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, 2025

OR

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

Commission File Number 001-39083

Vir Biotechnology, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**81-2730369**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
1800 Owens Street, Suite 900 San Francisco, California	**94158**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 906-4324

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $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, 2025 was approximately $689.2 million based upon the closing price of its Common Stock on June 30, 2025 of $5.04 per share, as reported by The Nasdaq Global Select Market.

The number of shares of the Registrant's Common Stock outstanding as of February 17, 2026 was 139,517,278.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement, or the Proxy Statement, for the Registrant's 2026 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, 2025.

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

Table of Contents

[This page intentionally left blank]

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 portfolio, including our 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 "Vir Bio," "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 multiple solid tumors. In hepatitis delta, we have initiated our registrational ECLIPSE clinical program evaluating the tobevibart and elebsiran combination in people living with chronic hepatitis delta (CHD). The three randomized, controlled trials (ECLIPSE 1, 2, and 3) are ongoing, with ECLIPSE 1 and 3 completing enrollment ahead of the Company's expectations. Topline results from ECLIPSE 1 are expected in the fourth quarter of 2026 with topline results from ECLIPSE 2 and 3 expected in the first quarter of 2027. 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 CHD patients, for whom approved treatment options are either limited or unavailable. In oncology, we are advancing three Phase 1 clinical studies of dual-masked T-cell engagers (TCEs): VIR-5500 in patients with Prostate-Specific Membrane Antigen (PSMA)-expressing metastatic castration-resistant prostate cancer (mCRPC); VIR-5818 in patients with HER2-expressing tumors; and VIR-5525 in patients with EGFR-expressing tumors.

We are developing therapeutic candidates in HIV cure and multiple solid tumors. Our HIV broadly neutralizing antibodies (bnAbs) are being developed as a potential long-acting treatment or cure in combination with existing or investigational regimens. We have also made available for external partnerships our next-generation preclinical influenza A and B antibodies and antibody drug conjugates (ADCs), along with our next generation coronavirus (COVID) monoclonal antibodies.

We are advancing multiple undisclosed PRO-XTEN® 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.

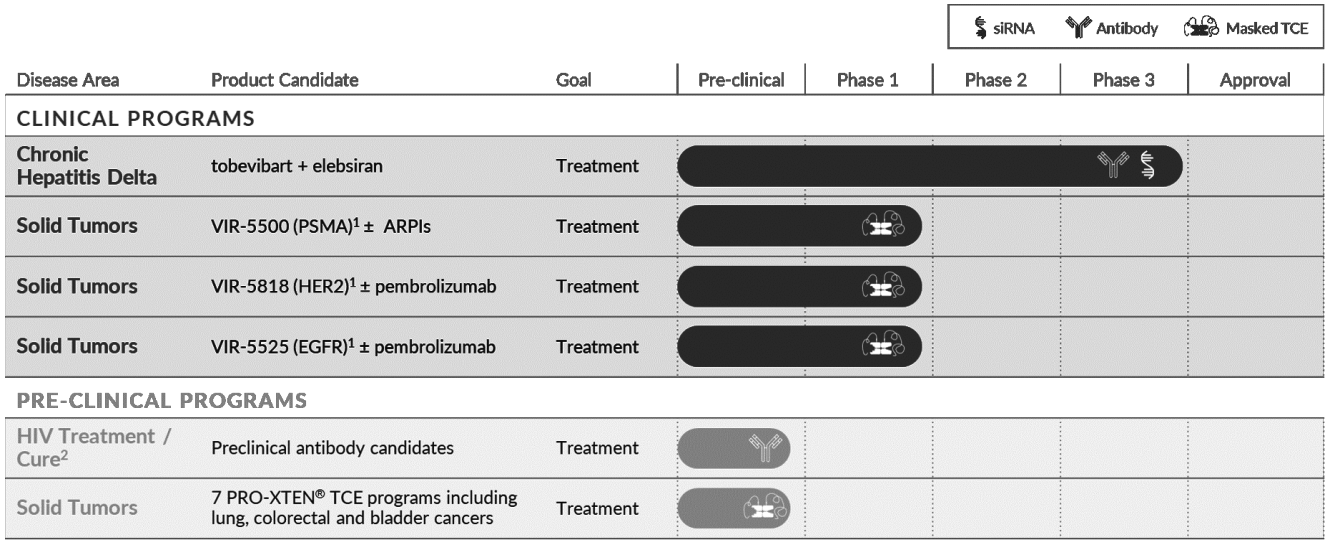
These research and development efforts are driven by Vir Bio's discovery engine, comprised of our exceptional protein engineering and antibody discovery expertise and our two core technology platforms — our proprietary dAIsY™ (data, AI structure and antibodY) platform utilizing artificial intelligence and machine learning (collectively referred to as AI) for antibody optimization, and the exclusive PRO-XTEN® (a trademark of Amunix Pharmaceuticals, Inc., a Sanofi company) masking platform, which we in-licensed from Sanofi for worldwide rights in oncology and infectious diseases. The PRO-XTEN® platform allows for the development of potentially best-in-class TCEs with improved safety and efficacy profiles across multiple therapeutic areas. The dAIsY™ and PRO-XTEN® platforms, individually and in combination, enable us to modulate the immune system in innovative ways, harnessing its power to combat viruses and fight cancer.

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 the lives of people living with these serious diseases.

Our Research and Development Pipeline

At Vir Bio, we are advancing our mission of powering the immune system with innovative medicines to transform lives, with the goal of driving better outcomes for patients in areas of high unmet medical need, such as infectious diseases and cancer. We use our world-class capabilities in antibody discovery and engineering, coupled with our proprietary AI engine dAIsY™ system, and the PRO-XTEN® masking platform, 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 to strategically expand our approach to address critical oncology indications with limited treatment options. Our pipeline includes multiple candidates in clinical development for diseases with significant unmet medical need, which is categorized by disease area in the chart below.



[1]: Masked TCEs licensed from Sanofi
[2] In collaboration with the Gates Foundation
ARPIs: androgen receptor pathway inhibitors; EGFR: epidermal growth factor receptor; HER2: human epidermal growth factor receptor 2; HIV: human immunodeficiency virus; PSMA: prostate-specific membrane antigen; siRNA: small interfering RNA; TCE: T-cell engager
Tobevibart incorporates Xencor's Xtend™ and other Fc technologies.
Norgine holds exclusive license for the commercial rights to the combination of tobevibart and elebsiran in Europe, Australia and New Zealand
Brii Bioscience retains rights to the combination of tobevibart and elebsiran in the Greater China Territory (People's Republic of China, Hong Kong, Taiwan and Macau)

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.

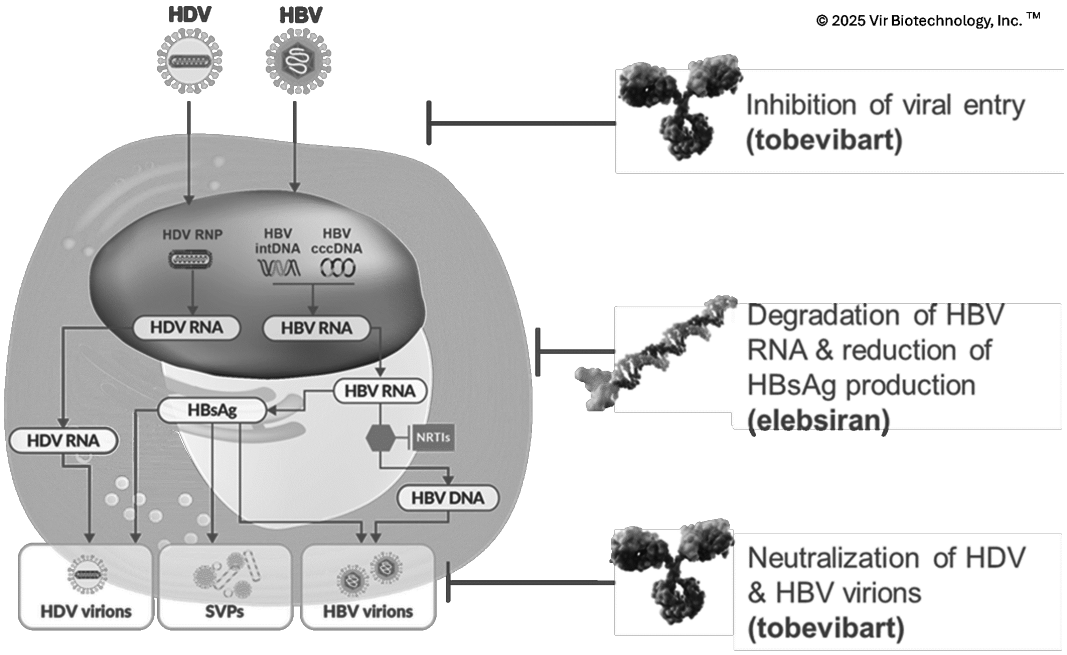
Elebsiran

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

CHD

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

Vir Bio 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

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 at 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). 48-week 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 Washington, D.C., in November 2025 and simultaneously published in the *New England Journal of Medicine*.

Additional data was later presented at the 44th Annual J.P. Morgan Healthcare Conference in January 2026. These data demonstrate that undetectable hepatitis delta virus RNA (HDV RNA Target Not Detected, TND) was achieved and maintained by 77% (24/31) of participants receiving the combination of tobevibart and elebsiran at Week 72, and this rate increased to 88% (21/24) in the subset of participants evaluated through Week 96. By contrast, HDV RNA TND was achieved by 53% (17/32) of participants receiving tobevibart antibody monotherapy at Week 72 and 46% (11/24) in the subset of participants evaluated through Week 96. Additionally, approximately 90% of participants receiving the combination therapy achieved reduction in HBsAg to values <10 IU/mL by Week 24 and kept that response through Week 72 and (for the subset of patients evaluable) Week 96, compared to approximately 20% of participants receiving antibody monotherapy at every time point. HBsAg reduction indicates suppression of the fundamental biologic mechanisms that HDV requires for viral replication. ALT was normalized in approximately half of participants by Week 72 and (for the subset of patients evaluable) Week 96. There were no grade 3 or higher treatment-related adverse events in the combination arm, and treatment emergent adverse events were generally mild to moderate and transient.

Vir Bio initiated its registrational clinical program, ECLIPSE, evaluating the tobevibart and elebsiran combination in people living with CHD, in March of 2025. The program includes three randomized, controlled trials (ECLIPSE 1, 2, and 3) designed to evaluate the combination therapy in comparison to deferred treatment or bulevirtide. All three trials are ongoing, with ECLIPSE 1 and 3 completing enrollment ahead of the Company's expectations. Topline results from ECLIPSE 1 are expected in the fourth quarter of 2026, and topline results from ECLIPSE 2 and ECLIPSE 3 are expected in the first quarter of 2027.

The combination of tobevibart and elebsiran has 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. The investigational combination therapy has been granted Breakthrough Therapy and Fast Track designations by the U.S. Food and Drug Administration (FDA), and Priority Medicines (PRIME) and orphan drug designations by the EMA.

On December 15, 2025, we and Norgine Pharma UK Limited (together with its affiliates in the Norgine group of companies, Norgine) entered into a License Agreement (the Norgine Agreement) with respect to certain commercial and certain development rights to the combination of tobevibart and elebsiran for the treatment of people living with CHD as described in further detail below under "—Our Collaboration, License and Grant Agreements," Under the terms of the Norgine Agreement, Vir Bio granted Norgine an exclusive license for the commercial rights and certain development rights to the combination for the treatment of CHD in Europe, Australia, and New Zealand (collectively, the Norgine Territory), while Vir Bio will retain commercial rights for the combination in the United States and all other international markets outside of the People's Republic of China and Taiwan.

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 reverse 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.

In July 2021 we initiated the MARCH two-part study to evaluate the combination of tobevibart and elebsiran in virally suppressed HBV patients. The latest results from the MARCH Part B Phase 2 trial evaluating the combination of tobevibart and elebsiran without or with pegylated interferon alpha (PEG-IFNα) were presented in an oral session at the European Association for the Study of the Liver (EASL) congress in Amsterdam (The Netherlands) in May 2025. The 24-week post-end of treatment data revealed that the study-defined primary endpoint, proportion of participants with undetectable HBsAg at 24 weeks post-end of treatment, was achieved by 17% (3/18) and 21% (3/14) of participants with baseline HBsAg<1,000 IU/mL receiving tobevibart and elebsiran without or with PEG-IFNα, respectively. These proportions were 8% (4/51) and 16% (5/32) for tobevibart and elebsiran without or with PEG-IFNα, respectively, in all participants. The safety and tolerability profile of tobevibart and elebsiran was consistent with prior studies, with no new safety concerns and generally only mild or moderate treatment emergent adverse events being reported throughout the study. Vir Bio decided not to pursue Phase 3 development of combinations of tobevibart, and elebsiran in CHB. We have streamlined the final stages of the MARCH Phase 2 program to ensure continued participant benefit and safety.

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 "—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 Greater China Territory (People's Republic of China, Hong Kong, Taiwan 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.

HIV treatment and functional cure

Despite major advances in HIV treatment, most people living with HIV must take daily antiretroviral medications for viral control. HIV broadly neutralizing antibodies (bnAbs) are a novel modality that has shown promise for controlling the virus without daily antiretroviral medications. Furthermore, HIV bnAb treatment can induce a state of viral control off therapy, effectively a functional cure. While these outcomes are currently only found in rare individuals and for limited time periods, it suggests that HIV bnAbs could be an important part of a functional cure regimen.

With the support of the Gates Foundation, we are developing a unique and innovative HIV bnAb therapeutic. We have in-licensed HIV bnAbs from Togontech GmbH, including the 04-A06 bnAb published in Nature Immunology, that shows what we believe to be favorable preclinical properties, including neutralization breadth and potency to combat the diversity of HIV strains worldwide and resistance to the ability of the virus to escape from therapeutic intervention. We are further engineering HIV 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.

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. Vir Bio'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, Vir Bio'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-5500 (Phase 1); VIR-5818 (Phase 1); and VIR-5525 (Phase 1). These molecules leverage the PRO-XTEN® masking technology with TCEs targeting CD3 on T-cells and HER2, PSMA and EGFR, respectively, on tumor cells.

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

Molecular Characteristics and Preclinical Data. 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 two 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 as a monotherapy in late-line mCRPC and standard-of-care combinations in earlier-line settings. Positive updated monotherapy dose-escalation data from the ongoing Phase 1 trial will be presented at the 2026 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium in February 2026. These data support VIR-5500's favorable safety and tolerability profile and show that treatment with VIR-5500 provided dose-dependent anti-tumor activity as measured by both PSA declines and radiographic responses.

Data across all patients receiving VIR-5500 monotherapy in the Phase 1 trial (n=58) show that VIR-5500 was generally well tolerated with no dose-limiting toxicities observed to date. Grade ≥3 treatment-related adverse events occurred in 12% (7/58) of patients and were manageable. Limited CRS was observed in 50% (29/58) of patients, with events generally limited to Grade 1 (fever only). Prophylactic steroids were not required and were only explored in a small cohort of three patients. Enrolled patients were heavily pretreated (median of four prior lines) and a substantial proportion presented with high tumor burden, including 45% (25/58) with visceral metastases.

