 2024, the FDA revoked EUA granted to sotrovimab. Going forward, 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.

2021 Expanded GSK Collaboration

In 2021, we entered into the 2021 GSK Agreement under which the parties agreed to expand the 2020 GSK Agreement, to include collaboration on three separate programs: (1) a program to research, develop and commercialize mAbs for the prevention, treatment or prophylaxis of the influenza virus, excluding VIR-2482 unless GSK exercises its exclusive option (the VIR-2482 Option) to co-develop and commercialize after the Company completes a Phase 2 clinical trial (the Influenza Program); (2) an expansion of the parties' current Functional Genomics Program to focus on functional genomics screens directed to targets associated with respiratory viruses (the Expanded Functional Genomics Program); and (3) additional programs to develop neutralizing mAbs directed to up to three non-influenza target pathogens selected by GSK (the Selected Pathogens, and such programs the Additional Programs).

In connection with the 2021 GSK Agreement, we entered into a stock purchase agreement with GGL pursuant to which we issued 1,924,927 shares of our common stock to GGL for an aggregate purchase price of approximately $120.0 million.

On February 21, 2024, the Company and GSK entered into a letter agreement (the Letter Agreement) pursuant to which the Company and GSK agreed to remove the Influenza Program from the 2021 GSK Agreement and to wind down and terminate the cost-sharing arrangements and all ongoing activities in relation to the Influenza Program. As of the effective date of the Letter Agreement, GSK's VIR-2482 Option was terminated. The Company has no further obligations to GSK with respect to VIR-2482. In addition, as of the effective date of the Letter Agreement, GSK exercised its opt-out option with respect to VIR-2372 and VIR-2981. The Company had no further obligations to GSK with respect to VIR-2372 and VIR-2981. As a result of GSK's opt-out to VIR-2372 and VIR-2981, the Company may continue to pursue the development and commercialization of those programs unilaterally. If either of those programs is commercialized, the Company will pay GSK a royalty on net sales in the low single digits.

As it relates to the Expanded Functional Genomics Program, all remaining targets selected were mutually rejected in the first quarter of 2024, with remaining exclusivity to such targets expiring in mid-2025. No further research activity is expected by either party under the program.

Regarding the Additional Programs, GSK selected RSV as its first pathogen in 2022. During the first quarter of 2024, we recognized contract revenue of $51.7 million as GSK's rights to select the remaining up to two additional non-influenza target pathogens expired on March 25, 2024. We opted-out of the RSV program during the fourth quarter of 2024. As a result of our opt-out, GSK may continue to pursue the development and commercialization of the RSV program unilaterally. If the RSV program reaches commercialization, GSK will pay us a royalty on net sales in the low single digits.

Collaboration and License Agreement with Alnylam

In October 2017, we and Alnylam Pharmaceuticals (Alnylam) entered into a collaboration and license agreement (the Alnylam Agreement). Pursuant to the Alnylam Agreement, we obtained a worldwide, exclusive license to develop, manufacture and commercialize the siRNA product candidates directed to HBV, including elebsiran, for all uses and purposes including the treatment of HBV and HDV. In addition, Alnylam granted us an exclusive option, for each of the infectious disease siRNA programs directed to our four selected targets, to obtain a worldwide, exclusive license to develop, manufacture and commercialize siRNA products directed to the target of each such program for all uses and purposes other than certain excluded fields. Our options are each exercisable during a specified period following selection of candidates for each program, or two years following the initiation of certain activities under an agreed-upon development plan, if earlier. On a product-by-product basis for each siRNA product directed to HBV and, if we exercise our license option, the siRNA products directed to the up to four infectious disease targets, Alnylam has an exclusive option, exercisable during a specified period for each such product, to negotiate and enter into a profit-sharing agreement for such product.

We and Alnylam were jointly responsible for funding the initial research and development activities for elebsiran through completion of proof of concept trials. Prior to the exercise of our option for each siRNA program directed to one of our selected infectious disease targets, Alnylam is responsible for conducting all development activities, at our expense, in accordance with an agreed-upon development plan. Following our exercise of an option for a program and payment of the program option exercise fee and any outstanding program costs due to Alnylam, we are solely responsible, at our expense, for conducting all development, manufacture and commercialization activities for products arising from each such program unless Alnylam exercises its profit-sharing option. We are required to use commercially reasonable efforts to develop and commercialize one siRNA product directed to HBV, whether for the treatment of HBV or HDV, as well as one siRNA product directed to the target of each other infectious disease program for which we exercise our option, in the United States and certain specified major markets. If Alnylam exercises a profit-sharing option for a product, such as elebsiran, we will negotiate the terms of such profit-sharing agreement. We retain final decision-making authority with respect to which infectious disease product candidates we advance and the development programs for the HBV and HDV, as well as infectious disease product candidates, subject to certain limitations. During the term of the Alnylam Agreement, neither we nor Alnylam may develop or commercialize any gene-silencing, oligonucleotide-based product directed to the same target as any product candidate under the Alnylam Agreement, other than pursuant to the Alnylam Agreement, subject to certain exceptions.

Pursuant to the Alnylam Agreement, we paid Alnylam an upfront fee of $10.0 million and issued to Alnylam 1,111,111 shares of our common stock. Upon the achievement of a certain development milestone, as further discussed below, we were obligated to issue shares of our common stock equal to the lesser of (i) 1,111,111 shares or (ii) a certain number of shares based on our stock price at the time such milestone was achieved. We are required to pay Alnylam up to $190.0 million in the aggregate for the achievement of specified development and regulatory milestones for the first siRNA product directed to HBV, whether for the treatment of HBV or HDV, and up to $115.0 million for the achievement of specified development and regulatory milestones for the first product directed to the target of each infectious disease siRNA program for which we exercised our option. In March 2020, we achieved one of the specified development milestones relating to elebsiran pursuant to the Alnylam Agreement. As such, we paid Alnylam $15.0 million in April 2020, thereby reducing the $190.0 million referenced above to $175.0 million of potential development and regulatory milestones remaining to be paid related to elebsiran. Following commercialization, we 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 siRNA products directed to HBV, whether for the treatment of HBV or HDV related to elebsiran, and up to $100.0 million for the achievement of specified levels of net sales by products directed to the target of each infectious disease siRNA program for which we exercised our option. We 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, and tiered royalties at percentages ranging from the high single-digits to the sub-teen double-digits on annual net sales of licensed infectious disease products, in each case subject to specified reductions and offsets. The royalties are payable on a product-by-product and country-by-country basis until the later of the expiration of all valid claims of specified patents covering such product in such country and 10 years after the first commercial sale of such product in such country. Alnylam is also entitled to receive a portion of any consideration we receive as a result of granting a sublicense under the licenses granted to us by Alnylam under the Alnylam Agreement or an option to acquire such a sublicense, determined based on the timing of the grant of such sublicense. In November 2018, in connection with the inclusion of the HBV siRNA program as the subject of a potential grant of a sublicense to Brii Bio under the Brii Agreement, as defined below), which triggered certain payment obligations under the Alnylam Agreement, we entered into a letter agreement with Alnylam (the Alnylam Letter), making certain modifications to the payments due to Alnylam as a result of the grant of the option and potential payments that would result from Brii Bio's exercise of rights under such sublicense. As a result of the rights granted under the Brii Agreement and pursuant to the Alnylam Letter, in February 2020 we transferred to Alnylam a specified percentage of the equity consideration allocable to the HBV siRNA program that we received from Brii Bio and its affiliated companies in connection with the entry into the Brii Agreement.

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

Exclusive License Agreement with the Institute for Research in Biomedicine

Prior to our acquisition of Humabs BioMed SA (referred to herein as Humabs) in August 2017, the former parent company of Humabs (later consolidated into Humabs) entered into an exclusive license agreement in December 2011 with the Institute for Research in Biomedicine (IRB, and the agreement, the IRB Agreement). The IRB Agreement amended and restated an original 2004 exclusive license agreement between the parties in connection with IRB's proprietary technologies relating to human monoclonal antibodies and the discovery of unique epitopes recognized by such antibodies. In May 2008, Humabs entered into an exclusive license agreement with IRB (the Humabs IRB Agreement, and together with the IRB Agreement, the Current IRB License Agreements). Pursuant to the Humabs IRB Agreement, IRB granted to Humabs an exclusive license under certain intellectual property rights for the development of certain monoclonal antibodies. In February 2012, Humabs and IRB entered into a research agreement, or the IRB Research Agreement, to provide for a continuing research collaboration between Humabs and IRB, and to coordinate the exploitation of intellectual property rights arising from the IRB Research Agreement with the rights granted under the Current IRB License Agreements. Under the terms of the IRB Research Agreement, IRB performs certain research activities for Humabs, and all intellectual property rights arising under the IRB Research Agreement are either owned by Humabs, or included in and licensed to Humabs pursuant to the terms of the Current IRB License Agreements.

We use technology licensed under the Current IRB License Agreements in our antibody platform and in our product candidate tobevibart.

Pursuant to the Current IRB License Agreements, IRB granted to Humabs an exclusive, worldwide, royalty-bearing, sublicensable license under patent and know-how rights covering or associated with IRB's proprietary technology platform relating to antibody discovery, as well as rights in certain antibodies, including as a result of activities under the IRB Research Agreement, in each case for all purposes, including to practice the licensed technology platform, and to develop, manufacture and commercialize any drug, vaccine or diagnostic product containing such licensed antibodies.

Humabs is required to use commercially reasonable efforts to develop and commercialize licensed products, as well as maintain an active program to commercialize licensed products. Humabs is required to pay to IRB a flat royalty on net sales of licensed products approved for non-diagnostic use in the low single-digits, and a flat royalty on licensed products for diagnostic use at 50% of the non-diagnostic product rate, in each case subject to standard reductions and offsets. Humabs is also required to pay to IRB a specified percentage in the sub-teen double-digits of consideration received in connection with the grant of a sublicense to a non-affiliate third party, subject to a specified maximum dollar amount for the first up front or milestone payment received under such sublicense for each licensed product, and a lower specified maximum dollar amount for subsequent up front or milestone payments for such licensed product.

Each of the Current IRB License Agreements remains in force until the expiration of all valid claims of the licensed patent rights and trade secrets included in the licensed IRB know-how. Humabs may terminate the IRB Agreement at will on 90 days' written notice to IRB, and either party may terminate either of the Current IRB License Agreements on 60 days' written notice for the uncured material breach of the other party.

Exclusive License Agreement with The Rockefeller University

In July 2018, we entered into an exclusive license agreement with The Rockefeller University, or Rockefeller, which was amended in May 2019, in September 2020, and in March 2021, or the Rockefeller Agreement. Pursuant to the Rockefeller Agreement, Rockefeller granted us a worldwide exclusive license under certain patent rights, and a worldwide non-exclusive license under certain materials and know-how covering certain antibody variants relating to a specified mutation leading to enhanced antibody function and utility, to develop, manufacture and commercialize infectious disease products covered by the licensed patents, or that involve the use or incorporation of the licensed materials and know-how, in each case for all uses and purposes for infectious diseases. The licenses granted to us are freely sublicensable to third parties. Rockefeller retains the right to use the licensed patents outside the field of use, and within the field of use solely in connection with educational, research and non-commercial purposes, as well as for certain research being conducted in collaboration with us. We are obligated to grant sublicenses to third parties with respect to products that are not being pursued and are not of interest to us following a specified anniversary of the May 2019 amendment date. Pursuant to the Rockefeller Agreement, we are required to use commercially reasonable efforts to develop and commercialize infectious disease products as soon as reasonably practicable, including by achieving certain specified development milestone events within specified time periods for products arising from our HBV and influenza programs.

We use technology licensed under the Rockefeller Agreement in our antibody platform and in our product candidate tobevibart.

Under the agreement we are required to pay annual license maintenance fees of $1.0 million, which will be creditable against royalties following commercialization. In addition, for the future achievement of specified development, regulatory and commercial success milestone events, we will be required to pay up to $80.3 million, in the aggregate, for up to six infectious disease products. Any follow-on products beyond six products may result in additional milestone event payments. We will also be required to pay Rockefeller a tiered royalty at a low single-digit percentage rate on net sales of licensed products, subject to certain adjustments. Our obligation to pay royalties to Rockefeller will terminate, on a product-by-product and jurisdiction-by-jurisdiction basis, upon the latest of the expiration of the last valid claim of a licensed patent in such jurisdiction, the expiration of all regulatory exclusivity in such jurisdiction or 12 years following the first commercial sale of the applicable licensed product in such jurisdiction. If we grant a sublicense to a non-affiliate third party under the Rockefeller technology, we will be required to pay to Rockefeller a specified percentage of the consideration received from such sublicensee for the grant of the sublicense, depending on the date of receipt of the applicable sublicense income from such sublicensee.

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

Collaboration, Option and License Agreement with Brii Bio

In May 2018, we entered into a collaboration, option and license agreement with Brii Biosciences Limited (Brii Bio Parent) (formerly known as BiiG Therapeutics Limited), and Brii Bio (and such agreement, the Brii Agreement), pursuant to which we granted to Brii Bio, with respect to up to four of our programs, an exclusive option to obtain exclusive rights to develop and commercialize compounds and products arising from such programs in the China Territory (People's Republic of China, Taiwan, Hong Kong and Macau), for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection, or the Field of Use. Our elebsiran program being developed under the Amended Alnylam Agreement (described above) is included within the Brii Agreement as a program for which Brii Bio has exercised one of its options that is further discussed below. Brii Bio may exercise each of its options following the achievement by us of proof of concept for the first product in such program. In partial consideration for the options granted by us to Brii Bio, Brii Bio Parent and Brii Bio granted us, with respect to up to four of Brii Bio Parent's or Brii Bio's programs, an exclusive option to be granted exclusive rights to develop and commercialize compounds and products arising from such Brii Bio programs in the United States for the Field of Use. The number of options that we may exercise for a Brii Bio program is limited to the corresponding number of options that Brii Bio exercises for a VirBio program. All options granted to Brii Bio under the Brii Agreement that are not exercised will expire no later than seven years following the effective date. All options granted to us under the Brii Agreement that are not exercised will expire no later than two years following the expiration of all options granted to Brii Bio.

We are responsible, at our expense and discretion, for the conduct of all development activities under our programs prior to the exercise of Brii Bio's options, and Brii Bio is responsible, at its expense and discretion, for all activities under its programs prior to the exercise of our options. Following the exercise of an option for a specified program by either us or Brii Bio, the exercising party is granted an exclusive, royalty-bearing license to develop, manufacture and commercialize products arising from the applicable program in the United States (where we are exercising the option) or the China Territory (where Brii Bio is exercising the option), and such party is thereafter responsible for all development and commercialization activities, at its expense, in the optioned territory. If Brii Bio exercises its option with respect to our development program being conducted under the Amended Alnylam Agreement, Brii Bio's rights will be subject to the terms of such amended agreement.

Under the terms of the Brii Agreement, following our option exercise, we are obligated to use commercially reasonable efforts to develop at least one licensed product arising from each optioned Brii Bio program, and to commercialize each such product in the United States following regulatory approval, and following Brii Bio's option exercise, Brii Bio is obligated to use commercially reasonable efforts to develop at least one licensed product arising from each optioned VirBio program and to commercialize each such product in the China Territory following regulatory approval.

With respect to programs for which Brii Bio exercises its options, Brii Bio will be required to pay us an option exercise fee for each such VirBio program ranging from the mid-single-digit millions up to $20.0 million, determined based on the commercial potential of the licensed program. Brii Bio will also be required to pay regulatory milestone payments on a licensed product-by-licensed product basis ranging from the mid-single-digit millions up to $30.0 million, also determined based on the commercial potential of such program. Following commercialization, Brii Bio will be required to make sales milestone payments based on certain specified levels of aggregate annual net sales of products arising from each licensed program in the China Territory, up to an aggregate of $175.0 million per licensed program. Brii Bio also will pay us royalties that range from the mid-teens to the high-twenties. On June 12, 2020, Brii Bio notified us of the exercise of its option to obtain exclusive rights to develop and commercialize compounds and products arising from elebsiran in the China Territory. Brii Bio paid us a $20.0 million option exercise fee in connection with the option exercise. We separately paid $10.0 million, half of the option proceeds, to Alnylam in connection with the Amended Alnylam Agreement. In July 2022, Brii Bio notified us of the exercise of its option to obtain exclusive rights to develop and commercialize compounds and products arising from tobevibart in the China Territory. Brii Bio paid us a $20.0 million option exercise fee in connection with the option exercise.

As partial consideration for our entry into the Brii Agreement, upon closing of Brii Bio Parent's Series A preferred stock financing, we received Class A ordinary shares equal to 9.9% of the outstanding shares in Brii Bio Parent. As a result of Brii Bio's right to exercise one of its options for our HBV siRNA program, under the terms of the Amended Alnylam Agreement, in February 2020 we transferred to Alnylam a specified percentage of such equity consideration allocable to such program. In July 2021, Brii Bio Parent completed its initial public offering, or the Brii Bio Parent IPO, on the Stock Exchange of Hong Kong Limited. Upon completion of the Brii Bio Parent IPO, our Class A ordinary shares held at Brii Bio Parent converted into the same single class of ordinary shares issued in the Brii Bio Parent IPO.

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

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

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

Patent License Agreements with Xencor

In August 2019, we entered into a patent license agreement, which was amended in February 2021, or the 2019 Xencor Agreement, with Xencor, pursuant to which we obtained a non-exclusive, sublicensable (only to our affiliates and subcontractors) license to incorporate Xencor's licensed technologies into, and to evaluate, antibodies that target influenza A and HBV, and a worldwide, non-exclusive, sublicensable license to develop and commercialize products containing such antibodies incorporating such technologies for all uses, including the treatment, palliation, diagnosis and prevention of human or animal diseases, disorders or conditions. We are obligated to use commercially reasonable efforts to develop and commercialize an antibody product that incorporates Xencor's licensed technologies, for each of the influenza A and HBV research programs. These technologies are used in tobevibart, incorporating Xencor's Xtend.

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

In March 2020, we entered into a patent license agreement, which was amended in February 2021, or the 2020 Xencor Agreement, with Xencor pursuant to which we obtained a non-exclusive license to Xencor's licensed technologies into, and to evaluate, antibodies that target any component of a coronavirus, including SARS-CoV-2, SARS-CoV and MERS-CoV, and a worldwide, non-exclusive, sublicensable license to develop and commercialize products containing such antibodies incorporating such technologies for all uses, including the treatment, palliation, diagnosis and prevention of human or animal diseases, disorders or conditions. We are obligated to use commercially reasonable efforts to develop and commercialize an antibody product that incorporates Xencor's licensed technologies, for each of the coronavirus research programs. These technologies are used in sotrovimab, incorporating Xencor's Xtend technology. In consideration for the grant of the license, we are obligated to pay royalties based on net sales of licensed products at the mid-single-digits. The royalties are payable, on a product-by-product and country-by-country basis, until the later of the expiration of the last to expire valid claim in the licensed patents covering such product in such country or 12 years.

The 2019 Xencor Agreement and 2020 Xencor Agreement will remain in force, on a product-by-product and country-by-country basis, until the expiration of all royalty payment obligations under each of the respective agreements. We may terminate each agreement in its entirety, or on a target-by-target basis, for convenience upon 60 days' written notice. Either party may terminate each agreement for the other party's uncured material breach upon 60 days' written notice (or 30 days in the case of non-payment) or in the event of bankruptcy of the other party immediately upon written notice. Xencor may terminate each agreement immediately upon written notice if we challenge, or upon 30 days' written notice if any of our sublicensees challenge, the validity or enforceability of any patent licensed to us under each respective agreement.

Amended and Restated Letter Agreement with the Gates Foundation

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 $10.0 million of shares of our Series A-1 convertible preferred stock in December 2016, $10.0 million of shares of our Series B convertible preferred stock in January 2019 and $40.0 million of shares of our common stock in January 2022. We were obligated to use the proceeds of the Gates Foundation's December 2016 and January 2019 investments in furtherance of its charitable purposes to (i) conduct our programs to develop products to treat or prevent infectious disease caused by HIV and tuberculosis, or TB, respectively, with at least 50% of the funds to be used for such programs and (ii) develop our HCMV-based vaccine technology platform in a manner reasonably expected to result in the generation of products for the treatment or prevention of other specified infectious diseases, and we were obligated to use the proceeds of the Gates Foundation's January 2022 investment in furtherance of its charitable purposes to develop our vaccinal antibody program, in each case for use in specified developing countries. We agreed to use reasonable efforts to achieve specified research and development milestones with respect to our HIV program, TB program and vaccinal antibody program, and, if requested by the Gates Foundation. Additionally, we are bound by specified global access commitments including a commitment to provide any products developed using the proceeds of the Gates Foundation's investment at an affordable price to the people most in need within the specified developing countries, not to exceed a specified percentage over our fully burdened manufacturing and sales costs.

If we fail to comply with (i) our obligations to use the proceeds of the Gates Foundation's investment for the purposes described in the paragraph above and to not use such proceeds for specified prohibited uses, (ii) specified reporting requirements or (iii) specified applicable laws, or if we materially breach our specified global access commitments (any such failure or material breach, a Specified Default), we will be obligated to redeem or arrange for a third party to purchase all of our stock purchased by the 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, such redemption or sale, a Gates Foundation Redemption. Following a Gates Foundation Redemption, if a sale of the company or all of our material assets relating to the Gates Agreement occurs prior to the six month anniversary of the first redemption or sale of any stock in such Gates Foundation Redemption, then the Gates Foundation will receive compensation equal to the excess of what it would have received in such transaction if it still held the stock redeemed or sold at the time of such sale transaction over what it actually received in the Gates Foundation Redemption. Additionally, if a specified default occurs, if we are unable or unwilling to continue the HIV program, TB 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.

In the event that we sell, exclusively license or transfer to a third party all or substantially all of our assets, the technology platform, or products arising from programs that are funded using the proceeds of the Gates Foundation's investment, such third party is required to assume our specified global access commitments on terms that are reasonably acceptable to the Gates Foundation. Additionally, we will not grant to any third party any rights or enter into any agreement with any third party that would restrict the Gates Foundation's rights with respect to our specified global access commitments unless such third party expressly assumes such commitments to the reasonable satisfaction of the Gates Foundation.. The global access commitments will continue for as long as the Gates Foundation continues to be a charitable entity.

In connection with the purchase of $40.0 million of shares of our common stock in January 2022, we entered into a stock purchase agreement, or the Gates Stock Purchase Agreement, with the Gates Foundation. The Gates Foundation purchased the shares of our common stock at $45.38 price per share.

In relation to the agreements discussed above, we have entered into various grant agreements with the Gates Foundation, to support our HIV vaccine program, TB 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. The grant agreements may be terminated early by the Gates Foundation for our breach, failure to progress the applicable funded projects, in the event of our change of control, change in our tax status, or significant changes in our leadership that the Gates Foundation reasonably believes may threaten the success of the applicable project. As of December 31, 2024, the Company had deferred revenue of $11.1 million, related to the grants with the Gates Foundation and $11.6 million within accrued and other liabilities, which may need to be refunded to the Gates Foundation.

In August 2024, we announced a strategic realignment that included phasing out certain research programs which include programs associated with the grant agreements for the HCMV-based vaccine technology platform, which includes the HIV vaccine program and the TB vaccine program, but excludes the HIV vaccinal antibody program.

Biomedical Advanced Research and Development Authority

On September 28, 2022, VirBio entered into a multi-year agreement under Other Transaction Authority (OTA) with the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services' (HHS) Administration for Strategic Preparedness and Response, with the potential for up to $1.0 billion to advance the development of a full portfolio of innovative solutions to address influenza and potentially other infectious disease threats.

BARDA initially invested $55.0 million for the development of VIR-2482, an investigational prophylactic mAb designed to protect against seasonal and pandemic influenza, with the balance of the award subject to BARDA exercising up to 12 options in further support of the development of pre-exposure prophylactic antibodies including and beyond VIR-2482 for the prevention of influenza illness or possibly supporting medical countermeasures for other pathogens of pandemic potential. The BARDA agreement also outlines potential support for VirBio's clinical development of additional future pandemic influenza mAbs, as well as the potential development of up to 10 emerging infectious disease or Chemical, Biological, Radiological, and Nuclear medical countermeasure candidates.

On September 28, 2023, BARDA awarded VirBio approximately $50.1 million in new funding to advance the development of novel mAb candidates and delivery solutions to widen the applicability of mAbs in COVID-19 and in pandemic preparedness and response. The new funding will support research and development of novel alternative mAb delivery technologies that have the potential to revolutionize mAb delivery by increasing expression relative to existing technologies. Such delivery could widen the breadth of administration options and shorten development and manufacturing timelines.

This new investment falls under VirBio's existing OTA. The balance of the potential remaining funding is subject to BARDA exercising up to 12 options in further support of the development of pre-exposure prophylactic antibodies for the prevention of influenza illness or supporting medical countermeasures for other pathogens of pandemic potential. $40 million of the total funds is part of 'Project NextGen,' an initiative by the HHS to advance a pipeline of new, innovative vaccines and therapeutics for COVID-19 and will support the development of VIR-7229 through Phase 1 in the context of developing alternative mAb delivery technologies.

VirBio was also awarded approximately $11.0 million in additional BARDA funding that was applied to wind down activities for the BARDA-supported Phase 2 pre-exposure prophylaxis trial of VIR-2482.

In September 2024, we and BARDA entered into Amendment No. P00003 to the BARDA Agreement, pursuant to which the parties agree to partially de-obligate certain funds from two of the exercised options related to the development of VIR-7229. Under this Amendment the current BARDA commitment was decreased by $42.1 million.

On October 25, 2024, we notified BARDA of intent to terminate the OTA on December 31, 2024. All remaining funds were de-obligated upon the date of termination.

Sales and Marketing

Given our stage of development, we have not yet established a meaningful commercial (sales or marketing) organization, nor distribution capabilities. We intend to build a commercial infrastructure to support the sales and marketing of our product candidates. We expect to manage sales, marketing and distribution through internal resources and third-party relationships. While we may commit significant financial and management resources to commercial activities, we will also consider collaborating with one or more biopharmaceutical companies to enhance our commercial capabilities.

Manufacturing

We manufacture product candidates for three therapeutic modalities: mAbs, masked TCEs and siRNA. We have established our own internal process, analytical and pharmaceutical development, manufacturing, supply chain and quality organizations that work with our selected CDMOs, to develop, manufacture, test and supply our early- and late-stage product candidates developed with our proprietary and external technology platforms. Contract development and manufacturing of our antibody, TCE and siRNA product candidates is supported at our San Francisco, California, corporate headquarters for process, analytical and formulation development, small-scale non-GMP manufacturing for preclinical studies and selected quality control testing. Our headquarters also conducts cell line development for our antibody and TCE product candidates.

We have established relationships with multiple CDMOs and have produced material to support preclinical studies and Phase 1, Phase 2 and Phase 3 clinical trials. Material for any Phase 3 clinical trials and commercial supply will generally require large-volume, low-cost-of-goods production. However, there are no assurances that our manufacturing and supply chain infrastructure will remain uninterrupted and reliable, or that the third parties we rely on to manufacture our products will be able to satisfy demand in a timely manner or not have supply chain disruptions, stock-outs due to raw material shortages, extended lead times, and/or greater than anticipated demand or quality issues.

Manufacturing Technology Platforms

Antibody

We currently leverage the antibody process platforms and manufacturing facilities of our CDMOs and strategic collaborators for development, manufacturing and supply of our preclinical, clinical and future commercial mAb product candidates. These manufacturing platforms are based on mAb technology and industrial processes that have been optimized, standardized and well-established across the biopharmaceutical industry over the last 30 years to enable process portability between biomanufacturing facilities and manufacturing with high success rates at most biologic CDMOs, as well as the partnered use of excess capacity with other biopharmaceutical companies. In 2023, we completed the build-out of additional in-house capabilities in our San Francisco headquarters for mAb cell line development, Phase 1/2 process development, and small-scale drug substance and drug product manufacturing to produce non-GMP material for preclinical studies. Our new process development laboratory was successfully brought on line in 2024.

T-Cell Engager - PRO-XTEN™

We have also established process, analytical and formulation development capabilities for our *E. coli* -derived TCEs in our San Francisco facility. Similar to our antibody programs, we leverage on the *E.coli* process platforms and manufacturing facilities of our CDMOs and strategic collaborators for further development and optimization, manufacturing and supply of our preclinical, clinical and future *E.coli* TCE product candidates. The manufacturing processes for TCE drug substances (DS) and drug products (DP) have been developed by our scientists based on established *E. coli* manufacturing technology and pharmaceutical industrial processes that have been optimized, standardized and well-established across the biopharmaceutical industry for other biologics.

siRNA

VirBio licensed and conducted a technology transfer of the siRNA DS and DP process for Elebsiran. Similarly, we rely on the siRNA process platforms and manufacturing facilities of our CDMOs and strategic collaborators for further development, optimization, manufacturing and supply of our siRNA product candidate.

Manufacturing Agreements

In first quarter of 2024, we and a large CDMO entered into various scopes of work and continue to do so with the respect to process performance qualification (PPQ) for Tobevibart drug substance (the Tobevibart agreements). Under the terms of these agreements, the CDMO is obligated to reserve these manufacturing slots and will manufacture the agreed upon number of batches in accordance with an agreed upon manufacturing schedule to successfully complete PPQ. As of December 31, 2024, we had unaccrued unpaid commitments of approximately $23 million under the Tobevibart Agreements. Future commercial supply will be subject to finalizing a commercial supply agreement and relevant terms at the appropriate time.

In the third and fourth quarter of 2024, we entered into binding commitments with a large CDMO for process characterization and manufacture through completion of PPQ of Elebsiran DS (the Elebsiran agreements). Under the terms of these agreements, the CDMO is obligated to reserve these manufacturing slots and will manufacture the agreed upon number of batches in accordance with an agreed upon manufacturing schedule to successfully complete PPQ. As of December 31, 2024, we had unaccrued unpaid commitments of approximately $9 million under the Elebsiran Agreements. Future commercial supply will be subject to finalizing a commercial supply agreement and relevant terms at the appropriate time.

For TCEs, we have agreements with CDMOs to manufacture our drug substance and drug products for clinical trials on a yearly basis with no long-term commitments.

Competition

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our executive and scientific team, research, clinical capabilities, development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

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

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety, convenience, and cost/access.

HDV

There are currently no FDA-approved treatments for chronic HDV infection. Gilead's bulevirtide is approved for use by the EMA. We understand that Gilead received a Complete Response Letter (CRL) for bulevirtide from the FDA in October 2022 and has indicated that it remains in active discussions with the FDA to work toward FDA approval. Bulevirtide has not been shown to lead to HDV clearance, and requires daily injections to maintain viral suppression. There are a few small pharmaceutical companies developing programs with various mechanisms of actions, including Bluejay Therapeutics, Huahui Health, and Assembly Biosciences (in partnership with Gilead).

HBV

Current FDA-approved treatments for chronic HBV infection are primarily oral antiviral agents such as NRTIs, marketed by Gilead and Bristol-Myers Squibb Company. These treatments do not lead to either a functional or a complete cure in the vast majority of patients, and in the case of NRTIs, require life-long therapy. Several large and small pharmaceutical companies are developing programs with various mechanisms of action, to be used alone or in combination, with the goal of achieving an HBV functional cure or complete cure. GSK is currently developing their lead asset, bepirovirsen, in a Phase 3 program. Companies with RNAi agents in clinical development include GSK, and Arbutus Biopharma. In addition, several companies are developing antibodies against surface antigen including Bluejay Therapeutics & Huahui Health. Several companies, including Gilead, Brii, and Virion have therapeutic vaccines in early clinical development.

HER2-associated Breast Cancer and Colorectal Cancer

There are several HER2 therapies currently approved and in development for HER2 associated cancers. For HER2 positive breast cancer, there are a number of approved drugs including antibody drug conjugates (ADCs) (e.g. ENHERTU from AstraZeneca and KADCYLA from Roche); monoclonal antibodies (e.g. HERCEPTIN & PERJETA from ROCHE); and inhibitors (e.g. Pfizer's TUKYSA). Roche recently discontinued their non-masked HER2 TCE, and we are unaware of other compounds currently in clinical development. While there are fewer HER2 therapies approved for HER2 positive CRC (ENHERTU from AstraZeneca and TUKYSA from Pfizer), the overall CRC space is highly competitive with standard of care agents (e.g. Roche's AVASTIN and Lilly's ERBITUX) as well as pipeline agents across a number of modalities.

Prostate Cancer

While there are many currently approved options in mCRPC, there are limited options available to patients in later lines that have additional therapeutic benefits with manageable safety profiles as patients relapse. There are several companies with ongoing efforts in development of later lines that are PSMA-targeting clinical-stage therapeutics. These include, but are not limited to: TCEs (e.g. Amgen's xaluritamig and Janux's JANX007); radioligand therapies (e.g. Novartis' PLUVICTO) and ADCs (e.g. Johnson & Johnson's ARX517). Competition can also vary by line of therapy for metastatic disease, and many pipeline agents are also being evaluate with standard of care regimens such as anti-androgens (e.g. Pfizer's XTANDI).

Intellectual Property

Our intellectual property is critical to our business and we strive to protect it, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, new therapeutic approaches and potential indications, and other inventions that are important to our business. Our policy is to seek to protect our proprietary and intellectual property position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important for the development and implementation of our business. We also rely on the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, we rely on confidentiality agreements to protect our interests. We require our employees, consultants and advisors to enter into confidentiality agreements prohibiting the disclosure of confidential information and requiring disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Our patent portfolio includes patents and patent applications that are licensed from a number of collaborators and other third parties, including Sanofi, Alnylam, the Institute for Research in Biomedicine, or IRB, Rockefeller and Xencor, and patents and patent applications that are owned by us. Our patent portfolio includes patents and patent applications that cover our product candidates sotrovimab, elebsiran, tobevibart, VIR-5818, VIR-5500, and VIR-5525, and the use of these candidates for therapeutic purposes. Our proprietary technology has been developed primarily through acquisitions, relationships with academic research centers and contract research organizations (CROs).

For our product candidates, we will, in general, initially pursue patent protection covering compositions of matter and methods of use. Throughout the development of our product candidates, we seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through additional methods of use, process of making, formulation and dosing regimen-related claims.

In total, our patent portfolio, including patents licensed from our collaborators and other third parties, comprises over 100 different patent families as of December 31, 2024, filed in various jurisdictions worldwide. Our patent portfolio includes over 1700 active cases with over 850 issued patents in the United States and abroad. Our patent portfolio for our product candidates and technology platforms is outlined below.

Patents and Proprietary Rights

U.S. and European Patent Expiration

We have a number of U.S. and foreign patents, patent applications and rights to patents related to our molecules, products and technology, but we cannot be certain that issued patents will be enforceable or provide adequate protection or that pending patent applications will result in issued patents.

The following table shows the estimated expiration dates (including patent term extensions, supplementary protection certificates and/or pediatric exclusivity where granted) in the United States and the European Union for the primary patents for our key product candidates as described above. Dates in parentheses reflect the estimated expiration date of patents which may issue from currently pending applications. The estimated expiration dates do not include any potential additional exclusivity (e.g., patent term extension, supplementary protection certificates or pediatric exclusivity) that has not yet been granted.