Dose-dependent activity was observed across the entire treatment group as measured by both prostate-specific antigen (PSA) declines and radiographic responses. Efficacy data were reported in the highest dose cohorts (≥3,000 µg/kg Q3W; n=22/58) as of the January 9, 2026 data cut-off. In these cohorts, among those patients who were PSA-evaluable (i.e., received a full cycle of treatment and had completed both pre- and post-treatment PSA assessments in accordance with applicable prostate cancer clinical trial guidance) (n=17), PSA50[1] declines occurred in 82% (14/17) and PSA90[2] declines occurred in 53% (9/17) of patients. Among RECIST (Response Evaluation Criteria in Solid Tumors)-evaluable patients, objective responses were seen in 45% (5/11). Of the five responders, four achieved confirmed responses with one patient pending confirmation. Reductions on PSMA-PET (positron emission tomography) affirm PSA declines and radiographic responses, with tumor shrinkage observed across multiple lesions, including visceral metastases. These findings support proof-of-concept and further evaluation in expansion cohorts.

We have concluded QW and Q3W monotherapy dose-escalation in late-line mCRPC and has defined a preliminary go-forward dose and regimen recommendation for expansion. In parallel, dose-escalation of VIR-5500 in combination with enzalutamide continues in early-line mCRPC patients. We anticipate initiating monotherapy dose-expansion cohorts in late-line mCRPC and combination dose-expansion cohorts in both early-line mCRPC and metastatic hormone-sensitive prostate cancer (mHSPC) in the second quarter of 2026 followed by pivotal Phase 3 trials in 2027.

[1] PSA decline of 50%-100% from baseline.
[2] PSA decline of 90%-100% from baseline.

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 below under "— Our Technology Platforms."

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). Early safety and efficacy data from the monotherapy cohort was presented 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 nine 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 six days, which may enable a less frequent dosing regimen, such as Q3W. VIR-5818 continues to advance through dose escalation as a monotherapy, and in combination with pembrolizumab, in multiple tumor types, including metastatic breast cancer and metastatic colorectal cancer.

VIR-5525

Molecular Characteristics and Preclinical Data. VIR-5525 is an investigational dual-masked TCE that combines a bispecific EGFR and CD3 binding TCE with the PRO-XTEN® masking technology. Similarly to VIR-5818 and VIR-5500, VIR-5525 is also conditionally activated and 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 EGFR, 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-5525, 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-5525 should remain predominantly masked and as an intact prodrug.

Phase 1 Trial of VIR-5525. VIR-5525 is being evaluated in a Phase 1 clinical trial designed to assess its safety, pharmacokinetics, and preliminary efficacy as a monotherapy and in combination with pembrolizumab in a variety of EGFR-expressing solid tumors, such as non-small cell lung cancer (NSCLC), CRC, head and neck squamous cell carcinoma (HNSCC), and cutaneous squamous cell carcinoma (cSCC). We announced in July 2025 that the first patient in the trial had been dosed. VIR-5525 continues to advance through Phase 1 dose escalation as a monotherapy.

Undisclosed PRO-XTEN® TCE Targets

We are advancing multiple undisclosed PRO-XTEN® 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.

Our Technology Platforms

Vir Bio 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.

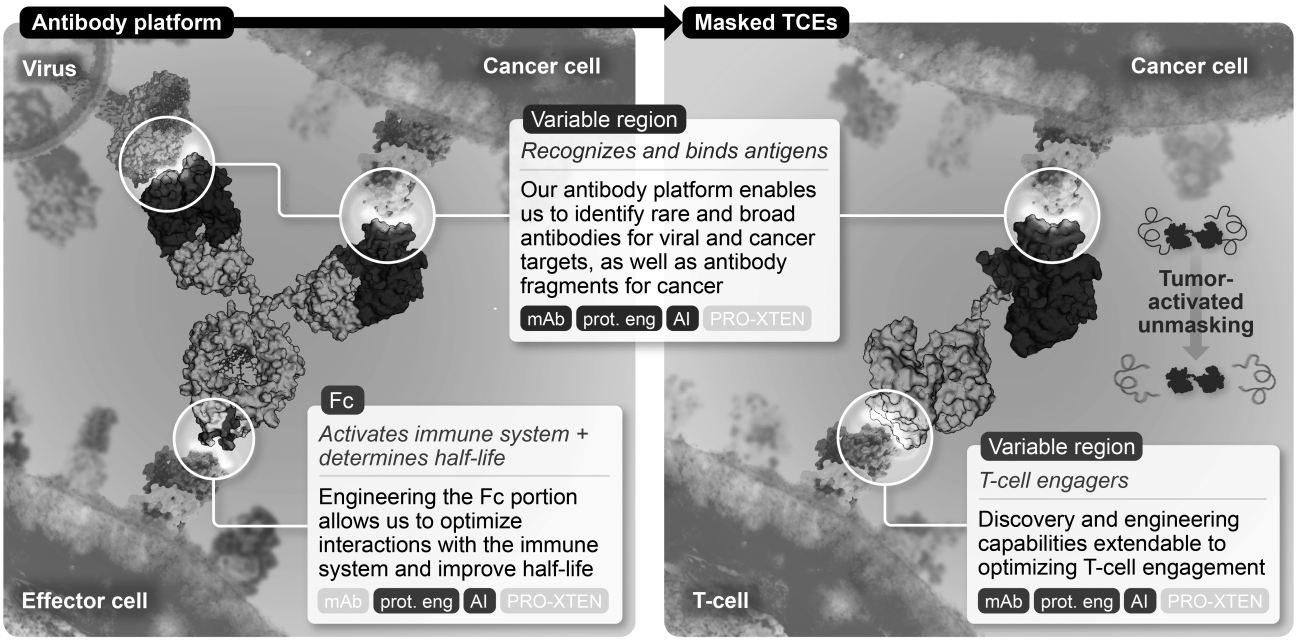
Platforms for the Creation of Transformative Medicines

Millions of people suffer from infectious diseases and cancer, both of which result in 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.

Vir Bio's Discovery Engine is propelled by our exceptional protein engineering and antibody discovery expertise and our two core technology platforms:

1. **Antibody and TCE Discovery and Engineering 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 Technology Platform:** This innovative technology aims to prevent potential toxicity of highly active drugs outside of their intended site of action. In oncology, this means anti-cancer agents, such as TCEs, become active selectively when entering the tumor microenvironment. This enhances tumor specificity while minimizing off-target effects, potentially improving both efficacy and safety. Masking also increases half-life in circulation, potentially resulting in more convenient dosing regimens for patients and clinicians. Importantly, the PRO-XTEN® masking technology is a universal platform – meaning that it can be used with different molecules without the need to tailor it every single time.

This discovery engine is 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 and TCE Discovery and Engineering Platform

Overview

We have developed cutting-edge platforms to identify and enhance rare, potent 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 PRO-XTEN® dual-masked TCEs targeting novel TAAs.

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:

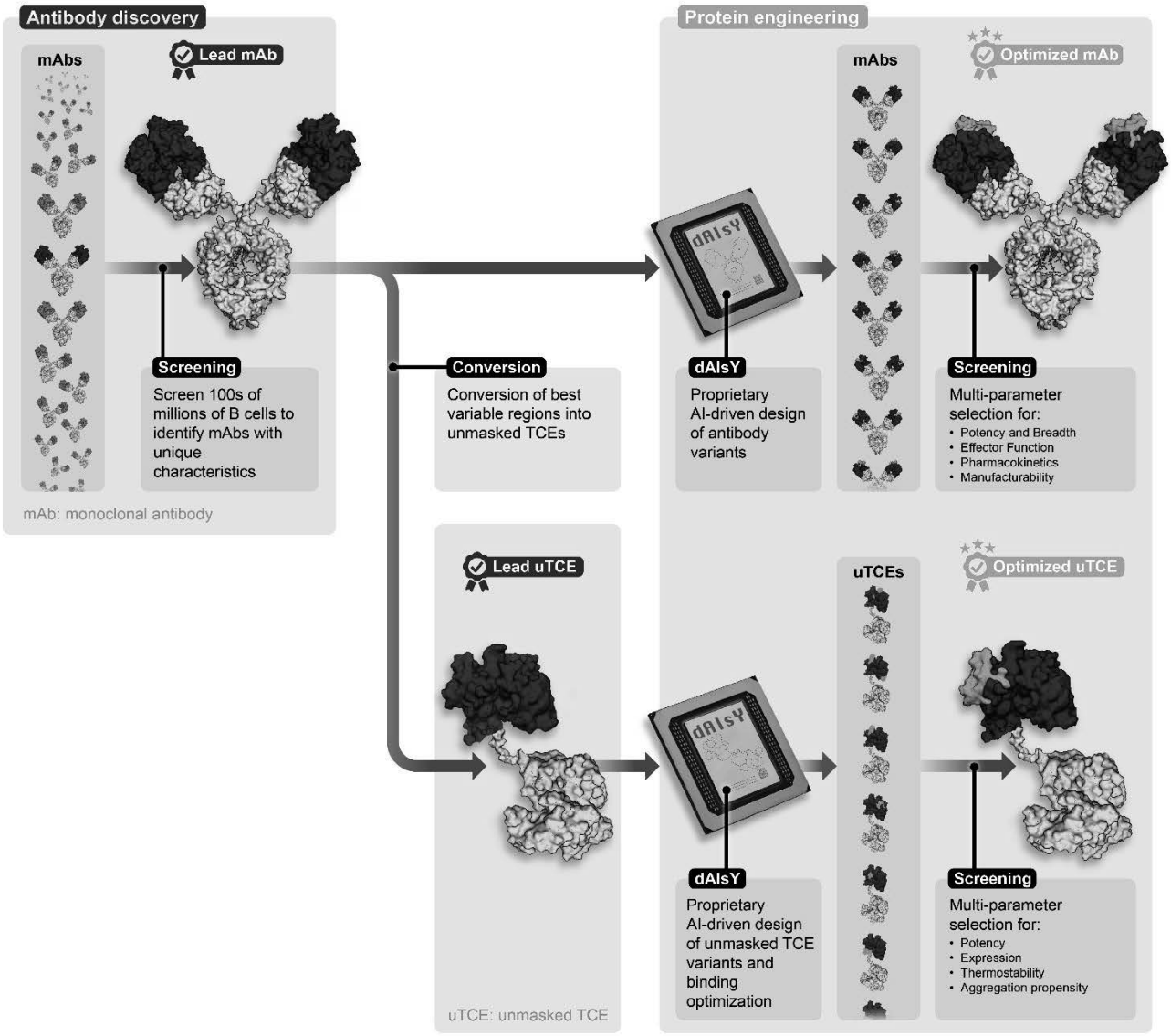
- Sotrovimab (Xevudy®): Anti-SARS-CoV-2 mAb, granted Emergency Use Authorization (EUA) or marketing authorization in multiple regions.
- Ansuvimab (Ebanga™): Anti-Ebola virus mAb developed in collaboration with the NIH and marketed by Ridgeback Biotherapeutics LP.

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 deep expertise in antibody discovery and engineering provides a strong foundation for developing next-generation TCEs as well as antibody-based therapeutics for multiple therapeutic areas, including cancer.

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.



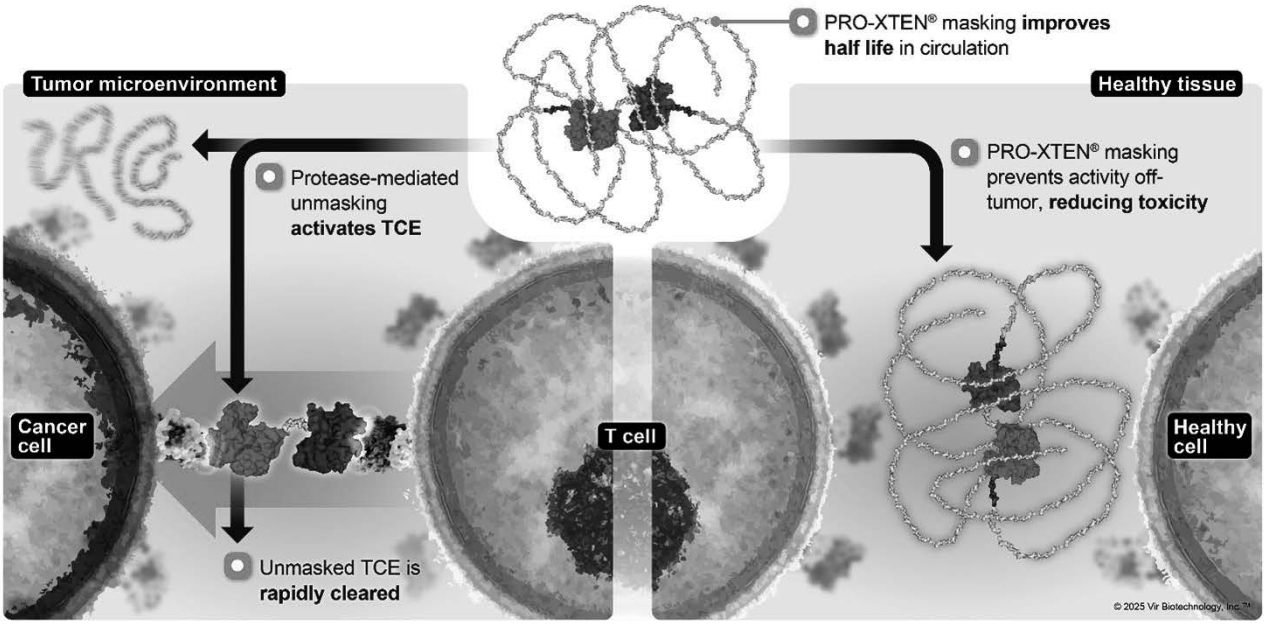
PRO-XTEN® Masking Technology Platform

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 selectively in tumor tissues. It can be applied to a variety of molecules such as TCEs or cytokines to broaden the therapeutic index for patients. The preferential release of the drug in the tumor microenvironment is designed to minimize on-target, off-tumor toxicity. The PRO-XTEN® mask is 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.

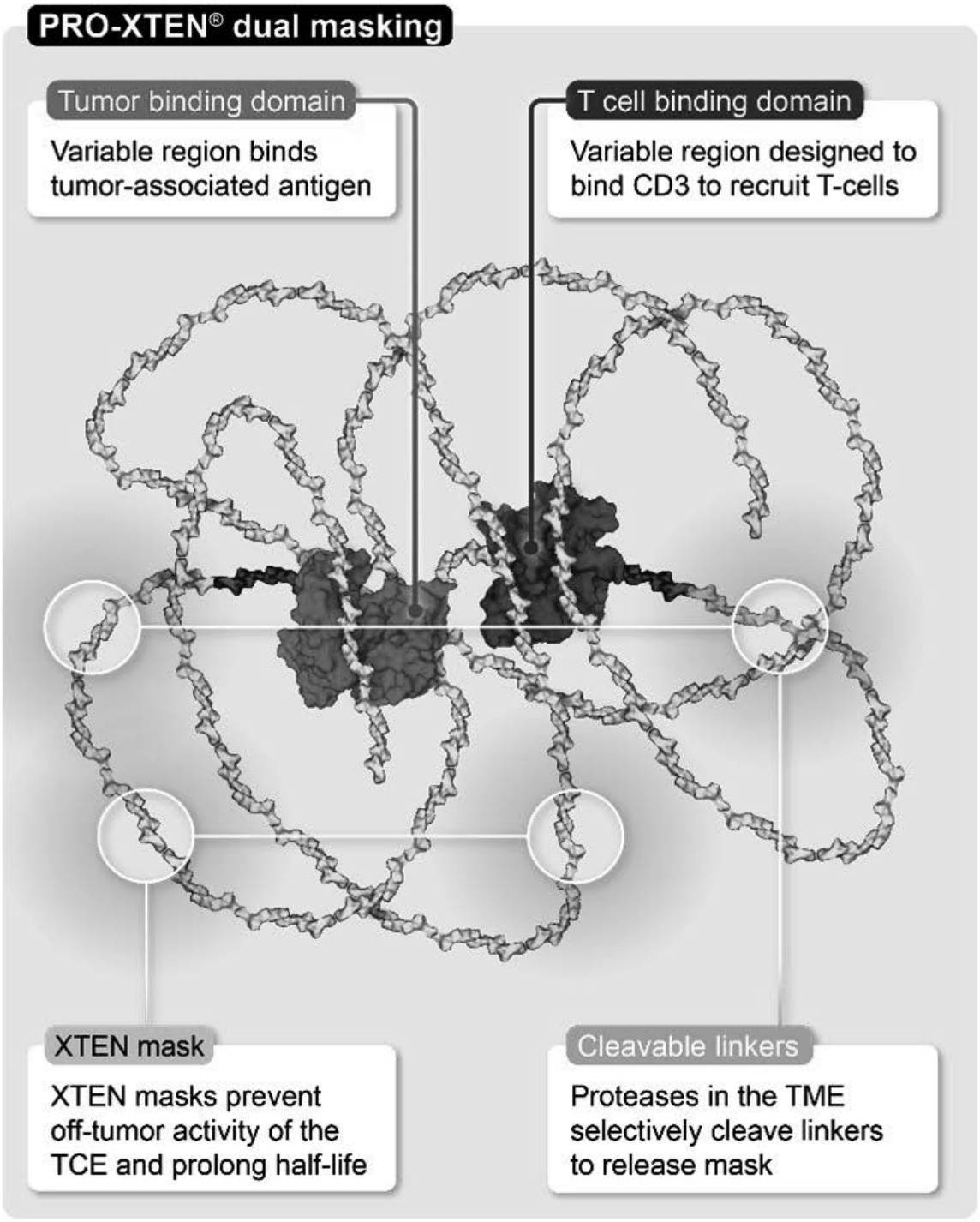
Our Approach

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 selectively 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 components and identifying novel TCE fragments for additional targets. 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

Collaboration and License Agreement with Astellas

On February 19, 2026, we and Astellas US LLC (together with its subsidiaries and affiliates (including its indirect parent, Astellas Pharma Inc.), Astellas) entered into a Collaboration and License Agreement (the Astellas Agreement). Upon closing of the transaction contemplated by the Astellas Agreement, we and Astellas will enter into a global strategic collaboration to co-develop and co-commercialize VIR-5500, an investigational PRO-XTEN® dual-masked CD3 TCE targeting PSMA for the treatment of prostate cancer that is currently in Phase 1 development, through a sharing of expenses and revenues. We have agreed to grant to Astellas, subject to certain intellectual property rights of Sanofi, an exclusive license to develop, manufacture, commercialize and otherwise exploit VIR-5500 and certain related derivative compounds throughout the world for therapeutic, prophylactic, palliative and diagnostic uses.

Under the terms of the Astellas Agreement, in the U.S., we will share profits and losses from future sales of VIR-5500 equally with Astellas, should VIR-5500 receive regulatory approval, and we will have the option to co-promote VIR-5500. Outside of the U.S., Astellas will obtain exclusive rights to commercialize VIR-5500 and be responsible for all commercialization costs. We will jointly develop VIR-5500, with global clinical development costs shared 40% by us and 60% by Astellas, while costs of U.S.-specific studies will be shared equally, and Astellas will be solely responsible for costs of ex-U.S.-specific studies. In addition, we have the option to opt out of development cost sharing responsibilities and U.S. profit sharing, and in such case, Astellas will pay us royalties on net sales made in the U.S., as described below.

We will receive $335 million in upfront and near-term milestone payments, including $240 million in cash, a $75 million equity investment pursuant to a separate Stock Purchase Agreement (the Astellas SPA, described further below), and a near-term $20 million milestone payment upon completion of manufacturing technology transfer, anticipated in the second quarter or third quarter of 2027. We will also be eligible to receive up to $1.37 billion in future development, regulatory and ex-U.S. sales milestones, along with tiered, double-digit royalties on ex-U.S. net sales, which royalties are subject to reduction under certain specified circumstances. If we elect to opt out of development cost sharing responsibilities and U.S. profit sharing, we would be eligible to receive up to $1.37 billion (or $1.60 billion if we have met a pre-defined limited funding threshold at the time of the opt-out) in future development, regulatory and global sales milestones, along with tiered, double-digit royalties on global net sales, which royalties are subject to reduction under certain specified circumstances. Further, certain opt-out milestones, if met, will include reimbursement of a portion of our previously expensed development and commercialization spend. The closing of the transaction is subject to the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

Under the terms of the Sanofi Agreement, we will share with Sanofi 20% of certain future collaboration proceeds, including the upfront payment, equity premium and the portion of milestones, profit-share and royalties that exceed amounts already owed to Sanofi.

Either party may terminate the Astellas Agreement in cases of uncured, material breaches or insolvency. Astellas may terminate the Astellas Agreement for convenience in its entirety (upon 90 days' notice to us if there has not been any commercial sale for any licensed product in any covered territory or else upon 180 days' written notice) or with respect to a licensed product and a given country (upon 90 days' written notice if there has been no commercial sale in the relevant country or else upon 180 days' written notice). Astellas may also terminate the agreement in its entirety or with respect to one or more products upon 30 days' written notice if Astellas determines in good faith that the risks to patients from continuing the development or commercialization of the relevant product or products are greater than the potential benefits of such development and commercialization. Subject to certain conditions, we have the right to terminate the agreement upon certain patent challenges by Astellas or if Astellas does not conduct any material development or commercialization activities or otherwise ceases or abandons all such activities for 12 consecutive months.

Concurrently with the execution of the Astellas Agreement, we have also entered into the Astellas SPA, pursuant to which Astellas has agreed to purchase 7,239,382 shares of our common stock for an aggregate purchase price of approximately $75 million, subject to customary closing conditions and the closing of the Astellas Agreement. The purchase price per share of our common stock of $10.36 is equal to a 50% premium of the 30-day volume weighted average price of a share of our common stock as of February 17, 2026. The Astellas SPA includes standstill, voting and lockup provisions, with customary exceptions, that expire one year after the date of the anticipated closing of the Astellas SPA. One year after the anticipated closing of the Astellas SPA, Astellas will have, under certain circumstances, a customary right to require us to register the resale of the shares purchased pursuant to the Astellas SPA.

License Agreement with Norgine

On December 15, 2025, we and Norgine Pharma UK Limited (together with its affiliates in the Norgine group of companies, Norgine) entered into a License Agreement (the Norgine Agreement) under which we granted Norgine an exclusive license for the commercial rights to the combination of tobevibart and elebsiran for the treatment of CHD in Europe, Australia, and New Zealand (collectively, the Norgine Territory), while we will retain commercial rights for the combination in the United States and all other international markets outside of the Greater China Territory. In exchange, we received an initial reimbursement of development costs from Norgine in the amount of €55 million in December 2025 and are eligible to receive up to an additional €495 million in clinical, regulatory and sales milestones, along with tiered, mid-teen to high-twenties percent royalties on net sales in the Norgine Territory. In addition, clinical development costs for the ongoing trials in our ECLIPSE registrational program (ECLIPSE 1, 2 and 3) will be shared, with Norgine contributing approximately 25% of go-forward external costs.

The Norgine Agreement will remain in force, on a licensed product-by-licensed product and country-by-country basis, until the latest of (a) the 12th anniversary of the first commercial sale; (b) the date of expiration of the last-to-expire valid claim of any licensed patent; and (c) the expiration of regulatory exclusivity. Either party may terminate the Norgine Agreement in cases of material breaches or insolvency. Norgine may terminate the Norgine Agreement with 180 days' prior written notice prior to the first commercial sale of any licensed product and with 12 months' prior written notice on or after the first commercial sale of any licensed product.

License Agreement with Sanofi

On September 9, 2024, we closed a license agreement with Amunix Pharmaceuticals Inc. (Amunix), 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, 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 was due to former shareholders of Amunix upon VIR-5525 achieving "first in human dosing" by 2026. In July 2025, the first patient was dosed in a phase 1 study evaluating VIR-5525 and as a result, we paid the $75.0 million milestone during the third quarter of 2025. 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 Vir Bio receiving certain sublicense income related to the licenses obtained from the Sanofi Agreement, Sanofi may be eligible to receive a portion of such income.

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 product-by-product 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 was originally structured around three categories of product candidates; however, only sotrovimab, VIR-7832, and certain related antibody variants remain active programs under the 2020 GSK Agreement. 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, at a price per share of $37.73 and an aggregate purchase price of approximately $250.0 million.

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.

Regarding sotrovimab, 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 the Greater China Territory 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 U.S. 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 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 license and collaboration revenue, if any, from our 2020 GSK Agreement, and we may incur negative license and 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 and to collaborate on three separate programs, all of which had been subsequently terminated except for an RSV program selected in 2022.

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.

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.

Collaboration and License Agreement with Alnylam

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

In connection with the Restated Alnylam Agreement and Alnylam's election to not opt-in to the profit-sharing arrangement, we paid Alnylam $30.0 million in April 2025, and we will be required to pay Alnylam up to $145.0 million for remaining development and regulatory milestones for elebsiran. Such development and regulatory milestones for elebsiran will be payable to Alnylam only once, irrespective of dosage, formulation forms, route of administration or indication. Following commercialization, we will be required to pay Alnylam up to $250.0 million in the aggregate for the first achievement of specified levels of net sales by elebsiran products directed to HBV, whether for the treatment of HBV or HDV indications. 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 indications, 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 entitled to receive a portion of consideration we receive as a result of granting a sublicense under the licenses granted to Vir Bio by Alnylam under the Alnylam Agreement.

The term of the Restated Alnylam Agreement will continue, on a product-by-product and country-by-country basis, until expiration of all royalty payment obligations under the Restated Alnylam Agreement. 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 Restated 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, it 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 performed at the IRB. 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 with certain proprietary technologies of the IRB. In February 2012, Humabs and IRB entered into a research agreement (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 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 certain IRB's proprietary technology platforms 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. In addition, no royalties shall be payable under IRB know-how for any licensed product in any country after ten years from the date of first commercialization of such licensed product in that country. 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 license maintenance fees of $1.0 million annually, 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 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 Greater China Territory, for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection, or the Field of Use. In partial consideration for the options granted by us to Brii Bio, Brii Bio Parent and Brii Bio in turn 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 Vir Bio program. All options granted to Brii Bio under the Brii Agreement that are not exercised expired in May 2025. 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 Greater 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 Vir Bio program and to commercialize each such product in the Greater China Territory following regulatory approval.

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 Greater China Territory. Brii Bio paid us a $20.0 million option exercise fee in connection with the option exercise. As mentioned above, our elebsiran program is being developed under the Amended Alnylam Agreement and as a result, we separately paid $10.0 million, half of the option proceeds, to Alnylam. 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 Greater China Territory. Brii Bio paid us a $20.0 million option exercise fee in connection with the option exercise.

With respect to elebsiran and tobevibart for which Brii Bio exercised its options, Brii Bio will 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 Greater 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.

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 elebsiran, 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 Vir Bio 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 Bio in the Greater 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 Greater China Territory, as applicable; the expiration or abandonment of licensed patent rights that cover such product in the United States or Greater China Territory, as applicable; and the expiration of regulatory exclusivity in the United States or the Greater 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.

The 2019 Xencor Agreement will remain in force, on a product-by-product and country-by-country basis, until the expiration of all royalty payment obligations. We may terminate the agreement in its entirety, or on a target-by-target basis, for convenience upon 60 days' written notice. Either party may terminate the 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 the 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 are 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 vaccinal antibody program, and, if requested by the Gates Foundation and agreed by us, on further development of such programs beyond stated milestones. 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 low- and middle-income countries, not to exceed a specified percentage over our fully burdened manufacturing and sales costs. As of December 31, 2025, the Company had stock purchase premium liability of $9.3 million, which will be recognized as we advance the development of our vaccinal antibody program with the Gates Foundation.

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 vaccinal antibody program or, if applicable, any 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 specified low- and middle-income countries (as defined in the Gates Agreement) 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 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 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. During the year, all of the grant agreements expired except for the HIV vaccine program, for which the term expires in June 2027. The remaining grant agreement 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.

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, if approved, including tobevibart and elebsiran for the treatment of CHD. We expect to manage sales, marketing and distribution through internal resources and third-party relationships, including with Norgine with respect to commercialization of the combination of tobevibart and elebsiran for the treatment of CHD patients in the Norgine Territory. While we may commit significant financial and management resources to commercial activities for tobevibart and elebsiran and our broader portfolio, we will also consider collaborating with one or more biopharmaceutical companies to enhance our commercial capabilities going forward, as we have with the exclusive license granted to Norgine.

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-current Good Manufacturing Practice (cGMP) manufacturing for preclinical studies. 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. We established 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-cGMP material for preclinical studies. Our new process development laboratory was successfully brought online 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. The manufacturing processes for TCE drug substances (DS) and drug products (DP) have been developed by our scientists based on standard E. coli manufacturing and pharmaceutical processes that have been well-established across the biopharmaceutical industry for other biologics. Similar to our antibody programs, we leverage 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.

siRNA

Vir Bio 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 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 DS (the Tobevibart Agreements). Under the terms of these agreements, the CDMO has reserved these manufacturing slots and will manufacture the agreed upon number of batches in accordance with an agreed upon manufacturing schedule to successfully complete PPQ. Future commercial supply will be subject to finalizing a commercial supply agreement and relevant terms by the end of 2026.

In 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 has reserved these manufacturing slots and will manufacture the agreed upon number of batches in accordance with the agreed upon manufacturing schedule to successfully complete PPQ. Future commercial supply will be subject to finalizing a commercial supply agreement and relevant terms in 2026. As of December 31, 2025, we had unaccrued unpaid commitments of approximately $24 million under the Tobevibart Agreements and Elebsiran Agreements.

For TCEs, we have agreements with CDMOs to manufacture our DS and DP for clinical trials on a yearly basis with commitments through 2028. In 2025, we entered into binding commitments with a CDMO for manufacture of our TCE products. As of December 31, 2025, we had unaccrued unpaid commitments of approximately $20 million for various TCE programs.