Key Product Candidates	Patent Expiration	
	U.S.	**E.U.**
HBV/HDV		
elebsiran (VIR-2218)	2035	2035
tobevibart (VIR-3434)	2036	2036
ONCOLOGY		
VIR-5818	2041	(2041)
VIR-5525	(2044)	(2044)
VIR-5500	(2044)	(2044)

Patent Portfolio by Technology Platform

Antibody Platform

Licensed Patents

We have exclusively licensed a patent family from Rockefeller. The 20-year term of any patents issuing from the application in this family is presently estimated to expire in 2038, absent any available patent term adjustments or extensions.

We have exclusively licensed from IRB two patent families that relate to our antibody platform technology. The 20-year term of the first of these families expired in 2024. The US patent in this family is, however, still in force as its term was extend until 2027 due to patent office delay. The 20-year term of the issued patents and any patent issuing from the pending patent applications in the second patent family is estimated to expire in 2038, absent any available patent term adjustments or extensions.

In addition, we have non-exclusively licensed a group of patents and applications from Xencor. The 20-year term of these patents and applications if granted is presently estimated to expire between 2024 and 2028, absent any available patent term adjustments or extensions.

Patents Owned by Us

We also own, with our subsidiary Humabs, one patent family that includes, as of December 31, 2024, 34 pending applications in both the US and abroad. These applications include composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims. The 20-year term of any patents issuing from patent applications in this family is presently estimated to expire in 2042, absent any available patent term adjustments or extensions.

PRO-XTEN™ Platform

Licensed Patents

We have exclusively licensed from Sanofi 13 different patent families related to our PRO-XTEN™ portfolio.

The 20-year term of the issued patents in these families is presently estimated to expire between 2036 and 2041, absent any available patent term adjustments or extensions.

Patent Term and Term Extensions

Individual patents have terms for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In addition, in certain instances, the term of a U.S. patent can be extended to recapture a portion of the delay from the U.S. Patent and Trademark Office (USPTO) in issuing the patent, as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the restoration period cannot extend the patent term beyond 14 years from FDA approval. In addition, only one patent applicable to an approved drug is eligible for the extension, and only those claims covering the approved drug, a method for using it, or a method of manufacturing may be extended. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. All taxes, annuities or maintenance fees for a patent, as required by the USPTO and various foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product by product basis, from country to country, and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions and the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Patent Protection and Certain Challenges

Patents and other proprietary rights are very important to our business. If we have a properly drafted and enforceable patent, it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, we actively seek patent protection both in the United States and internationally and file additional patent applications, when appropriate, to cover improvements in our molecules, products and technology.

Patents covering certain of our products are held by third parties. We acquired exclusive rights to these patents in the agreements we have with these parties.

We may obtain patents for certain products many years before marketing approval is obtained. Because patents have a limited life that may begin to run prior to the commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to apply for patent term extensions or supplementary protection certificates in some countries. For example, extensions for the patents or supplementary protection certificates on many of our products have been granted in the United States and in a number of European countries, compensating in part for delays in obtaining marketing approval. Similar patent term extensions may be available for other products we are developing, but we cannot be certain we will obtain them in some countries.

It is also important that we do not infringe the valid patents of third parties. If we infringe the valid patents of third parties, our reputation may be harmed and we may be required to pay significant monetary damages, we may be prevented from commercializing products or we may be required to obtain licenses from these third parties. We may not be able to obtain alternative technologies or any required license on reasonable terms or at all. If we fail to obtain these licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products.

Because patent applications are confidential for a period of time until a patent is issued, we may not know if our competitors have filed patent applications for technology covered by our pending applications or if we were the first to invent or first to file an application directed toward the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and proprietary rights that block or compete with our products. In addition, if competitors file patent applications covering our technology, we may have to participate in litigation, post-grant proceedings before the USPTO or other proceedings to determine the right to a patent or validity of any patent granted.

Future litigation or other proceedings regarding the enforcement or validity of our existing patents or any future patents could result in the invalidation of our patents or substantially reduce their protection.

Our pending patent applications and the patent applications filed by our collaborative partners may not result in the issuance of any patents or may result in patents that do not provide adequate protection. As a result, we may not be able to prevent third parties from developing compounds or products that are closely related to those which we have developed or are developing. In addition, certain countries do not provide effective enforcement of our patents, and third-party manufacturers may be able to sell generic versions of our products in those countries. For more information, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Trademarks and Know-How

In connection with the ongoing development and advancement of our products and services in the United States and various international jurisdictions, we seek to create protection for our marks and enhance their value by pursuing trademarks and service marks where available and when appropriate. In addition to patent and trademark protection, we rely upon know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, by using confidentiality agreements with our commercial partners, collaborators, employees and consultants, and invention assignment agreements with our employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed by our employees and through relationships with third parties. For more information, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and biologics such as those we are developing.

In the United States, the FDA approves and regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA). Biological products, or biologics, are licensed for marketing under the Public Health Service Act (PHSA) and regulated under the FDCA. A company, institution or organization which takes responsibility for the initiation and management of a clinical development program for such products is typically referred to as a sponsor. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or trials or seek approval or licensure of our product candidates.

U.S. Biopharmaceuticals Regulation

The process required by the FDA before drug and biologic product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and animal trials performed in accordance with applicable regulations, including the FDA's Good Laboratory Practice (GLP), regulations;
- design of a clinical protocol and submission to the FDA of an IND application which must become effective before clinical trials may begin;
- approval by an independent institutional review board or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials in accordance with FDA's Good Clinical Practice (GCP) regulations to establish the safety and efficacy of a drug candidate, and compliance with GMP to establish safety, purity and potency of a proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a new drug application (NDA) or biologics licensing application (BLA), as applicable, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with GMP and of selected clinical investigation sites to assess compliance with GCP;
- FDA review and approval of an NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States; and
- completion of any post-approval requirements, including the potential requirement to implement a risk evaluation and mitigation strategy, or REMS, and any post-approval studies required by the FDA.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Furthermore, an independent institutional review board for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the trial until completed.

Regulatory authorities, the institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial.

For purposes of biopharmaceutical development, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The investigational product is initially introduced into patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- *Phase 2.* The investigational product is administered to a limited patient population to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- *Phase 3.* The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 trials may be made a condition to approval of the application. Concurrent with clinical trials, companies must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements.

Under the PHSA, sponsors of clinical trials are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the NIH. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial.

NDA/BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical trials and clinical trials are submitted to the FDA as part of an NDA or BLA, as applicable, requesting approval to market the product for one or more indications.

Once an NDA or BLA has been accepted for filing, the FDA's goal is to review standard applications within 10 months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine whether a drug is safe and effective for its intended use and a BLA to determine whether a biologic is safe, pure and potent. The FDA also reviews whether the facility in which the product is manufactured, processed, packed or held meets standards designed to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may convene an advisory committee to provide clinical insight on application review questions.

Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

After the FDA evaluates an application and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be manufactured, the FDA may issue an approval letter or a CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the application, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the application with a risk evaluation and management strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS could include medication guides, physician communication plans, or other elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing trials.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The Fast Track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a Fast Track product has opportunities for frequent interactions with the review team during product development and, once an NDA or BLA is submitted, the product may be eligible for priority review. A Fast Track product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a product with a Fast Track designation and/or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as Priority Review and Accelerated Approval. A product is eligible for Priority Review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. Priority Review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date.

Fast Track designation, Breakthrough Therapy designation and Priority Review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, manufacturing and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications, manufacturing methods or amended labeling claims, are subject to prior FDA review and approval.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market trials or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biopharmaceutical products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling.

The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Regulatory Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has since approved a number of biosimilars products.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical trials, animal trials and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

Generic Drugs and Regulatory Exclusivity

Section 505 of the FDCA provides a pathway for generic manufacturers to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application (ANDA). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. The generic version must deliver the same amount of active ingredient(s) in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

Upon submission of an ANDA, an applicant must certify to the FDA that: (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA cannot be approved until all listed patents have expired, except where the ANDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification.

The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earliest of 30 months after the receipt of the Paragraph IV notice, expiration of the patent and a decision in the infringement case that is favorable to the ANDA applicant. If the applicant does not challenge the listed patents, or indicates that it is not seeking approval of a patented method of use, the ANDA will not be approved until all of the listed patents claiming the referenced product have expired.

The FDA also cannot approve an ANDA until all applicable non-patent exclusivities listed in the Orange Book for the branded reference drug have expired. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval.

Pediatric Exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity in the United States that provides for an additional six months of exclusivity under certain conditions. The conditions for pediatric exclusivity include the FDA's determination that the use of a new product in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric clinical trials, and the sponsor agreeing to perform, and reporting on, the requested clinical trials within the statutory timeframe. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, additional protection is granted.

Patent Term Restoration and Extension

In the United States, a patent claiming a new product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. The restoration period for a patent covering a product is typically one-half the time between the effective date of the IND involving human beings and the submission date of the NDA or BLA, plus the time between the submission date of the application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension.

Federal and State Fraud and Abuse, and Transparency Laws and Regulations

In addition to strict FDA regulation of marketing of biopharmaceutical products, federal and state healthcare laws strictly regulate business practices in the biopharmaceutical industry. These laws may impact, among other things, our current and future business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we market, sell and distribute our products for which we obtain marketing approval. These laws include anti-kickback and false claims laws and regulations, and transparency laws and regulations, including, without limitation, those laws described below.

The U.S. federal Anti-Kickback Statute prohibits any person or entity from, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The U.S. federal Anti-Kickback Statute has been interpreted to apply to, among others, arrangements between biopharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common arrangements and other activities from prosecution, the exceptions and safe harbors are drawn narrowly. Courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, which can be enforced by individuals through civil whistleblower and qui tam actions, and civil monetary penalties laws, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. A number of biopharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing payments or other items of value to customers with the expectation that the customers would bill federal programs for their products or services. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. As of January 2022, applicable manufacturers are also required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year. We may also be subject to similar state laws.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant criminal, civil and administrative penalties including damages, fines, imprisonment, disgorgement, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations.

Coverage and Reimbursement

The future commercial success of our product candidates, if approved, will depend in part on the extent to which third-party payors, such as governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors, provide coverage of and establish adequate reimbursement levels for our product candidates. Third-party payors decide which therapies they will pay for and establish reimbursement levels. In particular, in the United States, no uniform policy for coverage and reimbursement exists. Private health insurers and other third-party payors often provide coverage and reimbursement for products based on the level at which the government, through the Medicare program, provides coverage and reimbursement for such products, but also on their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement can differ significantly from payor to payor.

In the United States, the EU and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of products, particularly for new and innovative products, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage. These pressures can arise from rules and practices of managed care groups, judicial decisions and laws and regulations related to Medicare, Medicaid and healthcare reform, biopharmaceutical coverage and reimbursement policies and pricing in general.

Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Similarly, 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 are increasingly challenging the price and examining the medical necessity and cost-effectiveness of products, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic trials in order to demonstrate the medical necessity and cost-effectiveness of our product candidates. Adequate third-party payor reimbursement may not be available to enable us to realize an appropriate return on our investment in product development.

Healthcare Reform

The United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, if approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the biopharmaceutical industry has been a particular focus of these efforts, which include major legislative initiatives to reduce the cost of care through changes in the healthcare system, including limits on the pricing, coverage, and reimbursement of biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing. 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.

Pharmaceutical Prices

In August 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA: requires manufacturers of certain drugs to engage in price negotiations with Medicare (to go into effect in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (to go into effect in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

These provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter, beginning in 2025, at $2,000 a year. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

While it is currently unclear 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.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control biopharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, and wholesale distributors, to disclose information about pricing of pharmaceuticals. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These measures could reduce future demand for our products or put pressure on our pricing.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our product candidates. For example, in the EU, we must obtain authorization of a clinical trial application in each member state in which we intend to conduct a clinical trial. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Similar to the United States, other countries offer pathways for expedited review, such as the EMA's PRIME designation, which is granted to investigational medicines that target conditions with unmet medical needs for which no treatment option exists, or where they can offer a major therapeutic advantage over existing treatments. Orphan drug designation is also available in the EU for medicines intended to treat rare, life-threatening or chronically debilitating conditions where no other satisfactory treatment option is available, or where the medicine can be of significant benefit to those affected by a specific condition, and the benefits include access to specific scientific advice, fee reductions and 10 years of market exclusivity once the medicine is approved.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. The EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

Privacy Laws

We, and our service providers, receive, process, store and use personal information and other data about our clinical trial participants, employees, collaborators and others. Thus we are subject to local, state, federal and international privacy and data protection laws and regulations, which among other things, impose certain requirements related 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, subject to differing applications and interpretations, and in some cases inconsistencies or conflicts with other rules.

At the federal level, HIPAA, imposes specific requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Penalties for failure to comply with these requirements vary significantly, and include significant civil monetary penalties and, in certain circumstances, criminal penalties and/or imprisonment.

Various states, such as California, Colorado, Oregon, Texas, Utah and Virginia, among others, have adopted privacy laws, including laws and regulations similar to HIPAA, that impose restrictive requirements regulating the use and disclosure of health information and other types of personal information. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused.

Regulation of privacy, data protection and data security has also become more stringent in foreign jurisdictions. For example, the EU General Data Protection Regulation 2016/679 (GDPR) imposes onerous and comprehensive privacy, data protection,and data security obligations onto data controllers and processors, including, as applicable, contractual privacy, data protection and data security commitments, expanded disclosures to data subjects about how their personal information is used, honoring individuals' data protection rights, limitations on retention of personal information, additional requirements pertaining to sensitive information (such as health data) and pseudonymized (i.e., key-coded) data, data breach notification requirements, and higher standards for obtaining consent from data subjects. Penalties for non-compliance with the GDPR can be significant. Furthermore, European privacy, data protection, and data security laws, including the GDPR and the EU's Standard Contractual Clauses adopted in 2021, generally restrict the transfer of personal information to other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. Approximately 50 countries worldwide have modeled their data privacy regulations after the GDPR or adopted similar laws, and other countries outside of Europe have enacted or are considering enacting cross-border data transfer restrictions and laws requiring local data residency. There is uncertainty as to how to implement such safeguards and how to conduct such transfers in compliance with the GDPR or similar laws, and certain safeguards may not be available or applicable with respect to some or all the personal information processing activities necessary to research, develop and market our products and services. Assisting parties with whom we exchange personal data in complying with these laws and regulations, or complying with these laws and regulations ourselves, may cause us to incur substantial operational costs or require us to change our business practices.

We may rely on others, such as health care providers, to obtain valid and appropriate consents from data subjects whose data we process. The failure of third parties to obtain consents that are valid under applicable law could result in our own non-compliance with privacy laws. Such failure would expose us to risk of enforcement actions from data protection authorities in the United States, EU and elsewhere, with the potential for significant financial penalties and/or orders requiring us to change our practices if we are found to be non-compliant, as well as private lawsuits or adverse publicity, all of which could negatively affect our operating results and business.

Human Capital Management

Employees

Our inclusive, patient-centric culture is critical to delivering on our mission to transform patients' lives. Our human capital programs are aimed at fostering engagement, innovation and community.

As of December 31, 2024, we had 408 employees, 312 of whom were primarily engaged in research and development activities. Our employees who work full-time in the office are predominantly located in San Francisco, California and Bellinzona, Switzerland, and employees not within commuting distance of our office locations work remotely. None of our employees are represented by a labor union and we consider our employee relations to be good.

The principal purpose of our annual incentive plan is to attract, retain, and motivate our employees through cash bonuses based on the achievement of the most significant drivers of our near-term goals. The principal purpose of our equity incentive plan is to encourage long-term, sustainable performance and ongoing retention of our employees, non-employee directors, and consultants with stock-based compensation as well as to align their interests with those of our stockholders.

In addition to highly competitive base compensation, cash bonuses granted pursuant to our annual incentive plan and stock-based awards granted pursuant to our equity incentive plan, we offer numerous benefits to employees on a country-by-country basis, including a 401(k) plan with matching, health (medical, dental and vision) insurance, life insurance, paid time off, paid parental leave and short-term and long-term disability. To drive further engagement and individual ownership of the Company, we also maintain an employee stock purchase plan, which provides eligible employees an opportunity to purchase additional Company stock at a discounted price.

Equity, Inclusion and Development

We take a proactive approach to promoting equity and inclusion. In addition to being an equal opportunity employer, we proactively use a specialized software tool to reduce bias in our job postings to ensure that we utilize inclusive language to reach the broadest range of applicants. We support formalized employee resource groups and initiatives such as heritage and inclusivity focused events, open forum discussions, ongoing mentoring, and networking for our employees. To ensure pay equity at all levels, we use a leading independent third party pay equity firm to perform an annual independent audit of our pay practices.

We offer ongoing, targeted inclusive developmental training for employees and leaders. We cultivate an environment where all employees can develop personally and professionally. Within this, we focus on individual opportunities for growth, developing people managers' skills and cultivating our leaders' capabilities to align the organization in service of our mission.

Additionally**,** we value the diversity of our leaders, with women and minorities comprising 36% and 60% of our board of directors and executive management team, respectively, as of December 31, 2024.

Our Corporate Information

We were incorporated under the laws of the State of Delaware on April 7, 2016. Our principal executive offices are located at 1800 Owens Street, Suite 900, San Francisco, California 94158, and our telephone number is (415) 906-4324. Our corporate website address is www.vir.bio. Information contained on, or accessible through, our website shall not be deemed incorporated into and is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this report is an inactive textual reference only. We make available free of charge through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. We may use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the SEC. These disclosures will be included on our website under the "Investors" section.

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 Annual Report on Form 10-K, including our audited 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 Annual Report on Form 10-K 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.
- 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 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 loss of $522.0 million and $615.1 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $759.8 million.

We expect to continue to incur significant expenses and will continue to incur 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. 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 BLA-approved, commercial-scale product or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives, including with respect to our technology platforms and product candidates.

We may require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our research and development programs or other operations.

As of December 31, 2024, we had cash, cash equivalents and investments of $1.1 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 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 or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain applicable regulatory approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical studies of FDA-regulated products. Specifically, as further detailed in FDA's Draft Guidance entitled, "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies" issued in June 2024, actions plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. The Trump Administration's January 2025 Executive Order pausing certain diversity, equity and inclusion efforts has left uncertain how, whether or when the statute's requirements will become operative. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical studies, our development plans may be impacted.

Furthermore, even if we obtain regulatory approval for our product candidates, we may still need to develop a commercial organization, establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors, including government health administration authorities. As a company, we have no prior experience in these areas. If we are unable to successfully commercialize our product candidates or if there is an insufficient demand for our product candidates, we may not be able to generate sufficient revenue to continue our business.

The development of additional product candidates is risky and uncertain, and we can provide no assurances that we will be able to 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 31, 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 in 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 this Annual Report on Form 10-K.

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 SAEs 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 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" of this Annual Report on Form 10-K.

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" of this Annual Report on Form 10-K.

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 BPCIA creates an abbreviated pathway for the approval of biosimilar and interchangeable biologic products following the approval of an original BLA. 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" of this Annual Report on Form 10-K.

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 this Annual Report on Form 10-K. 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, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future product candidates or additional pricing pressures.

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 this Annual Report on Form 10-K.

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: mAbs, siRNAs and TCEs. Except for limited early-clinical phase process, analytical and formulation development, cell line development, small-scale non-GMP manufacturing for preclinical studies, and quality control testing capabilities in certain of our facilities that is either established or is currently being built, we do not own or operate facilities for full process development or product manufacturing, storage and distribution, or testing. We are dependent on third parties, including strategic collaborators and CDMOs, to develop the large-scale manufacturing process and manufacture the clinical supplies of our current and any future product candidates. We have established relationships with multiple third parties that have developed the large-scale manufacturing processes and produced material to support our preclinical, Phase 1, 2, and 3 clinical studies. We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our future product candidates. Certain of our product candidates may have to compete with existing and future products 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 manufacturing process 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 no 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 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;
- 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 CDMOs as a result of consolidation in the contract manufacturing industry;
- breach, termination or nonrenewal of development and manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for product raw materials or components;
- lack of qualified backup suppliers for those raw materials or components that are currently purchased from a sole or single-source supplier;
- lack of ownership to the intellectual property rights to any improvements made by our third parties in the manufacturing process for our product candidates;
- price increases or decreased availability of product raw materials or components;
- disruptions to operations of our third-party suppliers and 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 a series of tariffs on certain products manufactured outside the United States, 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 and clinical manufacturing 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 GLP and 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 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.

We entered into the Gates Agreement in January 2022, which amends and restates the original letter agreement with the Gates Foundation that we entered into in December 2016. In connection with the original letter agreement, the Gates Foundation purchased $20.0 million of shares of our convertible preferred stock which converted to shares of our common stock after our initial public offering and purchased $40.0 million of shares of our common stock. We are obligated to use the proceeds of the 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 this Annual Report on Form 10-K.

If we fail to comply with (i) our obligations to use the proceeds of the Gates Foundation's investment for the purposes described in the paragraph above and to not use such proceeds for specified prohibited uses, (ii) specified reporting requirements or (iii) specified applicable laws, or if we materially breach our specified global access commitments (any such failure or material breach, a specified default), we will be obligated to redeem or arrange for a third party to purchase all of our stock purchased by the Gates Foundation under the Gates Agreement, at the Gates Foundation's request, at a price equal to the greater of (1) the original purchase price or (2) the fair market value, which amount may increase in the event of a sale of our company or all of our material assets relating to the Gates Agreement. Additionally, if a specified default occurs or if we are unable or unwilling to continue the HIV program, tuberculosis program, vaccinal antibody program or, if applicable, the mutually agreed additional program (except for scientific or technical reasons), or if we institute bankruptcy or insolvency proceedings, then the 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 Annual Report on Form 10-K.

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 U.S. Securities and Exchange Commission 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, Colorado, Oregon, Texas, Utah and Virginia, among others, 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, 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 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.

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 VirBio 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 lor 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 $450.2 million for state tax purposes. If not utilized, federal carryforwards will begin expiring in 2036 and state carryforwards will begin expiring in 2031. Our ability to use our federal and state NOLs to offset potential future taxable income is dependent upon our generation of future taxable income before any expiration dates of the NOLs, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs.

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

Risks Related to Ownership of Our Common Stock

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

We expect our financial condition and results of operations to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. Factors that may cause fluctuations in our financial condition and results of operations include, without limitation, those listed elsewhere in this "Risk Factors" section.

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 II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk" in this Annual Report on Form 10-K.

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 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Our Board of Directors (the "Board") and management recognize the importance of maintaining the trust and confidence of our patients, investors, business partners and employees. The Board and our Audit Committee are actively involved in oversight of our cybersecurity program as part of our approach to risk management. Our cybersecurity policies, processes and practices are integrated into our operations and are based on recognized standards such as the National Institute of Standards and Technology Cybersecurity Framework. In general, we seek to address cybersecurity risks through a comprehensive, coordinated approach that is focused on preserving the confidentiality, security, and availability of the information that we create through our business operations by identifying, preventing, and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Risk Management and Strategy

As one of the important elements that comprise and has been integrated into our overall enterprise risk management approach, our cybersecurity program includes the following:

Governance: As discussed in more detail below under the heading "Governance," our Board's oversight of cybersecurity risk management is supported by the Audit Committee of the Board, which regularly reviews operational risks. Our Senior Director, IT Application & Compliance and Interim Head of Information Technology ("HIT"), together with our Head of Information Security ("HIS"), and other members of our management team meet regularly to review current cybersecurity risks. The HIT and management team representatives also meet with the Audit Committee at least on a quarterly basis to discuss and review our cybersecurity program and risk landscape.

Collaborative Approach: We have implemented a cross-functional approach involving all employees to help in identifying, preventing, and mitigating cybersecurity threats and incidents. We have implemented processes that provide for the prompt escalation of known cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by our management team, together with the Audit Committee, in a timely manner.

Technical Safeguards: We deploy technical safeguards designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, and access controls. We also employ multi-factor authentication and a managed endpoint detection and response solution for malware. These measures are evaluated and improved through vulnerability assessments and penetration testing completed by third party experts, as well as cybersecurity threat intelligence.

Incident Response and Recovery: We have established and maintain an incident response plan that addresses our response to a cybersecurity incident. This plan is evaluated regularly.

Third-Party Risk Management: We maintain a risk-based approach to identifying and overseeing cybersecurity risks presented by third parties, including vendors, service providers and third-party systems.

Education and Awareness: We provide regular training on cybersecurity threats to equip our personnel with effective tools to address them and to communicate our latest information security policies, processes and practices.

We periodically evaluate and test our policies, standards, processes, and practices to address cybersecurity threats and incidents. These efforts include a wide range of activities, including third party assessments, vulnerability testing, and other exercises focused on evaluating the effectiveness of our cybersecurity measures. The results of such assessments and reviews are reported to our management team, the Audit Committee and the Board, and we adjust our cybersecurity program as necessary based on the information provided by these assessments and reviews.

Governance

Our Board, in coordination with the Audit Committee, oversees our risk management approach, including the management of risks arising from cybersecurity threats. The Board and the Audit Committee each receive regular presentations and reports on cybersecurity risks, which address a wide range of topics including recent developments, evolving standards, vulnerability assessments, third-party and independent expert reviews, the threat environment, technological trends, and any material risks identified with our third parties. The Audit Committee also receives prompt and timely information regarding any significant cybersecurity incidents, as well as ongoing updates regarding any such incidents until they have been remediated. Our HIT, Audit Committee and Board review and discuss our approach to cybersecurity risk on an annual basis.

The HIT and HIS, in coordination with our management team, which includes our Chief Executive Officer ("CEO"), Chief Financial Officer ("CFO") and General Counsel, work collaboratively to implement a program designed to protect our information systems from cybersecurity threats and to promptly respond to any cybersecurity incidents in accordance with our incident response plan. Through an ongoing process, the HIS monitors the prevention, detection, mitigation, and remediation of cybersecurity threats and incidents in real time, and reports such threats and incidents to the HIT, management team, and when appropriate, the Audit Committee.

Selected Management and Director Qualifications

The HIS and HIT have both served in various roles in information technology and information security for many years, including serving in similar roles at other publicly traded companies. The HIS holds several industry accreditations, including being a certified Chief Information Security Officer, and has worked in the information technology field for over 25 years, specializing in Information Security for the last 15 years. The HIT has an undergraduate degree in computer science and business administration and has worked in healthcare information technology for over 20 years. Our CEO, CFO and General Counsel each hold undergraduate and graduate degrees in their respective fields, and each have over 20 years of experience managing risks at VirBio and at similarly situated companies, including risks arising from cybersecurity threats. For example, our CFO has been responsible for leading and managing Information Technology departments at two separate publicly traded companies, including our Company, and has leadership experience in business continuity planning in various roles. Additionally, one of our directors formerly served as the United States Secretary of Homeland Security, in which capacity she had ultimate responsibility for the cybersecurity of the critical infrastructure of the United States of America, and as President of the University of California with responsibility for cybersecurity matters related to the university's various networks.

Risk and Issues Disclosure

We describe the risks we face, including cybersecurity risks, in Section 1A above, titled "Risk Factors". For the period covered by this Annual Report on Form 10-K, we are unaware of any specific cybersecurity threats that have materially affected the Company, its business strategy, results of operations or financial condition.

Item 2. Properties.

Our corporate headquarters is located in San Francisco, California, where we lease approximately 133,896 square feet of office, research and development, engineering, and laboratory space pursuant to one lease agreement that expire in 2033. We also have leased approximately 21,496 square feet of office and laboratory space in Bellinzona, Switzerland. The lease agreements associated with our Bellinzona, Switzerland site will expire by 2035, with an option to extend for five years. We believe that our existing facilities are adequate for our near-term needs, but if required, we believe that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. 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 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information for Common Stock

Our common stock has been listed on The Nasdaq Global Select Market under the symbol "VIR" since October 11, 2019.

Holders of Record

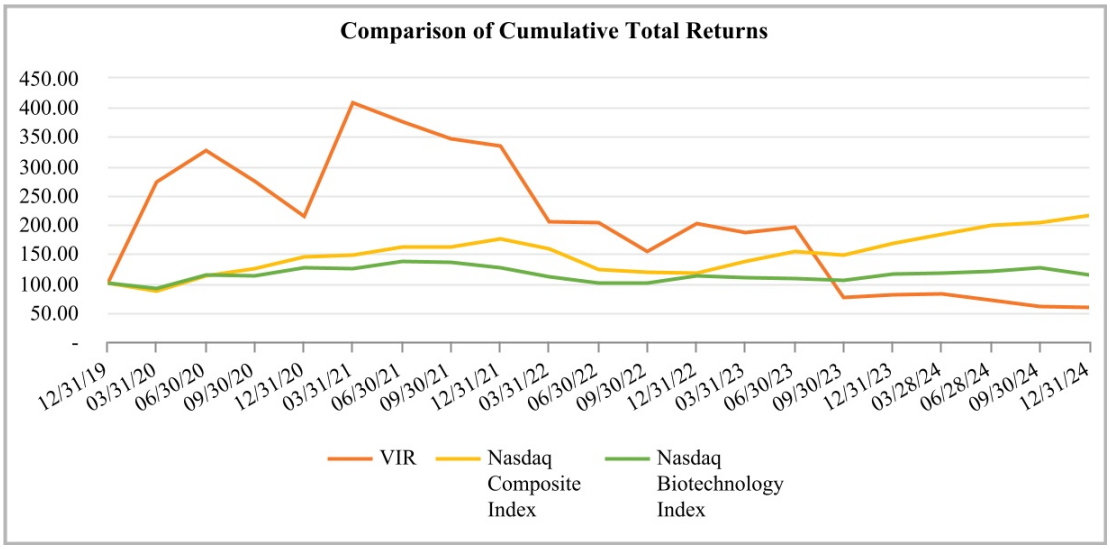
As of February 20, 2025, there were approximately 156 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We currently intend to retain future earnings, if any, for use in operation of our business and to fund future growth. We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Stock Performance Graph

The following graph shows the total stockholder's return on an investment of $100 in cash at market close on December 31, 2019 through December 31, 2024 for (i) our common stock, (ii) the Nasdaq Composite Index and (iii) the Nasdaq Biotechnology Index. Pursuant to applicable Securities and Exchange Commission, rules, all values assume reinvestment of the full amount of all dividends; however, no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder return. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in PART III Item 12 of this Annual Report on Form 10-K.

Use of Proceeds from Registered Securities

None.

Recent Sales of Unregistered Equity Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. [Reserved]

Item 7. 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 audited consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Unless the context requires otherwise, references in this Annual Report on Form 10-K to the "Company", "VirBio," "we," "our" and "us" refer to Vir Biotechnology, Inc. and its consolidated subsidiaries.

Our discussion and analysis below are focused on our financial results and liquidity and capital resources for the years ended December 31, 2024 and 2023, including year-over-year comparisons of our financial performance and condition for these years. Discussion and analysis of the year ended December 31, 2022 specifically, as well as the year-over-year comparison of our financial results and liquidity and capital resources for the years ended December 31, 2023 and 2022, are located in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on February 26, 2024. For a detailed discussion on our business environment, please read Item 1. Business, included in this Annual Report on Form 10-K. For additional information on the risks that could negatively impact our business, please read Item 1A. Risk Factors, included in this Annual Report on Form 10-K.

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. At Vir, we have a bold vision – powering the immune system to transform lives. Our clinical-stage portfolio includes infectious disease programs for CHD and CHB infections and multiple dual-masked 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 HDV and various solid tumors. In hepatitis delta, our phase 3 ECLIPSE registrational program evaluating the combination of tobevibart and elebsiran is scheduled to commence in the first half 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 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 first half 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 and 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 significant developments affecting our business that have occurred and that we have reported since the filing of our Annual Report on Form 10-K for the year ended December 31, 2023.

Pipeline Programs

Chronic Hepatitis Delta (CHD)

- ECLIPSE Phase 3 registrational clinical program in CHD is advancing with the first patient in expected during the first half of 2025.
- Positive data from the SOLSTICE Phase 2 clinical trial were presented in at the AASLD The Liver Meeting® in November 2024. This data demonstrated the potential of the first-of-its-kind investigational combination to address a critical unmet need in CHD, showing rapid and sustained virologic suppression, using the most stringent measure of zero detectable hepatitis delta RNA in the blood or target not detected (TND defined as HDV RNA < 0 IU/mL), and no treatment-related SAEs.

- Tobevibart and elebsiran combination therapy has received multiple regulatory designations potentially supporting an expedited development and review process and recognizing the significant unmet need in CHD: U.S. FDA Breakthrough Therapy designation, U.S. FDA Fast Track designation, European PRIME designation and European Orphan Drug designation.

Solid Tumors

- In January 2025, we presented encouraging early safety and efficacy data in ongoing Phase 1 dose escalation trials for its dual-masked TCE programs.
  - VIR-5818, the only dual-masked HER2-targeting TCE in clinical trials, showed tumor shrinkage across various tumor types in 50% (10/20) of participants receiving doses ≥400 µg/kg, with cPRs in 33% (2/6) of participants with HER2-positive CRC.
  - VIR-5500, the only dual-masked PSMA-targeting TCE in clinical trials, showed PSA declines in 100% (12/12) of mCRPC patients after an initial dose ≥120 µg/kg. PSA_{50} response was confirmed in 58% (7/12) of participants.
  - Both clinical candidates have shown promising safety profiles, with MTD not yet reached, no dose-limiting CRS observed and no CRS greater than grade 2.
- Initial clinical data demonstrate 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.
- We are advancing VIR-5818 and VIR-5500 through ongoing Phase 1 dose escalation studies, aiming to further optimize dosing and efficacy. Additionally, we plan to initiate a Phase 1 study of VIR-5525, a dual-masked EGFR-targeting TCE, in the first quarter of 2025, evaluating its potential across a number of solid tumor indications.

Chronic Hepatitis B (CHB)

- We anticipate functional cure data from the 24-week follow-up of the MARCH Part B Phase 2 study in the second quarter of 2025.
- Positive end-of-treatment results of the MARCH Part B Phase 2 trial evaluating tobevibart and elebsiran in combination with PEG-IFNα or tobevibart and elebsiran alone were presented at AASLD The Liver Meeting® in November 2024. The data demonstrated compelling HBsAg loss and anti-HBs development at the end of treatment.
- Future advancement in CHB by us will be contingent on securing a worldwide development and commercialization partner outside of the China Territory to best enable further development in this area of high unmet need.

Preclinical Pipeline Candidates

- We are advancing multiple undisclosed dual-masked TCEs targeting clinically validated targets with potential applications across a variety of solid tumors. These preclinical candidates leverage the PRO-XTEN™ masking technology with novel TCEs discovered and engineered using our antibody discovery platform and our proprietary dAIsY™ AI engine.
- We will continue to advance our HIV broadly neutralizing antibody program for HIV cure in collaboration with the Gates Foundation.

Corporate Update

- In January 2025, we announced Maninder Hora, Ph.D. will assume the role of Executive Vice President, Chief Technical Operations in February 2025, on departure of our current Chief Technology Officer, Aine Hanley, Ph.D.
- In September 2024, we announced the appointment of Jason O'Byrne as Executive Vice President and Chief Financial Officer, effective October 2, 2024.

- In August 2024 we announced an exclusive worldwide license to use of the proprietary PRO-XTEN™ universal masking technology for oncology and infectious disease and to three clinical-stage masked TCEs with potential applications in a range of cancers. The agreement became effective on September 9, 2024.
    - Certain former employees of Sanofi joined us following the closing of the agreement.
- In August 2024 we announced the phase-out of clinical programs in influenza, COVID-19, and its T-cell based viral vector platform. The Company is seeking partners to advance these clinical programs through further development. Additionally, the Company announced a workforce reduction of approximately 25%, or approximately 140 employees.
- In May 2024, we announced the appointment of Mark D. Eisner, M.D., M.P.H. as Executive Vice President and Chief Medical Officer, effective June 3, 2024.
- Effective May 3, 2024, Sung Lee, Executive Vice President and Chief Financial Officer stepped down from his role to pursue another career opportunity.
- In April 2024, we announced that founding board members Phillip Sharp, Ph.D. and Robert Perez would not stand for reelection. Effective May 29, 2024, two new independent directors were elected in their place, including Norbert Bischofberger, Ph.D., who brings close to 40 years of biotech leadership experience and Ramy Farid, Ph.D., whose pioneering work applying advanced computational methods to drug discovery has enabled high-quality, novel molecules for drug development and materials applications.

Financial Overview

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

We have financed our operations primarily through sales of our common stock from our initial public offering, subsequent follow-on offering, and payments received under our grant and collaboration agreements. As of December 31, 2024, we had $1.1 billion in cash, cash equivalents, and investments. Based upon our current operating plan, we believe that the $1.1 billion will enable us to fund our operations 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. In addition, as of December 31, 2024, we had $95.7 million in restricted cash and cash equivalents, which includes the $75.0 million subject to VIR-5525 achieving “first in human dosing” by 2026. See the section titled “Liquidity, Capital Resources and Capital Requirements—Funding Requirements and Conditions” below for additional information.

Our net loss was $522.0 million for the year ended December 31, 2024, compared to net loss of $615.1 million for the year ended December 31, 2023 and net income of $515.8 million for the year ended December 31, 2022, respectively. As of December 31, 2024, we had accumulated deficit of $759.8 million. Although we recorded net income for the years ended December 31, 2022 and 2021, we have otherwise incurred net losses since inception and may continue to incur net losses in the foreseeable future.

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, conducting preclinical studies and clinical trials, and to a lesser extent, selling, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. In particular, we expect our expenses and losses to increase over time as we continue our research and development efforts, advance our product candidates through preclinical and clinical development, seek regulatory approval, and begin to prepare for commercialization. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials expenditures and our expenditures on other research and development activities.

We manufacture product candidates for three therapeutic modalities: mAbs, masked TCEs and siRNA. We have established our own internal process, analytical and pharmaceutical development, manufacturing, supply chain and quality organizations that work with our selected CDMOs, to develop, manufacture, test and supply our early- and late-stage product candidates developed with our proprietary and external technology platforms. Contract development and

manufacturing of our antibody, TCE and siRNA product candidates is supported at our San Francisco, California, corporate headquarters for process, analytical and formulation development, small-scale non-GMP manufacturing for preclinical studies and selected quality control testing. Our headquarters also conducts cell line development for our antibody and TCE product candidates.

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 the section titled "Business—Our Collaboration, License and Grant Agreements" and Note 5 *Grant Agreements* and Note 6 *Collaboration and License Agreements* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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. Although we have previously recognized revenue from our profit-share related to sotrovimab under our definitive collaboration agreement with GSK executed in June 2020, or the 2020 GSK Agreement, we may continue to incur net operating losses for the foreseeable future. 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 the 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, such as expected commercial demand, commercial supply plan, manufacturing commitments, risks related to expired or obsolete inventories, and risks related to potential product returns or contract terminations.

Manufacturing costs include inventory revaluation adjustments, lower of cost or market inventory adjustments, inventory write-downs and write-offs, and binding purchase commitments with a third-party manufacturer, among other manufacturing costs. Our contractual share of the profit-sharing amounts is subject to potential future adjustments to allowable expenses, which we account for as a form of variable consideration. In 2023, GSK reported to us certain allowable manufacturing expenses related to excess sotrovimab supply and binding reserved manufacturing capacity not utilized, which we had previously reserved as a constraint on our cumulative profit-sharing amounts. GSK may continue to adjust allowable manufacturing expenses for our share of the excess supply write-offs and unused binding manufacturing capacity and report to us as cost-sharing amounts in future periods. We evaluate the latest available facts and circumstances to update our evaluation of whether any portion of profit-sharing amounts should continue to be constrained. We re-assess these estimates at each reporting period. Actual results could materially differ from estimates.

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.

License revenue from a related party is comprised of revenue related to Brii Bio's exercise of its option to obtain exclusive rights to develop and commercialize compounds arising from tobevibart in China Territory recognized in the year ended December 31, 2022.

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, 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 license agreement with Sanofi, we may incur additional clinical, and regulatory milestone payments based on the development progress of certain oncology 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 Annual 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 during the second half of 2024 and 2023, respectively, including severance and other employee-related expenses and long-lived assets impairment charges and disposal losses.

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) Income, Net

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

Benefit from (Provision for) Income Taxes

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

Net Loss Attributable to Noncontrolling Interest

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

Results of Operations

Comparison of Years Ended December 31, 2024 and 2023

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

	Years Ended December 31,		
	2024	2023	Change
Revenues:			
Collaboration revenue	$ 8,379	$ 37,266	$ (28,887)
Contract revenue	55,333	2,228	53,105
Grant revenue	10,493	46,686	(36,193)
Total revenues	74,205	86,180	(11,975)
Operating expenses:			
Cost of revenue	845	2,765	(1,920)
Research and development	506,499	579,720	(73,221)
Selling, general and administrative	119,031	174,441	(55,410)
Restructuring, long-lived assets impairment and related charges	34,995	13,559	21,436
Total operating expenses	661,370	770,485	(109,115)
Loss from operations	(587,165)	(684,305)	97,140
Other income:			
Change in fair value of equity investments	(5,528)	(21,888)	16,360
Interest income	71,809	86,990	(15,181)
Other expense, net	(2,221)	(8,991)	6,770
Total other income	64,060	56,111	7,949
Loss before benefit from income taxes	(523,105)	(628,194)	105,089
Benefit from income taxes	1,145	13,077	(11,932)
Net loss	(521,960)	(615,117)	93,157
Net loss attributable to noncontrolling interest	—	(56)	56
Net loss attributable to VirBio	$ (521,960)	$ (615,061)	$ 93,101

Revenues

The decrease in collaboration revenue for the year ended December 31, 2024 compared to the same period in 2023 was due to lower revenues from the release of sotrovimab profit-sharing amount previously constrained under our 2020 GSK Agreement.

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

The decrease in grant revenue for the year ended December 31, 2024 compared to the same period in 2023 was primarily due to lower revenue recognized in accordance with our agreement with BARDA and to a lesser extent, lower revenue recognized from the Gates Foundation. In August 2024, we announced a strategic realignment that included phasing out certain research programs, which impacted certain programs funded by Gates Foundation grants. We continue to advance our HIV broadly neutralizing antibody program for HIV cure in collaboration with the Gates Foundation. We terminated our agreement with BARDA on December 31, 2024.

Cost of Revenue

The decrease in cost of revenue for the year ended December 31, 2024 compared to the same period in 2023 was due to lower third-party royalties owed based on the lower collaboration revenue under the 2020 GSK Agreement.

Research and Development Expenses

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

	Years Ended December 31,		
	2024	2023	Change
Contract manufacturing	$ 40,081	$ 114,262	$ (74,181)
Clinical costs	57,624	121,422	(63,798)
Personnel	162,960	189,418	(26,458)
Licenses, collaborations and contingent consideration	129,846	30,215	99,631
Other	115,988	124,403	(8,415)
Total research and development expenses	$ 506,499	$ 579,720	$ (73,221)

The decrease in research and development expenses for the year ended December 31, 2024 compared to the same period in 2023 was primarily due to lower contract manufacturing costs and clinical costs associated with the wind down of our Phase 2 PENINSULA trial evaluating VIR-2482, lower contract manufacturing costs associated with elebsiran used in the our CHD and CHB clinical trials, and lower personnel costs associated with the reduction in the headcount resulting from the cost saving initiatives implemented in 2023 and 2024, partially offset by the increase in licenses, collaboration and contingent consideration expenses primarily due to a portion of the upfront payment made to Sanofi allocated to in-process research and development and expensed.

Selling, General and Administrative Expenses

The decrease in selling, general and administrative expenses for the year ended December 31, 2024 compared to the same period in 2023 was primarily due to savings realized through headcount reductions and the closing of our St. Louis, Missouri and Portland, Oregon sites, as part of our cost saving initiatives implemented in 2023 and 2024.

Restructuring, long-lived assets impairment and related charges

The increase in restructuring, long-lived assets impairment and related charges for the year ended December 31, 2024 compared to the same period in 2023 was primarily due to the right-of-use asset and leasehold improvement impairment charges related to closing our facilities in St. Louis, Missouri and Portland Oregon in 2024, which was previously announced on December 13, 2023, and severance charges incurred related to our strategic restructuring announcement in August 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 year ended December 31, 2024, we recognized an unrealized loss of $5.5 million due to the change in fair value, compared to an unrealized loss of $21.9 million for the same period in 2023.

Interest Income

The decrease in interest income was primarily due to lower balances of cash, cash equivalents, and investments for the year ended December 31, 2024 compared to the same period in 2023.

Other Expense, Net

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

Benefit from Income Taxes

The benefit from income taxes for the year ended December 31, 2024 was nomimal. The benefit from income taxes for the year ended December 31, 2023 was primarily due to a pre-tax loss and our ability to carry back the research and development credit to 2022.

Liquidity, Capital Resources and Capital Requirements

Sources of Liquidity

To date, we have financed our operations primarily through sales of our common stock from our initial public offering and subsequent follow-on offering, sales of our convertible preferred securities, and payments received under our grant and collaboration agreements. As of December 31, 2024, we had $1.1 billion in cash, cash equivalents, and investments. In addition, as of December 31, 2024, we had $95.7 million in restricted cash and cash equivalents, which included the $75.0 million subject to VIR-5525 achieving "first in human dosing" by 2026. In November 2023, we entered into a sales agreement (the "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 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 December 31, 2024, 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 December 31, 2024 as noted above will enable us to fund our operations for at least the next 12 months from the filing date of this Annual Report on Form 10-K.

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.

We have various operating lease arrangements for office and laboratory spaces located in California and Switzerland with contractual lease periods expiring between 2033 and 2035. As of December 31, 2024, we expect to make total lease payments of $123.5 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 the sections titled "Business—Our Collaboration, License and Grant Agreements," as well as Note 6 *Collaboration and License Agreements* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. For information related to our future commitments under our facilities and manufacturing agreements, see Note 9 *Leases* and

Note 10 *Commitments and Contingencies* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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 years presented (in thousands):

	Years Ended December 31,	
	2024	**2023**
Net cash (used in) provided by:		
Operating activities	$ (446,352)	$ (778,785)
Investing activities	499,367	164,629
Financing activities	4,388	7,480
Net increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents	$ 57,403	$ (606,676)

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 decreased in 2024 compared to 2023 primarily due to lower payments to GSK related to profit-sharing amount constrained under the 2020 GSK Agreement, and lower clinical development and contract manufacturing activities related to the wind down of the Phase 2 PENINSULA trial evaluating VIR-2482, partially offset by the $103.7 million upfront payment made under our license agreement with Sanofi. Cash used in operating activities decreased in 2023 compared to 2022 primarily due to lower cash received for the sales of sotrovimab and higher cash payments made to GSK related to profit-sharing amount constrained as part of the 2020 GSK Agreement.

Investing Activities

Cash provided by investing activities during 2024 was primarily due to $1.7 billion in proceeds received from investments that matured or sold during the year, partially offset by purchases of investments of $1.2 billion.

Cash provided by investing activities during 2023 was primarily due to $2.2 billion in proceeds received from investments that matured or sold during the period, partially offset by purchases of investments of $2.0 billion and property and equipment of $21.6 million.

Financing Activities

Cash provided by financing activities during 2024 was primarily due to of proceeds from the issuance of common stock under our employee stock purchase plan of $3.8 million.

Cash provided by financing activities during 2023 was primarily due to of proceeds from the issuance of common stock under our employee stock purchase plan of $4.3 million and exercises of stock options of $3.5 million.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States. The preparation of our 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. The critical accounting policies, estimates and judgments that we believe to have the most significant impacts on our consolidated financial statements are described below. For more details on our critical accounting policies, refer to Note 2 *Summary of Significant Accounting Policies* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Asset Acquisitions

We make certain judgments to determine whether acquisitions and other similar transactions should be accounted for as acquisitions of assets or business combinations using the guidance in Accounting Standard Codification, or ASC, Topic 805, *Business Combinations,* by first applying a screen test to assess if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further assessment is required to determine whether we have acquired inputs and a substantive process that together significantly contribute to the ability to create outputs, which would meet the definition of a business.

If determined to be an asset acquisition, we account the transaction using the cost accumulation and allocation method. Under this method, the cost of the acquisition, including direct acquisition-related costs, is allocated to the assets acquired or liabilities assumed on a relative fair value basis. Goodwill is not recognized in an asset acquisition, and any difference between consideration transferred and the fair value of the net assets acquired is allocated to the certain identifiable assets acquired based on their relative fair values.

Contingent consideration payments in asset acquisitions are recognized when the contingency is resolved and the consideration is paid or becomes payable (unless the contingent consideration payments are subject to guidance in ASC 480, *Distinguishing Liabilities from Equity*, or ASC 815, *Derivatives and Hedging*). Upon recognition of the contingent consideration payments, the amount is included in the cost of the acquired asset or group of assets.

Accrued R&D expenses

We expense all research and development costs in the periods in which they are incurred. Clinical development costs compose a significant component of research and development costs. We typically contract with third parties, including CROs and CDMOs to conduct and manage preclinical studies and clinical trials, research services, and clinical manufacturing services on our behalf. When billing terms under these contracts do not coincide with the timing of when the work is performed, we estimate our obligations for services provided but not yet billed as of the period end based on a number of factors that include, but are not limited to, our 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. We obtain information regarding unbilled services directly from outside service providers and perform procedures to support our estimates based on our internal understanding of the services provided to date. However, we may also be required to estimate these services based on information available to our internal clinical and manufacturing administrative staff if such information is not able to be obtained timely from our service providers. Accrued R&D expenses are included in accrued and other liabilities on the consolidated balance sheets. In the event that advance payments are made to a CRO, CDMO or other outside service providers, the payments are recorded within prepaid expenses and/or other current assets and other assets on the consolidated balance sheet and subsequently recognized as research and development expense when the associated services are performed. The status and timing of actual services performed may vary from our estimates, resulting in adjustments to expense in future periods. Changes in these estimates could materially affect our results of operations.

Contingent Consideration associated with a Business Combination

Contingent consideration related to a business combination are initially measured at their estimated fair values on the transaction date and subsequently remeasured each subsequent reporting period with changes recorded in the consolidated statement of operations.

The estimated fair value of the contingent consideration related to the Humabs acquisition is determined by calculating the probability-weighted clinical and regulatory milestone payments based on the assessment of the likelihood and estimated timing that certain milestones will be achieved, as well as by using a Monte Carlo simulation model that includes significant estimates and assumptions pertaining to commercialization events and sales targets. The estimated fair value uses certain significant unobservable inputs categorized within level 3 of the fair value hierarchy, including the probabilities of achieving clinical and regulatory approval of the development projects, the subsequent commercial success and discount rates.

Recent Accounting Pronouncements Not Yet Adopted

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

Item 7A. 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 $318.7 million as of December 31, 2024, 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 $868.1 million as of December 31, 2024. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration and 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 December 31, 2024.

Foreign Currency

The functional currency of our foreign subsidiaries is the U.S. dollar. Monetary assets and liabilities of our foreign subsidiaries are translated into U.S. dollars at period-end exchange rates and non-monetary assets and liabilities are translated to U.S. dollars using historical exchange rates. Revenue and expenses are translated at average rates throughout the respective periods. As of the date of this Annual Report on Form 10-K, we are exposed to foreign currency risk primarily related to the operations of our Swiss and Australian subsidiaries and our collaboration with GSK and consequently the Swiss Franc, Australian dollar and British pound. Transaction gains and losses are included in other (expense) income, net on the consolidated statements of operations and are not material for the years ended December 31, 2024, 2023 and 2022.

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 consolidated statements of operations. The fair value of these equity securities was approximately $4.4 million as of December 31, 2024. Changes in the fair value of these equity securities are impacted by the volatility of the stock market and changes in general economic conditions, among other factors. A hypothetical 10% increase or decrease in the stock prices of these equity securities would increase or decrease their fair value as of December 31, 2024 by approximately $0.4 million.

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Vir Biotechnology, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Vir Biotechnology, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 26, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Expense accruals for clinical trials

Description of the Matter

The Company accrued $29.2 million of research and development expenses as of December 31, 2024, a portion of which relates to expense accruals for clinical trials. As described in Note 2 and Note 7 to the consolidated financial statements, the Company determines accruals for clinical trials based on a number of factors, including the Company's knowledge of the research and development programs, the status of the programs and activities, invoicing to date, and the provisions in the contracts.

Auditing management's accounting for expense accruals for clinical trials is especially challenging because the evaluation is dependent on a high volume of data exchanged between third-party service providers, internal clinical personnel, and the Company's finance team.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls over the Company's process for accounting for expense accruals for clinical trials, including management's controls over the completeness and accuracy of data used in determining these costs, as well as management's process for estimating work completed under the service agreements.

To test expense accruals for clinical trials, our audit procedures included, amongst others, i) inspecting terms and conditions for selected clinical research organization (CRO) contracts, ii) meeting with internal clinical personnel to understand the status of clinical activities for selected trials, iii) testing management's determination of work performed by CROs by inspecting the terms and timelines of significant projects, iv) obtaining external confirmations from selected CROs, and v) inspecting selected invoices received and payments processed after the balance sheet date to determine whether services performed prior to the balance sheet date have been properly accrued for as of December 31, 2024.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

San Mateo, California

February 26, 2025

VIR BIOTECHNOLOGY, INC.

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

	December 31,	
	2024	**2023**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 222,947	$ 241,576
Short-term investments	678,051	1,270,980
Restricted cash and cash equivalents, current	89,385	13,268
Equity investments	4,350	9,853
Prepaid expenses and other current assets	47,725	52,549
Total current assets	1,042,458	1,588,226
Intangible assets, net	8,120	22,565
Goodwill	16,937	16,937
Property and equipment, net	63,183	96,018
Operating right-of-use assets	59,680	71,182
Restricted cash and cash equivalents, noncurrent	6,363	6,448
Long-term investments	190,015	105,275
Other assets	12,057	12,409
TOTAL ASSETS	$ 1,398,813	$ 1,919,060
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,081	$ 6,334
Accrued and other liabilities	85,873	104,220
Deferred revenue, current	12,648	64,853
Contingent consideration obligation, current	16,060	—
Total current liabilities	119,662	175,407
Operating lease liabilities, noncurrent	90,139	111,673
Contingent consideration obligation, noncurrent	24,050	25,960
Other long-term liabilities	14,577	15,784
TOTAL LIABILITIES	248,428	328,824
Commitments and contingencies (Note 10)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of December 31, 2024 and 2023, respectively; no shares issued and outstanding as of December 31, 2024 and 2023	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of December 31, 2024 and 2023, respectively; 136,959,446 and 134,781,286 shares issued and outstanding as of December 31, 2024 and 2023, respectively	14	13
Additional paid-in capital	1,911,872	1,828,862
Accumulated other comprehensive loss	(1,717)	(815)
Accumulated deficit	(759,784)	(237,824)
TOTAL STOCKHOLDERS' EQUITY	1,150,385	1,590,236
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,398,813	$ 1,919,060

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

VIR BIOTECHNOLOGY, INC.

Consolidated Statements of Operations
(in thousands, except share and per share data)

	Years Ended December 31,		
	2024	**2023**	**2022**
Revenues:			
Collaboration revenue	$ 8,379	$ 37,266	$ 1,505,469
Contract revenue	55,333	2,228	52,714
License revenue from a related party	—	—	22,289
Grant revenue	10,493	46,686	35,325
Total revenues	74,205	86,180	1,615,797
Operating expenses:			
Cost of revenue	845	2,765	146,319
Research and development	506,499	579,720	474,648
Selling, general and administrative	119,031	174,441	161,762
Restructuring, long-lived assets impairment and related charges	34,995	13,559	—
Total operating expenses	661,370	770,485	782,729
(Loss) income from operations	(587,165)	(684,305)	833,068
Other income (loss):			
Change in fair value of equity investments	(5,528)	(21,888)	(111,140)
Interest income	71,809	86,990	28,092
Other (expense) income, net	(2,221)	(8,991)	4,260
Total other income (loss)	64,060	56,111	(78,788)
(Loss) income before benefit from (provision for) income taxes	(523,105)	(628,194)	754,280
Benefit from (provision for) income taxes	1,145	13,077	(238,443)
Net (loss) income	(521,960)	(615,117)	515,837
Net loss attributable to noncontrolling interest	—	(56)	—
Net (loss) income attributable to VirBio	$ (521,960)	$ (615,061)	$ 515,837
Net (loss) income per share attributable to VirBio, basic	$ (3.83)	$ (4.59)	$ 3.89
Net (loss) income per share attributable to VirBio, diluted	$ (3.83)	$ (4.59)	$ 3.83
Weighted-average shares outstanding, basic	136,246,865	134,130,924	132,606,767
Weighted-average shares outstanding, diluted	136,246,865	134,130,924	134,810,908

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

VIR BIOTECHNOLOGY, INC.

Consolidated Statements of Comprehensive (Loss) Income
(in thousands)

	Years Ended December 31,		
	2024	**2023**	**2022**
Net (loss) income	$ (521,960)	$ (615,117)	$ 515,837
Other comprehensive (loss) income:			
Unrealized gain (loss) on investments	503	9,310	(7,524)
Pension actuarial loss	(1,405)	(1,003)	(499)
Total other comprehensive (loss) income	(902)	8,307	(8,023)
Comprehensive (loss) income	(522,862)	(606,810)	507,814
Comprehensive loss attributable to noncontrolling interest	—	(56)	—
Comprehensive (loss) income attributable to VirBio	$ (522,862)	$ (606,754)	$ 507,814

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

VIR BIOTECHNOLOGY, INC.

Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	VirBio Stockholders' Equity						
	Common Stock						
	Share	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	(Accumulated Deficit) Retained Earnings	Noncontrolling interest	Total Stockholders' Equity
Balance at December 31, 2021	131,161,404	$ 13	$ 1,571,535	$ (1,099)	$ (138,600)	$ —	$ 1,431,849
Issuance of common stock in connection with a grant agreement	881,365	—	28,462	—	—	—	28,462
Vesting of restricted common stock	349,496	—	—	—	—	—	—
Exercise of stock options	696,963	—	4,534	—	—	—	4,534
Issuance of common stock under employee stock purchase plan	147,459	—	3,222	—	—	—	3,222
Stock-based compensation	—	—	102,082	—	—	—	102,082
Other comprehensive loss	—	—	—	(8,023)	—	—	(8,023)
Net income	—	—	—	—	515,837	—	515,837
Balance at December 31, 2022	133,236,687	13	1,709,835	(9,122)	377,237	—	2,077,963
Vesting of restricted common stock	734,662	—	—	—	—	—	—
Exercise of stock options	487,014	—	3,484	—	—	—	3,484
Issuance of common stock under employee stock purchase plan	322,923	—	4,283	—	—	—	4,283
Stock-based compensation	—	—	111,316	—	—	—	111,316
Other comprehensive income	—	—	—	8,307	—	—	8,307
Contributions from noncontrolling interest owners	—	—	—	—	—	100	100
Increase in ownership interest in a subsidiary	—	—	(56)	—	—	(44)	(100)
Net loss	—	—	—	—	(615,061)	(56)	(615,117)
Balance at December 31, 2023	134,781,286	13	1,828,862	(815)	(237,824)	—	1,590,236
Vesting of restricted common stock	1,368,362	1	—	—	—	—	1
Exercise of stock options	322,366	—	790	—	—	—	790
Issuance of common stock under employee stock purchase plan	487,432	—	3,763	—	—	—	3,763
Stock-based compensation	—	—	78,457	—	—	—	78,457
Other comprehensive loss	—	—	—	(902)	—	—	(902)
Net loss	—	—	—	—	(521,960)	—	(521,960)
Balance at December 31, 2024	136,959,446	$ 14	$ 1,911,872	$ (1,717)	$ (759,784)	$ —	$ 1,150,385

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

VIR BIOTECHNOLOGY, INC.

Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2024	**2023**	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net (loss) income	$ (521,960)	$ (615,117)	$ 515,837
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Changes in estimated constraint on profit-sharing amount	685	(28,118)	369,535
Depreciation and amortization	14,559	19,451	6,783
Amortization of premiums (accretion of discounts) on investments, net	5,397	(8,706)	(8,943)
Noncash lease expense	5,248	7,658	8,709
Change in fair value of equity investments	5,528	21,888	111,140
Change in estimated fair value of contingent consideration	14,149	1,024	2,115
Stock-based compensation	78,457	111,316	102,082
Change in deferred income taxes	(2,949)	(1,063)	(15,186)
In-process research and development impairment	14,550	9,658	—
Non-cash restructuring, long-lived assets impairment and related charges	24,173	7,662	—
Payment of contingent consideration in excess of acquisition date fair value	—	—	(93,803)
Other non-cash items, net	(182)	153	(383)
Changes in operating assets and liabilities:			
Receivable from collaboration	(6,513)	(565)	770,038
Prepaid expenses and other current assets	10,186	64,970	(39,358)
Other assets	353	2,161	(11,795)
Accounts payable	(988)	732	797
Accrued liabilities and other long-term liabilities	(10,287)	(356,498)	(15,513)
Operating lease liabilities	(23,027)	(13,046)	(5,502)
Deferred revenue	(53,731)	(2,345)	(33,300)
Net cash (used in) provided by operating activities	(446,352)	(778,785)	1,663,253
CASH FLOWS FROM INVESTING ACTIVITIES:			
Proceeds from sale of property and equipment	3,372	—	—
Purchases of property, equipment and intangible assets	(7,301)	(21,573)	(68,006)
Purchases of investments	(1,235,339)	(2,016,189)	(1,476,965)
Maturities and sales of investments	1,738,635	2,202,391	351,510
Net cash provided by (used in) investing activities	499,367	164,629	(1,193,461)

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

VIR BIOTECHNOLOGY, INC.

Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2024	**2023**	**2022**
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock under ESPP	3,763	4,283	3,222
Proceeds from exercise of stock options	790	3,484	4,534
Proceeds from issuance of common stock in connection with a grant agreement	—	—	28,462
Payment of contingent consideration	—	—	(1,197)
Other financing activities	(165)	(287)	(260)
Net cash provided by financing activities	4,388	7,480	34,761
Net increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents	57,403	(606,676)	504,553
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	261,292	867,968	363,415
Cash, cash equivalents and restricted cash and cash equivalents at end of period	$ 318,695	$ 261,292	$ 867,968
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Net refund received (cash paid) for income tax	$ 786	$ 2,676	$ (252,030)
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH AND CASH EQUIVALENTS TO THE CONSOLIDATED BALANCE SHEETS:			
Cash and cash equivalents	$ 222,947	$ 241,576	$ 848,631
Restricted cash and cash equivalents, current	89,385	13,268	12,681
Restricted cash and cash equivalents, noncurrent	6,363	6,448	6,656
Total cash, cash equivalents and restricted cash and cash equivalents	$ 318,695	$ 261,292	$ 867,968

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

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

1. *Organization*

Vir Biotechnology, Inc. ("VirBio" 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 ("HDV") and chronic hepatitis B infections ("HBV") and multiple dual-masked T-cell engagers ("TCEs") across validated targets in solid tumor indications. VirBio also has a preclinical portfolio of programs across a range of infectious diseases and oncologic malignancies. VirBio 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.

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

Sales Agreement

In November 2023, the Company entered into a sales agreement ("Sales Agreement") with Cowen and Company, LLC, as sales agent ("TD Cowen"), pursuant to which the Company may from time to time offer and sell shares of its common stock for an aggregate offering price of up to $300.0 million, through or to TD Cowen, acting as sales agent or principal. The shares will be offered and sold under the Company's shelf registration statement on Form S-3 and a related prospectus filed with the Securities and Exchange Commission ("SEC") on November 3, 2023. The Company will pay TD Cowen a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide TD Cowen with customary indemnification and contribution rights. As of December 31, 2024, no shares have been issued under the Sales Agreement.

Need for Additional Capital

Although the Company recorded net income for the years ended December 31, 2022 and 2021, it has otherwise incurred net losses since inception. The Company expects to continue to incur net losses over the next several years and may need to raise additional capital to fully implement its business plan. As of December 31, 2024, the Company had accumulated deficit of $759.8 million. The Company had $1.1 billion in cash, cash equivalents, and investments as of December 31, 2024. Based on the Company's current operating plan, management believes that the $1.1 billion as of December 31, 2024 will be sufficient to fund its operations through at least the next 12 months from the issuance date of these consolidated financial statements. The Company also had $95.7 million in restricted cash and cash equivalents as of December 31, 2024.

2. *Summary of Significant Accounting Policies*

Basis of Presentation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. The consolidated financial statements include the accounts of VirBio and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

Foreign Currency

The functional currency of the Company's foreign subsidiaries is the U.S. dollar. Monetary assets and liabilities of 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 exchange rates throughout the respective periods. Transaction gains and losses are included in other (expense) income, net on the consolidated statements of operations.

Use of Estimates

The preparation of the 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 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.

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. The accounting policies of the segment are the same as those described in the summary of significant accounting policies.

Concentration of Credit Risk, Credit Loss and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and investments. Cash and cash equivalents are deposited in checking and sweep accounts at financial institutions. Such deposits may, at times, exceed federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents. Management believes that the Company is not currently exposed to significant credit risk as the Company's investments are held in custody at reputable third-party financial institutions.

The Company's investment policy limits investments to certain types of securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and investments and issuers of the investments to the extent recorded on the consolidated balance sheets. As of December 31, 2024 and 2023, the Company has no off-balance sheet concentrations of credit risk.

The Company is exposed to credit losses primarily through receivables from collaborators and through its available-for-sale debt securities. The Company's expected loss allowance methodology for the receivables is developed using historical collection experience, current and future economic market conditions, a review of the current aging status and financial condition of the entities. Specific allowance amounts are established to record the appropriate allowance for customers that have a higher probability of default. Balances are written off when determined to be uncollectible. The Company's expected loss allowance methodology for the debt securities is developed by reviewing the extent of the unrealized loss, the size, term, geographical location, and industry of the issuer, the issuers' credit ratings and any changes in those ratings, as well as reviewing current and future economic market conditions and the issuers' current status and financial condition. There was no allowance for losses on available-for-sale debt securities attributable to credit risk as of December 31, 2024 and 2023.

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 which mature at, or less than 12 months from the 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 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) income, net on the 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.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation and amortization and, if applicable, impairment charges. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are amortized over the lesser of their useful lives or the remaining life of the lease. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the balance sheet, and the resulting gain or loss is reflected in operations in the period realized. Maintenance and repairs are charged to operations as incurred.

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset (group) may not be recoverable. Recoverability is measured by comparing the carrying amount to the future net undiscounted cash flows that the asset (group) is expected to generate. If such asset (group) is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset (group) exceeds its fair value projected discounted future net cash flows arising from the asset (group).

Acquired Intangible Assets

The Company's intangible assets were acquired via business combinations or asset acquisitions.

In-process research and development ("IPR&D") acquired as part of an asset acquisition is recorded at cost and expensed immediately if they have no alternative future uses. IPR&D acquired in a business combination is recorded as indefinite-lived intangible assets using the estimated fair value. The Company reviews indefinite-lived intangible assets for impairment at least annually or more frequently if events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. If the carrying value of an indefinite-lived intangible asset exceeds its fair value, then it is written down to its fair value. If a product candidate derived from the indefinite-lived intangible asset is commercialized, the useful life will be determined, and the carrying value will be amortized prospectively over that estimated useful life. Alternatively, if a product candidate is abandoned, the carrying value of the intangible asset will be charged to research and development expenses.

Finite-lived intangible assets acquired in a business combination are initially recognized at their fair value at the acquisition date. Finite-lived intangible assets acquired in an asset acquisition are initially recognized at cost. Amortization is computed using the straight-line method over the estimated useful lives of the respective finite-lived intangible assets, generally seven to 15 years. Finite-lived intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset (group) may not be recoverable, like that of property and equipment.

Goodwill

Goodwill represents the excess of the purchase price over the estimated fair value of the net tangible and intangible assets acquired in a business combination. The Company tests goodwill for impairment at least annually or more frequently if events or changes in circumstances indicate that this asset may be impaired. In testing for goodwill impairment, the Company has the option of first performing a qualitative assessment to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. If the Company elects to bypass the qualitative assessment, or if a qualitative assessment indicates it is more likely than not that the carrying value exceeds its fair value, the Company performs a quantitative goodwill impairment test to compare the fair value of its reporting unit to its carrying value, including goodwill. If the carrying value, including goodwill, exceeds the reporting unit's fair value, the Company will recognize an impairment loss for the amount by which the carrying amount exceeds the reporting unit's fair value (but not in excess of the carrying value of goodwill).

Revenue Recognition

Collaboration, License and Contract Revenue

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

For collaborative arrangements that fall within the scope of ASC 808, Collaborative Arrangements ("ASC 808"), the Company first determines which elements of the collaboration are deemed to be a performance obligation with a customer within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808 and are not subject to the guidance in ASC 606, the Company applies the revenue recognition model under ASC 606, including the royalty exception guidance and variable consideration guidance under ASC 606 as described below, or other guidance, as deemed appropriate. The Company is considered an agent in elements of collaboration arrangements within the scope of ASC 808 when the collaboration partner controls the product before transfer to the customers and has the ability to direct the use of and obtain substantially all of the remaining benefits from the product. In these instances, collaboration revenue is recorded in the period in which such sales occur and is based upon the net sales reported by the Company's collaboration partners, net of cost of goods sold and allowable expenses (e.g., manufacturing, distribution, medical affairs, selling, and marketing expenses) in the period.

In order to record collaboration revenue, the Company utilizes certain information from its collaboration partner, including actual net product sales and costs incurred for sales activities, and makes key judgments based on business updates related to commercial and clinical activities such as expected commercial demand, commercial supply plan, manufacturing commitments, risks related to expired or obsolete inventories, and risks related to potential product returns or contract terminations. The Company uses these estimates to determine whether payments due to it under its collaboration arrangements, such as profit-share payments, should be recognized as revenue in the period that they become due, or whether any portion of the payments due should be constrained from revenue recognition because it is not probable that recognizing such amounts will not result in a significant reversal of cumulative revenues recognized in future reporting periods.

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

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

For performance obligations satisfied over time, the Company estimates the efforts needed to complete the performance obligation and recognizes revenue by measuring the progress towards complete satisfaction of the performance obligation using an input measure.

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

Grant Revenue

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

Acquisitions

The Company evaluates acquisitions and other similar transactions using the guidance in ASC Topic 805, Business Combinations ("ASC 805"), to determine whether the transaction should be accounted for as a business combination or an acquisition of asset(s) by first applying a screen test to assess if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an acquisition of asset(s). If the screen test is not met, further assessment is required to determine whether the Company has acquired inputs and a substantive process that together significantly contribute to the ability to create outputs, which would meet the definition of a business.