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 CHD. Gilead’s bulevirtide is approved for use by the EMA. Gilead has refiled for bulevirtide with the FDA and has announced that they expect a U.S. launch in the first half of 2026 should bulevirtide be approved by the FDA. Bulevirtide has led to limited HDV clearance and requires daily injections to maintain viral suppression. Mirum recently acquired Bluejay Therapeutics and their pipeline asset, brelovitug, which is currently in pivotal trials. Additionally, there are two known small pharmaceutical companies developing programs with various mechanisms of action, including Huahui Health and Assembly Biosciences (in partnership with Gilead).

Prostate Cancer

Novartis' lutetium Lu 177 vipivotide tetraxetan is the only currently approved PSMA-targeted therapy for prostate cancer. There are a number of PSMA therapies in development for prostate cancer including TCEs (e.g., Janux's JANX007), ADC's (e.g., Johnson & Johnson's JNJ-8177) and other mechanisms of action from various companies, including Regeneron, GSK, and Bayer, among others. Beyond PSMA-targeted therapies, there are other clinical development programs focused on other prostate cancer targets (STEAP1, KLK2, B7-H3, etc.) utilizing various mechanisms of action that are sponsored by various companies, including J&J, Amgen, Novartis, Merck (MSD), Pfizer, and AstraZeneca, among others.

HER2-Expressing Solid Tumors

There are several HER2 therapies currently approved and in development for HER2-expressing solid tumors. For HER2 positive breast cancer, there are a number of approved drugs including ADCs (e.g. AstraZeneca's and Daiichi Sankyo's trastuzumab deruxtecan, Roche's trastuzumab emtansine); monoclonal antibodies (e.g. Roche's trastuzumab & pertuzumab); and inhibitors (e.g. Pfizer's tucatinib). Outside of HER2 positive breast cancer, there are other companies evaluating HER2 therapies in HER2-expressing solid tumors with various mechanisms of action including AstraZeneca, Daiichi Sankyo, Pfizer, Remegen, Jazz, BioNTech, Duality Bio, Hengrui Pharma, Adagene among others. Beyond HER2 therapies, companies are also developing programs targeting other tumor targets (non-HER2) that could also compete in HER2-expressing solid tumors.

EGFR-Expressing Solid Tumors

There are several EGFR therapies currently approved and in development for EGFR-expressing solid tumors. For colorectal cancer, EGFR-targeting mAbs including Lilly's cetuximab and Amgen's cetuximab are currently approved globally. Outside of colorectal cancer, there are also other companies evaluating EGFR therapies in EGFR-expressing solid tumors with various mechanisms of action including Janux, Regeneron, J&J, Genmab, Bicara, BMS, SystImmune, Affimed, AstraZeneca and others. Beyond EGFR therapies, companies are also developing programs targeting other tumor targets (non-EGFR) that could also compete in EGFR-expressing solid tumors.

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 several collaborators and other third parties, including Sanofi, Alnylam, 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 elebsiran, tobevibart, VIR-5500, VIR-5818, and VIR-5525, and the use of these candidates for therapeutic purposes. Our proprietary technology has been developed primarily through in-licenses, 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 90 different patent families as of December 31, 2025, filed in various jurisdictions worldwide. Our patent portfolio includes over 1,500 active cases with over 690 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 have not yet been granted.

Key Product Candidates	Patent Expiration	
	U.S.	**E.U.**
HBV/HDV		
Elebsiran (VIR-2218)	2039	2039
Tobevibart (VIR-3434)	2042	2039
ONCOLOGY		
VIR-5818	2041	(2041)
VIR-5525	(2044)	(2044)
VIR-5500	2044	(2044)

Platform 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 extended 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, 2025, 33 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 several 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 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 "Item 1A. 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, as a sponsor, 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, seek approval or licensure or commercialize 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 current Good Laboratory Practice (cGLP), regulations;
- design of a clinical protocol and submission to the FDA of an application(s) 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 current Good Clinical Practice (cGCP) regulations to establish the safety and efficacy of a drug candidate, and compliance with cGMP to establish safety, purity and potency of a proposed 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 whether the application is accepted for filing;
- 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 cGMP and of selected clinical investigation sites to assess compliance with cGCP;
- 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 to maintain the marketed status in the US of an approved drug.

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 cGCP, 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 or healthy volunteers. 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 benefit-risk 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 or as a condition to full approval to gain more information about the safety and efficacy of the product. 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 can be 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 and conducts inspections to determine 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.

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 (Complete Response Letter). 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.

In 2025, the FDA announced a new pilot program called National Priority Voucher (CNPV). This program is designed to further accelerate drug review time for companies supporting US national interests. The review time may be reduced from 10-12 months to just 1-2 months under this pilot program.

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 their 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 testing, animal trials and clinical 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 providers, payers, and other third parties 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 uses.

The federal Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA), created additional federal healthcare fraud 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 intended to be 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 prior Part D coverage gap discount program with the new Manufacturer Discount Program (effective in January 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 whether 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 and although we are not considered to be a covered entity or business associate under HIPAA, certain third parties with whom we collaborate in administering our clinical studies (or may collaborate with in the future for any clinical, regulatory or commercial activities) are within the scope of HIPAA. 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. Congress has also considered passing a federal privacy law.

Numerous U.S. states, such as California, Colorado, Oregon, Texas, Utah and Virginia, among others, have adopted comprehensive privacy laws, including laws and regulations similar to HIPAA, that impose restrictive requirements regulating the processing of "sensitive" data (which includes health data in some cases). 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 civil or criminal 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, 2025, we had 367 employees, 282 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 Company stock at a discounted price.

Equity, Inclusion and Development

We take a proactive approach to promoting equity and inclusion. 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 independent audit of our pay practices periodically.

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.

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 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, which exposes us to additional risks.
- Success in preclinical 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 United States 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 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 or components, could adversely affect our business, reputation or financial results, and our competitors may be able to utilize such technologies more effectively than we can.
- Our product candidates, if approved, may fail to achieve adoption by physicians, patients, third-party payors, clinical guidelines or others in the healthcare community necessary for commercial success.
- We rely on third parties to produce clinical and future commercial supplies of our product candidates. There could be delays or supply shortages beyond our control limiting our access to clinical and future commercial 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 $438.0 million and $522.0 million for the years ended December 31, 2025, and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $1.2 billion.

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

It could be several years, if ever, before we are able to commercialize any of our product candidates. Any net losses we incur may fluctuate significantly from quarter to quarter and year to year based on operating expenses and other factors. To become profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical and clinical studies of our current and future product candidates, obtaining regulatory approval, procuring commercial-scale manufacturing and marketing, and selling any products for which we obtain regulatory approval (including through third parties), as well as discovering or acquiring and developing additional product candidates. We are only in the preliminary stages of most of these activities, and we may never attain a level of commercial success that will generate sufficient revenue to offset our expenses and maintain profitability. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses, or if we will be able to return to profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical studies or the development of any of our product candidates, our expenses could increase.

Our failure to return to profitability could decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

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

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

As an organization, beyond sotrovimab for COVID-19, we have not yet demonstrated an ability to successfully manufacture a new drug application (NDA)- or biologics licensing application (BLA)-approved, commercial-scale product or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer history of commercialization. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives, including with respect to our technology platforms and product candidates.

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

As of December 31, 2025, we had cash, cash equivalents and investments of $781.6 million. Based upon our current operating plans, we believe that this amount will 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, 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. The dynamic and rapidly evolving nature of our business also makes it difficult to estimate with certainty our future revenue and expenses after any such successful development and commercialization.

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.

For example, on February 19, 2026, we and Astellas entered into the Astellas Agreement. Upon closing of the transaction contemplated by the Astellas Agreement, we and Astellas will enter into a global strategic collaboration to co-develop and co-commercialize VIR-5500 for the treatment of prostate cancer, and we will receive a $240 million upfront cash payment. Concurrently with the execution of the Astellas Agreement, we also entered into the Astellas SPA, pursuant to which Astellas has agreed to purchase 7,239,382 shares of our common stock for an aggregate purchase price of approximately $75 million, subject to customary closing conditions and the closing of the Astellas Agreement. Certain of the closing conditions for each of the Astellas Agreement and the Astellas SPA are beyond our control, and no assurance can be given that the closing will take place on the timeline currently anticipated, or at all, or that we will receive the entire amount of expected proceeds on the timeline currently anticipated, or at all. Any failure to close one or both of these transactions could materially and adversely impact our business, financial condition, results of operations and liquidity.

General economic conditions, both inside and outside the United States, 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 development programs or commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

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 and clinical studies can be interpreted in different ways, and even if we believe that the preclinical or clinical data for our product candidates are promising, such data may not be sufficient for the FDA and comparable foreign regulatory authorities to approve further development, manufacturing or commercialization of our product candidates. The FDA or these other regulatory authorities may also require us to conduct additional preclinical or clinical studies for our product candidates, or may object to elements of our clinical development program and require us to alter them. Additionally, the acceptance of data by the FDA from clinical trials conducted outside the United States, or by comparable foreign regulatory authorities for trials conducted outside of their respective jurisdictions, may be subject to conditions imposed by such regulatory authorities, including as relating to differences between medical practice, clinical endpoints, trial conduct and patient populations between the United States and foreign countries.

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

Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects. In addition, the FDA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations, experience disruptions or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain applicable regulatory approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Furthermore, even if we obtain regulatory approval for our product candidates, we may still need to build 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 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 (VIR-5818, VIR-5500 and VIR-5525) and the PRO-XTEN® universal masking platform 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 may seek marketing approval for our current and future product candidates outside of the United States. We have limited prior experience in marketing approved products outside of the United States, and marketing products in foreign countries would subject us to additional risks. 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, and such efforts may be expensive, time-consuming and 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 development of the combination of tobevibart and elebsiran as a treatment for CHD, which includes both our ECLIPSE registrational trial program evaluating the doublet combination and an ongoing Phase 2 clinical trial evaluating tobevibart as a monotherapy in addition to the doublet combination. Each of these product candidates has demonstrated direct antiviral activity and the potential to stimulate an effective immune response.

In our early-stage oncology programs, we are evaluating each of VIR-5818 and VIR-5525 in combination with pembrolizumab in Phase 1 basket studies across multiple tumor types, including metastatic breast cancer and metastatic CRC for VIR-5818 and NSCLC, CRC, HNSCC and cSCC for VIR-5525. 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 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.

Certain of our clinical programs have in the past, and may in the future, not yield positive results in late-stage studies. 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 United States or similar designations in any other regulatory jurisdictions will maintain such designations or receive regulatory approval any sooner than other product candidates that do not have such designations, or at all.

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

A failure or significant delay of a clinical study can occur at any stage. For example, during initial dose escalation, we, the FDA or comparable foreign regulatory authorities have in the past imposed and may in the future impose, restrictions relating to chemistry, manufacturing and control standards, and such restrictions could delay or limit our evaluation of a product candidate and its subsequent advancement to late-stage studies. In addition, we, the FDA or comparable foreign regulatory authorities, or any institutional review boards for any planned or ongoing study, could impose a clinical hold on such study, which could halt enrollment and/or require discontinuation for any product candidates under evaluation. Also, the availability of superior or competitive therapies coupled with changing standards of care could limit our ability to perform placebo-controlled studies or require us to enroll a larger number of subjects to address competing treatments. Moreover, preclinical and clinical data are susceptible to varying interpretations and analyses that can result in product candidates failing to obtain marketing approval. Any of these or other unforeseen events 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. 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.

If the results of our clinical studies are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- 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);
- 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, contraindications or safety warnings, or determine not to pursue any approval at all;
- 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 regulatory approval. In addition, the compounds we are developing may not demonstrate in patients the chemical and pharmacological properties ascribed to them in preclinical studies, and they may interact with human biological systems in unforeseen, ineffective or harmful ways, which may result in our voluntary termination of related clinical development programs.

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 factors outside our control.

Identifying and qualifying patients to participate in our clinical studies is critical to our success. 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 current and 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, as well as out-license select product candidates or technologies to other companies for further development and potential commercialization. Certain of these agreements contain obligations that require us to make substantial payments in the event certain milestone events are achieved with respect to an in-licensed product candidate, or alternatively relinquish certain rights relating to the development and commercialization of an out-licensed product candidate.

A core element of our business strategy includes continuing to acquire, in-license or out-license, or otherwise collaborate on 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 or technologies, as well as commercial, financial or other 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;
- while we have assumed regulatory sponsorship for all current TCE trial programs, we may, during any transition period with respect to future 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 resources and management's attention from our core business;
- 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 or components, could adversely affect our business, reputation or financial results, and 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, including through the use of our proprietary dAIsY™ AI engine, and we might utilize AI in the future in connection with drug discovery activities. AI can be difficult to deploy successfully due to operational and technical issues inherent in such methods. In particular, AI algorithms' use of machine learning and predictive analytics could lead to flawed, biased or inaccurate results, which, if detected, 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 each 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. Furthermore, 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 a material 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 demonstrate stronger safety and efficacy data, 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 for their products. These advantages could render our product candidates obsolete or non-competitive before we can recover the development and commercialization costs of such product candidates. For additional information regarding our competitors, see the section titled "*Part I, Item 1. Business—Competition*" in this Annual Report on Form 10-K.

Our product candidates, if approved, may fail to achieve adoption by physicians, patients, third-party payors, clinical guidelines or others in the healthcare community necessary for commercial success.

Even if our product candidates receive regulatory 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 the degree of market acceptance 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 our sales and marketing efforts;
- acceptance in the medical and patient communities of our products as 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 our 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 safety profiles of our products including as compared to alternative treatments and therapies; and
- any restrictions on the use of our products together with other medications.

The resulting inability of any approved products to generate significant revenue would compromise our ability to return to profitability.

Our product candidates, if approved, will remain subject to ongoing regulatory oversight and potential enforcement actions.

Even if we obtain regulatory approval in any particular jurisdiction, the applicable regulatory authorities may still impose significant restrictions on the indicated uses, marketing, manufacturing or distribution of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Additionally, the holder of an approved NDA or BLA is required to comply with FDA rules, including relating to record-keeping, reporting of adverse events and product deviations, periodic reporting, product sampling and distribution, lot release, and advertising and promotion, and is subject to FDA review and periodic inspections, in addition to other potentially applicable federal and state laws, to ensure compliance with cGMP and current Good Distribution Practice, as well as adherence to commitments made in the NDA or BLA.

If we or any regulatory agency discovers previously unknown problems with an approved product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, such 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 for that jurisdiction. 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 authorities 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 by applicable regulatory authorities ranging from warning or untitled letters to product seizures or significant fines or monetary penalties, among other actions. The FDA and other state and federal government agencies, including the U.S. Department of Justice (DOJ), closely regulate and monitor the marketing and promotion of products in the United States 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 Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws, which violations may result in the imposition of significant administrative, civil and criminal penalties. Any government investigation of alleged violations of laws or regulations could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue. For additional information regarding regulatory approval and ongoing regulatory oversight, see the section titled "*Part I, Item 1. Business—Government Regulation and Product Approval*" in this Annual Report on Form 10-K.

We may never obtain approval for our product candidates 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 European Commission following the opinion of the EMA if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a product candidate is approved, the EMA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical 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 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. Negative 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 accepting, our product candidates as treatments in lieu of, or in addition to, existing and more familiar treatments for which greater clinical data may be available. Any 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 those 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 those product candidates that are approved; or
- a suspension or withdrawal of approval by regulatory authorities of our product candidates that are approved.