If determined to be an acquisition of asset(s), the Company accounts the transaction using the cost accumulation and allocation method under ASC 805-50. Under this method, the cost of the acquisition, including direct acquisition-related costs, is allocated to the assets acquired or liabilities assumed on a relative fair value basis. Goodwill is not recognized in an asset acquisition, and any difference between consideration transferred and the fair value of the net assets acquired is allocated to the certain identifiable assets acquired based on their relative fair values.

Contingent consideration payments in asset acquisitions are recognized when the contingency is resolved and the consideration is paid or becomes payable (unless the contingent consideration payments are subject to guidance in ASC 480, Distinguishing Liabilities from Equity, or ASC 815, Derivatives and Hedging). Upon recognition of the contingent consideration payments, the amount is included in the cost of the acquired asset or group of assets.

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method, assets acquired, including IPR&D projects, and liabilities assumed are recorded at their respective fair values as of the acquisition date. Any excess fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with the business combination are recorded at their fair values on the acquisition date, are remeasured each subsequent reporting period until the related contingencies are resolved and are classified as contingent consideration on the consolidated balance sheets. The changes in fair values of contingent consideration related to the achievement of various milestones are recorded within research and development expenses or selling, general and administrative expenses based on the nature of the relevant underlying activities.

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.

Stock-based Compensation

The Company's stock-based compensation programs grant awards that have included stock options, restricted stock units, restricted stock awards, and shares issued under its employee stock purchase plan. Grants are awarded to employees, directors, and non-employee service providers. The Company calculates the estimated fair value of stock options and employees' purchase rights under the Company's 2019 employee stock purchase plan ("ESPP") using the Black-Scholes valuation model, which requires the use of subjective assumptions including volatility and expected term, among others. The fair value of restricted stock awards ("RSAs") and restricted stock units ("RSUs") is based on the market value of the Company's common stock on the date of grant. Stock-based compensation is recognized using the straight-line method for awards that vest only upon the employee's or non-employee's continued service to the Company. Stock-based compensation expense of the employees' purchase rights under the ESPP is recognized over the offering period. Forfeitures are recognized as they occur.

Leases

In accordance with ASC 842, Leases, the Company determines if an arrangement is or contains a lease at inception by assessing whether the arrangement contains an identified asset and whether it has the right to control the identified asset. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Lease liabilities are recognized at the lease commencement date based on the present value of future lease payments over the lease term. ROU assets are based on the measurement of the lease liability and also include any lease payments made prior to or on lease commencement and exclude lease incentives and initial direct costs incurred, as applicable. On the lease commencement date, the Company estimates and includes in its lease payments any lease incentive amounts based on future events when (1) the events are within the Company's control and (2) the event triggering the right to receive the incentive is deemed reasonably certain to occur. If the lease incentive received is greater or less than the amount recognized at lease commencement, the Company recognizes the difference as an adjustment to ROU asset and/or lease liability, as applicable.

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

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

ROU assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset (group) may not be recoverable, like that of property and equipment.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. Deferred income tax assets and liabilities are determined based on the differences between the financial statement reporting and tax bases of assets and liabilities and net operating losses and credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized. The Company's tax positions are subject to income tax audits. The Company recognizes the tax benefit of an uncertain tax position only if it is more likely than not that the position is sustainable upon examination by the taxing authority, based on the technical merits. The tax benefit recognized is measured as the largest amount of benefit which is more likely than not to be realized upon settlement with the taxing authority. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on several factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues. The provision for income taxes includes the effects of any accruals that the Company believes are appropriate, as well as any related net interest and penalties.

Net (Loss) Income Per Share

Basic net (loss) income per common share is computed by dividing the net (loss) income attributable to VirBio by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net (loss) income per common share is computed by dividing the net (loss) income attributable to VirBio 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.

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 ("ASU 2023-09"), which modifies the rules on income tax disclosures to require entities to disclose (1) specific categories in the rate reconciliation, (2) the income or loss from continuing operations before income tax expense or benefit (separated between domestic and foreign) and (3) income tax expense or benefit from continuing operations (separated by federal, state and foreign). ASU 2023-09 also requires entities to disclose their income tax payments to international, federal, state and local jurisdictions, among other changes. The guidance is effective for annual periods beginning after December 15, 2024. Early adoption is permitted. ASU 2023-09 should be applied on a prospective basis, but retrospective application is permitted. The Company is currently evaluating the impact the adoption of ASU 2023-09 may have on its consolidated financial statements and related disclosures.

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. 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 consolidated balance sheets to conform to the current period presentation and enhance comparability. As a result, the prior period amounts from *deferred revenue, noncurrent* were reclassified to *other long-term liabilities*. These reclassifications had no impact on previously reported total assets, total liabilities, or total stockholders' equity.

Certain reclassifications have been made to prior period amounts on the Company's 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 *research and development* and *selling, general and administrative*, were reclassified to *restructuring, long-lived assets impairment and related charges*. These reclassifications had no impact on previously reported total revenues, total operating expenses, or net loss.

3. *Fair Value Measurements*

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

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

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

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 (in thousands):

		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 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

		December 31, 2023			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Money market funds	Level 1	$ 278,187	$ —	$ —	$ 278,187
U.S. government treasuries	Level 2	1,162,124	1,017	(80)	1,163,061
U.S. government agency bonds and discount rates	Level 2	181,189	27	(50)	181,166
Equity securities	Level 1	N/A	N/A	N/A	9,853
Total financial assets		$ 1,621,500	$ 1,044	$ (130)	$ 1,632,267
Reconciliation to cash, cash equivalents and investments on consolidated balance sheet					
Minus: Restricted cash equivalents invested in money market funds					(19,716)
Plus: Cash deposits					15,133
Total cash, cash equivalents and investments					$ 1,627,684

Accrued interest receivable excluded from both the fair value and amortized cost basis of the available-for-sale debt securities are presented within prepaid expenses and other current assets in the consolidated balance sheets. Accrued interest receivable amounted to $5.0 million and $4.0 million as of December 31, 2024 and 2023, respectively. The Company did not write off any accrued interest receivable during the years ended December 31, 2024, 2023 and 2022.

The Company recognized total net unrealized gains of $1.4 million and $0.9 million in accumulated other comprehensive loss as of December 31, 2024 and 2023, respectively. The gross unrealized losses as of December 31, 2024 and 2023 were due to changes in interest rates. The Company determined that the gross unrealized losses on our investments as of December 31, 2024 and 2023 were temporary in nature. The Company currently does not intend, and it is highly unlikely that it will be required, to sell these securities before recovery of their amortized cost basis. As of December 31, 2024, no securities have contractual maturities (or weighted average life for asset-backed securities) of longer than two years.

As of December 31, 2024, the Company's equity investment consisted solely of ordinary shares of Brii Biosciences Limited ("Brii Bio Parent"). The equity securities of Brii Bio Parent are listed on the Stock Exchange of Hong Kong Limited and are considered to be marketable equity securities measured at fair value at each reporting date. As of December 31, 2024, the Company remeasured the equity investment at a fair value of $4.4 million. For the years ended December 31, 2024, 2023 and 2022, the Company recognized unrealized losses of $5.5 million, $21.9 million and $111.1 million, respectively, as other income (loss) in the consolidated statements of operations. For the years ended December 31, 2024, 2023 and 2022, the unrealized loss related to foreign currency translation were immaterial.

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 December 31, 2024 and 2023. The estimated fair value of the contingent consideration related to the Humabs acquisition was determined by calculating the probability-weighted clinical, regulatory and commercial milestone payments based on the assessment of the likelihood and estimated timing that certain milestones would be achieved.

As of December 31, 2024, the Company calculated the estimated fair value of the remaining clinical and regulatory milestones related to tobevibart using the following significant unobservable inputs:

Unobservable input	Range (Weighted-Average)[1]
Discount rates	10.8% - 12.3% (11.5%)
Probability of achievement	16.2% - 95.0% (69.7%)

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

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

Unobservable input	Value
Volatility	55.0%
Discount rate	10.0%
Probability of achievement	56.2%

The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. As of December 31, 2024 and 2023, the estimated fair value of the contingent consideration related to the Humabs acquisition was $40.1 million and $26.0 million, respectively, with changes in the estimated fair value recorded in research and development expenses in the 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 (in thousands):

	Contingent Consideration
Balance at December 31, 2023	$ 25,961
Changes in fair value	14,149
Balance at December 31, 2024	$ 40,110

4. *Goodwill and Intangible assets*

Goodwill

Goodwill of $16.9 million represents the excess of the purchase price over the estimated fair value of the net assets acquired from Humabs. There was no impairment for the years ended December 31, 2024, 2023 and 2022.

Intangible Assets

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

	December 31,		Weighted-Average Remaining Useful Life (Years)
	2024	2023	
Developed technology	$ 4,260	$ 4,260	4.8
Contract-based intangible assets	914	502	8.5
Finite-lived intangible assets, gross	5,174	4,762	
Less accumulated amortization	(3,576)	(3,270)	
Finite-lived intangible assets, net	$ 1,598	$ 1,492	

The developed technology primarily includes the antibody platform acquired in connection with the business combination of Humabs in 2017. The contract-based intangible assets include intangibles from the product approval of a sublicensed intellectual property right in December 2020, which was previously accounted for as IPR&D, and intangibles recognized for workforce capitalized under the Company's Sanofi Agreement (as defined in Note 6 *Collaboration and License Agreements*). Amortization expense related to finite-lived intangible assets totaled $0.3 million, $0.5 million and $0.5 million for the years ended December 31, 2024, 2023 and 2022, respectively, primarily included as research and development expenses on the consolidated statements of operations. There was no impairment for the years ended December 31, 2024, 2023 and 2022.

The estimated future amortization expense for the next five years is as follows (in thousands):

Years Ending December 31:	
2025	$ 270
2026	296
2027	296
2028	296
2029	241
Total	$ 1,399

Indefinite-Lived Intangible Assets

As of December 31, 2024 and 2023, the Company had indefinite-lived intangible assets of $6.5 million and $21.1 million, respectively, related to the IPR&D from the Humabs acquisition. For the years ended December 31, 2024 and 2023, $14.6 million and $9.7 million impairment losses were recorded as part of research and development expenses for IPR&D assets related to non-prioritized or abandoned research programs, respectively. No impairment losses were recorded for the year ended December 31, 2022.

5. *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 earlier terminated 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 project.

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 include the HIV vaccine program and the tuberculosis vaccine program currently 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 $4.6 million, $13.3 million, and $8.6 million for the years ended December 31, 2024, 2023, and 2022, respectively. As of December 31, 2024 and 2023, the Company had deferred revenue of $11.1 million and $13.1 million, respectively. As of December 31, 2024 and 2023, the Company had $11.6 million and $9.2 million, respectively, within accrued and other liabilities, which may need to be refunded to the Gates Foundation.

Biomedical Advanced Research and Development Authority

In September 2022, the Company entered into a multi-year agreement (the "BARDA Agreement") under Other Transaction Authority (OTA) with the Biomedical Advanced Research and Development Authority ("BARDA"), part of the U.S. Department of Health and Human Services' Administration for Strategic Preparedness and Response, with the potential for up to $1.0 billion to advance the development of a full portfolio of innovative solutions to address influenza and potentially other infectious disease threats. Under the BARDA Agreement, the Company was initially awarded $55.0 million for the development of VIR-2482, an investigational prophylactic monoclonal antibody designed with the aim to protect against seasonal and pandemic influenza.

In September 2023, the Company and BARDA entered into Amendment No. P00001 to the BARDA Agreement, pursuant to which BARDA awarded the Company $50.1 million in new funding upon the exercise of an additional option. $40.0 million was used to support the development of VIR-7229 through a Phase 1 clinical trial and $10.1 million to support the discovery of new monoclonal antibody against a second pathogen of pandemic potential. Additionally, the Company was awarded up to $11.2 million of additional funding to wind down activities related to VIR-2482.

In September 2024, the Company and BARDA entered into Amendment No. P00003 to the BARDA Agreement, pursuant to which the parties agreed to partially de-obligate certain funds previously awarded to the development of VIR-7229. Under this Amendment the current BARDA commitment was decreased by $42.1 million. In October 2024, the Company notified BARDA of intent to terminate the OTA on December 31, 2024. All remaining funds were de-obligated upon the date of termination.

The Company receives BARDA funding as it incurs eligible costs. The Company recognized grant revenue related to BARDA of $5.9 million, $33.4 million. and $26.4 million for the years ended December 31, 2024, 2023, and 2022, respectively, and other receivables in prepaid expenses and other current assets of $0.1 million and $7.6 million as of December 31, 2024 and 2023, respectively.

6. *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 (the "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 cancer 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 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 VirBio 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):

IPR&D	$	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.

Collaboration Agreements with GSK

2020 GSK Agreement

In 2020, the Company, Glaxo Wellcome UK Limited and Beecham S.A. entered into a collaboration agreement (the "2020 GSK Agreement"). Subsequently, Beecham S.A. assigned and transferred all its rights, title, interest, and benefit in the 2020 GSK Agreement to GlaxoSmithKline Biologicals S.A. (Glaxo Wellcome UK Limited and GlaxoSmithKline Biologicals S.A., referred to, individually and together, as "GSK"). Under the terms of the 2020 GSK Agreement, the Company and GSK agreed to collaborate to research, develop and commercialize products for the prevention, treatment and prophylaxis of diseases caused by SARS-CoV-2, the virus that causes COVID-19, and potentially other coronaviruses. The collaboration initially focused on the development and commercialization of three programs: (1) antibodies targeting SARS-CoV-2 and potentially other coronaviruses (the "Antibody Program"); (2) vaccines targeting SARS-CoV-2 and potentially other coronaviruses (the "Vaccine Program"), and (3) products based on genome-wide CRISPR screening of host targets expressed in connection with exposure to SARS-CoV-2 and potentially other coronaviruses (the "Functional Genomics Program").

On February 8, 2023, the Company and GSK entered into two amendments to the 2020 GSK Agreement. Pursuant to the amendments, the Company and GSK agreed to remove the Vaccine Program from the 2020 GSK Agreement, and to wind down and terminate the cost-sharing arrangements and all ongoing activities in relation to the Vaccine Program. As of the effective date of the amendments, the Vaccine Program had not yet advanced to its predefined development candidate stage. The Company retains the right to progress development of vaccine products directed to SARS-CoV-2 and other coronaviruses independently (including with or for third parties) outside the scope of the 2020 GSK Agreement, subject to the payment of tiered royalties to GSK on net sales of any vaccine products covered by certain GSK intellectual property rights in the low single digits. In addition, the Company and GSK agreed to modify the Antibody Program to remove from the collaboration all coronavirus antibodies other than sotrovimab and VIR-7832, and certain variants thereof, which remain subject to the terms of the 2020 GSK Agreement. The Company retains the sole right to progress the development and commercialization of the terminated antibody products independently (including with or for third parties), subject to the payment of tiered royalties to GSK on net sales of such terminated antibody products at percentages ranging from the very low single digits to the mid-single digits, depending on the nature of the antibody product being commercialized.

Subject to an opt-out mechanism, the parties share all development costs, manufacturing costs, and costs and expenses for the commercialization of the collaboration products, with the Company bearing 72.5% of such costs for sotrovimab, except that GSK has the sole right to develop (including to seek, obtain or maintain regulatory approvals), manufacture and commercialize sotrovimab in and for People's Republic of China, Hong Kong, Macau and Taiwan at GSK's sole cost and expense, and equal sharing of such costs for the functional genomics products.

The 2020 GSK Agreement will remain in effect with respect to sotrovimab for as long as it is being commercialized by the lead party. Either party has the right to terminate the 2020 GSK Agreement in the case of the insolvency of the other party, an uncured material breach of the other party with respect to a collaboration program or collaboration product, or as mutually agreed by the parties.

In May 2021, the U.S. Food and Drug Administration ("FDA") granted an emergency use authorization ("EUA") in the United States for sotrovimab, the first collaboration product under the Antibody Program. In April 2022, the FDA excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. In December 2024, the FDA revoked EUA granted to sotrovimab.

GSK is the lead party for manufacturing and commercialization of sotrovimab. As the agent, the Company recognizes its contractual share 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. Manufacturing costs include inventory revaluation adjustments, lower of cost or market inventory adjustments, inventory write-downs and write-offs, and binding purchase commitments with a third-party manufacturer among other manufacturing costs. In periods when allowable expenses exceed amounts recognized for net product sales of sotrovimab, negative revenue will be reported in our consolidated statements of operations. The Company's contractual share of the profit-sharing amounts is subject to potential future adjustments to allowable expenses, which represents a form of variable consideration. At each reporting period, the Company evaluates the latest available facts and circumstances to determine whether any portion of profit-sharing amounts should be constrained.

In 2023, GSK reported to the Company certain allowable manufacturing expenses related to excess sotrovimab supply and binding reserved manufacturing capacity not utilized, which the Company had previously reserved as a constraint on its cumulative profit-sharing amounts. For the year ended December 31, 2024 and 2023, the Company paid GSK $0.7 million and $341.3 million relating to these manufacturing expenses. GSK may continue to adjust the allowable manufacturing expenses. As of December 31, 2024, the accrued liability balance for the Company's share of the remaining estimated manufacturing expenses related to excess sotrovimab supply and binding reserved manufacturing capacity not utilized is immaterial. The Company re-assesses these estimates each reporting period.

During the years ended December 31, 2024, 2023, and 2022, the Company recorded profit-sharing amounts, profit-sharing amounts constrained, and profit-sharing amounts previously constrained, released as components of collaboration revenue in the consolidated statements of operations, as follows (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Collaboration revenue, net			
Profit-sharing amount	$ 9,078	$ 1,536	$ 1,875,147
Profit-sharing amount constrained	(699)	—	(369,678)
Profit-sharing amount previously constrained, released	—	35,730	—
Total collaboration revenue, net	$ 8,379	$ 37,266	$ 1,505,469

Royalties earned by third-party licensors on net sales of sotrovimab are reported as cost of revenue on the consolidated statement of operations, which the Company recognized $0.8 million, $2.8 million, $146.3 million for the years ended December 31, 2024, 2023, and 2022, respectively.

Costs associated with co-development activities performed under the 2020 GSK Agreement are included in research and development expenses on the consolidated statements of operations, with any reimbursement of costs by GSK reflected as a reduction of such expenses. Under the 2020 GSK Agreement, the Company recognized additional net research and development expenses of $7.7 million, $23.4 million, and $31.4 million during the years ended December 31, 2024, 2023, and 2022, respectively.

2021 Expanded GSK Collaboration

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

On February 21, 2024, the Company and GSK entered into a letter agreement (the "Letter Agreement") pursuant to which the Company and GSK agreed to remove the Influenza Program from the 2021 GSK Agreement and to wind down and terminate the cost-sharing arrangements and all ongoing activities in relation to the Influenza Program. As of the effective date of the Letter Agreement, the VIR-2482 Option was terminated. As it relates to the Expanded Functional Genomics Program, the Company and GSK mutually rejected all targets selected in the first quarter of 2024, with remaining exclusivity to such targets expiring in mid-2025. Regarding the Additional Programs, GSK selected respiratory syncytial virus ("RSV") as its first pathogen in 2022, and as a result the Company recognized the $39.8 million as contract revenue. During the first quarter of 2024, the Company recognized $51.7 million deferred revenue as contract revenue as GSK's rights to select the remaining up to two additional non-influenza target pathogens expired on March 25, 2024. During the fourth quarter of 2024, the Company opted-out of the RSV program. GSK continues to pursue the development and commercialization of the RSV program unilaterally. If the RSV program is commercialized, GSK will pay to the Company a royalty on net sales at the low single digits.

Costs associated with co-development activities performed under the 2021 GSK Agreement are included in research and development expenses in the consolidated statements of operations, with any reimbursement of costs by GSK reflected as a reduction of such expenses. During the year ended December 31, 2024, the Company recognized reimbursement of research and development expenses of $0.8 million. During the years ended December 31, 2023, and 2022, the Company recognized additional net research and development expenses of $2.2 million and $2.3 million, respectively.

Brii Biosciences

In 2018, the Company entered into a collaboration, option and license agreement (the "Brii Agreement") with Brii Bio Parent and Brii Biosciences Offshore Limited ("Brii Bio"), pursuant to which the Company granted to Brii Bio, with respect to up to four of the Company's programs, an exclusive option to obtain exclusive rights to develop and commercialize compounds and products arising from such programs in People's Republic of China, Taiwan, Hong Kong and Macau (collectively, the "China Territory") for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection (the "Field of Use"). To date, Brii Bio has opted in for elebsiran and tobevibart to develop and commercialize in the China Territory under the Brii Agreement. In partial consideration for the options granted by the Company to Brii Bio, Brii Bio Parent and Brii Bio granted the Company, with respect to up to four of Brii Bio Parent's or Brii Bio's programs, an exclusive option to be granted exclusive rights to develop and commercialize compounds and products arising from such Brii Bio programs in the United States for the Field of Use. To date, the Company has not exercised any of its options.

In July 2022, Brii Bio exercised its option to obtain exclusive rights to develop and commercialize compounds and products arising from tobevibart in the China Territory. In consideration of the Company's grant to Brii Bio of an exclusive license related to tobevibart in the China Territory, the Company received a $20.0 million option exercise fee in connection with the option exercise. The Company evaluated the tobevibart transaction under ASC 606 and identified one performance obligation consisting of the license granted to Brii Bio. Under the Brii Agreement, Brii Bio is responsible for performing all research and development activities, and the Company does not have any other performance obligations within the context of ASC 606 under the arrangement after the option exercise. The transaction price was determined to be $22.3 million, which consists of the $20.0 million option exercise fee and $2.3 million of the deferred revenue allocated to the tobevibart option at the inception of the Brii Agreement. The Company determined that the license is considered a functional intellectual property that is a distinct performance obligation. Specifically, the Company believes the license is capable of being distinct, as Brii Bio has the capabilities to develop the license either on its own or by contracting with other third parties. Brii Bio can benefit from the license at the time of grant and, therefore, the related performance obligation is satisfied at a point in time.

The Company holds a minority equity interest in Brii Bio through Brii Bio Parent (refer to Note 3 *Fair Value Measurements*). Through the second quarter of 2024, one member of the Company's board of directors had served on Brii Bio Parent's board of directors, and thus Brii Bio Parent and Brii Bio were considered the Company's related parties. For the year ended December 31, 2024 and 2023, the Company recognized no license revenue from a related party. For the years ended December 31, 2022, the Company recognized $22.3 million license revenue from a related party. As of December 31, 2024, the Company recorded $1.5 million deferred revenue, which represents Brii Bio's option to opt in up to two of the Company's programs that will expire in May 2025.

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 directed to HBV, including elebsiran, for all uses and purposes including the treatment of HBV and HDV. In addition, Alnylam granted the Company an exclusive option, for each of the infectious disease siRNA programs directed to the Company's four selected targets, to obtain a worldwide, exclusive license to develop, manufacture and commercialize siRNA products directed to the target of each such program for all uses and purposes other than certain excluded fields. Following the Company's exercise of an option for a program and payment of the program option exercise fee and any outstanding program costs due to Alnylam, the Company is solely responsible, at the Company's expense (subject to Alnylam's exercise of a profit-sharing option), for conducting all development, manufacture and commercialization activities for products arising from each such program. If Alnylam exercises its profit-sharing option, the parties will negotiate and enter into a profit-sharing agreement for such product.

The Company is required to pay Alnylam up to $190.0 million in the aggregate for the achievement of specified development and regulatory milestones for the first siRNA product directed to HBV, whether for the treatment of HBV or HDV. The Company achieved a specified development milestone relating to elebsiran and paid Alnylam $15.0 million in 2020, thereby reducing the $190.0 million initial amount to $175.0 million of potential development and regulatory milestones remaining to be paid related to elebsiran. 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 siRNA products directed to HBV, whether for the treatment of HBV or HDV related to elebsiran. The Company may also be required to pay Alnylam tiered royalties at percentages ranging from the low double-digits to mid-teens on annual net sales of siRNA products directed to HBV, such as elebsiran, whether for the treatment of HBV or HDV. The royalties are payable on a product-by-product and country-by-country basis until the later of the expiration of all valid claims of specified patents covering such product in such country and 10 years after the first commercial sale of such product in such country.

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

The Company did not incur any expenses under the Alnylam Agreement during the year ended December 31, 2024 and incurred expenses of $1.7 million and $1.4 million during the years ended December 31, 2023 and 2022, respectively.

Xencor

In August 2019, the Company entered into a patent license agreement, which was amended in February 2021, with Xencor (the "2019 Xencor Agreement"). In 2020, the Company entered into a patent license agreement (the "2020 Xencor Agreement"). Under these agreements, the Company obtained non-exclusive, sublicensable (only to its affiliates and subcontractors) licenses to incorporate Xencor's licensed technologies into, and to evaluate, antibodies that target influenza A, HBV, and any component of a coronavirus, including SARS-CoV-2, SARS-CoV and MERS-CoV, and worldwide, non-exclusive, sublicensable licenses to develop and commercialize products containing such antibodies incorporating such technologies for all uses. These technologies are used in tobevibart and sotrovimab, incorporating Xencor's Xtend technology.

In consideration for the grant of the license, the Company is obligated to pay regulatory and commercial milestones along with tiered royalties based on net sales of licensed products ranging from the low- to mid-single-digits. The royalties are payable, on a product-by-product and country-by-country basis, until the later of the expiration of the last to expire valid claim in the licensed patents covering such product in such country or 12 years. During the years ended December 31, 2024, 2023, and 2022, the Company recognized $0.6 million, $2.2 million, and $114.5 million, respectively, as cost of revenue for royalties due to Xencor from the sales of sotrovimab.

The 2019 Xencor Agreement and 2020 Xencor Agreement will remain in force, on a product-by-product and country-by-country basis, until the expiration of all royalty payment obligations under each of the respective agreements. The Company may terminate each agreement in its entirety, or on a target-by-target basis, for convenience upon 60 days' written notice. Either party may terminate each agreement for the other party's uncured material breach upon 60 days' written notice (or 30 days in the case of non-payment) or in the event of bankruptcy of the other party immediately upon written notice. Xencor may terminate each agreement immediately upon written notice if the Company challenges, or upon 30 days' written notice if any of the Company's sublicensees challenge, the validity or enforceability of any patent licensed to the Company under each respective agreement.

7. *Balance Sheet Components*

Property and Equipment, net

Property and equipment, net consists of the following (in thousands). Depreciation and amortization expenses were $14.2 million, $18.9 million, and $6.3 million for the years ended December 31, 2024, 2023 and 2022, respectively.

	Useful life (in years)	December 31, 2024	December 31, 2023
Leasehold improvements	8 - 12	$ 53,992	$ 80,290
Laboratory equipment	5	39,428	43,728
Computer equipment	3	2,778	2,783
Furniture and fixtures	5	2,696	2,887
Construction in progress	NA	1,074	226
Property and equipment, gross		99,968	129,914
Less: accumulated depreciation and amortization		(36,785)	(33,896)
Total property and equipment, net		$ 63,183	$ 96,018

Accrued and Other Liabilities

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

	December 31, 2024	December 31, 2023
Payroll and related expenses	$ 31,165	$ 41,322
Research and development expenses	29,225	33,129
Excess funds payable under grant agreements	11,589	9,202
Operating lease liabilities, current	7,752	12,867
Other professional and consulting expenses	2,268	3,418
Other accrued expenses	3,874	4,282
Total accrued and other liabilities	$ 85,873	$ 104,220

8. *Restructuring, Impairment and Related Costs*

In December 2023, the Company initiated strategic steps to reduce operating expenses and focus its capital allocation on programs with the highest potential for patient impact and value creation (“2023 Restructuring Plan”). As part of the steps, the R&D facilities in St. Louis, Missouri and Portland, Oregon were closed in 2024. In addition, approximately 75 net positions, or 12% of the workforce, were eliminated, which includes reductions from the Company’s discontinuation of its innate immunity small molecule group that was initiated in the third quarter of 2023. In August 2024, the Company initiated a strategic restructuring to advance the development of its hepatitis programs and focus on the highest near-term value opportunities (“2024 Restructuring Plan”). The organizational realignment and optimization included phasing out programs in influenza, COVID-19, and the Company’s T cell-based viral vector platform, as well as a workforce reduction of approximately 25% or approximately 140 employees. The actions related to 2023 Restructuring Plan and 2024 Restructuring Plan were substantially completed by the end of 2024.

The following table is a summary of restructuring charges incurred under both the 2023 and 2024 Restructuring Plans and a roll forward of accrued restructuring costs (in thousands).

	Severance and other employee-related expenses	Long-lived assets impairment and disposal losses	Lease termination gain	Total
Accrued restructuring charges at December 31, 2022	**$ —**	**$ —**	**$ —**	**$ —**
Restructuring charges, net	5,898	7,661[1]	—	13,559
Cash payment	(1,444)	—	—	(1,444)
Non-cash activity	—	(7,661)	—	(7,661)
Accrued restructuring charges at December 31, 2023	**$ 4,454**	**$ —**	**$ —**	**$ 4,454**
Restructuring charges, net	10,822	26,499[2]	(2,326)[3]	34,995
Cash payment	(13,664)	—	—	(13,664)
Non-cash activity	—	(26,499)	2,326	(24,173)
Accrued restructuring charges at December 31, 2024	**$ 1,612**	**$ —**	**$ —**	**$ 1,612**
Reconciliation of accrued restructuring charges to the consolidated balance sheets				
Accrued and other liabilities	$ 1,612	$ —	$ —	$ 1,612

[1] Disclosed amount primarily consists of $5.4 million impairment charges recorded upon the Company ceasing to use the leased space at 499 Illinois Street, San Francisco, California, former corporate headquarter in 2023. The related ROU assets and leasehold improvements were evaluated for impairment as a separate asset group, the carrying value of which was determined to be not recoverable. $4.2 million impairment related to the ROU assets and $1.2 million impairment related the leasehold improvements were recognized to reduce the carrying value to an estimated fair value of zero.

[2] Disclosed amount primarily consists of $25.3 million impairment charges recorded due to the closure of the R&D facilities in St. Louis, Missouri and Portland, Oregon in 2024. The related ROU assets and leasehold improvements were evaluated for impairment as two separate asset groups and determined to be abandoned upon the closure of the R&D facilities. $20.3 million impairment related to the leasehold improvements and $5.0 million related to the ROU assets were recognized to write off the carrying value. The lease agreement related to the R&D facility in St. Louis, Missouri was terminated in December 2024.

[3] Disclosed amount relates to the $2.3 million gain from the de-recognition of lease liability upon the termination of the lease agreement related to the R&D facility in St. Louis, Missouri in December 2024.

9. *Leases*

The Company has various operating lease arrangements for office and laboratory spaces located in California and Switzerland with contractual lease periods expiring at various dates through 2035. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain lease agreements also provide the Company with the option to renew for five years or the option to terminate the lease early. These options are not considered in the lease term unless it is reasonably certain that the Company will exercise such options, upon which the ROU assets and lease liabilities are remeasured. Throughout the term of the lease agreements, the Company is responsible for paying certain operating costs, in addition to rent, such as common area maintenance, taxes, utilities and insurance. These additional charges are considered variable lease costs and are recognized in the period in which the costs are incurred. The discount rate used to determine the present value of the lease payments is our estimated collateralized incremental borrowing rate, based on the yield curve for the respective lease terms, as we generally cannot determine the interest rate implicit in the leases.

The following table contains a summary of the lease costs recognized under ASC 842 and additional information related to operating leases (in thousands, except weighted average amounts):

	Years Ended December 31,		
	2024	2023	2022
Operating lease cost	$ 11,446	$ 13,934	$ 15,910
Variable lease cost	10,306	10,996	10,176
Total lease cost	$ 21,752	$ 24,930	$ 26,086
Other Information			
Weighted average remaining lease term (in years)	9.0	8.9	10.0
Weighted average incremental borrowing rate (%)	5.2	5.1	5.2
Cash paid for amounts included in the measurement of operating lease liabilities	$ 28,566	$ 19,584	$ 12,716

The maturity of the Company's operating lease liabilities as of December 31, 2024 was as follows (in thousands):

	Amounts
2025	$ 12,637
2026	12,625
2027	12,912
2028	13,265
2029	13,547
Thereafter	58,523
Total lease payments	123,509
Less: imputed interest	(25,618)
Present value of operating lease liabilities	$ 97,891

The following amounts were recorded in the consolidated balance sheets as of December 31, 2024 and 2023 (in thousands) for various operating leases:

	December 31,	
	2024	2023
Operating ROU assets	59,680	71,182
Accrued and other liabilities	$ 7,752	$ 12,867
Operating lease liabilities, noncurrent	90,139	111,673
Total operating lease liabilities	$ 97,891	$ 124,540

10. *Commitments and Contingencies*

Manufacturing and Supply Agreements

In the first quarter of 2024, the Company and a third-party contract development manufacturing organization entered into various scopes of work with respect to the manufacturing of tobevibart (the "Tobevibart Agreements"). As of December 31, 2024, the Company had unaccrued unpaid commitments of approximately $23 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 (the "Elebsiran Agreements"). As of December 31, 2024, the Company had unaccrued unpaid commitments of approximately $9 million under the Elebsiran Agreements.

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 Company's consolidated balance sheets, consolidated statements of operations, or consolidated statements of cash flows.

11. *Stock-Based Awards*

2019 Equity Incentive Plan

In September 2019, the Company's board of directors adopted, with the approval of its stockholders, the 2019 Equity Incentive Plan (the "2019 Plan") for the issuance of incentive stock options ("ISO"), non-qualified stock options ("NSO"), stock appreciation rights ("SARs"), restricted stock, other stock awards and performance cash awards, to employees, non-employee directors, and consultants. The 2019 Plan became effective concurrent with the Company's initial public offering ("IPO"). Awards granted under the 2019 Plan expire no later than 10 years from the date of grant. For ISO and NSO, the option price generally shall not be less than 100% of the estimated fair value on the date of grant. Options granted typically vest over a four-year period but may be granted with different vesting terms. As of December 31, 2024, there are 22,086,974 shares available for the Company to grant under the 2019 Plan.

2016 Equity Incentive Plan

In September 2016, the Company adopted the 2016 Equity Incentive Plan (the "2016 Plan") for the issuance of ISO, NSO, SARs, restricted stock and other stock awards, to employees, non-employee directors, and consultants under terms and provisions established by the Company's board of directors and approved by the stockholders. Awards granted under the 2016 Plan expire no later than 10 years from the date of grant. For ISO and NSO, the option price shall not be less than 100% of the estimated fair value on the date of grant. Options granted typically vest over a four-year period but may be granted with different vesting terms. In conjunction with adopting the 2019 Plan, the Company discontinued the 2016 Plan with respect to the new equity awards.

2019 Employee Stock Purchase Plan

In September 2019, the Company's board of directors adopted, with the approval of its stockholders, the Employee Stock Purchase Plan ("ESPP"). The ESPP became effective on the completion of the Company's IPO. The ESPP initially authorized the issuance of 1,280,000 shares of the Company's common stock under purchase rights granted to its employees or employees of any of the Company's designated affiliates. The number of shares of the Company's common stock reserved for issuance is subject to an automatic increase at each calendar year. Under the ESPP, the Company may specify offerings with durations of not more than 27 months and may specify shorter purchase periods within each offering. The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their earnings, subject to any plan limitations. Unless otherwise determined by the Company's board of directors, employees can purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first date of an offering or the purchase date. During the year ended December 31, 2024, 487,432 shares were issued under the ESPP.

Stock Option Activity

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

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
			(Years)	(in thousands)
Outstanding at December 31, 2023	11,352,219	$ 30.47	7.1	
Granted	2,908,450	$ 9.71		
Exercised	(322,366)	$ 2.45		
Forfeited	(4,332,712)	$ 30.70		
Outstanding at December 31, 2024	9,605,591	$ 25.03	6.9	$ 2,938
Vested and expected to vest at December 31, 2024	9,605,591	$ 25.03	6.9	$ 2,938
Vested and exercisable at December 31, 2024	5,903,872	$ 30.72	5.6	$ 2,938

The aggregate intrinsic value of options exercised during the years ended December 31, 2024, 2023 and 2022 was $2.4 million, $5.9 million, and $12.1 million, respectively. During the years ended December 31, 2024, 2023, and 2022, the estimated weighted-average grant date fair value of the options granted was $7.40, $19.13, and $22.69 per share, respectively. As of December 31, 2024, the Company expects to recognize the remaining unamortized stock-based compensation expense of $41.5 million related to stock options, over an estimated weighted average period of 2.5 years.

Stock Options Granted to Employees

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

	Years Ended December 31,		
	2024	2023	2022
Expected term of options (in years)	5.5 – 6.1	5.5 – 6.1	5.3 – 6.1
Expected stock price volatility	89.2% – 91.8%	99.0% – 101.5%	101.4% – 111.2%
Risk-free interest rate	3.5% – 4.6%	3.4% – 4.9%	1.6% – 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.

Employees Stock Purchase Plan

In June 2021, the Company initiated its first offering period under the ESPP. Each offering period is six months, which commences on the grant date on or after June 1 and December 1 of each year and ends on the purchase date on or before November 30 and May 31 of each year.

The fair value of employees' purchase rights under the ESPP was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Years Ended December 31,		
	2024	2023	2022
Expected term of ESPP (in years)	0.5	0.5	0.5
Expected stock price volatility	56.6% - 64.4%	41.2% - 95.1%	59.0% - 86.0%
Risk-free interest rate	4.3% - 5.2%	4.5% - 5.2%	0.1% - 4.5%
Expected dividend yield	—	—	—

The expected term of employees' purchase rights is equal to the purchase period. The expected volatility was determined based on the Company's historical volatility. The risk-free interest rate is based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of the grant over the expected term of the employees' purchase rights. 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. Based on the Black-Scholes option-pricing model, the estimated weighted-average grant date fair value of the employees' purchase rights granted for the years ended December 31, 2024, 2023 and 2022 was $2.99, $4.93 and $9.09 per share, respectively.

Restricted Stock Activity

The Company's RSUs activity was summarized as follows:

	Shares	Weighted Average Grant Date Fair Value Per Share
Unvested as of December 31, 2023	4,804,967	$ 28.56
Granted	4,086,171	$ 9.66
Vested	(1,368,362)	$ 30.62
Forfeited	(2,541,694)	$ 20.26
Unvested as of December 31, 2024	4,981,082	$ 16.73

The unvested shares of RSUs have not been included in the shares issued and outstanding. As of December 31, 2024, there was $58.2 million of total unrecognized compensation cost related to unvested restricted stock units, all of which is expected to be recognized over a remaining weighted-average period of 2.7 years.

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 the ESPP in the consolidated statements of operations (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Research and development	$ 43,917	$ 62,745	$ 53,153
Selling, general and administrative	34,540	48,571	48,929
Total stock-based compensation	$ 78,457	$ 111,316	$ 102,082

12. *Net (Loss) Income Per Share*

Basic net (loss) income per common share is computed by dividing the net (loss) income by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net (loss) income per common share is computed by dividing the net (loss) income 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) income per share (in thousands, except share and per share data):

	Years ended December 31,		
	2024	2023	2022
Net (loss) income attributable to VirBio	$ (521,960)	$ (615,061)	$ 515,837
Weighted-average shares outstanding, basic	136,246,865	134,130,924	132,606,767
Weighted-average effect of dilutive securities:			
Options to purchase common stock	—	—	2,130,212
Restricted shares subject to future vesting	—	—	73,851
Shares to purchase under Employee Stock Purchase Plan	—	—	78
Weighted-average shares outstanding, diluted	136,246,865	134,130,924	134,810,908
Net (loss) income per share attributable to VirBio, basic	$ (3.83)	$ (4.59)	$ 3.89
Net (loss) income per share attributable to VirBio, diluted	$ (3.83)	$ (4.59)	$ 3.83

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

	Years ended December 31,		
	2024	2023	2022
Options issued and outstanding	9,605,591	11,124,181	8,853,734
Restricted shares subject to future vesting	4,981,082	5,260,229	2,646,748
Total	14,586,673	16,384,410	11,500,482

13. *Defined Contribution Plan*

The Company sponsors a 401(k) retirement savings plan for the benefit of its employees. Eligible employees may contribute a percentage of their compensation to this plan, subject to statutory limitations. The Company made contributions to the plan for eligible participants, and recorded contribution expenses of $4.3 million, $4.6 million, and $4.0 million for the years ended December 31, 2024, 2023, and 2022, respectively.

14. *Income Taxes*

(Loss) income before benefit from (provision for) income taxes consists of the following (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Domestic	$ (499,680)	$ (608,134)	$ 692,445
Foreign	(23,425)	(20,060)	61,835
Total (loss) income before benefit from (provision for) income taxes	$ (523,105)	$ (628,194)	$ 754,280

The components of benefit from (provision for) income taxes consist of the following (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Current:			
Federal	$ (965)	$ 12,774	$ (238,550)
State	1,254	(685)	(2,432)
Foreign	(2,093)	(75)	(12,647)
	(1,804)	12,014	(253,629)
Deferred:			
Federal	2,105	406	15,186
State	900	598	—
Foreign	(56)	59	—
	2,949	1,063	15,186
Benefit from (provision for) income taxes	$ 1,145	$ 13,077	$ (238,443)

A reconciliation between the U.S. federal statutory income tax rate and the reported effective income tax rate is as follows:

	Years Ended December 31,		
	2024	2023	2022
U.S. federal statutory income tax rate	21.0 %	21.0 %	21.0 %
Foreign tax at less than federal statutory rate	(0.1)	—	(0.3)
State taxes, net of federal benefit	(0.7)	5.3	0.1
Research and development tax credit	2.4	2.4	(2.0)
Permanent items	(2.4)	(1.6)	(7.4)
Changes in valuation allowance	(18.5)	(24.2)	21.1
Other	(1.5)	(0.8)	(0.9)
Effective income tax rate	0.2 %	2.1 %	31.6 %

The tax effects of temporary differences that give rise to significant portions of the Company's deferred tax assets and liabilities as of December 31, 2024, and 2023, are related to the following (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 180,130	$ 138,257
Capitalized research and development	175,835	136,962
Intangible assets	40,593	19,060
Research and development tax credit carryforward	30,549	17,917
Equity compensations	23,776	34,875
Lease liabilities	20,502	29,047
Reserves and accruals	7,543	21,745
Valuation allowance	(453,394)	(356,833)
Deferred tax assets	25,534	41,030
Deferred tax liabilities:		
ROU assets	(12,219)	(16,536)
Property and equipment	(10,628)	(19,610)
Unrealized gain on investments	—	(1,190)
IPR&D	(1,928)	(5,884)
Deferred tax liabilities	(24,775)	(43,220)
Net deferred tax assets (liabilities)	$ 759	$ (2,190)

Although the Company has taxable income for the years ended December 31, 2022, and 2021, it has otherwise incurred accumulated tax losses since inception. Based on the available objective evidence, the Company cannot conclude it is more likely than not that the deferred tax assets will be fully realizable. Accordingly, the Company has provided a valuation allowance against its deferred tax assets. For the year ended December 31, 2024, the Company recorded a valuation allowance increase of $96.6 million. As of December 31, 2024, the Company has net operating loss carryforwards of $645.3 million for federal purposes and $450.2 million for state tax purposes. If not utilized, these carryforwards will begin to expire in 2036 for federal and in 2037 for state tax purposes. As of December 31, 2024, the Company also has net operating loss carryforwards of $31.9 million for Australian tax purposes, which have an indefinite carryforward period, and $29.5 million net operating loss carryforwards for Swiss tax purposes, which have a seven-year carryforward period.

Under the Tax Reform Act of 1986, the amounts of and benefits from net operating loss carryforwards may be impaired or limited in certain circumstances. Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50% over a three-year period. The Company completed its Section 382 analysis as of December 31, 2024, and based on this analysis, it does not expect that the annual limitations will significantly impact its ability to utilize its net operating loss or tax credit carryforwards prior to expiration.

As of December 31, 2024, the Company has research and development tax credit carryforwards of $11.6 million and $26.5 million for federal and state tax purposes, respectively. If not utilized, the federal carryforward will expire in various amounts beginning in 2036. The California credits can be carried forward indefinitely.

The Tax Cuts and Jobs Act of 2017 subjects a U.S. shareholder to current tax on global intangible low-taxed income ("GILTI") earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740 No. 5, Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary differences expected to reverse as GILTI in future years or provide for the tax expense related to GILTI in the year the tax is incurred. The Company has elected to recognize the tax on GILTI as a period expense in the period the tax is incurred.

Uncertain Tax Positions

As of December 31, 2024, and 2023, the Company had an unrecognized tax benefit balance of $17.9 million and $13.6 million, respectively, primarily related to transfer pricing and research and development tax credits. A portion of the unrecognized tax benefits as of December 31, 2024, if recognized, would increase the Company's effective tax rate by 1.8%. Other unrecognized tax benefits as of December 31, 2024, if recognized, would be in the form of net operating loss and tax credit carryforwards, which attract a full valuation allowance offset, and would not impact the Company's effective tax rate. There are no provisions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date. Because the statute of limitations does not expire until after the net operating loss and credit carryforwards are actually used, the statutes are still open on calendar years ending December 31, 2017 and forward for federal and state purposes.

The Company recognized $1.0 million expense for interest and penalties related to uncertain tax positions during 2024, all of which was recorded as accrued and other liabilities as of December 31, 2024. The Company files U.S. federal, state, Switzerland and Australia tax returns. The Company's tax years remain open for all years. As of December 31, 2024, the Company was not under examination by the Internal Revenue Service or any state or foreign tax jurisdiction.

A reconciliation of the beginning and ending amounts of the liability for uncertain tax positions is as follows (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Gross unrecognized tax benefits at January 1	$ 13,583	$ 10,638	$ 7,422
Addition for tax positions taken in the prior years	2,014	29	—
Reduction for tax positions taken in the prior years	(20)	—	(12)
Addition for tax positions taken in current year	2,369	2,916	3,228
Gross unrecognized tax benefits at December 31	$ 17,946	$ 13,583	$ 10,638

15. *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) income that also is reported on the consolidated statements of operations as consolidated net (loss) income. The measure of segment assets is reported on the balance sheet as total consolidated assets. The CODM uses segment net (loss) income 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.

VIR BIOTECHNOLOGY, INC.
Notes to Consolidated Financial Statements

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

	Years Ended December 31,		
	2024	2023	2022
Segment revenue	$ 74,205	$ 86,180	$ 1,615,797
Less: Segment expenses [1]			
Cost of sales	845	2,765	146,319
Research and development			
Contract manufacturing	40,081	114,262	47,960
Clinical costs	57,624	121,422	118,849
Personnel [2]	162,960	189,418	157,167
Licenses, collaborations and contingent consideration [3]	129,846	30,215	54,087
Other R&D [4]	115,988	124,403	96,585
Selling, general and administrative [2]	119,031	174,441	161,762
Restructuring, long-lived assets impairment and related charges	34,995	13,559	—
Plus: Other segment items [5]	65,205	69,188	(317,231)
Segment and consolidated net (loss) income	$ (521,960)	$ (615,117)	$ 515,837

[1] Refer to Note 7 *Balance Sheet Components* for depreciation and amortization expenses included in segment expenses.

[2] Refer to Note 11 *Stock-Based Awards* for stock-based compensation expenses included in segment expenses.

[3] 2024 license collaboration and contingent consideration expenses include $102.8 million expenses related to the portion of the upfront payment under the Sanofi license agreement that was allocated to IPR&D and expensed. Refer to Note 6 *Collaboration and License Agreements* for more details.

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

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

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 (refer to Note 6 *Collaboration and License Agreements* for further details), contract revenue generated from clinical supplies provided to foreign companies, and license revenue from the Company's collaboration with Brii Bio.

	Years Ended December 31,		
Segment revenues attributed to:	2024	2023	2022
U.S. customers	$ 11,525	$ 47,138	$ 39,699
Foreign customers			
GSK	60,309	37,265	1,552,229
Other	2,371	1,777	23,869
Total segment and consolidated revenue	$ 74,205	$ 86,180	$ 1,615,797

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

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. 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 Rule 13a-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 Annual Report on Form 10-K. 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 Annual Report on Form 10-K, 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 Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act). Our internal control over financial reporting is designed under the supervision of our Chief Executive Officer and Chief Financial Officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control — Integrated Framework (2013 Framework). Based on our assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

The effectiveness of our internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report herein, which expresses an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2024.

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 quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Vir Biotechnology, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Vir Biotechnology, Inc.'s internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Vir Biotechnology, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes and our report dated February 26, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Mateo, California

February 26, 2025

Item 9B. Other Information.

Director and Officer Trading Arrangements

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

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

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

On November 15, 2024, 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 Jason O'Byrne, MBA, our Executive Vice President and Chief Financial Officer.

Additionally, on September 13, 2024, Mr. O'Byrne entered into a 10b5-1 trading arrangement that is intended to qualify as an "eligible sell-to-cover transaction" (as described in Rule 10b5-1(c)(1)(ii)(D)(3) of the Exchange Act) with respect to certain RSUs (the "Sell-to-Cover Instructions"). The Sell-to-Cover-Instructions provide for the automatic sale of shares of our common stock that would otherwise be issuable on each settlement of RSUs in amounts necessary to satisfy the Company's applicable tax withholding obligation, which is based on the fair market value of the shares of the Company's common stock subject to the RSUs that are settled on each applicable vesting date. The proceeds of any such sale will be delivered to the Company in satisfaction of such tax withholding obligations. The Sell-to-Cover Instructions are subject to applicable "cooling-off periods", consistent with Rule 10b5-1(c)(1)(ii)(B) of the Exchange Act. Mr. O'Byrne's Sell-to-Cover Instructions apply with respect to the first award of RSUs granted on or after his hire date and any RSUs that may, from time to time following such date, be granted to them by the Company, other than any future granted RSUs which by the terms of the applicable award agreements require the Company to withhold shares to satisfy tax withholding obligations in connection with the vesting and settlement of such RSUs, and therefore do not permit sell-to-cover transactions. The number of shares that will be sold under these RSU sell-to-cover tax withholding arrangements is not currently determinable as the number will vary based on the extent to which vesting conditions are satisfied and the market price of our common stock at the time of settlement.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Proposal 1—Election of Directors," "Information Regarding the Board of Directors and Corporate Governance—Code of Business Conduct and Ethics," "Delinquent Section 16(a) Reports," "Information Regarding the Board of Directors and Corporate Governance—Nominating and Corporate Governance Committee" and "Information Regarding the Board of Directors and Corporate Governance—Audit Committee" in our definitive proxy statement for our 2025 Annual Meeting of Stockholders, or the Proxy Statement.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Executive Compensation" in our Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation—Equity Compensation Plan Information" in our Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Information Regarding the Board of Directors and Corporate Governance—Independence of the Board of Directors," Information Regarding the Board of Directors and Corporate Governance—Audit Committee," Information Regarding the Board of Directors and Corporate Governance—Compensation Committee," Information Regarding the Board of Directors and Corporate Governance—Nominating and Corporate Governance Committee" and "Transactions with Related Persons" in our Proxy Statement.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to the information set forth in the section titled "Proposal 3—Ratification of Appointment of Independent Registered Public Accounting Firm" in our Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The financial statements, financial statement schedules and exhibits filed as part of this Annual Report on Form 10-K are as follows:

(a)(1) Financial Statements

Reference is made to the financial statements included in Item 8 of Part II hereof.

(a)(2) Financial Statement Schedules

All financial statements schedules are omitted because the required information is included in the consolidated financial statements or the notes thereto included in Item 8 of Part II hereof.

(a)(3) Exhibits

		Incorporation by Reference				
Exhibit Number	Description	Form	File Number	Exhibit Reference	Filing Date	Filed Herewith
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	
4.1	Form of Common Stock Certificate of the Company	S-1	333-233604	4.1	09/30/2019	
4.2	Amended and Restated Investors' Rights Agreement, by and among the Company and certain of its stockholders, dated November 29, 2017	S-1	333-233604	4.2	09/03/2019	
4.3	Description of Capital Stock	10-K	001-39083	4.4	03/26/2020	
10.1+	Vir Biotechnology, Inc. 2019 Equity Incentive Plan	S-8	333-234212	4.8	10/15/2019	
10.2+	2019 Employee Stock Purchase Plan	S-8	333-234212	4.11	10/15/2019	
10.3+	Form of Indemnity Agreement by and between the Company and its directors and executive officers	S-1	333-233604	10.1	09/03/2019	
10.4+	Forms of Option Grant Notice and Option Agreement under Vir Biotechnology, Inc. 2019 Equity Incentive Plan	S-1	333-233604	10.3	09/03/2019	
10.5+	Forms of Restricted Stock Unit Grant Notice and Unit Award Agreement under Vir Biotechnology, Inc. 2019 Equity Incentive Plan	10-K	001-39083	10.5	02/25/2021	
10.6+	Amended and Restated Vir Biotechnology, Inc. 2016 Equity Incentive Plan, as amended	S-1	333-233604	10.5	09/03/2019	
10.7+	Forms of Incentive Stock Option Notice and Agreement, Non-Qualified Stock Option Notice and Agreement, Restricted Stock Agreement and Restricted Stock Purchase Agreement under the Vir Biotechnology, Inc. 2016 Equity Incentive Plan	S-1	333-233604	10.6	09/03/2019	
10.8+	Non-Employee Director Compensation Policy					X
10.9+	Vir Biotechnology, Inc. Discretionary Bonus Plan					X
10.10+	Offer Letter between the Company and Marianne De Backer, dated January 19, 2023	10-Q	001-39083	10.1	05/08/2023	
10.11+	Offer Letter between the Company and Jason O'Byrne, dated September 6, 2024	10-Q	001-39083	10.2	11/05/2024	
10.12+	Promotion Letter between the Company and Vanina de Verneuil, dated November 1, 2023					X

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit Reference	Filing Date	
10.13+	Offer Letter between the Company and Mark Eisner, dated May 20, 2024					X
10.14+	Amended and Restated Employment Letter Agreement between the Company and Ann (Aine) M. Hanly, dated May 4, 2021	10-Q	001-39083	10.6	05/06/2021	
10.15+	Vir Biotechnology, Inc. Change in Control and Severance Benefit Plan					X
10.16+	Amended and Restated Employment Letter Agreement between the Company and George Scangos, dated August 27, 2019	S-1	333-233604	10.9	09/03/2019	
10.17†	Collaboration, Option, and License Agreement between the Company and Brii Biosciences Limited (previously named BiiG Therapeutics Limited), dated May 23, 2018	S-1	333-233604	10.16	09/03/2019	
10.18†	Collaboration and License Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated October 16, 2017	S-1	333-233604	10.17	09/03/2019	
10.19†	Amendment No. 1 to the Collaboration and License Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated December 17, 2019	10-K	001-39083	10.19	03/26/2020	
10.20†	Amendment No. 2 to the Collaboration and License Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated March 3, 2020	10-K	001-39083	10.20	03/26/2020	
10.21†	Amendment No. 3 to the Collaboration and License Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated April 1, 2020	S-1	333-239689	10.21	07/06/2020	
10.22†	Letter Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated December 23, 2020	10-K	001-39083	10.24	02/25/2021	
10.23†	Common Stock Issuance Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated October 16, 2017	S-1	333-233604	10.18	09/03/2019	
10.24†	Amendment No. 1 to the Common Stock Issuance Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated December 17, 2019	10-K	001-39083	10.22	03/26/2020	
10.25†	Letter Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated November 13, 2018	S-1	333-233604	10.19	09/03/2019	
10.26†	License Agreement between the Company and MedImmune, LLC, dated September 7, 2018	S-1	333-233604	10.20	09/03/2019	
10.27†	Amendment No. 1 to License Agreement between the Company and MedImmune, LLC, dated September 1, 2020	10-K	001-39083	10.29	02/25/2021	
10.28†	Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated January 26, 2018	S-1	333-233604	10.26	09/03/2019	
10.29†	Amendment No. 1 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated April 18, 2019	10-K	001-39083	10.31	03/26/2020	
10.30†	Amendment No. 2 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated February 24, 2020	10-K	001-39083	10.32	03/26/2020	
10.31†	Amendment No. 3 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated May 22, 2020	10-K	001-39083	10.38	02/25/2021	

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit Reference	Filing Date	
10.32†	Amendment No. 4 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated December 8, 2020	10-K	001-39083	10.39	02/25/2021	
10.33†	Amendment No. 5 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated June 2, 2021)	10-Q	001-39083	10.3	08/05/2021	
10.34†	Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated March 16, 2018	S-1	333-233604	10.27	09/03/2019	
10.35†	Amendment No. 1 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated April 22, 2019	10-K	001-39083	10.34	03/26/2020	
10.36†	Amendment No. 2 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated October 28, 2019	10-K	001-39083	10.35	03/26/2020	
10.37†	Amendment No. 3 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated May 29, 2020	10-Q	001-39083	10.12	08/11/2020	
10.38†	Amendment No. 4 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated June 16, 2021	10-Q	001-39083	10.4	08/05/2021	
10.39†	Amendment No. 5 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated December 8, 2021	10-K	001-39083	10.43	02/28/2022	
10.40†	Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated November 5, 2021	10-K	001-39083	10.44	02/28/2022	
10.41†	Amended and Restated Letter Agreement between the Company and the Bill & Melinda Gates Foundation, dated January 12, 2022	10-K	001-39083	10.45	02/28/2022	
10.42	Stock Purchase Agreement between the Company and the Bill & Melinda Gates Foundation, dated January 12, 2022	10-K	001-39083	10.46	02/28/2022	
10.43†	Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated January 12, 2022	10-K	001-39083	10.47	02/28/2022	
10.44†	Amended and Restated Exclusive License Agreement between the Company (as successor in interest to Humabs BioMed SA (f/k/a Humabs Holding GmbH)) and the Institute for Research in Biomedicine, dated December 16, 2011	S-1	333-233604	10.28	09/03/2019	
10.45†	Amendment to Amended and Restated Exclusive License Agreement between the Company (as successor in interest to Humabs BioMed SA (f/k/a Humabs Holding GmbH)) and the Institute for Research in Biomedicine, dated February 10, 2012	S-1	333-233604	10.29	09/03/2019	
10.46†	Exclusive License Agreement between the Company (as successor in interest to Humabs BioMed SA) and the Institute for Research in Biomedicine, dated December 16, 2011	S-1	333-233604	10.30	09/03/2019	
10.47	Amendment to License Agreement between the Company (as successor in interest to Humabs BioMed SA) and the Institute for Research in Biomedicine, dated February 10, 2012	S-1	333-233604	10.31	09/03/2019	

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit Reference	Filing Date	
10.48†	Amendment Agreement between the Company (as successor in interest to Humabs BioMed SA) and the Institute for Research in Biomedicine, dated January 29, 2018	S-1	333-233604	10.32	09/03/2019	
10.49†	Exclusive License Agreement between the Company and The Rockefeller University, dated July 31, 2018	S-1	333-233604	10.33	09/03/2019	
10.50†	Amendment to Exclusive License Agreement between the Company and The Rockefeller University, dated May 17, 2019	S-1	333-233604	10.34	09/03/2019	
10.51†	Second Amendment to Exclusive License Agreement between the Company and The Rockefeller University, dated September 28, 2020	10-K	001-39083	10.51	02/25/2021	
10.52†	Third Amendment to Exclusive License Agreement between the Company and The Rockefeller University, dated March 1, 2021	10-Q	001-39083	10.5	05/06/2021	
10.53†	Sub-License and Collaboration Agreement between the Company (as successor in interest to Humabs BioMed SA) and MedImmune, LLC, dated March 20, 2012	S-1	333-233604	10.35	09/03/2019	
10.54†	Amendment 1 to Sub-License and Collaboration Agreement between the Company (as successor in interest to Humabs BioMed SA) and MedImmune, LLC, dated April 19, 2013	S-1	333-233604	10.36	09/03/2019	
10.55†	Amendment 2 to Sub-License and Collaboration Agreement between the Company (as successor in interest to Humabs BioMed SA) and MedImmune, LLC, dated April 27, 2015	S-1	333-233604	10.37	09/03/2019	
10.56†	Amendment 3 to Sub-License and Collaboration Agreement between the Company (as successor in interest to Humabs BioMed SA) and MedImmune, LLC, dated December 31, 2015	S-1	333-233604	10.38	09/03/2019	
10.57†	Amendment 4 to Sub-License and Collaboration Agreement between the Company (as successor in interest to Humabs BioMed SA) and MedImmune, LLC, dated August 29, 2016	S-1	333-233604	10.39	09/03/2019	
10.58†	Amendment 5 to Sub-License and Collaboration Agreement between the Company (as successor in interest to Humabs BioMed SA) and MedImmune, LLC, dated July 15, 2017	S-1	333-233604	10.40	09/03/2019	
10.59†	Amendment 6 to Sub-License and Collaboration Agreement between the Company (as successor in interest to Humabs BioMed SA) and MedImmune, LLC, dated September 7, 2018	S-1	333-233604	10.41	09/03/2019	
10.60	Lease Agreement between the Company and ARE-SAN FRANCISCO NO. 43, LLC, dated March 30, 2017	S-1	333-233604	10.42	09/03/2019	
10.61	First Amendment to Lease Agreement between the Company and ARE-SAN FRANCISCO NO. 43, LLC, dated April 10, 2019	S-1	333-233604	10.43	09/03/2019	
10.62†	Lease Agreement between the Company and KRE Exchange Owner LLC, dated December 16, 2021	10-K	001-39083	10.66	02/28/2022	
10.63†	Patent License Agreement between the Company and Xencor, Inc., dated August 15, 2019	S-1	333-233604	10.44	09/03/2019	
10.64†	Amendment 1 to Patent License Agreement between the Company and Xencor, Inc., dated February 23, 2021	10-Q	001-39083	10.3	05/06/2021	

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit Reference	Filing Date	
10.65†	Patent License Agreement between the Company and Xencor, Inc., dated March 25, 2020	8-K	001-39083	99.1	06/19/2020	
10.66†	Amendment 1 to Patent License Agreement between the Company and Xencor, Inc., dated February 23, 2021	10-Q	001-39083	10.4	05/06/2021	
10.67†	Definitive Collaboration Agreement between the Company, Glaxo Wellcome UK Limited and Beecham S.A., dated June 9, 2020	S-1	333-239689	10.54	07/06/2020	
10.68	Stock Purchase Agreement between the Company and Glaxo Group Limited, dated April 5, 2020	S-1	333-239689	10.55	07/06/2020	
10.69†	Amendment No. 1 to the Definitive Collaboration Agreement between the Company and Glaxo Wellcome UK Limited dated May 27, 2022	10-Q	001-39083	10.2	08/09/2022	
10.70†	Amendment No. 2 to the Definitive Collaboration Agreement between the Company and Glaxo Wellcome UK Limited, dated February 8, 2023	10-Q	001-39083	10.3	05/08/2023	
10.71†	Amendment No. 3 to the Definitive Collaboration Agreement between the Company and Glaxo Wellcome UK Limited, dated February 8, 2023	10-Q	001-39083	10.4	05/08/2023	
10.72†	License Agreement between the Company and Amunix Pharmaceuticals, Inc., dated as July 31, 2024	10-Q	001-39083	10.1	11/04/2024	
19	Insider Trading Policy					X
21.1	List of subsidiaries of the Company					X
23.1	Consent of Independent Registered Public Accounting Firm					X
24.1	Power of Attorney (included on the signature page to this report)					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 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 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
97	Dodd-Frank Compensation Recovery Policy	10-K	001-39083	97	02/26/2024	
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.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit Reference	Filing Date	
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).					X

+ 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 that accompany this Annual Report on Form 10-K is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

VIR BIOTECHNOLOGY, INC.

Date: February 26, 2025 By: /s/ Marianne De Backer

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

Date: February 26, 2025 By: /s/ Jason O'Byrne

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Marianne De Backer, M.Sc., Ph.D., MBA, Jason O'Byrne, MBA, and Vanina de Verneuil, J.D., and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Marianne De Backer Marianne De Backer, M.Sc., Ph.D., MBA	Chief Executive Officer and Director *(Principal Executive Officer)*	February 26, 2025
/s/ Jason O'Byrne Jason O'Byrne, MBA	Executive Vice President and Chief Financial Officer *(Principal Financial Officer)*	February 26, 2025
/s/ Brent Sabatini Brent Sabatini, CPA, MBA	Senior Vice President and Chief Accounting Officer *(Principal Accounting Officer)*	February 26, 2025
/s/ Vicki Sato Vicki Sato, Ph.D.	Chairman of the Board of Directors	February 26, 2025
/s/ Norbert Bischofberger Norbert Bischofberger, Ph.D.	Director	February 26, 2025
/s/ Ramy Farid Ramy Farid, Ph.D.	Director	February 26, 2025
/s/ Jeffrey S. Hatfield Jeffrey S. Hatfield	Director	February 26, 2025
/s/ Robert More Robert More	Director	February 26, 2025
/s/ Janet Napolitano Janet Napolitano	Director	February 26, 2025
/s/ Robert Nelsen Robert Nelsen	Director	February 26, 2025
/s/ Saira Ramasastry Saira Ramasastry	Director	February 26, 2025
/s/ George Scangos George Scangos, Ph.D.	Director	February 26, 2025
/s/ Elliott Sigal Elliott Sigal, M.D., Ph.D.	Director	February 26, 2025

VIR BIOTECHNOLOGY, INC.

Non-Employee Director Compensation Policy

Each member of the Board of Directors (the "***Board***") of Vir Biotechnology, Inc. (the "***Company***") who is not also serving as an employee of the Company or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (this "***Policy***"). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be. This Policy may be amended at any time in the sole discretion of the Board, or by the Compensation Committee of the Board at the recommendation of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments to be paid thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
   a. All Eligible Directors: $40,000
   b. Non-executive chairperson of the Board: $75,000 (inclusive of Annual Board Service Retainer)

2. Annual Committee Member Service Retainer:
   a. Member of the Audit Committee: $10,000
   b. Member of the Compensation Committee: $7,500
   c. Member of the Nominating and Corporate Governance Committee: $5,000
   d. Member of the Science and Technology Committee: $7,500

3. Annual Committee Chair Service Retainer (inclusive of Committee Member Service Retainer):
   a. Chairperson of the Audit Committee: $20,000
   b. Chairperson of the Compensation Committee: $15,000
   c. Chairperson of the Nominating and Corporate Governance Committee: $10,000
   d. Chairperson of the Science and Technology Committee: $15,000

The Company will also reimburse each of the Eligible Directors for his or her travel expenses incurred in connection with his or her attendance at Board and committee meetings. Such reimbursements shall be paid on the same date as the annual cash fees are paid.

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2019 Equity Incentive Plan (the "***Plan***"). All stock options granted under this Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan), and a term of 10 years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Grant: For each Eligible Director who is first elected or appointed to the Board following the effective date of this Policy, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted two equity awards (the "***Initial Grants***") with a value of $385,000 in the aggregate comprised of (i) a stock option to purchase shares of the Company's common stock (the "***Initial Option Grant***") and (ii) a restricted stock unit award covering shares of the Company's common stock (the "***Initial RSU Grant***"). The total number of shares subject to the Initial Option Grant will be initially calculated in accordance with the Black-Scholes valuation methodology and the total number of shares subject to the Initial RSU Grant will be initially calculated in accordance with the Fair Market Value as of the grant date, and such resulting number of shares shall be divided between the Initial Grants based on a fixed ratio of two shares subject to the Initial Option Grant for every one share subject to the Initial RSU Grant, with the number of shares subject to the Initial Option Grant rounded down to the nearest whole share and in no event exceeding 16,000 shares and the number of shares subject to the Initial RSU Grant rounded down to the nearest whole share and in no event exceeding 8,000 shares.

   One-third of the shares subject to each Initial Option Grant will vest on the one-year anniversary of the Eligible Director's initial election or appointment to the Board and thereafter the remainder of the shares subject to each such Initial Grant will vest monthly over a two-year period, subject to the Eligible Director's Continuous Service (as defined in the Plan) on each vesting date, and will vest in full upon a Change in Control (as defined in the Plan), subject to the Eligible Director's Continuous Service (as defined in the Plan) on such date. The Initial RSU Grant will vest in three equal installments on the first, second and third anniversaries of the Eligible Director's initial election or appointment to the Board, subject to the Eligible Director's Continuous Service (as defined in the Plan) on each vesting date, and will vest in full upon a Change in Control (as defined in the Plan), subject to the Eligible Director's Continuous Service (as defined in the Plan) on such date.

   In addition, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted the additional awards (the "***Additional Awards***") on the same terms as the Annual Grants (as defined below), except (i) the $385,000 aggregate value of the additional awards shall first be multiplied by a fraction, the numerator of which equals 12 minus the number of calendar months that have occurred since the last annual meeting of stockholders and the denominator of which equals 12, and (ii) such additional awards will vest in full upon the earlier of (i) the one-year anniversary of the date the Annual Grants to the Eligible Directors were last made and (ii) the next annual meeting of stockholders, subject to the Eligible Director's Continuous Service (as defined in the Plan) on the vesting date, and will vest in full upon a Change in Control (as defined in the Plan), subject to the Eligible Director's Continuous Service (as defined in the Plan) on such date.
   In no event may the sum of the value of the Initial Grants and the value of the Additional Awards exceed two times the value of the Annual Grants.

2. Annual Grant: On the first market trading day after each annual stockholders meeting of the Company, each Eligible Director who continues to serve as a member of the Board following such stockholders meeting will be automatically, and without further action by the Board or Compensation Committee of the Board, granted two equity awards (collectively, the "***Annual Grants***") with a value of $385,000 in the aggregate comprised of (i) a stock option to purchase shares of the Company's common stock (the "***Annual Option Grant***"); and (ii) a restricted stock unit award covering shares of the Company's common stock (the "***Annual RSU Grant***"). The shares subject to each Annual Grant will vest in full on the one-year anniversary of the grant date, subject to the Eligible Director's Continuous Service (as defined in the Plan) on the vesting date, and will vest in full upon a Change in Control (as defined in the Plan), subject to the Eligible Director's Continuous Service (as defined in the Plan) on such date. The total number of shares subject to the Annual Option Grant will be initially calculated in accordance with the Black-Scholes valuation methodology as of the grant date and the total number of shares subject to the Annual RSU Grant will be initially calculated in accordance with the Fair Market Value as of the grant date, and such resulting number of shares shall be divided between the Annual Grants based on a fixed ratio of two shares subject to the Annual Option Grant for every one share subject to the Annual RSU Grant, with the number of shares subject to the Annual Option Grant rounded down to the nearest whole share and in no event exceeding 16,000 shares and the number of shares subject to the Annual RSU Grant rounded down to the nearest whole share and in no event exceeding 8,000 shares.