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 operational risks that we identify; however, we may fail to correctly anticipate or quantify insurable operational 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 insurance coverage at all because of high cost and/or limited availability, and our financial condition could be negatively impacted should such risks come to fruition.

Risks Related to Regulatory Compliance

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

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

Physicians, other healthcare professionals and third-party payors, both 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, patients, 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, civil monetary penalty laws, the False Claims Act (FCA) and other federal civil and criminal false claims laws, the healthcare fraud provisions of HIPAA and the Physician Payments Sunshine Act. Civil and criminal false claims laws and civil monetary penalty laws can be enforced through civil whistleblower or *qui tam* actions and prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of federal government funds, including in federal healthcare programs, that are false or fraudulent.

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 "*Part I, Item 1. Business—Government Regulation and Product Approval*" 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.

Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations can be expensive and time-consuming and could divert management's attention from our core business. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if research 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 a material adverse effect on our ability to compete in the marketplace.

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 private health insurers. Third-party payors decide which therapies they will pay for and establish coverage conditions and reimbursement levels. While no uniform policy for coverage and reimbursement exists in the United States, third-party commercial payors may rely upon Medicare or Medicaid 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 and may be delayed, particularly with regard to new drugs, and subject to change. 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 cost-sharing 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 healthcare professionals prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients may be less likely to use our products if coverage is limited, including through utilization management and/or high cost-sharing requirements. In addition, because certain of our product candidates are physician-administered, physicians that purchase products must receive sufficient reimbursement to cover their acquisition costs. In such physician-administered settings, separate reimbursement for the product itself may or may not be available, and, if it is not, 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, including through utilization management or other restrictions on coverage of a product. We cannot be sure that adequate 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.

In order for our products to be eligible for coverage under certain government health care programs, we will be required to enter into agreements with the government and provide complex pricing calculations that, in turn, may influence government reimbursement rates. For instance, reimbursement for our products under Medicaid and Medicare Part B will require participation in the Medicaid Drug Rebate Program and payment of a rebate for each unit of product reimbursed by state Medicaid programs. We will also be required to participate in the 340B Drug Pricing Program and an agreement with the U.S. Department of Veterans Affairs. Changes to these programs may impact government program reimbursement for our products and in turn could adversely affect our business, results of operations, financial condition and prospects.

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

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

It is currently unclear how certain new measures, including the drug pricing provisions of the Inflation Reduction Act of 2022 (and subsequent rulemaking and guidance) and changes to Medicaid eligibility requirements in the OBBBA, will ultimately be effectuated. Accordingly, we cannot predict with certainty what impact these or any other federal or state health reforms will have on us, including whether finalized rules will be implemented or withstand judicial review. Any 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, financial condition and prospects. In addition, it is unclear whether the new Trump Administration will reverse or modify any existing regulatory requirements, pursue the reform initiatives outlined in various executive orders and administrative proposals (such as the May 12, 2025 executive order supporting a "most favored nation" approach to drug pricing and related price reduction agreements with certain manufacturers) 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 healthcare legislative, administrative and other reform measures, see the sections titled "*Part I, Item 1. Business—Government Regulation and Product Approval—Healthcare Reform*" and "*Part I, Item 1. Business—Government Regulation and Product Approval—Pharmaceutical Prices*" 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, Medicaid 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 or attain profitability from commercializing 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 be expensive and time-consuming, and could divert resources and management's attention from our core business.

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 divert resources and management's attention from our core business, as well as cause us to incur significant defense costs and other professional fees. Enforcement actions and sanctions could further harm our business, reputation, financial condition, results of operations and prospects.

Risks Related to Our Dependence on Third Parties

We rely on third parties to produce clinical and future commercial supplies of our product candidates. There could be delays or supply shortages beyond our control limiting our access to clinical and future commercial supplies.

We are currently conducting process development and manufacturing materials for product candidates of three different therapeutic modalities: monoclonal antibodies, siRNAs and TCEs. Except for process, analytical and formulation development, cell line development, non-cGMP manufacturing and quality control testing for preclinical studies, we do not own or operate facilities for large-scale process development or product manufacturing, storage and distribution, or testing. We are dependent on multiple third parties, including strategic collaborators and CDMOs, to obtain product raw materials and components, develop large-scale manufacturing processes for and manufacture clinical and future commercial supplies of our product candidates. The actual cost to manufacture our product candidates, including the requisite scale-up activities for commercial supplies, is difficult to estimate and could affect the commercial viability and competitive position of our product candidates. Additionally, scaling up a biologic manufacturing process is a difficult and uncertain task and involves additional risks, including cost overruns, process reproducibility, stability issues, cGMP compliance, lot consistency and timely availability of sufficient quantity of raw materials.

The facilities used by our CDMOs to develop and manufacture our product candidates must be inspected and approved by the FDA or other regulatory authorities. We do not control the day-to-day operations of, and are completely dependent on, our CDMOs for compliance with cGMP requirements. If our CDMOs cannot successfully manufacture materials that conform to the requirements of the FDA or other health authorities, we will not be able to secure or maintain regulatory approval for our product candidates. In addition, we have limited control over the oversight of personnel or subcontractors of our CDMOs. 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, 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. Any significant delay in the supply of a product candidate, or its raw material components, for an ongoing clinical trial could considerably delay completion of our clinical studies, product testing and potential regulatory approval.

We also intend to rely on CDMOs to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization. Any shortfall in a CDMO's manufacturing capacity or reduction in anticipated manufacturing titer, yield per batch or batch success rates may adversely impact our ability to meet market demand. Furthermore, if we are not able to produce supply at low enough costs, it could negatively impact our ability to generate revenue, harm our reputation, and could have a material 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 materials available to us, delay the procurement or supply of such materials or adversely affect our ability to secure significant commitments from governments to purchase our potential therapies.

Our reliance on third-party suppliers and CDMOs exposes us to other risks, including:

- the commitment of excess manufacturing capacity or excess raw materials due to insufficient market demand for our product candidates and responsibility for the associated costs;
- costs and validation of new equipment and facilities required for scale-up;
- inability of our CDMOs to execute process development, technology transfers, cGMP manufacturing, manufacturing or testing procedures, and other logistical support requirements appropriately or on a timely basis;
- inability to negotiate development and manufacturing agreements with third parties under commercially reasonable terms, if at all;
- greater costs and competition for access to an increasingly smaller pool of potential CDMO as a result of consolidation in the contract manufacturing industry;
- breach, termination or nonrenewal of development and manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for raw materials or components, including the risk that such single source may not remain in business or will be purchased by a competitor or other company not interested in continuing production, or the lack of qualified backup suppliers for those raw materials or components;

- limited 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, facility outages (including due to contamination), transportation and labor disruptions, global competition for resources, regulatory requirements or actions (including recalls or failure by the supplier or CDMO to comply with cGMP), adverse financial developments or the bankruptcy of the supplier or CDMO, or general economic conditions;
- 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 to which our third-party suppliers or CDMOs may be differently exposed than us; and
- carrier disruptions or increased costs that are beyond our control, including increases in materials, labor or other manufacturing-related costs or higher supply chain logistics costs.

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, 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. Due to limited knowledge of the manufacturing process during development stages, potential product loss and contaminations could lead to batch failures.

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. Our CDMOs could face risks in meeting our delivery time requirements or provide adequate amounts of synthetic siRNAs to meet our needs, which may include extended lead times, delays or shortages of raw materials and components, synthesis and purification failures and/or contamination during the manufacturing process, or difficulty complying with the applicable manufacturing requirements. To fulfill our siRNA supply requirements, we may need to secure alternative suppliers of synthetic siRNAs or key raw materials and components, and such alternative third-party suppliers are limited and may not be readily available, or we may be unable to enter into agreements with them on reasonable terms and in a timely manner. Further, alternative suppliers would require filing and regulatory approvals.

Changes in U.S. and international trade policies may adversely impact our business and operating results.

The U.S. government has made statements and taken actions that have led to certain changes and may lead to additional changes to U.S. and international trade policies. For example, President Trump has imposed or signaled to impose a series of tariffs on certain products manufactured outside the United States, including pharmaceutical products and raw materials and components for pharmaceutical products, and it is unknown whether and to what extent additional tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry. Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may affect the demand for our product candidates, the competitive position of our product candidates, and import or export of raw materials and product used in our drug development, clinical manufacturing and future commercial activities. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or if the U.S. government takes retaliatory trade actions due to the ongoing trade tensions, such changes could have an adverse effect on our business, financial condition and results of operations.

Our business involves the use of hazardous materials, and we and our third-party suppliers and CDMOs must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do, or interrupt our, business.

Our research and development activities and the activities of our third-party manufacturers and suppliers involve the generation, storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds and wastes. We and our third-party suppliers and CDMOs are subject to environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, generation, storage, handling, transportation, discharge and disposal of these hazardous materials and wastes and worker health and safety. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our CDMOs' facilities pending their use, collection, and appropriate disposal. We cannot eliminate the risk of contamination or injury, which could result in an interruption of our commercialization efforts, research and development efforts and business operations, damages and significant cleanup costs and liabilities under applicable environmental, health and safety laws and regulations. We also cannot guarantee that the safety procedures utilized by our CDMOs for handling and disposing of these materials and wastes generally comply with the standards prescribed by these laws and regulations. We may be held liable for any resulting damages costs or liabilities, which could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Failure to comply with these environmental, health and safety laws and regulations may result in substantial fines, penalties or other sanctions. We do not currently carry hazardous waste insurance coverage, and our financial condition could be negatively impacted should such risks come to fruition.

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 cGLP and cGCP, 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 cGCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct cGLP-compliant and cGCP-compliant preclinical and clinical studies, we remain responsible for ensuring that each of our cGLP 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 cGCP, the clinical data generated in our clinical studies may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical studies, which would delay the regulatory approval process.

Our reliance on third parties to conduct clinical studies will result in less direct control over the management of data developed through clinical studies than would be the case if we were relying entirely upon our own staff. Communicating with CROs and other third parties can be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines or fail to comply with regulatory requirements, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical studies may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

In addition, principal investigators for our clinical studies may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval or rejection of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates.

Risks Related to Our Intellectual Property

If we breach our license agreements or any of the other agreements under which we acquired, or will acquire, the intellectual property rights to our product candidates, we could lose the ability to continue the development and commercialization of the related product candidates.

We license a number of technologies to form our antibody platform, and we license the PRO-XTEN® platform from Sanofi and the siRNA technology from Alnylam. We have also developed certain product candidates using intellectual property licensed from third parties or in-licensed certain product candidates from third parties. A core element of our business strategy includes continuing to acquire or in-license additional technologies or product candidates for the treatment and prevention of serious infectious diseases and other serious conditions. If we fail to meet our obligations under these agreements, our licensors may have the right to terminate our licenses. If any of our license agreements are terminated, and we lose our intellectual property rights under such agreements, this may result in a complete termination of our product development and any commercialization efforts for the product candidates which we are developing under such agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under such agreements, we may not be able to do so in a timely manner, at an acceptable cost or at all. We may also be subject to risks related to disputes between us and our licensors regarding the intellectual property subject to a license agreement. We could also be subject to expensive litigation which would detract us from our core business of researching and developing product candidates.

If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and our technology. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and our technology that are important to our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or patents at a reasonable cost or in a timely manner. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In addition, changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the term, enforcement or defense of issued patents. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from infringing our patents in all countries outside of the United States, or from selling or importing products that infringe our patents in and into the United States or other jurisdictions.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In addition, if the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates, or could result in licensees seeking release from their license agreements.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our owned and in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent rights depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The U.S. Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will have to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our service providers or our licensors to pay these fees. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property.

Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or technologies, or if our patent rights become limited, including as a result of geopolitical events (such as the Russian Federation's recent limitations on patents originating from certain countries that have supported Ukraine, including the United States), we may not be able to use such patents and patent applications or stop a competitor from marketing products that are the same as or similar to our product candidates, which would have an adverse effect on our business. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us or out-licensed by us, any of the foregoing could expose us to liability to the applicable patent owner or licensee, respectively.

Patent terms may be inadequate to protect the competitive position of 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, and we may also 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 could divert resources and 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, and if research 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 material adverse effect 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 can be expensive and time-consuming and could divert resources and management's attention from our core business.

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 can be expensive and time-consuming and could divert resources and management's attention from our core 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 have a material adverse effect on our business, financial condition, results of operations and prospects.

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 can be expensive and time-consuming, and we may not be able to prosecute all necessary or desirable trademark applications at a reasonable cost or in a timely manner or obtain trademark protection in all jurisdictions that we consider to be important to our business. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications in certain jurisdictions, as in currently pending oppositions filed against the Portuguese applications for our Vir Biotechnology house mark and logo by Industria Quimica y Farmaceutica Vir. S.A., a Spanish company which claims exclusive rights in the term VIR in Spain and Portugal. Third parties may also challenge our use of our trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary product name we propose to use with our current or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

The potential exercise by the Gates Foundation of its licenses to certain of our intellectual property and its development and commercialization of products that we are also developing and commercializing could have an adverse impact on our market position.

In January 2022, we entered into the Gates Agreement, which amended and restated the original letter agreement with the Gates Foundation that we entered into in December 2016. In connection with the Gates Agreement, the Gates Foundation purchased an aggregate of $20.0 million of shares of our convertible preferred stock (which later converted to shares of our common stock after our initial public offering) and purchased $40.0 million of shares of our common stock in January 2022. We are obligated to use the proceeds of the Gates Foundation's investment in furtherance of its charitable purposes to perform certain activities set forth in the Gates Agreement. For additional information regarding our obligations under the Gates Agreement, see the section titled "*Part I, Item 1. Business—Our Collaboration, License and Grant Agreements—Amended and Restated Letter Agreement with the Gates Foundation*" in our 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 set forth in the Gates Agreement (and described in our filings with the SEC) and to not use such proceeds for specified prohibited uses, (ii) specified reporting requirements or (iii) specified applicable laws, or if we materially breach our specified global access commitments (any such failure or material breach, a specified default), we will be obligated to redeem or arrange for a third party to purchase all of our stock purchased by the Gates Foundation under the Gates Agreement, at the Gates Foundation's request, at a price equal to the greater of (a) the original purchase price or (b) the fair market value, which amount may increase in the event of a sale of our company or all of our material assets relating to the Gates Agreement. Additionally, if a specified default occurs or if we are unable or unwilling to continue the HIV program, tuberculosis program, vaccinal antibody program or, if applicable, any 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 specified low- and middle-income countries (as defined in the Gates Agreement) 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. We have in the past undergone leadership changes, and such management transitions may create uncertainty and divert resources and management's attention from our core business, 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. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

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 to 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 management's attention from our core business, 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 could divert management's attention from our core business 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 II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk*" in this Annual Report on Form 10-K.

We may not successfully integrate and 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 an 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 could divert business development resources and management's attention. 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. Our existing business continuity preparations may not sufficiently mitigate the occurrence of any of these business disruptions, which 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 can be 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 can 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 have in the past and may in the future experience server malfunction, software or hardware failures, supply-chain cyber-attacks, loss of data or other computer assets and other similar issues. In addition, we have in the past and may in the future experience security events affecting our information technology systems, such as through business email compromises or other network intrusions, including threats to exfiltrate and disclose proprietary information; however, none of these attacks to date, either individually or in the aggregate, have had a material adverse effect on our business, financial condition, results of operations or prospects. 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 various targets. Any significant system failure, accident or security breach could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 significant security breach were to occur and cause significant 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. Such requirements include rules adopted by the SEC in 2023, pursuant to which we must publicly disclose certain cybersecurity incidents. These 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. Moreover, 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 and evolving laws, regulations, policies and contractual obligations related to data privacy and security, and failure by us or the third parties with whom we work to comply with such requirements could subject us to significant fines, penalties, investigations and/or reputational harm.

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 our use of AI and machine learning may subject us to additional laws and evolving regulations.

Numerous U.S. states, including California where our headquarters is located, have passed comprehensive privacy laws, and other states are considering passing similar 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, and although we are not considered to be a covered entity or business associate under HIPAA, certain third parties with whom we collaborate in administering our clinical studies (or may collaborate with in the future for any clinical, regulatory or commercial activities) are within the scope of HIPAA. Congress has also considered passing a federal privacy law. These laws may impact our business activities, including our identification of clinical research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

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. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our collaboration partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to €20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. The U.K. and Switzerland, as well as other countries outside of Europe, have adopted privacy and data security laws that are comparable to the GDPR.

In addition, we may be unable to transfer personal data from EEA countries and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. We must devote significant resources to understanding and complying with this changing landscape, and our efforts may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. 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 civil or criminal 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. Further, if we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. 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, results of operations or prospects.

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures, reckless and/or negligent conduct or unauthorized activities that violates (i) the laws and regulations of FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad, (iv) laws that require the true, complete and accurate reporting of financial information or data, (v) insider trading laws that restrict the buying and selling of shares of securities while in possession of material non-public information, (vi) federal and state data privacy laws and regulations and (vii) contractual obligations of Vir Bio or such parties. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical studies, creating fraudulent data in our preclinical or clinical studies or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation.

It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these contractual provisions, laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud, violations or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

Our ability to use our net operating losses, or NOLs, to offset future taxable income may be subject to certain limitations.

As of December 31, 2025, we had net operating loss carryforwards of $1.2 billion for federal tax purposes and $446.4 million for state tax purposes. If not utilized, federal carryforwards will begin expiring in 2036 and state carryforwards will begin expiring in 2037. Our ability to use our federal and state NOLs to offset potential future taxable income is dependent upon our generation of future taxable income before any expiration dates of the NOLs, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures and required taxpayers to capitalize and amortize them over five or fifteen years pursuant to Section 174 of the Internal Revenue Code of 1986, as amended (the Code), which reduced our net operating losses. The OBBBA suspends the requirement to capitalize and amortize domestic "research or experimental expenditures" (as defined in the OBBBA) over five years and instead allows taxpayers to immediately deduct such expenses for tax years beginning after December 31, 2024. In addition, with respect to domestic research or experimental expenditures incurred in a taxable year beginning after December 31, 2021 and before January 1, 2025, taxpayers may elect to accelerate the remaining unamortized amounts of such expenses over a one- or two-year period. Both aforementioned changes under the OBBBA to the treatment and deductibility of such expenses could potentially increase our anticipated net operating losses. The treatment of foreign research and development expenses remains unchanged, requiring amortization over 15 years. We are continuing to evaluate the future impacts of the OBBBA as additional information is provided.

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 license and 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 United States, 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 can be expensive and time-consuming and could divert resources and management's attention from our core business. 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.

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 price could decline. Similarly, if analysts publish favorable reports about our competitors or unfavorable comparisons of our products or product candidates relative to competing products, our stock price could also decline. Moreover, if analysts fail to publish reports on us regularly or cease coverage of us entirely, 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, which are subject to change and new rulemaking. Stockholder activism and litigation can also increase the costs of being a public company, such as by making it more difficult and expensive to obtain director and officer liability insurance. We have incurred and will continue to incur significant legal, accounting, investor relations and other expenses to comply with these rules and regulations.

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. Even if resolved in our favor, the defense of any such claims can be expensive and time-consuming and could divert resources and management's attention from our core business, and we may further be required to pay damages if any such claims or proceedings are not resolved in our favor. 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 amended and restated certificate of incorporation 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 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 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 meet with the Audit Committee routinely 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 Vir Bio 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, above under "Item 1A. — 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 expires in 2033. We also have leased approximately 58,265 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

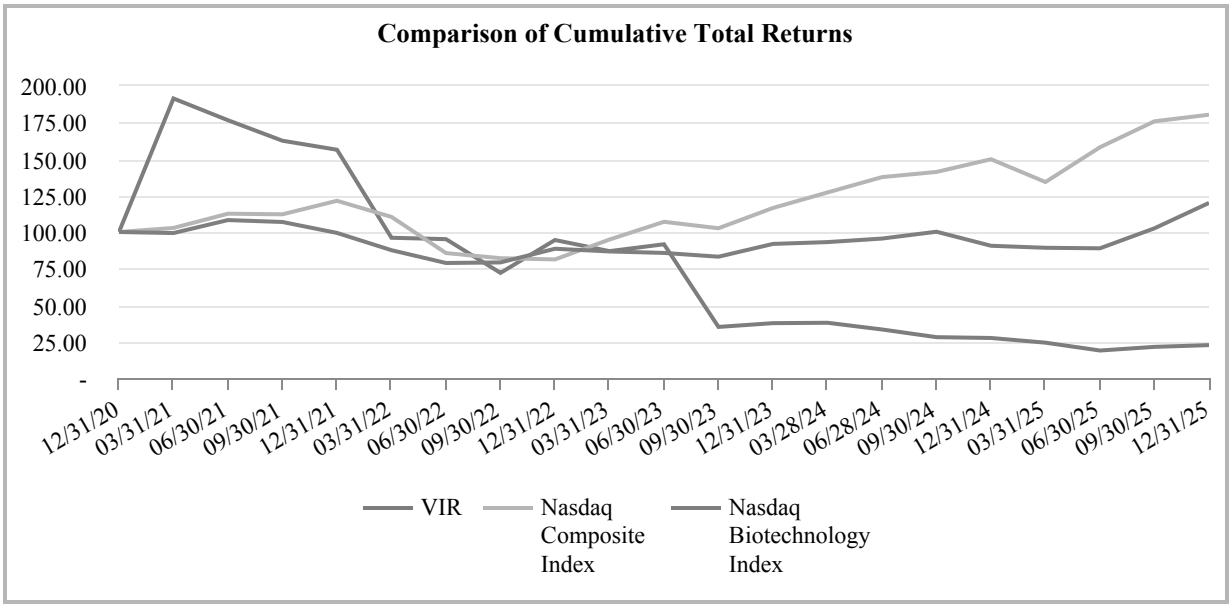
As of February 17, 2026, there were approximately 119 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. 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, 2020 through December 31, 2025 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", "Vir Bio," "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, 2025 and 2024, including year-over-year comparisons of our financial performance and condition for these years. Discussion and analysis of the year ended December 31, 2023 specifically, as well as the year-over-year comparison of our financial results and liquidity and capital resources for the years ended December 31, 2024 and 2023, 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, 2024, as filed with the SEC on February 26, 2025. 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 Bio, we have a bold vision – powering the immune system to transform lives. Our clinical-stage portfolio includes programs for CHD and multiple PRO-XTEN® dual-masked TCEs across validated targets in solid tumor indications. We also have a portfolio of preclinical programs across a range of infectious diseases and oncologic malignancies.

In HDV, our ECLIPSE registrational program is fully underway with all three trials initiated. 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-5500 in patients with PSMA-expressing mCRPC and VIR-5818 in patients with HER2-expressing tumors. We are also advancing our third TCE program, VIR-5525, in patients with EGFR-expressing tumors, with the first patient dosed in phase 1 clinical studies in July 2025. In addition, we are developing therapeutic candidates in HIV cure and other solid tumors, leveraging our expertise and platform strengths, and we have made available for external partnerships our next-generation preclinical influenza A and B antibodies and ADCs along with our next generation COVID mAbs.

We have an industry-leading management team and board of directors with significant immunology, infectious diseases, and oncology experience, including a proven track record of progressing product candidates from early-stage research through clinical development, and worldwide regulatory approval and commercialization experience. Given the global impact of infectious diseases and cancer, we are committed to developing transformative therapies that can make a meaningful difference in patients' lives.

Significant Developments

Following is a summary of 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, 2024.

Pipeline Programs

CHD

- To support global commercialization of the combination of tobevibart and elebsiran for the treatment of CHD, the Company granted Norgine an exclusive commercial license in Europe, Australia and New Zealand.
- Phase 2 SOLSTICE data presented at the 44th Annual J.P. Morgan Healthcare Conference in January 2026 showed the combination of tobevibart and elebsiran is well tolerated and achieved undetectable hepatitis delta virus RNA (HDV RNA TND) in 88% (21/24) of CHD participants evaluable at 96 Weeks of treatment. Previous positive Phase 2 SOLSTICE data at Week 48 were presented at the AASLD The Liver Meeting® 2025 and simultaneously published in the *New England Journal of Medicine.*[3]

[3] Asselah T, Chattergoon MA, Jucov A, et al. "A Phase 2 Trial of Tobevibart plus Elebsiran in Hepatitis D" *N Engl J Med*. vol. 394, no. 4 (2026), 343-353, doi:10.1056/NEJMoa2508827.

- The ECLIPSE 1 and ECLIPSE 3 Phase 3 trials have completed enrollment. The ECLIPSE 2 Phase 3 trial continues enrolling well. Topline data from the ECLIPSE 1 trial are expected in the fourth quarter of 2026. Topline data from the ECLIPSE 2 and ECLIPSE 3 trials are expected in the first quarter of 2027.
- Tobevibart and elebsiran combination therapy is supported by multiple U.S. and EU regulatory designations, including FDA Breakthrough Therapy designation, U.S. FDA Fast Track designation, European PRIME designation and European Orphan Drug designation, signifying the significant unmet need in CHD.
- ECLIPSE 1 evaluates the combination of tobevibart and elebsiran compared to deferred treatment in regions such as the U.S. where bulevirtide is not available or in other regions where its use is limited. ECLIPSE 2 evaluates the switch to the combination of tobevibart and elebsiran in participants who have not achieved undetectable hepatitis delta virus RNA with bulevirtide treatment. ECLIPSE 3 evaluates the combination of tobevibart and elebsiran compared to bulevirtide monotherapy in bulevirtide treatment-naïve participants. ECLIPSE 1 and 2 are designed to provide the registrational efficacy and safety data needed for potential submission to global regulatory agencies, including agencies in the U.S. and Europe. ECLIPSE 3 is expected to provide important supportive data to help establish access and reimbursement in key markets.

Solid Tumors

VIR-5500

- On February 19, 2026, we executed a global strategic collaboration with Astellas to advance PSMA-targeted PRO-XTEN® dual-masked TCE VIR-5500, currently in development for metastatic castration-resistant prostate cancer. Upon closing of the transaction, the parties will co-develop and co-commercialize VIR-5500. We will have the option to co-promote with Astellas in the U.S., and Astellas will obtain exclusive rights to commercialize outside the U.S.

  Under the terms of the agreement, we will receive $335 million in upfront and near-term milestone payments, including $240 million in cash, $75 million in equity investment at a 50% premium, and a $20 million near-term milestone upon completion of manufacturing process technology transfer, anticipated in mid-2027. Global development costs for VIR-5500 will be shared between Astellas and Vir Biotechnology with a 60:40 split. Profits and losses will be shared equally in the U.S, and outside the U.S. we are entitled to receive tiered, double-digit royalties on net sales. In addition, we are eligible to receive up to $1.37 billion in additional development, regulatory and ex-U.S. sales milestones. Under the terms of our licensing agreement with Sanofi, we will share with Sanofi 20% of certain future collaboration proceeds from the Astellas collaboration agreement, including the upfront payment, equity premium and the portion of milestones, profit-share and royalties that exceed amounts already owed to Sanofi. The closing of the transaction is subject to the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.
- Positive updated Phase 1 data for VIR-5500 monotherapy shows dose-dependent anti-tumor activity and a well-tolerated safety profile to date in patients with mCRPC. The data will be shared in an oral presentation at the 2026 ASCO Genitourinary Cancers Symposium on February 26 (Oral Abstract #17). The oral presentation will be delivered by Dr. Johann de Bono, Principal Investigator and Director of the Drug Development Unit and Head of Prostate Cancer Targeted Therapy Group at the Institute of Cancer Research.
- Phase 1 monotherapy dose-escalation of weekly and once every three weeks dosing of VIR-5500 is complete, and we have defined a preliminary go-forward dose and regimen recommendation for expansion. In parallel, dose-escalation of VIR-5500 in combination with enzalutamide continues in early line mCRPC patients.
- We anticipate initiating monotherapy dose-expansion cohorts in late-line mCRPC and combination dose-expansion cohorts in both early-line mCRPC and metastatic hormone-sensitive prostate cancer (mHSPC) in the second quarter of 2026, followed by pivotal, Phase 3 trials in 2027.

VIR-5818

- Phase 1 dose-escalation of VIR-5818, a HER2-targeted PRO-XTEN® dual-masked TCE, in combination with pembrolizumab continues, with response data expected in the second half of 2026. VIR-5818 is the only dual-masked HER2-targeting TCE in clinical development and is being evaluated in multiple tumor types, including CRC.

VIR-5525

- The Phase 1 study of VIR-5525, an EGFR-targeted PRO-XTEN® dual-masked TCE, continues enrollment as expected. VIR-5525 is being evaluated in a variety of EGFR-expressing solid tumors in areas of high unmet need, such as NSCLC, CRC, HNSCC and cSCC.

Preclinical Pipeline Candidates

- We are currently progressing a number of PRO-XTEN® masked TCEs in preclinical studies directed at clinically validated targets with potential applications across a variety of solid tumors, including lung, colorectal and bladder. These preclinical candidates integrate the PRO-XTEN® masking technology with novel TCEs discovered and engineered using our antibody discovery platform and our proprietary dAIsY™ AI engine.
- We have advanced a broadly neutralizing antibody to development candidate status in our HIV cure program in collaboration with the Gates Foundation.

Corporate Update

- In March 2025, we and Alnylam amended and restated their collaboration agreement (Restated Alnylam Agreement), with Alnylam electing not to opt-in to its profit-sharing option for elebsiran in CHB and CHD indications.

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, 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, 2025, we had $781.6 million in cash, cash equivalents, and investments. Based upon our current operating plan, we believe that the $781.6 million 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, 2025, we had $8.9 million in restricted cash and cash equivalents. See the section titled "*Liquidity, Capital Resources and Capital Requirements—Funding Requirements and Conditions*" below for additional information.

Our net loss was $438.0 million for the year ended December 31, 2025, compared to net loss of $522.0 million and $615.1 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2025, we had an accumulated deficit of $1.2 billion. 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-cGMP 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 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 expect to 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 license and collaboration revenue in the future from the sale of sotrovimab for the treatment of COVID-19.