Eligible Director Compensation Limit

Notwithstanding anything herein to the contrary, the cash compensation and equity compensation that each Eligible Director is entitled to receive under this Policy shall be subject to the limits set forth in Section 3(d) of the Plan.

Approved by the Board of Directors: February 24, 2025
Effective: January 1, 2025

Exhibit 10.9

VIR BIOTECHNOLOGY, INC.
DISCRETIONARY BONUS PLAN

ARTICLE 1

PURPOSE OF THE PLAN

This Discretionary Bonus Plan (the "Plan") is established to provide an incentive to selected employees to promote the success of Vir Biotechnology, Inc. (the "Company") by offering an opportunity to receive additional compensation based on corporate performance measured against corporate goals, adjusted for, among other things, personal performance. The Plan is intended to achieve the following:

1.1 Encourage employees to work to meet objectives consistent with enhancing the Company's shareholder value.

1.2 Facilitate the Company's ability to attract, retain, and motivate top talent.

1.3 Ensure that employees are held accountable, and appropriately rewarded, for both Company and individual performance.

ARTICLE 2

DEFINITIONS

1.4 Base Salary – For salaried employees, Base Salary may be one of the following: (a) the regular base salary of a Participant at the end of the relevant Plan Year, (b) the weighted average of a Participant's base salary for a Plan Year, or (c) some other base salary calculation as reasonably and in good faith determined by Company management from time to time. For hourly employees, Base Salary is the base straight time rate of pay paid to the employee during the relevant calendar year. In each such case Base Salary excludes any incentive compensation, commissions, over-time payments, option exercise income, any equity-related amounts, retroactive payments (e.g., make-whole payments) and any other payments of compensation of any kind. Base Salary will be determined by the Company in its sole discretion.

1.5 Board – The Board of Directors of the Company.

1.6 Committee – The Compensation Committee of the Board as from time to time appointed or constituted by the Board, provided that the Board may act as the Committee at any time.

1.7 Company Group – Vir Biotechnology, Inc. and those subsidiaries that the Board has, from time to time, designated as participating employers, if any.

1.8 Employee – Any person who is employed by the Company Group and who is paid on the Company Group's normal employee payroll. Unless required by applicable law, the term shall not include (a) any employee who, during any part of a Plan Year, was represented by a collective bargaining agent, unless the relevant collective bargaining agreement provides for participation in this Plan, (b) anyone whose compensation is paid by a third party (other than the Company's third party payroll administrator), or (c) anyone who was classified by the Company Group as a temporary employee, independent contractor, consultant, intern or agent, even if such classification is wrong.

1.9 Participant – Any Employee selected to participate in the Plan in accordance with its terms.

1.10 Plan – This Vir Biotechnology, Inc. Discretionary Bonus Plan.

1.11 Plan Year – The calendar year, but the Plan Year may be changed at any time by the Committee.

ARTICLE 3

ELIGIBILITY FOR PARTICIPATION

Participants generally are all Employees of the Company Group, as long as they are employed with the Company Group no later than September 30 of the relevant Plan Year, remain employed with the Company Group through the end of the relevant Plan Year and do not voluntarily resign before the date of bonus payment as established by the Company. For clarity, employees who are terminated involuntarily due to substandard job performance or misconduct, as determined in the Company's sole discretion, are not eligible to participate in the Plan. Eligible Participants who work a partial calendar year will be eligible for a pro-rated bonus based on the Participant's number of active calendar days of employment divided by 365.

Each Participant will be assigned a target bonus (based on a percentage of annual base pay) aligned to the Participant's level in the Company's job architecture (the "Target Award").

BONUS ATTAINMENT

1.12 During each Plan Year, the Board will determine the corporate goals and corporate attainment factors relevant to the Plan. The Board may, at any time, prospectively or retroactively, revise the applicable corporate goals and corporate attainment factors.

1.13 As early as feasible after the end of each Plan Year, the Board and/or the Compensation Committee, in their sole discretion respectively, shall determine corporate goal attainment for the prior calendar year ("Corporate Attainment"), expressed as a percentage of attainment.

1.14 Based on Corporate Attainment, the Company's executive management shall recommend to the Company's Chief Executive Officer ("CEO") for her or his review and approval an award amount for each Participant below the level of CEO ("Proposed Awards"), which the Company's CEO, in her or his sole discretion, may accept, increase within the range approved by the Committee, or decrease, including to zero (the "Award"). In turn, the Compensation Committee will determine the CEO's Award based on Corporate Attainment and adjusted for individual performance. To complete the process, the Compensation Committee will review and authorize final approval of all employee Awards.

1.15 For the sake of clarity, the amount of a Participant's Award may be different than the percentage approved by the Committee and/or any award proposed by executive management (including being reduced to zero) based on, among other things, a Participant's non-compliance with applicable law and/or Company Group policies, conduct, job performance, performance evaluations, having received a performance improvement plan, letter of reprimand, job performance counseling, professional conduct counseling, other form of discipline, and/or any other legitimate, non-discriminatory business factors determined relevant during the Award determination process.

1.16 The sum of the Awards for a Plan Year may not exceed the bonus pool (as determined based on Corporate Attainment) for the applicable Plan Year. The entire bonus pool need not be paid to Participants, as determined by the Chief Executive Officer in her or his sole discretion.

1.17 Incentive compensation payments will be made in accordance with Article 4.

1.18 Any bonus budget and the Awards do not represent a segregated fund of assets. Participants have no claim on any particular Company Group assets, either before or after the Proposed Awards or Awards are determined or authorized for the Plan Year. Any incentive compensation paid with respect to the Plan will be paid from the general assets of the Company.

ARTICLE 4

INCENTIVE COMPENSATION PAYMENTS

1.19 AUTHORIZATION OF PAYMENTS – No Award is payable under the Plan for any Plan Year unless and until the Board determines Corporate Attainment and the Committee authorizes the Awards for Participants generally and for Participants who are members of the Section 16 Group in particular.

1.20 METHOD AND TIME OF PAYMENT

(a) Any Award authorized for each Participant with respect to each Plan Year shall be paid to such Participant in cash, Company equity awards (including awards of Company common stock), or in any other form or combination determined by the Committee following the close of the Plan Year and within two and one-half months after the close of the Plan Year.

(b) All Incentive compensation payments shall be paid net of any taxes or other amounts required to be withheld.

(c) CLAW-BACK – Each and every payment to a Participant pursuant to the Plan shall be subject to the right of the Company to recover the payment (and reasonable interest thereon) (a) in the event that the Committee determines in good faith that the Participant's fraud or misconduct has caused or partially caused the need for a material restatement of the Company's financial statements for the Plan Year to which the Plan payment relates or (b) pursuant to any Company claw-back policy in effect from time to time. The Committee's decision regarding whether the Participant has forfeited awards is final and binding in the absence of demonstrable fraud or bad faith on the part of the Committee in making such a decision.

1.21 RIGHTS OF PARTICIPANTS

(a) Participation for one Plan Year does not mean that an individual will be a Participant in future Plan Years. Likewise receipt of an Award for one Plan Year does not mean that the individual will receive Awards in future Plan Years.

(b) The establishment of a bonus pool, if any, in a given Plan Year is subject to the discretion of the Board and/or the Compensation Committee. No Participant shall have any right to require establishment of a bonus pool for any Plan Year. No Participant shall have any vested interest or property right or any share in any amounts that may be established as a bonus pool.

(c) All payments are subject to the discretion of the Committee. No Participant shall have any right to require the Committee to authorize any Awards under the Plan. Even though the Participant's performance may be assessed periodically during the Plan Year, the final determination of a Participant's Award, if any, is subject to the Company's sole and absolute discretion. The mere existence of periodic assessments or tracking does not give the Participant any basis for claiming any incentive compensation under this Plan on a pro rata basis for the Plan Year or otherwise.

(d) Nothing in this Plan gives a Participant the right to remain in the employ of the Company Group. Except to the extent explicitly provided otherwise in a then effective written employment contract executed by Participant and the Company Group, or as otherwise required by applicable law, each Participant is an at will employee whose employment may be terminated without liability at any time for any reason.

ARTICLE 5

ADMINISTRATION

(e) The Plan shall be administered under the direction of the Committee. The Committee shall have the right to construe the Plan, to interpret any provision of the Plan, including to interpret or construe ambiguous, unclear, or implied (but omitted) terms in any fashion the Committee deems appropriate in its sole and absolute discretion, to make rules and regulations relating to the Plan, and to determine any factual question arising in connection with the Plan's operation. Any decision made by the Committee under the provisions of this Article shall be conclusive and binding on all parties concerned. The validity of any such interpretation, construction, decision, or finding of fact shall not be given de novo review if challenged in court or in any other forum and shall be upheld unless clearly arbitrary or capricious.

(f) The Committee may delegate to the officers or employees of the Company the authority to execute and deliver those instruments and documents, to do all acts and things, and to take all other steps deemed necessary, advisable or convenient for the effective administration of this Plan in accordance with its terms and purpose. For the avoidance of doubt, the Committee may not delegate the duty to approve Corporate Attainment or to authorize Awards.

ARTICLE 6

AMENDMENT OR TERMINATION OF PLAN

The Board or the Committee shall have the unilateral right to terminate or amend this Plan at any time with respect to all or some Participants with respect to any unpaid bonus amounts, and to suspend and/or discontinue the Plan. Notwithstanding the foregoing, the Committee shall not have the right to amend the plan to divest the Board of the unilateral right to determine the Corporate Attainment or to amend, suspend or terminate the Plan.

ARTICLE 7

GOVERNING LAW

With respect to each Participant in the United States, the Plan shall be governed and administered in accordance with the laws applicable to the jurisdiction in which each Participant primarily worked during the relevant Plan Year. With respect to each Participant outside of the United States, the Plan shall be governed and administered in accordance with Delaware law, without regard to any provision of Delaware law that would result in the application of another jurisdiction's laws.

ARTICLE 8

EFFECTIVE DATE

The Plan was first effective for the 2025 calendar year.

Exhibit 10.12

November 1, 2023

Dear Vanina,

I want to thank you for your contributions to Vir, and to let you know that they are very much appreciated.

I am pleased to announce your promotion to EVP, General Counsel and Corporate Secretary.

As a result of your promotion, you will receive a base salary increase of $45,000, bringing your new base salary to $470,000 effective November 1, 2023. This increase will be reflected in your November 15, 2023 paycheck. You will be a participant in Vir's 2023 Bonus Plan with an annual target incentive of 45.0% of your base salary.

Subject to Compensation Committee approval on December 14, 2023, you will be granted a stock option award under Vir's 2019 Equity Incentive Plan (the "Plan") to purchase 30,000 shares of Vir's Common Stock (the "Option"). The Option will have an exercise price equal to the fair market value of Vir's common stock on the date of grant and will vest over four (4) years from the commencement date, with 25% of the total number of shares subject to the Option vesting on the one-year anniversary of the vesting commencement date and, the remainder vesting in 36 equal monthly installments thereafter.

Also subject to Committee approval on December 14, 2023, you will be granted 15,000 Restricted Stock Units (RSUs). The RSUs will vest over four (4) years from commencement date, with 25% of the total number of RSUs vesting on each of the four anniversaries of the vesting commencement date.

Vesting of the Option and RSUs will be contingent on your continued service with Vir through the applicable vesting date and will be subject to the terms and conditions of the Plan and the applicable equity award agreement.

All other terms of your employment remain the same.

Thank you again for your support and continuing contributions to Vir's success!

Exhibit 10.13

May 20, 2024

[***]
[***]
[***]

Dear Mark,

Congratulations! We are excited to welcome you to Vir Biotechnology, Inc. ("Vir" or the "Company"). It is my pleasure to extend an offer as a full-time employee of Vir.

Title and Reporting Relationship: You will have the position of Executive Vice President, Chief Medical Officer based in Vir's San Francisco office and reporting to its Chief Executive Officer. This is a full-time position and classified as exempt.

Start Date: This offer is contingent upon your agreement to start work on June 3, 2024 ("Start Date"), unless you and Vir agree in writing to a different start date.

Base Salary: This position is full-time exempt, with an annualized base salary of $650,000, paid on a semi-monthly basis in accordance with Vir's regular payroll cycle.

Annual Bonus: You will be eligible for an annual (calendar year) target bonus, with a target amount equal to 45% of your annual base salary, contingent upon the achievement of individual and Vir performance objectives and granted at the discretion of Vir's Board of Directors (the "Board"). Vir performance objectives will be established by Vir while individual performance objectives will set by your manager. To receive payment of any bonus, you must be employed by Vir at the time bonuses are paid. Any bonus awarded will generally be paid on or before March 15th of the year following the year for which the bonus is awarded and may be pro-rated for any year in which you provide less than a full year of service; provided, however that no bonus will be paid for any year in which less than three months of service is provided. Annual bonus payments and plans are discretionary and subject to the approval and/or modification by the Board in its sole discretion.

Equity: Following commencement of your employment and subject to approval of the Board, Vir will grant you two equity awards under Vir's 2019 Equity Incentive Plan, as may be amended from time to time (the "Equity Plan"). The equity awards will include: (1) an option to purchase 150,000 shares of Vir's common stock (the "Option") and (2) an award of restricted stock units ("RSUs") covering 75,000 shares of Vir's common stock. The Option will have an exercise price equal to the fair market value of Vir's common stock on the date prior to the grant date.

As will be specified in an equity award Grant Notice and Agreement (to be delivered to you separately after the Board approves the Option), the Option will vest over four (4) years, with 25% of the total number of shares subject to the Option vesting on June 15, 2024, if your Start Date occurs in May 2024 *or, alternatively,* on July 15, 2024, if your Start Date occurs in June 2024. The remainder of the Option shares will vest in 36 equal monthly installments thereafter. The RSUs will vest over four (4) years, with one-quarter of the total number of RSUs vesting on each of the first four anniversaries of June 15, 2024, if your Start Date occurs in May 2024 *or, alternatively,* on July 15, 2024, if your Start Date occurs in June 2024.

Vesting of the Option and RSUs will be contingent on your continued service with Vir through the applicable vesting dates and will be subject to the terms and conditions of the Equity Plan and the applicable equity award agreements.

Change in Control & Severance Plan: As a full-time employee and executive of the company, you will be eligible to participate in Vir's Change in Control and Severance Benefit plan, the terms of which are governed by relevant plan document.

Signing Bonus: You are eligible to receive a single signing bonus, paid in two equal installments, in the aggregate gross amount of $750,000 (the "Signing Bonus"), subject to applicable deductions and withholding. This first installment of the Signing Bonus will be paid to you on the first payroll after your Start Date, and the second installment of the Signing Bonus will be paid on the payroll immediately following the first anniversary of your Start Date.

Benefits: You will be eligible to participate in the employee benefit plans maintained by Vir that are in effect from time to time and generally available to Vir employees, subject in each case to the terms and conditions of the relevant plan document. Any benefits offered by Vir are subject to change without notice at Vir's sole discretion.

Paid Time Off ("PTO") and Paid Sick Time: During your employment, you will be eligible for Paid Time Off consistent with Vir's policy. We currently employ a non-accrued, flexible paid time off policy. This plan grants you time off from work as reasonably requested subject to prior written approval by your manager. Approval will be based on the needs of the business, work performance and ability to meet your work commitments and duties.

All employees also receive ten (10) days of Paid Sick Time at the beginning of each calendar year. The permitted uses of Paid Sick Time are described in Vir's Time Away from Work Policy.

At Will Employment Relationship. Employment with Vir is for no specific period of time. Your employment with the Company will be "at will," meaning that either you or the Company may terminate your employment at any time and for any reason, with or without reason and with or without prior notice. Any contrary representations which may have been made to you are superseded by this offer. This is the full and complete agreement between you and the Company on this term. Although your job duties, title, reporting line, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at will" nature of your employment may only be changed in an express written agreement signed by you and the Company. Accordingly, this letter is not a contract and should not be construed as creating contractual obligations.

No Debarment: By signing this letter, you represent and warrant that you have not been debarred under Section (a) or (b) of 21 U.S.C. Section 335a and you do not appear on the United States Food and Drug Administration debarment list. You represent and warrant that you have not committed any crime or conduct that could result in such debarment or your exclusion from any governmental healthcare program. You represent and warrant that, to your knowledge, no investigations, claims or proceedings with respect to any such crimes or conduct are pending or threatened against you. You agree and will undertake to promptly notify the Company if you become debarred or proceedings have been initiated against you with respect to debarment at any time during the term of your employment.

No VISA Sponsorship: You agree that you do not now, and will not in the future, request or require Vir to sponsor you for any type of VISA or similar work permit to perform your job at Vir, as described herein, or to legally remain in the United States. By signing below, you confirm that Vir has not made any representations to you to the contrary.

Background Check: Employment in this position is contingent upon your consent to, and successful completion of, a background check. Although individuals occasionally may start work at Vir before the background check process have been fully completed, continued employment will require completion of a background investigation that is satisfactory to Vir in its sole discretion. Vir reserves the right to terminate the employment of an employee who has started work, but ultimately fails to satisfy the requirements of the pre-employment background check.

Proprietary Information: In your work for Vir, you will be expected not to use or disclose any confidential information, including trade secrets, of any former employer or other person to whom you have an obligation of confidentiality. You agree that you will not bring onto Vir premises any unpublished documents or property belonging to any former employer or other person to whom you have an obligation of confidentiality. You hereby represent that you have disclosed to Vir any conflicts of Interest or contract you have signed that may restrict your employment eligibility or activities on behalf of Vir. Further, you agree to protect against unauthorized disclosure of confidential information and to return any confidential information and other Company property when your employment ends.

Miscellaneous: The offer of employment set forth in this letter is contingent upon: (i) your execution of our standard Employee Confidential Information and Invention Assignment Agreement ("CIIAA"), attached hereto as Exhibit A, along with your execution of this letter; (ii) your consent to a background check with results satisfactory to Vir in its sole discretion; and (iii) your presentation of satisfactory documentary evidence of your identity and authorization to work in the U.S. within three (3) business days of your Start Date. Your employment is subject to Vir's personnel policies, procedures and benefit plans as they may be interpreted, adopted, revised or deleted from time to time in Vir's sole discretion.

By signing this letter, you: (i) represent that you have full authority to accept this position and perform the duties of the position; (ii) specifically warrant that you are not subject to an employment agreement or restrictive covenant preventing full performance of your duties to Vir; (iii) agree to honor all obligations to former employers during your employment with Vir; (iv) acknowledge that the terms described in this letter, together with the CIIAA, set forth the entire understanding between us and supersedes any prior representations or agreements, whether written or oral; there are no terms, conditions, representations, warranties or covenants other than those contained herein; (v) agree that no term or provision of this letter may be amended waived, released, discharged or modified except in writing, signed by you and an authorized officer of Vir, except that Vir may, in its sole discretion, adjust salaries, incentive compensation, stock plans, benefits, job titles, locations, duties, responsibilities, reporting relationships and other terms and conditions of employment; and (vi) agree that this letter will be governed by the laws of the state of California.

If you agree with the terms of this offer of employment, please sign below.

Sincerely,

/s/ Jenny Gumm
Jenny Gumm
EVP, Chief Human Resources Officer

Understood and Accepted:

/s/ Mark Eisner
Mark Eisner

5/20/2024
Date Signed

Exhibit A – CIIAA

For California Employees

VIR BIOTECHNOLOGY, INC.

EMPLOYEE CONFIDENTIAL INFORMATION AND INVENTION ASSIGNMENT AGREEMENT

In consideration of my employment or continued employment by **Vir Biotechnology, Inc.**, its subsidiaries, parents, affiliates, successors and assigns (together "***Company***"), and the compensation paid to me now and during my employment with Company, I hereby enter into this Employee Confidential Information and Invention Assignment Agreement (the "***Agreement***") and agree as follows:

1. Confidential Information Protections.

1.1. Recognition of Company's Rights; Nondisclosure. I understand and acknowledge that my employment by Company creates a relationship of confidence and trust with respect to Company's Confidential Information (as defined below) and that Company has a protectable interest therein. At all times during and after my employment, I will hold in confidence and will not disclose, use, lecture upon, or publish any of Company's Confidential Information, except as such disclosure, use or publication may be required in connection with my work for Company, or unless an officer of Company expressly authorizes such disclosure. I will obtain Company's written approval before publishing or submitting for publication any material (written, oral, or otherwise) that discloses and/or incorporates any Confidential Information. I hereby assign to Company any rights I may have or acquire in such Confidential Information and recognize that all Confidential Information shall be the sole and exclusive property of Company and its assigns. I will take all reasonable precautions to prevent the inadvertent accidental disclosure of Confidential Information.

Notwithstanding the foregoing, pursuant to 18 U.S.C. Section 1833(b), I understand that:

(1) I shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that: (1) is made in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (2) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

(2) An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal; and does not disclose the trade secret, except pursuant to court order.

(3) Nothing in this Agreement shall interfere with or discourage a good faith disclosure to any governmental entity related to a suspected violation of the law. I further understand that the Company will not retaliate against me in any way for a disclosure made in accordance with the law.

1.2. Confidential Information. The term "***Confidential Information***" shall mean any and all confidential knowledge, data or information of Company. By way of illustration but not limitation, "***Confidential Information***" includes (a) trade secrets, inventions, mask works, ideas, processes, formulas, software in source or object code, data, programs, other works of authorship, know-how, improvements, discoveries, developments, designs and techniques and any other proprietary technology and all Intellectual Property Rights (as defined below) therein (collectively, "***Inventions***"); (b) information regarding research, development, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, margins, discounts, credit terms, pricing and billing policies, quoting procedures, methods of obtaining business, forecasts, future plans and potential strategies, financial projections and business strategies, operational plans, financing and capital-raising plans, activities and agreements, internal services and operational manuals, methods of conducting Company business, suppliers and supplier information, and purchasing; (c) information regarding customers and potential customers of Company, including customer lists, names, representatives, their needs or desires with respect to the types of products or services offered by Company, proposals, bids, contracts and their contents and parties, the type and quantity of products and services provided or sought to be provided to customers and potential customers of Company and other non-public information relating to customers and potential customers; (d) information

regarding any of Company's business partners and their services, including names, representatives, proposals, bids, contracts and their contents and parties, the type and quantity of products and services received by Company, and other non-public information relating to business partners; (e) information regarding personnel, employee lists, compensation, and employee skills; and (f) any other non-public information which a competitor of Company could use to the competitive disadvantage of Company. Notwithstanding the foregoing, it is understood that, at all such times, I am free to use information which was known to me prior to my employment with Company or which is generally known in the trade or industry through no breach of this Agreement or other act or omission by me, and I am free to discuss the terms and conditions of my employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act.

1.3. Third Party Information. I understand, in addition, that Company has received and in the future will receive from third parties their confidential and/or proprietary knowledge, data or information (**"*Third Party Information*"**) subject to a duty on Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. During the term of my employment and thereafter, I will hold Third Party Information in confidence and will not disclose to anyone (other than Company personnel who need to know such information in connection with their work for Company) or use, except in connection with my work for Company, Third Party Information or unless expressly authorized by an officer of Company in writing.

1.4. Term of Nondisclosure Restrictions. I understand that Confidential Information and Third Party Information is never to be used or disclosed by me, as provided in this Section 1. If a temporal limitation on my obligation not to use or disclose such information is required under applicable law, and the Agreement or its restriction(s) cannot otherwise be enforced, I agree and Company agrees that the two year period after the date my employment ends will be the temporal limitation relevant to the contested restriction; ***provided, however*****,** that this sentence will not apply to trade secrets protected without temporal limitation under applicable law.

1.5. No Improper Use of Information of Prior Employers and Others. During my employment by Company, I will not improperly use or disclose confidential information or trade secrets, if any, of any former employer or any other person to whom I have an obligation of confidentiality, and I will not bring onto the premises of Company any unpublished documents or any property belonging to any former employer or any other person to whom I have an obligation of confidentiality unless consented to in writing by that former employer or person.

2. Assignments of Inventions.

2.1. Definitions. As used in this Agreement, the term **"*Intellectual Property Rights*"** means all trade secrets, Copyrights, trademarks, mask work rights, patents and other intellectual property rights recognized by the laws of any jurisdiction or country; the term "***Copyright***" means the exclusive legal right to reproduce, perform, display, distribute and make derivative works of a work of authorship (as a literary, musical, or artistic work) recognized by the laws of any jurisdiction or country; and the term "***Moral Rights***" means all paternity, integrity, disclosure, withdrawal, special and any other similar rights recognized by the laws of any jurisdiction or country.

2.2. Excluded Inventions and Other Inventions. Attached hereto as **Exhibit A** is a list describing all existing Inventions, if any, (a) that are owned by me or in which I have an interest and were made or acquired by me prior to my date of first employment by Company, (b) that may relate to Company's business or actual or demonstrably anticipated research or development, and (c) that are not to be assigned to Company ("***Excluded Inventions***"). If no such list is attached, I represent and agree that it is because I have no Excluded Inventions. For purposes of this Agreement, "***Other Inventions***" means Inventions in which I have or may have an interest, as of the commencement of my employment or thereafter, other than Company Inventions (as defined below) and Excluded Inventions. I acknowledge and agree that if I use any Excluded Inventions or any Other Inventions in the scope of my employment, or if I include any Excluded Inventions or Other Inventions in any product or service of Company, or if my rights in any Excluded Inventions or Other Inventions may block or interfere with, or may otherwise be required for, the exercise by Company of any rights assigned to Company under this Agreement, I will immediately so notify Company in writing. Unless Company and I agree otherwise in writing as to particular Excluded Inventions or Other Inventions, I hereby grant to Company, in such circumstances (whether or not I give Company notice as required above), a non-

exclusive, perpetual, transferable, fully-paid and royalty-free, irrevocable and worldwide license, with rights to sublicense through multiple levels of sublicensees, to reproduce, make derivative works of, distribute, publicly perform, and publicly display in any form or medium, whether now known or later developed, make, have made, use, sell, import, offer for sale, and exercise any and all present or future rights in, such Excluded Inventions and Other Inventions. To the extent that any third parties have rights in any such Other Inventions, I hereby represent and warrant that such third party or parties have validly and irrevocably granted to me the right to grant the license stated above.

2.3. Assignment of Company Inventions. Inventions assigned to Company or to a third party as directed by Company pursuant to Section 2.6 are referred to in this Agreement as "***Company Inventions***." Subject to Section 2.4 and except for Excluded Inventions set forth in **Exhibit A** and Other Inventions, I hereby assign to Company all my right, title, and interest in and to any and all Inventions (and all Intellectual Property Rights with respect thereto) made, conceived, reduced to practice, or learned by me, either alone or with others, during the period of my employment by Company. To the extent required by applicable Copyright laws, I agree to assign in the future (when any copyrightable Inventions are first fixed in a tangible medium of expression) my Copyright rights in and to such Inventions. Any assignment of Company Inventions (and all Intellectual Property Rights with respect thereto) hereunder includes an assignment of all Moral Rights. To the extent such Moral Rights cannot be assigned to Company and to the extent the following is allowed by the laws in any country where Moral Rights exist, I hereby unconditionally and irrevocably waive the enforcement of such Moral Rights, and all claims and causes of action of any kind against Company or related to Company's customers, with respect to such rights. I further acknowledge and agree that neither my successors- in-interest nor legal heirs retain any Moral Rights in any Company Inventions (and any Intellectual Property Rights with respect thereto).

2.4. Unassigned or Nonassignable Inventions. I recognize that this Agreement will not be deemed to require assignment of any Invention that is covered under California Labor Code section 2870(a) (the "***Specific Inventions Law***") except for those Inventions that are covered by a contract between Company and the United States or any of its agencies that require full title to such patent or Invention to be in the United States.

2.5. Obligation to Keep Company Informed. During the period of my employment, I will promptly and fully disclose to Company in writing all Inventions authored, conceived, or reduced to practice by me, either alone or jointly with others. At the time of each such disclosure, I will advise Company in writing of any Inventions that I believe fully qualify for protection under the provisions of the Specific Inventions Law; and I will at that time provide to Company in writing all evidence necessary to substantiate that belief. Company will keep in confidence and will not use for any purpose or disclose to third parties without my consent any confidential information disclosed in writing to Company pursuant to this Agreement relating to Inventions that qualify fully for protection under the Specific Inventions Law. I will preserve the confidentiality of any Invention that does not fully qualify for protection under the Specific Inventions Law.

2.6. Government or Third Party. I agree that, as directed by Company, I will assign to a third party, including without limitation the United States, all my right, title, and interest in and to any particular Company Invention.

2.7. Ownership of Work Product. I agree that Company will exclusively own all work product that is made by me (solely or jointly with others) within the scope of my employment, and I hereby irrevocably and unconditionally assign to Company all right, title and interest worldwide in and to such work product. I acknowledge that all original works of authorship which are made by me (solely or jointly with others) within the scope of my employment and which are protectable by Copyright are "works made for hire," pursuant to United States Copyright Act (17 U.S.C., Section 101). I understand and agree that I have no right to publish on, submit for publishing, or use for any publication any work product protected by this Section, except as necessary to perform services for Company.

2.8. Enforcement of Intellectual Property Rights and Assistance. I will assist Company in every proper way to obtain, and from time to time enforce, United States and foreign Intellectual Property Rights and Moral Rights relating to Company Inventions in any and all countries. To that end I will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as Company may reasonably request for use in applying for, obtaining,

perfecting, evidencing, sustaining and enforcing such Intellectual Property Rights and the assignment thereof. In addition, I will execute, verify and deliver assignments of such Intellectual Property Rights to Company or its designee, including the United States or any third party designated by Company. My obligation to assist Company with respect to Intellectual Property Rights relating to such Company Inventions in any and all countries will continue beyond the termination of my employment, but Company will compensate me at a reasonable rate after my termination for the time actually spent by me at Company's request on such assistance. In the event Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in the preceding paragraph, I hereby irrevocably designate and appoint Company and its duly authorized officers and agents as my agent and attorney in fact, which appointment is coupled with an interest, to act for and on my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me. I hereby waive and quitclaim to Company any and all claims, of any nature whatsoever, which I now or may hereafter have for infringement of any Intellectual Property Rights assigned under this Agreement to Company.

2.9. Incorporation of Software Code. I agree that I will not incorporate into any Company software or otherwise deliver to Company any software code licensed under the GNU General Public License or Lesser General Public License or any other license that, by its terms, requires or conditions the use or distribution of such code on the disclosure, licensing, or distribution of any source code owned or licensed by Company **except** in strict compliance with Company's policies regarding the use of such software.

3. Records.

I agree to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that is required by Company) of all Confidential Information developed by me and all Company Inventions made by me during the period of my employment at Company, which records will be available to and remain the sole property of Company at all times.

4. Duty of Loyalty During Employment.

I agree that during the period of my employment by Company, I will not, without Company's express written consent, directly or indirectly engage in any employment or business activity which is directly or indirectly competitive with, or would otherwise conflict with, my employment by Company. I further understand and acknowledge that I am bound by a duty of loyalty pursuant to the California Labor Code.

5. Reasonableness of Restrictions.

5.1. I agree that I have read this entire Agreement and understand it. I agree that this Agreement does not prevent me from earning a living or pursuing my career. I agree that the restrictions contained in this Agreement are reasonable, proper, and necessitated by Company's legitimate business interests. I represent and agree that I am entering into this Agreement freely and with knowledge of its contents with the intent to be bound by the Agreement and the restrictions contained in it.

5.2. In the event that a court finds this Agreement, or any of its restrictions, to be ambiguous, unenforceable, or invalid, I and Company agree that the court will read the Agreement as a whole and interpret the restriction(s) at issue to be enforceable and valid to the maximum extent allowed by law.

5.3. If the court declines to enforce this Agreement in the manner provided in subsection 5.2, Company and I agree that this Agreement will be automatically modified to provide Company with the maximum protection of its business interests allowed by law and I agree to be bound by this Agreement as modified.

6. No Conflicting Agreement or Obligation.

I represent that my performance of all the terms of this Agreement and as an employee of Company does not and will not breach any agreement to keep in confidence information acquired by me in confidence or in trust prior to my employment by Company. I have not entered into, and I agree I will not enter into, any agreement either written or oral in conflict with this Agreement.

7. Return of Company Property.

When I leave the employ of Company, I will deliver to Company any and all drawings, notes, memoranda, specifications, devices, formulas and documents, together with all copies thereof, and any other material containing or disclosing any Company Inventions, Third Party Information or Confidential Information of Company. I agree that I will not copy, delete, or alter any information contained upon my Company computer or Company equipment before I return it to Company. In addition, if I have used any personal computer, server, or e-mail system to

receive, store, review, prepare or transmit any Company information, including but not limited to, Confidential Information, I agree to provide Company with a computer-useable copy of all such Confidential Information and then permanently delete and expunge such Confidential Information from those systems; and I agree to provide Company access to my system as reasonably requested to verify that the necessary copying and/or deletion is completed. I further agree that any property situated on Company's premises and owned by Company, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Company's personnel at any time with or without notice. Prior to leaving, I will cooperate with Company in attending an exit interview and completing and signing Company's termination statement if required to do so by Company.

8. Termination Certification.

Upon separation from employment with the Company, I agree to immediately sign and deliver to the Company the "Termination Certification" in a form identical or similar to the sample attached hereto as Exhibit B.

9. AUDIT.

I acknowledge that I have no reasonable expectation of privacy in any computer, technology system, correspondence, calendar entries, telephone logs, and other business records, such as emails, voicemails, text messages, instant messages (IMs), instant messages, calendars, word processing files, spreadsheets, PDFs, JPEGs, PowerPoint presentations, databases, cloud-based storage, external media, hard drives, DVDs, CDs, USBs, thumb drives, temporary internet files, cookies, .ZIP files, and all other forms of electronic information, wherever it resides, including the Internet or the Company's network. All information, data, and messages created, received, sent, or stored in these systems are, at all times, the property of the Company. As such, the Company has the right to audit and search all such items and systems, without further notice to me, to ensure that the Company is licensed to use the software on the Company's devices in compliance with the Company's software licensing policies, to ensure compliance with the Company's policies, and for any other business-related purposes in the Company's sole discretion. I understand that I am not permitted to add any unlicensed, unauthorized, or non- compliant applications to the Company's technology systems, including, without limitation, open source or free software not authorized by the Company, and that I shall refrain from copying unlicensed software onto the Company's technology systems or using non-licensed software or websites. I understand that it is my responsibility to comply with the Company's policies governing use of the Company's documents and the internet, email, telephone, and technology systems to which I will have access in connection with my employment.

I am aware that the Company has or may acquire software and systems that are capable of monitoring and recording all network traffic to and from any computer I may use. The Company reserves the right to access, review, copy, and delete any of the information, data, or messages accessed through these systems with or without notice to me and/or in my absence. This includes, but is not limited to, all e-mail and instant messages sent or received, all website visits, all chat sessions, all news group activity (including groups visited, messages read, and postings by me), and all file transfers into and out of the Company's internal networks. The Company further reserves the right to retrieve previously deleted messages from instant messaging systems, e-mail or voicemail and monitor usage of the Internet, including websites visited and any information I have downloaded. In addition, the Company may review Internet and technology systems activity and analyze usage patterns and may choose to publicize this data to assure that technology systems are devoted to legitimate business purposes.