Our revenues consist of the following:

License and collaboration revenue includes revenues generated from license rights issues to Norgine and GSK, including our profit-share from the sales of sotrovimab pursuant to the 2020 GSK Agreement.

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

Other revenue includes recognition of revenue generated from research and development services under third-party contracts and from a third-party clinical supply agreement.

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 CDMO, 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 and other licensors, we may incur additional clinical, and regulatory milestone payments based on the development progress of certain clinical programs. We may also be required to pay commercial milestone payments and royalties in the event of a successful product launch and our receipt of commercial revenues. Therefore, we are unable to predict the timing or the final cost to complete our clinical programs or validation of our manufacturing and supply processes and delays may occur due to numerous factors. Factors that could cause or contribute to delays or additional costs include, but are not limited to, those discussed in the "*Part I, Item 1A. 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, Net

Restructuring, long-lived asset impairment and related charges, net 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, Net

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

(Provision for) Benefit from Income Taxes

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

Results of Operations

Comparison of Years Ended December 31, 2025 and 2024

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

	Years Ended December 31,		
	2025	2024	Change
Revenues:			
License and collaboration revenue	$ 63,130	$ 61,370	$ 1,760
Grant revenue	2,036	10,493	(8,457)
Other revenue	3,390	2,342	1,048
Total revenues	68,556	74,205	(5,649)
Operating expenses:			
Cost of revenue	26	845	(819)
Research and development	455,966	506,499	(50,533)
Selling, general and administrative	92,074	119,031	(26,957)
Restructuring, long-lived assets impairment and related charges, net	(182)	34,995	(35,177)
Total operating expenses	547,884	661,370	(113,486)
Loss from operations	(479,328)	(587,165)	107,837
Other income:			
Change in fair value of equity investments	1,729	(5,528)	7,257
Interest income	40,238	71,809	(31,571)
Other expense, net	(409)	(2,221)	1,812
Total other income	41,558	64,060	(22,502)
Loss before (provision for) benefit from income taxes	(437,770)	(523,105)	85,335
(Provision for) benefit from income taxes	(217)	1,145	(1,362)
Net loss	$ (437,987)	$ (521,960)	$ 83,973

Revenues

The increase in license and collaboration revenue for the year ended December 31, 2025 compared to the same period in 2024 was primarily due to the recognition of $64.3 million license revenue related to the initial payment received under the Norgine Agreement. We granted Norgine an exclusive license with respect to commercial rights to the combination of tobevibart and elebsiran for the treatment of CHD in Europe, Australia, and New Zealand. Such increase was partially offset by $51.7 million 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, and lower GSK profit-sharing revenue in 2025 from GSK under our 2020 GSK Agreement.

The decrease in grant revenue for the year ended December 31, 2025 compared to the same period in 2024 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. All but one of our grant agreements with the Gates Foundation expired in 2025, and we terminated our agreement with BARDA at the end of 2024.

The change in other revenue for the year ended December 31, 2025 compared to the same period in 2024 was nominal.

Cost of Revenue

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

Research and Development Expenses

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

	Years Ended December 31,		
	2025	2024	Change
Personnel	$ 125,274	$ 162,960	$ (37,686)
Licenses, collaborations and contingent consideration	125,058	129,846	(4,788)
Clinical costs	87,173	57,624	29,549
Contract manufacturing	47,622	40,081	7,541
Other	70,839	115,988	(45,149)
Total research and development expenses	$ 455,966	$ 506,499	$ (50,533)

The decrease in research and development expenses for the year ended December 31, 2025 compared to the same period in 2024 was primarily due to:

- lower other R&D expenses related to de-prioritized research and development programs and other ongoing cost savings;
- lower personnel expenses associated with headcount reductions;
- lower license, collaborations and contingent consideration expenses due to the expensing of $102.8 million in-process research and development obtained as part of our license agreement with Sanofi in the third quarter of 2024, partially offset by the $75.0 million milestone payment due upon VIR-5525 achieving first-in-human dosing in the third quarter of 2025, the $30.0 million expense in connection with signing the Restated Alnylam Agreement, and milestone payments due upon the enrollment of the first patient in phase 3 ECLIPSE registrational program for CHD in the first quarter of 2025.

partially offset by:

- higher clinical cost due to the initiation of our phase 3 ECLIPSE registrational program and progression of our oncology programs.

Selling, General and Administrative Expenses

The decrease in selling, general and administrative expenses for the year ended December 31, 2025 compared to the same period in 2024 was primarily due to efficiencies and cost savings from previously announced restructuring initiatives.

Restructuring, Long-Lived Assets Impairment and Related Charges, Net

The decrease in restructuring, long-lived assets impairment and related charges for the year ended December 31, 2025 compared to the same period in 2024 was primarily due to the substantial completion of previously announced restructuring initiatives by the end of 2024.

Change in Fair Value of Equity Investments

Our equity investment consisted solely of shares of Brii Bio Parent, which is a marketable equity investment and remeasured to fair value at each reporting period. For the year ended December 31, 2025, we recognized an unrealized gain of $1.7 million, compared to an unrealized loss of $5.5 million for the same period in 2024.

Interest Income

The decrease in interest income was primarily due to lower balances of cash, cash equivalents, and investments and lower interest rates for the year ended December 31, 2025 compared to the same period in 2024.

Other Expense, Net

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

(Provision for) Benefit from Income Taxes

The change in (provision for) benefit from income taxes for the year ended December 31, 2025 compared to the same period in 2024 was nominal.

Liquidity, Capital Resources and Capital Requirements

Sources of Liquidity

To date, we have financed our operations primarily through sales of our common stock from our initial public offering and subsequent follow-on offering, sales of our convertible preferred securities, and payments received under our grant and collaboration agreements. As of December 31, 2025, we had $781.6 million in cash, cash equivalents, and investments. 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, 2025, no shares have been issued under the Sales Agreement. The Sales Agreement will expire in November 2026.

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, 2025 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, 2025, we expect to make total lease payments of $121.4 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 "*Part I, Item 1. 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,	
	2025	**2024**
Net cash (used in) provided by:		
Operating activities	$ (391,781)	$ (446,352)
Investing activities	310,371	499,367
Financing activities	3,785	4,388
Net (decrease) increase in cash, cash equivalents and restricted cash and cash equivalents	$ (77,625)	$ 57,403

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 2025 compared to 2024 primarily due to $64.3 million initial payment received under the Norgine Agreement and ongoing cost saving realized through headcount reductions, the closing of our St. Louis, Missouri and Portland, Oregon sites and de-prioritized research and development programs in 2025, along with $103.7 million upfront payment made under our license agreement with Sanofi in 2024. The decrease was partially offset by $75 million milestone payment related to the first patient dosed in Phase 1 study evaluating VIR-5525 and $50.5 million milestone payments related to the enrollment of the first patient in ECLIPSE registrational program for CHD in 2025.

Investing Activities

Cash provided by investing activities during 2025 decreased compared to the same period in 2024 primarily due to lower cash provided by maturities and sales of investment, net of investment purchases.

Financing Activities

Cash provided by financing activities during 2025 compared to the same period in 2024 was nominal.

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 $241.1 million as of December 31, 2025, which primarily consisted of deposits in checking and sweep accounts at financial institutions and money market funds. We also had short-term and long-term investments of $543.3 million as of December 31, 2025. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration and consist of U.S. government treasuries, U.S. government agency bonds and discount notes, and securities issued by institutions with investment-grade credit ratings mature prior to our expected need for liquidity, we believe that our exposure to interest rate risk is not significant, and one percent movement in market interest rates would not have a significant impact on the total value of our portfolio. We had no debt outstanding as of December 31, 2025.

Foreign Currency

The majority of our transactions occur in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar. The functional currency of our foreign subsidiaries is the U.S. dollar. Monetary assets and liabilities of our foreign subsidiaries are translated into U.S. dollars at period-end exchange rates and non-monetary assets and liabilities are translated to U.S. dollars using historical exchange rates. Revenue and expenses are translated at average rates throughout the respective periods. As of the date of this Annual Report on Form 10-K, we are exposed to foreign currency risk primarily related to the operations of our Swiss subsidiaries and our license agreement with Norgine and consequently the Swiss Franc and Euros. Transaction gains and losses are included in other expense, net on the consolidated statements of operations and are not material for the years ended December 31, 2025, 2024 and 2023.

Equity Investment Risk

We hold ordinary shares of Brii Bio Parent, which we acquired in connection with our collaboration, option and license agreement. These equity securities are measured at fair value with any changes in fair value recognized in our consolidated statements of operations. The fair value of these equity securities was approximately $6.1 million as of December 31, 2025. Changes in the fair value of these equity securities are impacted by the volatility of the stock market and changes in general economic conditions, among other factors. A hypothetical 10% increase or decrease in the stock prices of these equity securities would increase or decrease their fair value as of December 31, 2025 by approximately $0.6 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, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, 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, 2025, 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 23, 2026 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 $35.3 million of research and development expenses as of December 31, 2025, 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, 2025.

/s/ Ernst & Young LLP

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

San Mateo, California

February 23, 2026

VIR BIOTECHNOLOGY, INC.

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

	December 31,	
	2025	**2024**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 232,185	$ 222,947
Short-term investments	228,753	678,051
Restricted cash and cash equivalents, current	1,922	89,385
Equity investments	6,077	4,350
Prepaid expenses and other current assets	45,143	47,725
Total current assets	514,080	1,042,458
Intangible assets, net	7,850	8,120
Goodwill	16,937	16,937
Property and equipment, net	55,620	63,183
Operating right-of-use assets	62,099	59,680
Restricted cash and cash equivalents, noncurrent	6,963	6,363
Long-term investments	314,575	190,015
Other assets	24,699	12,057
TOTAL ASSETS	$ 1,002,823	$ 1,398,813
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 9,803	$ 5,081
Accrued and other liabilities	83,012	98,521
Contingent consideration obligation, current	—	16,060
Total current liabilities	92,815	119,662
Operating lease liabilities, noncurrent	89,054	90,139
Contingent consideration obligation, noncurrent	34,100	24,050
Other long-term liabilities	21,578	14,577
TOTAL LIABILITIES	237,547	248,428
Commitments and contingencies (Note 10)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of December 31, 2025 and 2024, respectively; no shares issued and outstanding as of December 31, 2025 and 2024	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of December 31, 2025 and 2024, respectively; 139,474,954 and 136,959,446 shares issued and outstanding as of December 31, 2025 and 2024, respectively	14	14
Additional paid-in capital	1,965,090	1,911,872
Accumulated other comprehensive loss	(2,057)	(1,717)
Accumulated deficit	(1,197,771)	(759,784)
TOTAL STOCKHOLDERS' EQUITY	765,276	1,150,385
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,002,823	$ 1,398,813

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,		
	2025	**2024**	**2023**
Revenues:			
License and collaboration revenue	$ 63,130	$ 61,370	$ 37,382
Grant revenue	2,036	10,493	46,686
Other revenue	3,390	2,342	2,112
Total revenues	68,556	74,205	86,180
Operating expenses:			
Cost of revenue	26	845	2,765
Research and development	455,966	506,499	579,720
Selling, general and administrative	92,074	119,031	174,441
Restructuring, long-lived assets impairment and related charges, net	(182)	34,995	13,559
Total operating expenses	547,884	661,370	770,485
Loss from operations	(479,328)	(587,165)	(684,305)
Other income:			
Change in fair value of equity investments	1,729	(5,528)	(21,888)
Interest income	40,238	71,809	86,990
Other expense, net	(409)	(2,221)	(8,991)
Total other income	41,558	64,060	56,111
Loss before (provision for) benefit from income taxes	(437,770)	(523,105)	(628,194)
(Provision for) benefit from income taxes	(217)	1,145	13,077
Net loss	(437,987)	(521,960)	(615,117)
Net loss attributable to noncontrolling interest	—	—	(56)
Net loss attributable to Vir Bio	$ (437,987)	$ (521,960)	$ (615,061)
Net loss per share attributable to Vir Bio, basic and diluted	$ (3.16)	$ (3.83)	$ (4.59)
Weighted-average shares outstanding, basic and diluted	138,520,419	136,246,865	134,130,924

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

VIR BIOTECHNOLOGY, INC.

Consolidated Statements of Comprehensive loss
(in thousands)

	Years Ended December 31,		
	2025	**2024**	**2023**
Net loss	$ (437,987)	$ (521,960)	$ (615,117)
Other comprehensive (loss) income:			
Unrealized (loss) gain on investments	(314)	503	9,310
Pension actuarial loss	(26)	(1,405)	(1,003)
Total other comprehensive (loss) income	(340)	(902)	8,307
Comprehensive loss	(438,327)	(522,862)	(606,810)
Comprehensive loss attributable to noncontrolling interest	—	—	(56)
Comprehensive loss attributable to Vir Bio	$ (438,327)	$ (522,862)	$ (606,754)

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)

	Vir Bio Stockholders' Equity						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Retained Earnings (Accumulated Deficit)	Noncontrolling interest	Total Stockholders' Equity
	Share	Amount					
Balance at December 31, 2022	133,236,687	$ 13	$ 1,709,835	$ (9,122)	$ 377,237	$ —	$ 2,077,963
Vesting of restricted common stock	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 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
Vesting of restricted common stock	1,571,496	—	—	—	—	—	—
Exercise of stock options	298,260	—	1,349	—	—	—	1,349
Issuance of common stock under employee stock purchase plan	645,752	—	2,797	—	—	—	2,797
Stock-based compensation	—	—	49,072	—	—	—	49,072
Other comprehensive loss	—	—	—	(340)	—	—	(340)
Net loss	—	—	—	—	(437,987)	—	(437,987)
Balance at December 31, 2025	139,474,954	$ 14	$ 1,965,090	$ (2,057)	$ (1,197,771)	$ —	$ 765,276

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,		
	2025	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (437,987)	$ (521,960)	$ (615,117)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	11,680	14,559	19,451
Amortization of premiums (accretion of discounts) on investments, net	9,474	5,397	(8,706)
Noncash lease expense	4,980	5,248	7,658
Change in fair value of equity investments	(1,729)	5,528	21,888
Change in estimated fair value of contingent consideration	11,490	14,149	1,024
Payment of contingent consideration in excess of acquisition date fair value	(17,140)	—	—
Stock-based compensation	49,072	78,457	111,316
In-process research and development impairment	—	14,550	9,658
Non-cash restructuring, long-lived assets impairment and related charges	654	24,173	7,662
Other non-cash items, net	172	(3,131)	(910)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	2,075	4,358	36,287
Other assets	(12,642)	353	2,161
Accounts payable	4,997	(988)	732
Accrued liabilities and other long-term liabilities	(9,509)	(64,018)	(358,843)
Operating lease liabilities	(7,368)	(23,027)	(13,046)
Net cash used in operating activities	(391,781)	(446,352)	(778,785)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Proceeds from sale of equipment	253	3,372	—
Purchases of long-lived assets	(4,832)	(7,301)	(21,573)
Purchases of investments	(886,334)	(1,235,339)	(2,016,189)
Maturities and sales of investments	1,201,284	1,738,635	2,202,391
Net cash provided by investing activities	310,371	499,367	164,629
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	1,349	790	3,484
Proceeds from issuance of common stock under ESPP	2,797	3,763	4,283
Other financing activities	(361)	(165)	(287)
Net cash provided by financing activities	3,785	4,388	7,480
Net (decrease) increase in cash, cash equivalents and restricted cash and cash equivalents	(77,625)	57,403	(606,676)
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	318,695	261,292	867,968
Cash, cash equivalents and restricted cash and cash equivalents at end of period	$ 241,070	$ 318,695	$ 261,292
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Operating lease liabilities obtained in exchange of right-of-use asset	$ 7,329	$ —	$ —
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH AND CASH EQUIVALENTS TO THE CONSOLIDATED BALANCE SHEETS:			
Cash and cash equivalents	$ 232,185	$ 222,947	$ 241,576
Restricted cash and cash equivalents, current	1,922	89,385	13,268
Restricted cash and cash equivalents, noncurrent	6,963	6,363	6,448
Total cash, cash equivalents and restricted cash and cash equivalents	$ 241,070	$ 318,695	$ 261,292

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

1. *Organization*

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

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, 2025, no shares have been issued under the Sales Agreement. The Sales Agreement will expire in November 2026.