10. Legal and Equitable Remedies.

10.1. I agree that it may be impossible to assess the damages caused by my violation of this Agreement or any of its terms. I agree that any threatened or actual violation of this Agreement or any of its terms will constitute immediate and irreparable injury to Company, and Company will have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that Company may have for a breach or threatened breach of this Agreement.

11. NOTICES. Any notices required or permitted under this Agreement will be given to Company at its headquarters location at the time notice is given, labeled "Attention Chief Executive Officer," and to me at my address as listed on Company payroll, or at such other address as Company or I may designate by written notice to the other. Notice will be effective upon receipt or refusal of delivery. If delivered by certified or registered mail, notice will be considered to have been given five business days after it was mailed, as evidenced

by the postmark. If delivered by courier or express mail service, notice will be considered to have been given on the delivery date reflected by the courier or express mail service receipt.

12. General Provisions.

12.1. Governing Law; Consent to Personal Jurisdiction. This Agreement will be governed by and construed according to the laws of the State of California as such laws are applied to agreements entered into and to be performed entirely within California between residents of California. I hereby expressly consent to the personal jurisdiction and venue of the state and federal courts located in California for any lawsuit filed there against me by Company arising from or related to this Agreement.

12.2. Severability. In case any one or more of the provisions, subsections, or sentences contained in this Agreement will, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect the other provisions of this Agreement, and this Agreement will be construed as if such invalid, illegal or unenforceable provision had never been contained in this Agreement. If moreover, any one or more of the provisions contained in this Agreement will for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it will be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it will then appear.

12.3. Successors and Assigns. This Agreement is for my benefit and the benefit of Company, its successors, assigns, parent corporations, subsidiaries, affiliates, and purchasers, and will be binding upon my heirs, executors, administrators and other legal representatives.

12.4. Survival. This Agreement shall survive the termination of my employment, regardless of the reason, and the assignment of this Agreement by Company to any successor in interest or other assignee.

12.5. Employment At-Will. I agree and understand that nothing in this Agreement will change my at-will employment status or confer any right with respect to continuation of employment by Company, nor will it interfere in any way with my right or Company's right to terminate my employment at any time, with or without cause or advance notice.

12.6. Waiver. No waiver by Company of any breach of this Agreement will be a waiver of any preceding or succeeding breach. No waiver by Company of any right under this Agreement will be construed as a waiver of any other right. Company will not be required to give notice to enforce strict adherence to all terms of this Agreement.

12.7. Export. I agree not to export, reexport, or transfer, directly or indirectly, any U.S. technical data acquired from Company or any products utilizing such data, in violation of the United States export laws or regulations.

12.8. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

12.9. Advice of Counsel. **I ACKNOWLEDGE THAT, IN EXECUTING THIS AGREEMENT, I HAVE HAD THE OPPORTUNITY TO SEEK THE ADVICE OF INDEPENDENT LEGAL COUNSEL, AND I HAVE READ AND UNDERSTOOD ALL OF THE TERMS AND PROVISIONS OF THIS AGREEMENT. THIS AGREEMENT WILL NOT BE CONSTRUED AGAINST ANY PARTY BY REASON OF THE DRAFTING OR PREPARATION OF THIS AGREEMENT.**

12.10. Entire Agreement. The obligations pursuant to Sections 1 and 2 (except Subsection 2.4 and the second sentence of Subsection 2.7) of this Agreement will apply to any time during which I was previously engaged, or am in the future engaged, by Company as a consultant if no other agreement governs nondisclosure and assignment of inventions during such period. This Agreement is the final, complete and exclusive agreement of the parties with respect to the subject matter of this Agreement and supersedes and merges all prior discussions between us. No modification of or amendment to this Agreement will be effective unless in writing and signed by the party to be charged. Any subsequent change or changes in my duties, salary or compensation will not affect the validity or scope of this Agreement.

[signatures to follow on next page]

EMPLOYEE or CONSULTANT:

I certify and acknowledge that I have read all of the provisions of this agreement carefully, that I understand its terms, and will fully comply with such provisions. I have completely filled out Exhibit A to this Agreement.

I further understand that this agreement is effective as of the date my employment or consultancy with the company commenced or will commence.

/s/ Mark Eisner

(Signature)

Mark Eisner

Name

5/20/2024

Date

[***]

Email

COMPANY: Vir Biotechnology, Inc.
Accepted and agreed

By:

Name:

Title:

Email:

Exhibit A Excluded Inventions

TO:	**Vir Biotechnology, Inc.**
FROM:	**Mark Eisner**
DATE:	**5/20/2024**

This List of Pre-Employment Inventions, along with any attached pages, is part of and incorporated by reference into the attached Confidential Information and Invention Assignment Agreement.

INSTRUCTIONS TO EMPLOYEE: Please identify below pre-existing documents which describe, and upon which you will rely to establish your ownership of, your pre-employment inventions. Please do not disclose to the Company your pre-employment inventions in detail unless the Company expressly requests that you do.

In filling out this document, please note that witnesses are people who have read and understood the referenced document and who therefore can testify to the existence of the inventions, ideas or works of authorship. Also, inventions, ideas, or works of authorship not owned by you (for example because they have been assigned to a prior employer) are not to be listed here. If any documents are identified below, then the Company may request you to provide the documents and other information to determine if any impediments to employment by the Company exist.

1. **Excluded Inventions Disclosure**. Except as listed in Section 2 below, the following is a complete list of all Excluded Inventions:

   ☒ No Excluded Inventions.

   ☐ See below:

   ☐ Additional sheets attached.

2. Due to a prior confidentiality agreement, I cannot complete the disclosure under Section 1 above with respect to the Excluded Inventions generally listed below, the intellectual property rights and duty of confidentiality with respect to which I owe to the following party(ies):

	Excluded Invention	Party(ies)	Relationship
1.			
2.			
3.			

   ☐ Additional sheets attached

3. Limited Exclusion Notification.

This is to notify you in accordance with Section 2872 of the California Labor Code that the foregoing Agreement between you and Company does not require you to assign or offer to assign to Company any Invention that you develop entirely on your own time without using Company's equipment, supplies, facilities or trade secret information, except for those Inventions that either:

a. **Relate at the time of conception or reduction to practice to Company's business, or actual or demonstrably anticipated research or development; or**
b. **Result from any work performed by you for Company.**

To the extent a provision in the foregoing Agreement purports to require you to assign an Invention otherwise excluded from the preceding paragraph, the provision is against the public policy of this state and is unenforceable.

This limited exclusion does not apply to any patent or Invention covered by a contract between Company and the United States or any of its agencies requiring full title to such patent or Invention to be in the United States.

Exhibit B

SAMPLE Termination Certification

This is to certify that I do not have in my possession, nor have I failed to return, any keys, devices, records, data, notes, reports, proposals, lists, correspondence, specifications, drawings, formulas, sketches, materials, equipment, any other Company documents or property, or reproductions of any and all aforementioned items belonging to **VIR BIOTECHNOLOGY, INC.**, its subsidiaries, affiliates, successors or assigns (together, the "**Company**").

I further certify that I have complied with all the terms of the Company's Confidential Information, and Invention Assignment Agreement (CIIAA) signed by me, including the reporting of any inventions and original works of authorship (as defined therein) conceived or made by me (solely or jointly with others), as covered by that agreement.

I further agree that, in compliance with the CIIAA, I will preserve as confidential all Company Confidential Information and associated Third Party Information, including trade secrets, confidential knowledge, data, or other proprietary information relating to products, processes, know-how, designs, formulas, developmental or experimental work, computer programs, databases, other original works of authorship, customer lists,, business plans, financial information, or other subject matter pertaining to any business of the Company or any of its employees, clients, partners, consultants, or licensees.

Date: _____

Signature: _____

Name of Employee (typed or printed): _____

Address for Notifications: _____

VIR BIOTECHNOLOGY, INC.

CHANGE IN CONTROL AND SEVERANCE BENEFIT PLAN

APPROVED BY THE BOARD OF DIRECTORS: MARCH 11, 2019, and Amended and Restated effective as of January 1, 2025

Section 1. INTRODUCTION.

The Vir Biotechnology, Inc. Change in Control and Severance Benefit Plan (the "***Plan***") established March 11, 2019 (the "***Effective Date***") is hereby amended and restated effective as of January 1, 2025. The purpose of the Plan is to provide for the payment of severance benefits to Eligible Employees in the event that such employees become subject to involuntary employment terminations, including in connection with a Change in Control. Except as otherwise provided in an individual Participation Agreement, this Plan shall supersede any severance benefit plan, policy or practice previously maintained by the Company, including any severance benefits set forth in any individually negotiated employment contract or agreement between the Company and any eligible employee. This Plan document also is the Summary Plan Description for the Plan.

For purposes of the Plan, the following terms are defined as follows:

(a) "***Affiliate***" means (i) any corporation (other than the Company) in an "unbroken chain of corporations" beginning with the Company, if each of the corporations other than the last corporation in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain and (ii) any Subsidiary of the Company.

(b) "***Base Salary***" means base pay (excluding incentive pay, premium pay, commissions, overtime, bonuses and other forms of variable compensation) as in effect immediately prior to a Covered Termination and prior to any reduction that would give rise to an employee's right to resign for Good Reason.

(c) "***Board***" means the Board of Directors of the Company; provided, however, that if the Board has delegated authority to administer the Plan to the Compensation Committee of the Board, then "***Board***" shall also mean the Compensation Committee.

(d) "***Cause***" means, with respect to a particular employee, the occurrence of any of the following events: (i) the employee's commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) the employee's attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (iii) the employee's intentional, material violation of any contract or agreement between the employee and the Company or of any statutory duty owed to the Company; (iv) the employee's unauthorized use or disclosure of the Company's confidential information or trade secrets; (v) the employee's failure to satisfactorily perform his or her job functions, responsibilities or duties, as determined in the Company's sole discretion; or (vi) the employee's gross misconduct. The determination whether a termination is for Cause shall be made by the Plan Administrator in its sole and exclusive judgment and discretion.

(e) "***Change in Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(1) Any Exchange Act Person becomes the owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur (i) on account of the acquisition of securities of the Company by any institutional investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions that are primarily a private financing transaction for the Company or (ii) solely because the level of ownership held by any Exchange Act Person (the "***Subject Person***") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the owner of any

additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(2) There is consummated a merger, consolidation or similar transaction involving, directly or indirectly, the Company if, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not own, directly or indirectly, either (i) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving entity in such merger, consolidation or similar transaction or (ii) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation or similar transaction; or

(3) There is consummated a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportion as their ownership of the Company immediately prior to such sale, lease, license or other disposition.

The term Change in Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.

(f) "***Change in Control Period***" means the period commencing upon the Closing of a Change in Control and ending twelve (12) months following the Closing of a Change in Control.

(g) "***Change in Control Termination***" means an Involuntary Termination that occurs within the Change in Control Period. For such purposes, if the events giving rise to an employee's right to resign for Good Reason arise within the Change in Control Period, and the employee's resignation occurs not later than thirty (30) days after the expiration of the Cure Period (as defined below), such termination shall be a Change in Control Termination.

(h) "***Closing***" means the initial closing of the Change in Control as defined in the definitive agreement executed in connection with the Change in Control. In the case of a series of transactions constituting a Change in Control, "Closing" means the first closing that satisfies the threshold of the definition for a Change in Control.

(i) "***COBRA***" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

(j) "***Code***" means the Internal Revenue Code of 1986, as amended.

(k) "***Company***" means Vir Biotechnology, Inc. or, following a Change in Control, the surviving entity resulting from such event.

(l) "***Covered Termination***" means a Regular Termination or a Change in Control Termination.

(m) "***Director***" means a member of the Board.

(n) "***Eligible Employee***" means an employee of the Company or an Affiliate who meets the requirements to be eligible to receive Plan benefits as set forth in Section 2.

(o) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(p) "***Exchange Act Person***" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities.

(q) "***Good Reason***" has the meaning set forth in Section 2(c)(1) below.

(r) "***Involuntary Termination***" means a termination of employment that is due to: (1) a termination by the Company without Cause or (2) an employee's resignation for Good Reason.

(s) "***Own,***" "***Owned,***" "***Owner***," "***Ownership***" means a person or Entity will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(t) "***Participation Agreement***" means an agreement between an employee and the Company in substantially the form of Appendix A attached hereto, which may include such other terms as the Board deems necessary or advisable in the administration of the Plan.

(u) "***Plan Administrator***" means the Board, the Compensation Committee of the Board, or a duly authorized committee thereof, prior to the Closing and the Representative upon and following the Closing.

(v) "***Regular Termination***" means an Involuntary Termination that is not a Change in Control Termination.

(w) "***Representative***" means one or more members of the Board or other persons or entities designated by the Board prior to or in connection with a Change in Control that will have authority to administer and interpret the Plan upon and following the Closing as provided in Section 7(a).

(x) "***Subsidiary***" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

(y) "***Target Bonus***" means with respect to an Eligible Employee, if there is a cash bonus plan applicable to such Eligible Employee for the year in which such Covered Termination occurs ("***Cash Bonus Plan***"), the cash bonus payable to such Eligible Employee under such Cash Bonus Plan as if all the applicable performance goals for such year were attained at a level of 100%. If no Cash Bonus Plan is in effect for the year in which such Covered Termination occurs, the Target Bonus Amount will be the target bonus, if any, in such Eligible Employee's then-effective employment agreement or offer letter with the Company, as if all of the applicable performance goals for such year were attained at a level of 100%.

Section 2. ELIGIBILITY FOR BENEFITS.

(a) Eligible Employee. An employee of the Company or of an Affiliate is eligible to participate in the Plan if (i) the employee is at the level of Vice President or higher; (ii) the Plan Administrator has designated such employee as eligible to participate in the Plan by providing such person with a Participation Agreement; (iii) such employee has signed and returned such Participation Agreement to the Company within the period specified therein; (iv) such employee's employment with the Company terminates due to a Covered Termination; and (v) such employee meets the other Plan eligibility requirements set forth in this Section 2. The determination of whether an employee is an Eligible Employee shall be made by the Plan Administrator, in its sole discretion, and such determination shall be binding and conclusive on all persons.

(b) Release Requirement. In order to be eligible to receive benefits under the Plan, the employee also must execute a general waiver and release in a form satisfactory to the Company and, specifically, in the event of a Change in Control only, in the form attached hereto as Appendix B (with such modifications as may be required to reflect changes in applicable law or, prior to a Change in Control, such changes as the Plan Administrator determines in good faith) (the "***Release***"), within the applicable time period set forth therein, but in no event more than fifty (50) days following the date of the applicable Covered Termination, and such Release must become effective in accordance with its terms.

(c) Exceptions to Benefit Entitlement. An employee who otherwise is an Eligible Employee will not receive benefits under the Plan in the following circumstances, as determined by the Plan Administrator in its sole discretion:

(1) The employee voluntarily terminates employment with the Company without Good Reason, the Company terminates the employee's employment with the Company for Cause or the employee terminates employment due to the employee's death or disability. Voluntary terminations include, but are not limited to, resignation, retirement or failure to return from a leave of absence on the scheduled date. "Good Reason" for an employee's resignation means the occurrence of any of the following events, conditions or actions taken by the Company without Cause and without such employee's consent: (i) a material reduction of such employee's annual base salary plus target bonus amount, which is a reduction of at least ten percent (10%) of such employee's base salary plus target bonus amount (unless pursuant to a salary or bonus reduction program applicable generally to the Company's similarly situated employees), regardless whether implemented in a single reduction or in a series of reductions; (ii) a material reduction or change in such employee's position, title, authority, duties or responsibilities, or the assignment to the employee of any duties materially inconsistent with the employee's position, duties, authority, responsibilities, or reporting requirements; for the avoidance of doubt, with respect to any Eligible Employee at the level of EVP or above, following a Change in Control such employee's ceasing to be the senior-most executive within such individual's department or function within the ultimate parent of the successor or surviving entity shall be deemed to be a material reduction in duties and responsibilities of such employee; (iii) a relocation of such employee's principal place of employment with the Company (or successor to the Company, if applicable) to a place that increases such employee's one-way commute by more than fifty (50) miles as compared to such employee's then-current principal place of employment immediately prior to such relocation (excluding regular travel in the ordinary course of business); provided that if such employee's principal place of employment is his or her personal residence, this clause (iii) shall not apply or (iv) a material breach by the Company of any written agreement between the employee and the Company; *provided, however*, that in each case above, in order for the employee's resignation to be deemed to have been for Good Reason, the employee must first give the Company written notice of the action or omission giving rise to "Good Reason" within thirty (30) days after the first occurrence thereof; the Company must fail to reasonably cure such action or omission within thirty (30) days after receipt of such notice (the "***Cure Period***"), and the employee's resignation must be effective not later than thirty (30) days after the expiration of such Cure Period;

(2) The employee voluntarily terminates employment with the Company in order to accept employment with another entity that is wholly or partly owned (directly or indirectly) by the Company or an Affiliate and recommences employment prior to the date benefits under the Plan are scheduled to commence; or

(3) The employee is rehired by the Company or an Affiliate and recommences employment prior to the date benefits under the Plan are scheduled to commence.

Section 3. AMOUNT OF BENEFIT.

(a) Tiers. Benefit amounts under this Plan will be determined based on Tiers, as follows:

Tier 1 = CEO

Tier 2 = Employees at or above the level of SVP, including EVPs (not including Tier 1)

Tier 3 = Employees at the VP Level (not including Tier 1 or Tier 2)

(b) Regular Termination. Subject to the terms of the Plan, including, without limitation, execution of the required Release within the applicable time period set forth herein and provided that such Release becomes effective in accordance with its terms, an Eligible Employee shall receive the following severance benefits upon a Regular Termination:

(1) *Cash Severance Benefit***.**

(i) The employee will be entitled to a lump sum cash severance payment which shall be payable within ten (10) business days following the effective date of the Release equal to the employee's Base Salary otherwise payable for the applicable period indicated below (such period of months, the "***Severance Period***"):

Tier	Severance Period
Tier 1	12 months
Tier 2	9 months
Tier 3	6 months

(ii) Tier 1 and 2 employees will additionally be entitled to a portion of such employee's Target Bonus, if any, established for the employee by the Board for the year in which the Regular Termination occurs, in an amount equal to the employee's annual Target Bonus for such year, if any, pro-rated for the number of days in which the employee provided services to the Company in the year in with the Regular Termination occurs, which shall be payable in a lump sum payment within ten (10) business days following the effective date of the Release. For the avoidance of doubt, Tier 3 employees will not be eligible for this benefit.

(2) *Payment of Continued Group Health Plan Benefits*. If the employee timely elects continued group health plan continuation coverage under COBRA the Company shall pay the full amount the employee's COBRA premiums, or shall provide coverage under any self-funded plan, on behalf of the employee for his or her continued coverage under the Company's group health plans, including coverage for the employee's eligible dependents, for the Severance Period (the "***COBRA Payment Period***"). Upon the conclusion of such period of insurance premium payments made by the Company, or the provision of coverage under a self-funded group health plan, the employee will be responsible for the entire payment of premiums (or payment for the cost of coverage) required under COBRA for the duration of the employee's eligible COBRA coverage period. For purposes of this Section, (i) references to COBRA shall be deemed to refer also to analogous provisions of state law and (ii) any applicable insurance premiums that are paid by the Company shall not include any amounts payable by the employee under an Internal Revenue Code Section 125 health care reimbursement plan, which amounts, if any, are the employee's sole responsibility.

(c) Change in Control Termination. Subject to the terms of the Plan, including, without limitation, execution of the required Release within the applicable time period set forth herein and provided that such Release becomes effective in accordance with its terms, an Eligible Employee shall receive the following severance benefits upon a Change in Control Termination. For the avoidance of doubt, in no event shall an employee be entitled to benefits under both Section 3(b) and this Section 3(c). If the employee is otherwise eligible for severance benefits under both Section 3(b) and this Section 3(c), the employee shall receive the benefits set forth in this 3(c) and such benefits shall be reduced by any benefits previously provided to the employee under Section 3(b).

(1) *Cash Severance Benefit***.**

(i) The employee will receive the Base Salary cash severance benefit described in Section 3(b)(1)(i) above, except that the Severance Period will be the applicable number of months provided below, and a lump sum payment shall be made within ten (10) business days following the later of (i) the effective date of the Release, or (ii) the effective date of the Closing.

Tier	Severance Period
Tier 1	18 months
Tier 2	12 months
Tier 3	9 months

(ii) In addition, Tier 1 and 2 employees will be entitled to a payment equal to the Target Bonus, if any, established for the employee by the Board for the year in which the Change in Control Termination occurs multiplied by the applicable multiple provided below (the "***Bonus Multiple***"), which shall be payable in a lump sum payment within ten (10) business days following the later of (i) the effective date of the Release, or (ii) the effective date of the Closing. For the avoidance of doubt, Tier 3 employees will not be eligible for this benefit.

Tier	Bonus Multiple
Tier 1	1.5
Tier 2	1

(2) *Payment of Continued Group Health Plan Benefits*. The employee will receive the payment for continued group health plan benefits described in Section 3(b)(2) above, except that the COBRA Payment Period will be equal to the Severance Period applicable to a Change in Control Termination as set forth in Section 3(c)(1)(i) above.

(3) *Equity Vesting.* Notwithstanding anything to the contrary set forth in the applicable equity plans, the vesting and exercisability (if applicable) of all outstanding unvested time-based equity awards granted under the Company's equity incentive plans that are held by the employee on the date of the Change in Control Termination will be accelerated in full. With respect to any performance-based vesting equity award, such award shall continue to be governed in all respects by the terms of the applicable equity award documents.

(d) Additional Benefits. Notwithstanding anything in this Plan to the contrary, the Company may, in its sole discretion, provide benefits to employees or consultants who are not Eligible Employees ("***Non-Eligible Employees***") chosen by the Plan Administrator, in its sole discretion, and the provision of any such benefits to a Non-Eligible Employee shall in no way obligate the Company to provide such benefits to any other Non-Eligible Employee, even if similarly situated. If benefits under the Plan are provided to a Non-Eligible Employee, references in the Plan to "Eligible Employee" (and similar references) shall be deemed to refer to such Non-Eligible Employee.

(e) Certain Reductions. The Company, in its sole discretion, shall have the authority to reduce an Eligible Employee's severance pay and benefits, in whole or in part, by any other severance pay and benefits provided during a period following written notice of a plant closing or mass layoff, pay and benefits in lieu of such notice, or other similar statutory or contractual notice period, notice pay and/or benefits payable to the Eligible Employee by the Company or an Affiliate that become payable in connection with the Eligible Employee's termination of employment pursuant to (i) any applicable legal requirement, including, without limitation, the Worker Adjustment and Retraining Notification Act, any similar local law, (ii) any employment framework that provides severance pay or benefits pursuant to local regulation or practice; (iii) any individually negotiated employment contract or agreement or any other written employment or severance agreement with the Company, or (iv) any Company policy or practice providing for the Eligible Employee to remain on the payroll for a limited period of time (not to exceed sixty (60) days) after being given notice of the termination of the Eligible Employee's employment, and the Plan Administrator shall so construe and implement the terms of the Plan. Any such reductions that the Company determines to make pursuant to this Section 3(e) shall be made such that any benefit under the Plan shall be reduced solely by any similar type of benefit under such legal requirement, agreement, policy or practice (*i.e.*, any cash severance benefits under the Plan shall be reduced solely by any cash payments or severance benefits under such legal requirement, agreement, policy or practice, and any continued insurance benefits under the Plan shall be reduced solely by any continued insurance benefits under such legal requirement, agreement, policy or practice). The Company's decision to apply such reductions to the severance benefits of one Eligible Employee and the amount of such reductions shall in no way obligate the Company to apply the same reductions in the same amounts to the severance benefits of any other Eligible Employee, even if similarly situated. In the Company's sole discretion, such reductions may be applied on a retroactive basis, with severance benefits previously paid being re-characterized as payments pursuant to the Company's statutory obligation.

(f) Parachute Payments.

(1) Any provision of the Plan to the contrary notwithstanding, if any payment or benefit an Eligible Employee would receive from the Company pursuant to the Plan or otherwise ("***Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then such Payment will be equal to the Reduced Amount (defined below). The "***Reduced Amount***" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Eligible Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for the Eligible Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

(2) In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, the Eligible Employee agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, the Eligible Employee will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

(3) Unless the Eligible Employee and the Company agree on an alternative accounting firm, at the Company's election, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the Closing shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, Entity or group effecting the Change in Control, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

Section 4. RETURN OF COMPANY PROPERTY.

An Eligible Employee will not be entitled to any severance benefit under the Plan unless and until the Eligible Employee returns all Company Property. For this purpose, "Company Property" means all Company documents (and all copies thereof) and other Company property which the Eligible Employee had in his or her possession at any time, including, but not limited to, Company files, notes, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, financial information, research and development information, sales and marketing information, operational and personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computers, facsimile machines, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions thereof in whole or in part).

Section 5. TIME OF PAYMENT AND FORM OF BENEFIT.

All severance payments under the Plan will be subject to applicable withholding for federal, state and local taxes. If an Eligible Employee is indebted to the Company on his or her termination date, the Company reserves the right to offset any severance payments under the Plan by the amount of such indebtedness. All severance benefits provided under the Plan are intended to satisfy the requirements for an exemption from application of Section 409A of the Code to the maximum extent that an exemption is available and any ambiguities herein shall be interpreted accordingly; provided, however, that to the extent such an exemption is not available, the severance benefits provided under the Plan are intended to comply with the requirements of Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly.

Notwithstanding anything to the contrary set forth herein, any payments and benefits provided under the Plan that constitute "deferred compensation" within the meaning of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively "***Section 409A***") shall not commence in connection with an Eligible Employee's termination of employment unless and until the Eligible Employee has also incurred a "separation from service," as such term is defined in Treasury Regulations Section 1.409A-1(h) ("***Separation from Service***"), unless the Company reasonably determines that such amounts may be provided to the Eligible Employee without causing the Eligible Employee to incur the adverse personal tax consequences under Section 409A.

It is intended that (i) each installment of any benefits payable under the Plan to an Eligible Employee be regarded as a separate "payment" for purposes of Treasury Regulations Section 1.409A-2(b)(2)(i), (ii) all payments of any such benefits under the Plan satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4) and 1.409A-1(b)(9)(iii), and (iii) any such benefits consisting of COBRA premiums also satisfy, to the greatest extent possible, the exemption from the application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(9)(v). However, if the Company determines that any such benefits payable under the Plan constitute "deferred compensation" under Section 409A and the Eligible Employee is a "specified employee" of the Company, as such term is defined in Section 409A(a)(2)(B)(i), then, solely to the extent necessary to avoid the imposition of the adverse personal tax consequences under Section 409A, (A) the timing of such benefit payments shall be delayed until the earlier of (1) the date that is six (6) months and one (1) day after the Eligible Employee's Separation from Service and (2) the date of the Eligible Employee's death (such applicable date, the "***Delayed Initial Payment Date***"), and (B) the Company shall (1) pay the Eligible Employee a lump sum amount equal to the sum of the benefit payments that the Eligible Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the benefits had not been delayed pursuant to this paragraph and (2) commence paying the balance, if any, of the benefits in accordance with the applicable payment schedule.

In no event shall payment of any benefits under the Plan be made prior to an Eligible Employee's termination date or prior to the effective date of the Release. If the Company determines that any payments or benefits provided under the Plan constitute "deferred compensation" under Section 409A, and the Eligible Employee's Separation from Service occurs at a time during the calendar year when the Release could become effective in the calendar year following the calendar year in which the Eligible Employee's Separation from Service occurs, then regardless of when the Release is returned to the Company and becomes effective, the Release will not be deemed effective any earlier than the latest permitted effective date (the "***Release Deadline***"). If the Company determines that any payments or benefits provided under the Plan constitute "deferred compensation" under Section 409A, then except to the extent that payments may be delayed until the Delayed Initial Payment Date pursuant to the preceding paragraph, on the first regular payroll date following the effective date of an Eligible Employee's Release, the Company shall (1) pay the Eligible Employee a lump sum amount equal to the sum of the benefit payments that the Eligible Employee would otherwise have received through such payroll date but for the delay in payment related to the effectiveness of the Release and (2) commence paying the balance, if any, of the benefits in accordance with the applicable payment schedule.

All severance payments under the Plan shall be subject to applicable withholding for federal, state and local taxes. If an Eligible Employee is indebted to the Company at his or her termination date, the Company reserves the right to offset any severance payments under the Plan by the amount of such indebtedness to the extent permitted by applicable law.

Section 6. REEMPLOYMENT.

In the event of an Eligible Employee's reemployment by the Company during the period of time in respect of which severance benefits pursuant to the Plan have been paid, the Company, in its sole and absolute discretion, may require such Eligible Employee to repay to the Company all or a portion of such severance benefits as a condition of reemployment.

Section 7. RIGHT TO INTERPRET AND ADMINISTER PLAN; AMENDMENT AND TERMINATION.

(a) Interpretation and Administration. Prior to the Closing, the Board, or a duly authorized committee thereof, shall be the Plan Administrator and shall have the exclusive discretion and authority to establish rules, forms, and procedures for the administration of the Plan and to construe and interpret the Plan and to decide any and all questions of fact, interpretation, definition, computation or administration arising in connection with the operation of the Plan, including, but not limited to, the eligibility to participate in the Plan and amount of benefits paid under the Plan. The rules, interpretations, computations and other actions of the Board shall be binding and conclusive on all persons. Upon and after the Closing, the Plan will be interpreted and administered in good faith by the Representative who shall be the Plan Administrator during such period. All actions taken by the Representative in interpreting the terms of the Plan and administering the Plan upon and after the Closing will be final and binding on all Eligible Employees. Any references in this Plan to the "Board" or "Plan Administrator" with respect to periods following the Closing shall mean the Representative.

(b) Amendment. The Plan Administrator reserves the right to amend this Plan at any time; *provided, however,* that any amendment of the Plan will not be effective as to a particular employee who is or may be adversely impacted by such amendment or termination and has an effective Participation Agreement without the written consent of such employee. Any action amending the Plan shall be in writing.

(c) Termination. The Plan shall have an initial term of five (5) years from the date of Board approval of the Plan and shall automatically renew for successive two (2) year terms thereafter unless notice of termination of the Plan is given to all participants at least six (6) months in advance of any such renewal date; *provided, however,* that no such termination shall occur once a Change in Control Period has commenced. In addition, no such termination may materially impair the rights of an Eligible Employee whose Covered Termination occurred prior to such termination, without the written consent of such Eligible Employee.

Section 8. NO IMPLIED EMPLOYMENT CONTRACT.

The Plan shall not be deemed (i) to give any employee or other person any right to be retained in the employ of the Company or (ii) to interfere with the right of the Company to discharge any employee or other person at any time, with or without cause, which right is hereby reserved.

Section 9. LEGAL CONSTRUCTION.

This Plan is intended to be governed by and shall be construed in accordance with the laws of the State of California (but not its conflicts of law provisions).

APPENDIX A
VIR BIOTECHNOLOGY, INC.
CHANGE IN CONTROL AND SEVERANCE BENEFIT PLAN

PARTICIPATION AGREEMENT

Name: _____

Section 1. ELIGIBILITY.

You have been designated as eligible to participate in the Vir Biotechnology, Inc. Change in Control and Severance Benefit Plan (the "***Plan***"), a copy of which is attached to this Participation Agreement (the "***Agreement***"). Capitalized terms not explicitly defined in this Agreement but defined in the Plan shall have the same definitions as in the Plan.

Section 2. SEVERANCE BENEFITS

Subject to the terms of the Plan, if you experience a Covered Termination, and meet all the other eligibility requirements set forth in the Plan, including, without limitation, executing the required Release within the applicable time period set forth therein and provided that such Release becomes effective in accordance with its terms, you will receive the applicable severance benefits set forth in Section 3 of the Plan.

Section 3. REQUIREMENTS DURING SEVERANCE PERIOD.

Your eligibility for and receipt of any severance benefits to which you may become entitled as described in Section 2 above is expressly contingent upon your timely execution of an effective Release and your compliance with the terms and conditions of the provisions of the Confidential Information and Invention Assignment Agreement between you and the Company, as may be amended from time to time (the "***CIIAA***"). Severance benefits under this Agreement shall immediately cease in the event of your violation of the provisions in this Section 3.

Section 4. ACKNOWLEDGEMENTS.

As a condition to participation in the Plan, you hereby acknowledge each of the following:

(a) The severance benefits that may be provided to you under this Agreement are subject to all of the terms of the Plan which is incorporated into and becomes part of this Agreement, including but not limited to the reductions under Section 3 of the Plan.

(b) This Agreement and the Plan supersedes any severance benefit plan, policy or practice previously maintained by the Company that may have been applicable to you or any individually negotiated employment contract or agreement between you and the Company.

(c) You may not sell, transfer, or otherwise assign or pledge your right to benefits under this Agreement and the Plan to either your creditors or to your beneficiary, except to the extent permitted by the Plan Administrator if such action would not result in adverse tax consequences under Section 409A.

To accept the terms of this Agreement and participate in the Plan, please sign and date this Agreement in the space provided below and return it to the head of Human Resources Officer, no later than ten (10) days from the date first set forth below.

VIR BIOTECHNOLOGY, INC.

By: _____

Name: _____

Title: _____

Date: _____

Appendix B

VIR BIOTECHNOLOGY, INC.

CHANGE IN CONTROL AND SEVERANCE BENEFIT PLAN

Release Agreement in the event of a change in control only

THIS RELEASE AGREEMENT (this "***Agreement***"), effective as of the date of the last signature below, is entered into by and between Vir Biotechnology, Inc. (the "***Company***") and [ ] ("***Executive***").

RECITALS

WHEREAS, Executive is an Eligible Employee as defined in the Company's Change in Control and Severance Benefit Plan (the "***Plan***");

WHEREAS, the parties agree that Executive will cease to be employed by the Company, and that Executive's employment with the Company will terminate, as the result of a Change in Control Termination (as defined in the Plan); and

WHEREAS, Executive and the Company desire to end the employment relationship amicably and to resolve and settle any and all claims that Executive has or may have against the Company, including claims arising from any aspect of Executive's employment with the Company or the termination of the employment relationship.

NOW, THEREFORE, in consideration of the mutual covenants and obligations contained herein, including the foregoing recitals, Executive and the Company, each intending to be legally held bound, agree as follows:

AGREEMENT

1. Termination Date. Executive's employment with the Company (and any of its subsidiaries or affiliates) will terminate as a result of a Change in Control Termination effective [DATE] (the "***Separation Date***"). Executive shall not be entitled to any further salary, bonuses, wages, benefits, retirement benefits, insurance, or other compensation or benefits of any type from the Company, its subsidiaries or its affiliates as of the Separation Date. Effective as of the Separation Date, Executive hereby resigns from all positions Executive holds as an officer, director or otherwise with respect to the Company, its subsidiaries and its affiliates.

2. Payments and Benefits. Provided that (a) this Agreement becomes effective in accordance with the terms herein and (b) Executive complies with Executive's obligations under this Agreement and the Plan, Executive shall be entitled to the payments and benefits set forth in Section [2][3] of the Plan. Except as otherwise set forth in the Plan, Executive acknowledges and agrees that Executive has forfeited all equity awards outstanding as of the Separation Date to the extent such awards were unvested as of such date, and that such unvested portion of such awards terminated as of the Separation Date.

3. Responsibility for Taxes. Executive shall be solely responsible for the reporting and payment of any federal, state and/or local income or employment taxes and/or any other withholdings, if any, on all compensation and benefits provided to Executive under this Agreement, except for the amounts actually withheld by the Company in compliance with this Agreement. Executive shall indemnify, hold harmless and defend the Company, its officers, directors and shareholders stockholders from any and all taxes, penalties, interest, claims, costs and fees (including attorneys' fees and costs), damages or actions based upon or arising out of or related to the foregoing.

4. Release.

   (a) Executive, for and on behalf of himself Executive and Executive's executors, administrators, heirs, personal representatives, successors and assigns, voluntarily, knowingly and willingly releases and forever discharges the Company, together with its

parents, subsidiaries, co-venturers and affiliates, and each of their respective predecessors, successors and assigns, and all of those entities' current and former partners, stockholders, members, owners, heirs, assigns, employees, agents, officers, directors, attorneys, and insurers, but only in their capacities as such (collectively, "***Releasees***") from any and all rights, claims, charges, actions, causes of action, complaints, sums of money, suits, debts, covenants, contracts, agreements, promises, obligations, damages, demands or liabilities of every kind whatsoever, in law or in equity, whether known or unknown, suspected or unsuspected (collectively, "***Claims***") which Executive or Executive's heirs, executors, administrators, successors or assigns ever had, now has or may hereafter claim to have by reason of any matter, cause or thing whatsoever: (i) arising from the beginning of time through the date upon which Executive signs this Agreement, including, but not limited to, (A) any such Claims arising out of or relating in any way to Executive's employment and/or other relationship with the Company or any other Releasees, or (B) any such Claims arising out of or related to the termination of Executive's employment and/or other relationship, or (ii) any such Claims arising under or relating to any policy, agreement, understanding or promise, written or oral, formal or informal, between the Company or any of the other Releasees and Executive, including, but not limited to, the Plan. The Claims released hereunder include, without limitation, any claims arising under any federal, local or state statute or regulation, including, without limitation, the Age Discrimination in Employment Act of 1967, as amended by the Older Workers Benefit Protection Act ("***ADEA***"), Title VII of the Civil Rights Act of 1964, Equal Pay Act, as amended, the Civil Rights Act of 1866, the Family and Medical Leave Act of 1993, the False Claims Act, the Worker Adjustment and Retraining Notification Act, as amended, the Fair Labor Standards Act, the Americans with Disabilities Act of 1990, the Executive Retirement Income Security Act of 1974, the California Equal Pay Law, as amended, the Moore-Brown-Roberti Family Rights Act of 1991, as amended, the California WARN Act, the California False Claims Act, the California Corporate Criminal Liability Act, the California Labor Code, the California Fair Employment and Housing Act, the California Family Rights Act, the California Constitution and the California Labor, Government, Civil and Business and Professions Codes, all as amended and including all of their respective implementing regulations and/or any other federal, state, local or foreign law (statutory, regulatory or otherwise) that may be legally waived and released; provided, however, that notwithstanding the foregoing, nothing contained in this Section 4 shall in any way diminish or impair: (I) any rights Executive may have to vested benefits under employee benefit plans sponsored by the Company; (II) Executive's ability to bring proceedings to enforce the right to receive separation benefits pursuant to Section 2 of this Agreement; (III) any Claims Executive may have that cannot be waived under applicable law, such as unemployment benefits, workers' compensation and disability benefits; or (IV) any rights Executive may have to bring any Claim for indemnification under any applicable directors and officers liability insurance policy or applicable state or federal law.

(b) Executive acknowledges and agrees that the Company and the Releasees have fully satisfied any and all obligations owed to Executive arising out of or relating to Executive's employment with the Company, and no further sums, payments or benefits are owed to Executive by the Company or any of the Releasees arising out of or relating to Executive's employment with the Company, except as expressly provided in this Agreement.

(c) This Agreement is intended to be effective as a general release of and bar to all claims as stated in this Section 4. Accordingly, Executive expressly waives all rights under Section 1542 of the California Civil Code ("***Section 1542***") or any similar statute or common law doctrine under applicable law in any other jurisdiction. Section 1542 states as follows: "A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY." Executive acknowledges that Executive may later discover claims or facts in addition to or different from those that Executive now knows or believes to exist with regard to the subject matter of this Agreement, and that, if known or suspected at the time of executing this Agreement, may have materially affected its terms. Nevertheless, Executive waives any and all claims that might arise as a result of such different or additional claims or facts.

5. Continuing Obligations. Executive acknowledges and agrees that the covenants in any other agreement between the Company and the Executive containing post-termination restrictive covenants or similar post-termination obligations remain in full force and effect and shall survive the execution, delivery and performance of this Agreement.

6. No Future Employment. Executive waives any rights to employment, engagement or services with the Company or any of its affiliated or successor entities and agrees not to seek employment, engagement or services with the Company or any of its affiliated or successor entities in the future.

7. No Assistance. Executive shall not assist in the presentation or prosecution of any disputes, differences, grievances, claims, charges or complaints on behalf of any private third party against any of the Releasees, unless under a lawful subpoena or other court order to do so.

8. Confidentiality.

   (a) Other than as may be required by law, and subject to Section 8(b) and Section 10, Executive agrees not to disclose to, or discuss with, any person, corporation, agency, group, or other organization, either directly or indirectly, except Executive's tax preparer, immediate family and/or attorneys (provided they agree to maintain confidentiality of such information), any information relating to the consideration hereunder or any other terms and conditions of this Agreement.

   (b) Nothing in this Agreement shall prohibit Executive from disclosing the underlying facts or circumstances relating to claims of discrimination, in violation of laws prohibiting discrimination, against the Company.

9. Cooperation. Executive agrees to cooperate voluntarily with the Company, to provide truthful information, and to memorialize any information provided in the course of interviews with representatives of the Company or its affiliates, regarding any actual or threatened litigation involving the Company or its affiliates. Executive further agrees that Executive will cooperate with the Company and its affiliates and provide the Company or its affiliates with truthful information regarding the work that Executive has done for the Company or its affiliates, including the location and contents of all files, including electronic files, relating to such work.

10. Permitted Disclosures.

   (a) Pursuant to 18 U.S.C. § 1833(b), Executive hereby acknowledges that Executive shall not have criminal or civil liability under any federal or state trade secret law for the disclosure of a trade secret that (i) is made (A) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney and (B) solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document that is filed under seal in a lawsuit or other proceeding. Executive understands that if Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, he may disclose the trade secret to Executive's attorney and use the trade secret information in the court proceeding if Executive (x) files any document containing the trade secret under seal, and (y) does not disclose the trade secret, except pursuant to court order. Nothing in this Agreement or any other agreement by and between the Company and Executive is intended to conflict with 18 U.S.C. § 1833(b) or create liability for disclosures of trade secrets expressly allowed by such section.

   (b) Further, nothing in this Agreement or any other agreement by and between the Company and Executive shall prohibit or restrict Executive from (i) voluntarily communicating with an attorney retained by Executive solely for the purpose of reporting or investigating a suspected violation of law, (ii) voluntarily communicating with any law enforcement, government agency, including the Securities and Exchange Commission ("***SEC***"), the Equal Employment Opportunity Commission, a local commission on human rights, or any self-regulatory organization regarding possible violations of law, in each case without advance notice to the Company, or otherwise initiating, testifying, assisting, complying with a subpoena from, or participating in any manner with an investigation conducted by such government agency, (iii) recovering a SEC whistleblower award as provided under Section 21F of the Securities Exchange Act of 1934, (iv) disclosing any confidential information to a court or other administrative or legislative body in response

to a subpoena, provided that Executive first promptly notifies and provides the Company with the opportunity to seek, and join in its efforts at the sole expense of the Company, to challenge the subpoena or obtain a protective order limiting its disclosure, or other appropriate remedy, or (v) filing or disclosing any facts necessary to receive unemployment insurance, Medicaid or other public benefits to which Executive is entitled.

11. Return of Property. Executive represents that Executive has returned to the Company all property of the Company in Executive's possession, custody or control, including, without limitation, any and all materials and equipment supplied by the Company, such as credit cards, computers, phones, tablets, other electronic equipment and keys, and any and all documents, contracts, agreements, plans, books, notes, instructional and policy manuals, mailing lists, computer software, financial and accounting records, reports and files, including, without limitation, any such documents or other materials which contain confidential information, and any copies of any of the foregoing. To the extent Executive has any of the foregoing property of the Company in Executive's possession, custody or control in electronic form (for example, in Executive's personal cloud storage or email account or on a personal computer), Executive has identified such documents to the Company, delivered identical copies of such documents to the Company (if the Company so requested), and followed the Company's instructions regarding the permanent deletion or retention of such documents. The property which must have been returned to the Company pursuant to this Section 11 must have been returned whether in Executive's possession, work area, home, vehicle or in the wrongful possession of any third party with Executive's knowledge or acquiescence, and whether prepared by Executive or any other person or entity.

12. Consultation With Counsel/Time To Review Agreement.

(a) Executive understands that under the Older Workers Benefit Protection Act, Executive has a right to review and revoke this Agreement as follows. Executive agrees and acknowledges that this Agreement includes a waiver and release of all claims that Executive has or may have under the Age Discrimination in Employment Act of 1967, as amended, 29 U.S.C. § 621, et seq. ("***ADEA***"). The following terms and conditions apply to and are part of the waiver and release of the ADEA claims under this general release. Executive acknowledges that (i) the Company has advised Executive to consult with an attorney of Executive's own choosing before signing this Agreement, (ii) Executive has been given the opportunity to seek the advice of counsel, (iii) Executive has carefully read and fully understands all of the provisions of this Agreement, (iv) the release provided herein specifically applies to any rights or claims Executive may have against the Releasees pursuant to the ADEA, (v) Executive is entering into this Agreement knowingly, freely and voluntarily in exchange for good and valuable consideration to which Executive is not otherwise entitled, and (vi) Executive has the full power, capacity and authority to enter into this Agreement. Executive intends that this Agreement shall not be subject to any claim for duress.

(b) Executive understands and agrees that Executive has twenty-one (21) calendar days following Executive's receipt of this Agreement (on [DATE]) to consider whether to sign this Agreement, although Executive may sign it sooner. For a period of seven (7) days after the date on which Executive signs this Agreement, Executive may, in Executive's sole discretion, rescind this Agreement by delivering a written notice of rescission to the Company and delivered, by email, by hand or overnight courier service or mailed by certified or registered mail, to [NAME/TITLE/ADDRESS] by no later than 5:00 p.m. Pacific Time on the seventh (7th) day following after Executive's execution of this Agreement. If Executive timely and properly revokes Executive's consent within such seven (7) calendar day period, the Company's offer of the payments and benefits set forth in Section 2(b) above shall be null and void, and the release in Section 4 above shall be of no force or effect. If Executive does not rescind this Agreement pursuant to this Section 12(b), this Agreement shall become final and binding and shall be irrevocable on the eighth (8th) calendar day following the date of Executive's execution of this Agreement. Changes to this Agreement, whether material or immaterial, shall not restart the running of the twenty-one (21) calendar day period.

13. Warranty. Executive acknowledges that all payments under Section 2 of this Agreement constitute additional compensation to which Executive would not be entitled except for Executive's decision to sign this Agreement and to abide by the terms of this Agreement.

Executive acknowledges that Executive has (a) received all monies and other benefits due to Employee as a result of his employment with and separation from the Company, and (b) no right, title, or interest in or entitlement to any other payments or benefits other than as set forth in this Agreement. Executive further represents that Executive has not sustained a work-related injury or illness which he has not previously been reported to the Company.

14. Non-Admission. Executive understands and agrees that neither this Agreement nor anything in it shall be considered as any admission by the Company or any other Releasee of any improper conduct whatsoever.

15. Fees and Costs. The parties shall bear all of their own attorney's fees and costs related to this Agreement, if any, including, without limitation, attorneys' fees.

16. Governing Law. This Agreement shall be construed in accordance with, and governed by, the substantive and procedural laws of the State of California without regard to the conflict of law principles of any jurisdiction. Any court of competent jurisdiction within the State of California shall have jurisdiction to hear and decide any controversy or claim between the Company and Executive arising under or relating to this Agreement.

17. Amendments; Waivers. No provision of this Agreement may be changed, extended, waived, modified, discharged or terminated, except by a written instrument executed by the parties hereto which expressly states it is an amendment.

18. Entire Agreement. This Agreement sets forth the entire understanding between the Company and Executive, and supersedes all prior agreements, representations, discussions and understandings concerning the subject matter addressed herein. The Company and Executive represent that, in executing this Agreement, each party has not relied upon any representation or statement made by the other party, other than those set forth herein, with regard to the subject matter, basis or effect of this Agreement.

19. Titles and Headings. Titles and headings to sections, subsections and sub-subsections of this Agreement are for the purposes of reference only and shall not affect the interpretation of this Agreement.

20. Interpretation. The language of all parts of this Agreement shall in all cases be construed as a whole, according to its fair meaning, and not strictly for or against either party.

21. Legally Binding. The terms of this Agreement contained herein are contractual, and not a mere recital.

22. Severability. In the event that any provision (or portion thereof) of this Agreement shall be held void, voidable or unenforceable, (a) such provision (or portion thereof) shall be deemed amended to provide the parties, to the maximum extent permitted by applicable law, the intent of such provision (or portion thereof), and (b) the remaining provisions hereof shall remain in full force and effect.

23. Counterparts. This Agreement may be executed and delivered in counterparts, each of which when so executed and delivered shall be the original, but such counterparts together shall constitute but one and the same instrument. Signature pages delivered by facsimile or as a PDF attachment to electronic mail shall be binding to the same extent as an original.

24. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and any successor organization which shall succeed to the Company by merger or consolidation or operation of law, or by acquisition of assets of the Company. Executive may not assign or delegate Executive's rights, duties or obligations under this Agreement.

25. Section 409A. The intent of Executive and the Company is that the payments and benefits under this Agreement comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and authoritative guidance promulgated thereunder ("***Section 409A***"), to the extent subject thereto, and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted and administered to be exempt from or in compliance therewith, as applicable. To the extent required to comply with the requirements of

Section 409A, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement until Executive would be considered to have incurred a “"separation from service"” from the Company within the meaning of Section 409A. For such purposes, references to a “termination,” “termination of employment” or like terms shall mean “separation from service.” Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive’s separation from service to be a “specified employee”
for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon separation from service set forth herein and/or under any other agreement with the Company are deemed to be deferred compensation, then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Code Section 409A, such payments shall not be provided to Executive prior to the earliest of (a) the expiration of the six-month period measured from the date of Executive’s separation from service with the Company, (b) the date of Executive’s death or (c) such earlier date as permitted under Code Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this paragraph shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. For purposes of this Agreement, each amount to be paid or benefit to be provided shall be construed as a separate identified payment for purposes of Section 409A, and any payments described herein that are due within the “short term deferral period” within the meaning of Section 409A shall not be treated as deferred compensation unless applicable law requires otherwise. In no event shall the timing of Executive’s execution of a release result, directly or indirectly, in Executive designating the calendar year of any payment hereunder, and, to the extent required by Section 409A, if a payment hereunder that is subject to execution of a release could be made in more than one (1) taxable year, payment shall be made in the later taxable year. The Company makes no representation that any or all of the payments or benefits to be provided pursuant to this Agreement will be exempt from or comply with Section 409A and makes no undertaking to preclude Section 409A from applying to any such payment or benefit. Executive shall be solely responsible for the payment of any taxes or penalties incurred under Section 409A.

(Signature Page Follows)

IN WITNESS WHEREOF, the parties have executed this Agreement on the dates indicated below.

DATED:

Vir Biotechnology, Inc.

DATED:

By:

Name:

Title:

Exhibit 19

Insider Trading Policy

1.0 INTRODUCTION

During the course of your relationship with **Vir Biotechnology, Inc.** (the "***Company***"), you may receive material information that is not yet public ("***material nonpublic information***") about the Company or about other publicly traded companies with which the Company has business relationships. Material nonpublic information may give you, or someone you pass that information on to, a leg-up over others when deciding whether to buy, sell or otherwise transact in the Company's securities or the securities of another publicly traded company. This policy sets forth guidelines with respect to transactions in the Company's securities by our directors, officers, employees and consultants who are advised that they are subject to this policy ("***designated consultants***") and their Related Persons as defined below. The Company's directors, officers, employees, and designated consultants are responsible for making sure that their Related Persons comply with this policy as described below. While the provisions of this policy are not applicable to transactions by the Company itself, transactions by the Company will only be made in accordance with applicable U.S. federal securities laws, including those relating to insider trading.

2.0 STATEMENT OF POLICY

Any person subject to this policy who is aware of material nonpublic information relating to the Company may not, directly or indirectly:

2.1 purchase, sell or donate Company's securities, except as otherwise specified under the heading "Exceptions to this Policy" below;

2.2 recommend the purchase, sale or donation of any of the Company's securities;

2.3 purchase, sell or donate any securities of another publicly traded company while he or she is aware of material nonpublic information concerning such other company or has material nonpublic information of another publicly traded company which he or she learned in the course of his or her service to the Company or recommend to another person that they do so;

2.4 disclose material nonpublic information concerning the Company or another company which he or she learned in the course of his or her service to the Company to persons within the Company whose jobs do not require them to have that information, or outside of the Company to other persons, such as family, friends, business associates, and investors, unless the disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company; or

2.5 assist anyone engaged in the above activities.

The prohibition against insider trading is absolute. It applies even if the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions. All that matters is whether you are aware of any material nonpublic information relating to the Company at the time of the transaction.

The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct. In some circumstances, you may need to forgo a planned transaction even if you planned it before becoming aware of the material nonpublic information. So, even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait.

It is also important to note that the laws prohibiting insider trading are not limited to trading by the insider alone; advising others to trade on the basis of material nonpublic information is illegal and squarely prohibited by this policy. Liability in such cases can extend both to the "tippee," the person to whom the insider disclosed material nonpublic information, and to the "tipper," the insider himself or herself. In such cases, you can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. For these and other reasons, it is the policy of the Company that no person subject to this policy may either (a) recommend to another person that they buy, hold, or sell the Company's securities at any time or (b) disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information, or outside of the Company to other persons (unless the disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company).

In addition, it is the policy of the Company that no person subject to this policy who, in the course of working for the Company, learns of material nonpublic information about another publicly traded company, may trade in or donate that company's securities until the information becomes public or is no longer material.

There are no exceptions to this policy, except as specifically noted above or below.

3.0 TRANSACTIONS SUBJECT TO THIS POLICY

This policy applies to all transactions in securities issued by the Company, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company's securities. Accordingly, for purposes of this policy, the terms "***trade***," "***trading***," and "***transactions***" include not only purchases and sales of the Company's common stock in the public market but also any other purchases, sales, donations, transfers, short sales or other acquisitions and dispositions of common or preferred equity, put or call options, warrants, and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities, such as hedging transactions and other inherently speculative transactions.

4.0 PERSONS SUBJECT TO THIS POLICY

This policy applies to you and all other directors, officers, employees and designated consultants of the Company and its subsidiaries. This policy also applies to members of your immediate family, persons with whom you share a household, persons who are your economic dependents, and any other individuals or entities whose transactions in securities you influence, direct, or control (including, e.g., a venture or other investment fund, if you influence, direct, or control transactions by the fund). However, this policy does not apply to any entity that invests in securities in the ordinary course of its business (e.g., a venture or other investment fund) if (and only if) such entity has established and certified to the Company that it has its own insider trading controls and procedures in compliance with applicable securities laws with respect to trading in the Company's securities. The foregoing persons who are deemed subject to this policy are referred to in this policy as "***Related Persons***." You are responsible for making sure that your Related Persons comply with this policy.

5.0 MATERIAL NONPUBLIC INFORMATION

It is not always easy to figure out whether you are aware of material nonpublic information. But there is one important factor to determine whether nonpublic information you know about a public company is material: whether the information could be expected to affect the market price of that company's securities or to be considered important by investors who are considering trading that company's securities. If the information makes you want to trade, it would probably have the same effect on others. Keep in mind that both positive and negative information can be material. There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances and is often evaluated by relevant enforcement authorities with the benefit of hindsight. If you possess material nonpublic information, you may not trade in a company's stock, advise anyone else to do so or communicate the information to anyone else until you know that the information has been publicly disseminated, as described below. This means that in some circumstances, you may have to forego a proposed transaction in a company's securities even if you planned to execute the transaction prior to learning of the inside information and even though you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting.

You may not participate in "chat rooms" or other electronic discussion groups or contribute to blogs, bulletin boards or social media forums on the internet, including but not limited to commenting on the Company's material nonpublic information on LinkedIn, concerning the business activities or operations of the Company (including all topics set forth in (a)-(t) below, regardless of whether such information has become public) or other companies with which the Company does business, even if you do so anonymously, unless doing so is part of your job responsibilities and you have explicit authorization from the individuals designated by the Company's board of directors as the clearing officers or his or her designee (each, a "***Clearing Officer***"). The Clearing Officers shall be the Chief Financial Officer and the General Counsel of the Company.

Although by no means an all-inclusive list, information about the following items may be considered to be material nonpublic information until it is publicly disseminated:

(a) financial results or Company forecasts of financial results;

(b) status of platform technology development;

(c) status of product or product candidate development or regulatory approvals;

(d) clinical data relating to products or product candidates;

(e) timelines for pre-clinical studies or clinical trials;

(f) acquisitions or dispositions of assets, divisions or companies;

(g) public or private sales of debt or equity securities;

(h) stock splits, dividends or changes in dividend policy;

(i) the establishment of a repurchase program for the Company's securities;

(j) gain or loss of a significant licensor, licensee or supplier;

(k) changes or new partner relationships, collaborations or grants;

(l) notice of issuance or denial of patents;

(m) regulatory developments;

(n) management or control changes;

(o) employee layoffs;

(p) a cybersecurity incident and/or a disruption in the Company's operations or breach or unauthorized access of its property or assets, including its facilities and information technology infrastructure;

(q) tender offers or proxy fights;

(r) accounting restatements;

(s) litigation or settlements; and

(t) impending bankruptcy.

When information is considered public

The prohibition on trading when you have material nonpublic information lifts after that information becomes publicly disseminated. But for information to be considered publicly disseminated, it must be widely disseminated through a press release, a filing with the Securities and Exchange Commission (the "***SEC***"), or other widely disseminated announcement. Once information is publicly disseminated, it is still necessary to afford the investing public with sufficient time to absorb the information. Generally speaking, information will be considered publicly disseminated for purposes of this policy only after two (2) full trading days have elapsed since the information was publicly disclosed. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Monday (in each case subject to any pre- clearance requirements set forth in this policy). Depending on the particular circumstances, the Company may determine that a longer or shorter waiting period should apply to the release of specific material nonpublic information.

6.0 STOCK TRADING BY DIRECTORS, OFFICERS, EMPLOYEES AND DESIGNATED CONSULTANTS

Pre-Clearance and Advance Notice of Transactions

Any person subject to this policy is required to notify and receive approval from a Clearing Officer prior to engaging in transactions in the Company's securities and observe other restrictions designed to minimize the risk of apparent or actual insider trading as set forth in Section 9.0. From time to time, we may also require that certain persons limit their transactions in the Company's securities to certain trading window periods as described below.

Trading Window Period and Trading Blackout Period

From time to time, the Company may prohibit anyone subject to this policy from buying, selling or donating securities outside of a time period the Company designates as an open trading window (such period when trading is allowed is referred to as a "***trading window period***" and such period when trading is not allowed is referred to as a "***trading blackout period***").

If and when the Company institutes a practice of having a trading window period, except as set forth in this paragraph and in Section VII of this policy, persons advised by the Company that they are subject to such trading window period may buy, sell or donate securities of the Company only during a trading window period. In general, any trading window period will not open until two (2) full trading days have elapsed after the public dissemination of the Company's annual or quarterly financial results and will close on the last trading day a set number of weeks before the end of the quarter. This window period may be closed early or may not open if, in the judgment of the Clearing Officer, there exists undisclosed information that would make trades inappropriate. In addition to a trading window period, the Company may close the trading window at any time and for any duration pending public release of material news. It is important to note that the fact that the trading window is closed should itself be considered inside information. Any person subject to this policy who believes that special circumstances require him or her to trade during a trading blackout period should consult with the Clearing Officer. Permission to trade during a trading blackout period will be granted only where the circumstances are extenuating and there appears to be no significant risk that the trade may subsequently be questioned. Any person wishing to trade during a trading blackout period must certify that they are not aware of material nonpublic information.

7.0 EXCEPTIONS TO THIS POLICY

This policy does not apply in the case of the following transactions, except as specifically noted:

7.1 ***Option Exercises***

This policy does not apply to the exercise of options granted under the Company's equity compensation plans for cash or, where permitted under the option, by a net exercise transaction with the Company or by delivery to the Company of already-owned stock of the Company. This policy does, however, apply to any sale of stock as part of a broker-assisted cashless exercise or any other market sale, whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes, except for sales pursuant to an automatic sale instruction as noted below.

7.2 ***Tax Withholding Transactions***. This policy does not apply to the surrender of shares directly to the Company or to the sale of shares in the market by the Company on behalf of an employee pursuant to an automatic sale instruction to satisfy tax withholding obligations arising exclusively from the vesting or exercise of restricted stock units, options, or other equity awards granted under the Company's equity compensation plans where the person subject to this policy does not otherwise exercise control over the timing of such sales. Any market sale of the stock received upon exercise or vesting of any such equity awards after the satisfaction of such tax withholding obligations; however, remains subject to all provisions of this policy.

7.3 ***ESPP.*** This policy does not apply to employees' initial election to participate in the Company's Employee Stock Purchase Plan *("**ESPP**")*, the purchase of stock by employees under the ESPP on periodic designated dates in accordance with the ESPP (e.g., an "instant sale") and/or pursuant to standing instructions in a form approved by the Company, or any subsequent changes by employees to their contribution rates under the ESPP. This policy does, however, apply to the subsequent sale of the stock acquired pursuant to the ESPP, and to any subsequent withdrawals and/or suspensions from ESPP.

7.4 ***10b5-1 Automatic Trading Programs***. Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("***Exchange Act***"), employees, directors, and designated consultants may establish a trading plan under which a broker is instructed to buy, sell or donate Company securities based on pre-determined criteria (a "***Trading Plan***"). So long as a Trading Plan is properly established, purchases, sales and donations of Company securities pursuant to that Trading Plan are not subject to this policy. To be properly established, a Trading Plan must be (i) established in compliance with the applicable affirmative defense conditions of Rule 10b5-1 of the Exchange Act, including as applicable the requirements applicable to an eligible sell-to-cover transaction as defined in Rule 10b5- 1(c)(1)(ii)(D)(3), (ii) in writing, and (iii) submitted to the Company for review prior to adoption in accordance with the pre-clearance requirements in this Policy.

7.5 ***Gifts***. This policy does not apply to *bona fide* gifts of Company securities that have been pre-cleared by the Company's Clearing Officer. Whether a gift is truly *bona fide* will depend on the facts and circumstances surrounding each gift. Pre- clearance must be obtained at least five (5) business days in advance of the proposed gift, and pre-cleared gifts not completed within two (2) business days will require new pre-clearance. The Company may choose to shorten this period.

8.0 SPECIAL AND PROHIBITED TRANSACTIONS

8.1 ***Inherently Speculative Transactions***. No one subject to this policy may engage in short sales, transactions in put options, call options, or other derivative securities on an exchange or in any other organized market, or in any other inherently speculative transactions with respect to the Company's stock.

8.2 ***Hedging Transactions***. Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars, and exchange funds. Such hedging transactions may permit a Company employee, director or designated consultant to continue to own the Company's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the employee, director or designated consultant of the Company may no longer have the same objectives as the Company's other stockholders. Therefore, Company employees, directors and designated consultants are prohibited from engaging in any such transactions.

8.3 ***Margin Accounts and Pledged Securities***. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in the Company's securities, persons subject to this policy are prohibited from holding securities of the Company in a margin account or otherwise pledging the Company's securities as collateral for a loan.

8.4 ***Standing and Limit Orders***. Standing and limit orders (except standing and limit orders under approved Trading Plans, as discussed above) create heightened risks for insider trading violations because there is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when an employee, director or designated consultant of the Company is in possession of material nonpublic information. The Company therefore discourages placing standing or limit orders on the Company's securities. If a person subject to this policy nevertheless determines to use a standing order or limit order (other than under an approved Trading Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to this policy.

9.0 PRE-CLEARANCE AND ADVANCE NOTICE OF TRANSACTIONS

In addition to the requirements listed above, any person subject to this policy may not engage in any transaction in the Company's securities, including any purchase or sale in the open market, loan, donation or other transfer of beneficial ownership, withdrawal or suspension from ESPP, or adoption of a Trading Plan without first obtaining pre-clearance of the transaction from the Clearing Officer. Requests should be submitted at least two (2) business days in advance of the proposed transaction. The Clearing Officer will then determine whether the transaction may proceed and assist, as applicable, in complying with the reporting requirements under Section 16(a) of the Exchange Act, if any. The Clearing Officers shall have sole discretion to decide whether to clear any contemplated transaction. Pre-cleared transactions not completed within three (3) business days shall require new pre-clearance under the provisions of this paragraph. The Company may, at its discretion, shorten such period of time. Notwithstanding receipt of pre-clearance if the person becomes aware of material nonpublic information or becomes subject to a trading blackout period before the transaction is effected, the transaction may not be completed.

Upon completion of any transaction, a director or Section 16 officer must immediately notify the Clearing Officer so that the Company may assist in any Section 16 reporting obligations. Such notification should include the type of transaction, the date of the transaction, the number of shares involved, the purchase or sale price and whether the transaction was effected pursuant to a Trading Plan. The ultimate responsibility, and liability, for compliance with such reporting obligations remains with the directors and Section 16 officers.

10.0 SHORT-SWING TRADING, CONTROL STOCK AND SECTION 16 REPORTS

Officers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care to avoid short-swing transactions (within the meaning of Section 16(b) of the Exchange Act), must comply with the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and must file all appropriate Section 16(a) reports (Forms 3, 4, and 5), which are described in the Company's Section 16 Compliance Program, and notices of sale required by Rule 144.

11.0 PROHIBITION OF TRADING DURING PENSION FUND BLACKOUT PERIODS

No director or executive officer of the Company may, directly or indirectly, purchase, sell or otherwise transfer any equity security of the Company (other than an exempt security) during any "pension fund blackout period" (as defined in Regulation BTR under the Exchange Act) if a director or executive officer acquires or previously acquired such equity security in connection with his or her service or employment as a director or executive officer. This prohibition does not apply to any transactions that are specifically exempted, including but not limited to, purchases or sales of the Company's securities made pursuant to, and in compliance with, an approved Trading Plan; compensatory grants or awards of equity securities pursuant to a plan that, by its terms, permits executive officers and directors to receive automatic grants or awards and specifies the terms of the grants and awards; or acquisitions or dispositions of equity securities involving a bona fide gift or by will or the laws of descent or pursuant to a domestic relations order. The Company will notify each director and executive officer of any pension fund blackout periods in accordance with the provisions of Regulation BTR. Because Regulation BTR is very complex, no director or executive officer of the Company should engage in any transactions in the Company's securities, even if believed to be exempt from Regulation BTR, without first consulting with the Company's Clearing Officer.

12.0 DURATION OF INSIDER TRADING LAWS

Insider trading laws continue to apply to your transactions in the Company's securities or the securities of other public companies even after your relationship with the Company has ended. If you are aware of material nonpublic information when your relationship with the Company ends, you may not trade the Company's securities or the securities of other applicable companies until the material nonpublic information has been publicly disseminated or is no longer material.

13.0 INDIVIDUAL RESPONSIBILITY; LIMITATION ON LIABILITY

Persons subject to this policy have ethical and legal obligations to maintain the confidentiality of information about the Company and to not engage in transactions in the Company's securities while aware of material nonpublic information. Each individual is responsible for making sure that he or she complies with this policy, and that any Related Persons also comply with this policy. In all cases, the responsibility for determining whether an individual is aware of material nonpublic information rests with that individual, and any action on the part of the Company or any employee or director of the Company pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by the Company for any conduct prohibited by this policy or applicable securities laws. See "Penalties" below.

No Clearing Officer or other employee will have any liability for any delay in reviewing, or refusal of, a Trading Plan submitted to the Company for review, a request for pre- clearance or a request to allow a pledge. Notwithstanding any review of a Trading Plan or pre-clearance of a transaction, none of the Company, a Clearing Officer or other employee assumes any liability for the legality or consequences of such Trading Plan or transaction to the person engaging in or adopting such trading plan or transaction.

14.0 PENALTIES

Anyone who engages in insider trading or otherwise violates this policy may be subject to both civil liability and criminal penalties. Violators also risk disciplinary action by the Company, including termination of employment. Anyone who has questions about this policy should contact their own attorney or the Company's Clearing Officers at equity@vir.bio for clearance on trading or the Company's General Counsel at vircompliance@vir.bio for compliance issues.

15.0 AMENDMENTS

The Company is committed to continuously reviewing and updating its policies and procedures. Any changes to this policy may only be made by the Nominating and Corporate Governance Committee and will be recommended to the Board of Directors for approval and effective upon approval by the Board of Directors. A current copy of the Company's policies regarding insider trading may be obtained by contacting the General Counsel at vircompliance@vir.bio.

Adopted by the Board of Directors: November 29, 2023

Effective: November 29, 2023

Exhibit 21.1

Subsidiaries of Vir Biotechnology, Inc.

Name of Subsidiary	State or Other Jurisdiction of Incorporation or Organization
Agenovir Corporation	Delaware
Encentrio Therapeutics, Inc.	Delaware
Humabs BioMed SA	Switzerland
TomegaVax, Inc.	Delaware
Vir AU Biotechnology Pty Ltd.	Australia

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statements (Forms S-8 Nos. 333-234212, 333-237410, 333-253547, 333-263088, 333-270108, and 333-277358) pertaining to the 2016 Equity Incentive Plan, 2019 Equity Incentive Plan and 2019 Employee Stock Purchase Plan of Vir Biotechnology, Inc.; and
2. Registration Statement (Form S-3 No. 333-275314) of Vir Biotechnology, Inc.;

of our reports dated February 26, 2025, with respect to the consolidated financial statements of Vir Biotechnology, Inc. and the effectiveness of internal control over financial reporting of Vir Biotechnology, Inc. included in this Annual Report (Form 10-K) of Vir Biotechnology, Inc. for the year ended December 31, 2024.

/s/ Ernst & Young LLP

San Mateo, California
February 26, 2025

Exhibit 31.1

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

I, Marianne De Backer, M.Sc., Ph.D., MBA, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vir Biotechnology, Inc.;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: February 26, 2025

By: **/s/ Marianne De Backer**

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

Exhibit 31.2

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

I, Jason O'Byrne, MBA, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vir Biotechnology, Inc.;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: February 26, 2025

By: **/s/ Jason O'Byrne**

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

Exhibit 32.1

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

In connection with the Annual Report of Vir Biotechnology, Inc. (the "Company") on Form 10-K for the period ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer and Director of the Company and Jason O'Byrne, MBA, Executive Vice President and Chief Financial Officer of the Company, each hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 26th day of February 2025.

/s/ **Marianne De Backer**	/s/ **Jason O'Byrne**
Marianne De Backer, M.Sc., Ph.D., MBA	**Jason O'Byrne, MBA**
Chief Executive Officer and Director *(Principal Executive Officer)*	**Executive Vice President and Chief Financial Officer** *(Principal Financial Officer)*

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