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, 2025, the Company had accumulated deficit of $1.2 billion. The Company had $781.6 million in cash, cash equivalents, and investments as of December 31, 2025. Based on the Company's current operating plan, management believes that the $781.6 million as of December 31, 2025 will be sufficient to fund its operations through at least the next 12 months from the issuance date of these consolidated financial statements.

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 Vir Bio 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, 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, 2025 and 2024, 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, 2025 and 2024.

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, net on the consolidated statements of operations.

Restricted Cash and Cash Equivalents

Restricted cash and cash equivalents primarily includes funds to secure standby letters of credit and security deposits with financial institutions under lease agreements and funds restricted as to withdrawal or usage under grant agreements and collaboration 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

License and Collaboration Revenue

The Company analyzes its license and collaboration arrangements to assess whether they are within the scope of *Accounting Standards Codification 808, Collaborative Arrangements ("ASC 808")* to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. For elements of collaboration arrangements that are accounted for pursuant to 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, Revenue from Contracts with Customers (ASC 606)*. The accounting policy pursuant to ASC 606 is outlined below. For elements of collaboration arrangements that are not subject to the guidance in ASC 606, an appropriate recognition method is determined and applied consistently. The Company's license and collaboration revenue is accounted for under ASC 606. The Company may receive reimbursement or make payments to a collaboration partner to satisfy cost sharing requirements. These payments are generally recorded as an offset or increase to research and development expenses, respectively.

Under 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.

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. The Company recognizes revenue as it fulfills its obligations under each of its agreements. 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.

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, license and 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. The Company evaluates 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.

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 for 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. The Company will adjust the fair value if any are determined to be spring-loaded. 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. 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 Company has elected to recognize the tax on GILTI as a period expense in the period the tax is incurred.

Net Loss Per Share

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

New Accounting Pronouncement

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 adopted ASU 2023-06 in this Annual Report on Form 10-K on a prospective basis.

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.

In September 2025, the FASB issued *ASU No. 2025-06, Targeted Improvements to the Accounting for Internal-Use Software (ASU 2025-06)*, which clarifies and modernizes the accounting for costs related to internal-use software in *ASC Topic 350-40, Intangibles —Goodwill and Other — Internal-Use Software (ASC 350-40)*. ASU 2025-06 removed all references to project stages throughout ASC 350-40, and requires entities to begin capitalizing software costs when both of the following occur: (1) management, with the relevant authority, implicitly or explicitly authorizes and commits to funding a computer software project; and (2) it is probable that the project will be completed and the software will be used to perform the function intended (referred to as the probable-to-complete recognition threshold). The guidance is effective for annual periods beginning after December 15, 2027 and interim periods within those annual reporting periods. Early adoption is permitted. ASU 2025-06 should be either applied on a prospective basis, retrospective or modified prospective basis based on the status of the project and whether software costs were capitalized before the date of adoption. The Company is currently evaluating the impact the adoption of ASU 2025-06 may have on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued *ASU No. 2025-07, Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606): Derivative Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract (ASU 2025-07)*, which refines the scope of Topic 815 by clarifying which contracts are subject to derivative accounting and expands the scope exception for certain contracts not traded on an exchange to include contracts for which settlement is based on operations or activities specific to one of the parties to the contract. The guidance also provides clarification under Topic 606 for share-based payments from a customer in a revenue contract. The guidance is effective for annual periods beginning after December 15, 2026 and interim periods within those annual reporting periods. Early adoption permitted. The Company early adopted ASU 2025-07 on a prospective basis in 2025.

Reclassification

Certain reclassifications have been made to prior period amounts on the Company's consolidated balance sheet to conform to the current period presentation and enhance comparability. As a result, certain amounts related to deferred revenue, previously reflected in *deferred revenue, current*, were reclassified to *accrued and other liabilities*.

Certain reclassifications have been made to prior period amounts on the Company's consolidated statement of operations to conform to the current period presentation and enhance comparability. As a result, the Company changed its presentation of *collaboration revenue* to *license and collaboration revenue* and its presentation of *contract revenue* to *other revenue*. In conjunction with these changes, certain license revenue, primarily related the Company's collaboration with Glaxo Wellcome UK Limited and GlaxoSmithKline Biologicals S.A. (GSK), which were presented as part of *contract revenue* in prior years, are now presented as part of *license and collaboration revenue*.

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

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, 2025			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Money market funds	Level 1	$ 86,607	$ —	$ —	$ 86,607
U.S. government treasuries	Level 2	310,148	341	(3)	310,486
U.S. government agency bonds and discount notes	Level 2	45,773	6	(16)	45,763
Asset-back securities	Level 2	84,676	277	—	84,953
Corporate bonds	Level 2	156,160	499	(1)	156,658
Equity securities	Level 1	N/A	N/A	N/A	6,077
Total financial assets		$ 683,364	$ 1,123	$ (20)	$ 690,544
Reconciliation to cash, cash equivalents and investments on consolidated balance sheet					
Minus: Restricted cash equivalents invested in money market funds					(7,916)
Plus: Cash deposits					98,962
Total cash, cash equivalents and investments					$ 781,590

		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 rates	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

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 $3.6 million and $5.0 million as of December 31, 2025 and 2024, respectively. The Company did not write off any accrued interest receivable during the years ended December 31, 2025, 2024 and 2023.

The Company recognized total net unrealized gains of $1.1 million and $1.4 million in accumulated other comprehensive loss as of December 31, 2025 and 2024, respectively. The gross unrealized losses as of December 31, 2025 and 2024 were due to changes in interest rates. The Company determined that the gross unrealized losses on our investments as of December 31, 2025 and 2024 were temporary in nature. The Company currently does not intend, and it is highly unlikely that it will be required, to sell these securities before recovery of their amortized cost basis. As of December 31, 2025, no securities have contractual maturities (or weighted average life for asset-backed securities) of longer than two years.

As of December 31, 2025, the Company's equity investment consisted solely of ordinary shares of Brii Biosciences Limited (Brii Bio Parent). The equity securities of Brii Bio Parent are listed on the Stock Exchange of Hong Kong Limited and are considered to be marketable equity securities measured at fair value at each reporting date. As of December 31, 2025, the Company remeasured the equity investment at a fair value of $6.1 million. For the year ended December 31, 2025, the Company recognized unrealized gain of $1.7 million as other income in the consolidated statements of operations. For the years ended December 31, 2024 and 2023, the Company recognized unrealized losses of $5.5 million and $21.9 million, respectively, as other income in the consolidated statements of operations. For the years ended December 31, 2025, 2024 and 2023, the unrealized gains or 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, 2025 and 2024. The estimated fair value of the contingent consideration related to the Humabs acquisition was determined by calculating the probability-weighted regulatory and commercial milestone payments based on the assessment of the likelihood and estimated timing that certain milestones would be achieved.

During the three months ended March 31, 2025, the Company achieved a $17.5 million clinical milestone upon the enrollment of the first patient in phase 3 ECLIPSE registrational program for chronic hepatitis delta, which was paid in April 2025. As of December 31, 2025, the Company calculated the estimated fair value of the remaining regulatory approval milestone related to tobevibart using the following significant unobservable inputs:

Unobservable input	Value
Discount rates	11.4%
Probability of achievement	85.5%

For the commercial milestones, the Company used a Monte Carlo simulation because of the availability of discrete revenue forecasts. As of December 31, 2025, the Monte Carlo simulation assumed a commercial product launch and associated discrete revenue forecasts, as well as the following significant unobservable inputs for the remaining commercial milestones related to tobevibart:

Unobservable input	Value
Volatility	65.0%
Discount rate	11.0%
Probability of achievement	85.5%

The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. As of December 31, 2025 and 2024, the estimated fair value of the contingent consideration related to the Humabs acquisition was $34.1 million and $40.1 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, 2024	$ 40,110
Changes in fair value	11,490
Payment	(17,500)
Balance at December 31, 2025	$ 34,100

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, 2025, 2024 and 2023.

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)
	2025	2024	
Developed technology	$ 4,260	$ 4,260	3.8
Contract-based intangible assets	914	914	7.0
Finite-lived intangible assets, gross	5,174	5,174	
Less accumulated amortization	(3,846)	(3,576)	
Finite-lived intangible assets, net	$ 1,328	$ 1,598	

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 $0.4 million, $0.3 million and $0.5 million for the years ended December 31, 2025, 2024 and 2023, respectively, primarily included as research and development expenses on the consolidated statements of operations. There was no impairment for the years ended December 31, 2025, 2024 and 2023.

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

Years Ending December 31:	
2026	$ 296
2027	296
2028	296
2029	241
2030	36
Total	$ 1,165

Indefinite-Lived Intangible Assets

As of December 31, 2025 and 2024, the Company had indefinite-lived intangible assets of $6.5 million related to the IPR&D from the Humabs acquisition. No impairment losses were recorded for the year ended December 31, 2025. 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.

5. *Grant Agreements*

Gates Foundation Grants

The Company previously entered into various grant agreements with the Gates Foundation (formerly known as the Bill & Melinda Gates Foundation), under which it was awarded grants to support its HIV vaccine program, tuberculosis vaccine program, HIV vaccinal antibody program and malaria vaccinal antibody program. During 2025 all of the grant agreements expired except for the HIV vaccine program. Upon the expiration of the vaccinal antibody program grant the Company returned $9.5 million of unused grant funds to the Gates Foundation. The term of the HIV vaccine program grant agreement will expire mid 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.

In 2022, 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, which is used in furtherance of Gates Foundation's charitable purposes to develop the Company's vaccinal antibody program, in each case for use in specified developing countries.

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. The stock purchase premium is recognized over time as required research and development activities are performed to advance the Company's vaccinal antibody program. As of December 31, 2025, the Company had unrecognized premium balance of $9.3 million, including $1.9 million as part of accrued and other liabilities and $7.4 million as part of other long-term liabilities.

Grant payments received in advance that are related to future research activities are deferred and recognized as grant revenue as the research and development activities are performed. The Company recognized grant revenue of $2.0 million, $4.6 million, and $13.3 million for the years ended December 31, 2025, 2024, and 2023, respectively. As of December 31, 2024, the Company had deferred revenue of $11.1 million, within accrued and other liabilities. No deferred revenue was recorded as of December 31, 2025. As of December 31, 2025 and 2024, the Company had $1.8 million and $11.6 million, respectively, within accrued and other liabilities, related to funds expected to be refunded to the Gates Foundation. The funds related to the $1.8 million liability as of December 31, 2025 is classified within restricted cash and cash equivalents, current.

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. 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. which was used to support the development of novel mAb candidates and delivery solutions to widen the applicability of mAbs in COVID-19 and in pandemic preparedness and response. Additionally, the Company was awarded up to $11.2 million of additional funding to wind down activities related to VIR-2482.

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 and $33.4 million for the years ended December 31, 2024 and 2023, respectively.

6. *Collaboration and License Agreements*

License Agreement with Norgine Pharma UK Limited

On December 15, 2025, the Company and Norgine Pharma UK Limited (together with its affiliates in the Norgine group of companies, Norgine) entered into a License Agreement (the Norgine Agreement) under which the Company granted Norgine an exclusive license with respect to commercial rights and certain development rights to the combination of tobevibart, an investigational monoclonal antibody, and elebsiran, an investigational small interfering ribonucleic acid (Licensed Product), for the treatment of people living with chronic hepatitis delta (CHD) in Europe, Australia, and New Zealand (collectively, the Norgine Territory), while Vir Bio will retain commercial rights for the Licensed Product in the United States and all other international markets outside of the People's Republic of China and Taiwan. The Company and Norgine will collaborate on the development and commercialization of Licensed Product in Norgine Territory under the oversight of various joint committees, with the Company primarily responsible for development activities for the ongoing trials in Vir Bio's ECLIPSE registrational program (ECLIPSE 1, 2 and 3) and Norgine primarily responsible for regulatory, medical affairs and commercialization activities. Vir Bio will also provide future commercial supply to Norgine. In exchange, Vir Bio received an initial reimbursement of historical development costs from Norgine in the amount of €55 million or $64.3 million in December 2025 and is eligible to receive up to an additional €495 million in clinical, regulatory and sales milestones, along with tiered, mid-teen to high-twenties percent royalties on net sales in the Norgine Territory. In addition, clinical development costs for the ongoing ECLIPSE registrational program will be shared, with Norgine contributing approximately 25% of external costs starting from January 1, 2026.

The Company determined that the Norgine Agreement is a collaborative arrangement given that both parties are (i) active participants in the development and commercialization of Licensed Product in Norgine Territory and (ii) exposed to significant risks and rewards dependent on the commercial success of Licensed Product. The Company further evaluated whether the Norgine Agreement is partially within the scope of ASC 606 and identified two performance obligations, the delivery of Norgine License and the promise to conduct development activities for the ongoing ECLIPSE registrational program. The Norgine License was considered distinct from the development activities as those activities will not significantly modify or customize the Norgine License, in-part due to the late clinical stage of development at contract inception. With respect to the promise to deliver commercial supplies in the future, it is at Norgine's option and will be provided at fair value, and therefore, it is not considered a material right or a performance obligation under the Norgine Agreement.

For each of the two units of account, the Company then assessed whether each unit was associated with a customer. The Company determined that Norgine is a customer with respect to the delivery of Norgine License and that Norgine is not a customer with respect to the development activities.

With respect to the delivery of Norgine License, the transaction price include the initial payment of €55 million, clinical, regulatory and sales milestones of up to €495 million and sales royalties. The clinical and regulatory milestones are variable considerations and are fully constrained at contract inception. Sales milestones and royalties are variable considerations and will be recognized when future sales occur. The Company will reassess revenue constraints each period. The performance obligation to deliver Norgine License was satisfied upon transfer of the license to Norgine in December 2025. With respect to the promise to conduct development activities and related cost share, the Company will account for the costs shared with Norgine as reduction of research and development expenses in the period when those costs are shared under the Norgine Agreement.

As a result, the Company recognized the €55 million or $64.3 million as license and collaboration revenue in year ended December 31, 2025.

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-stage clinical dual-masked TCEs that all leverage the PRO-XTEN® universal masking platform within a range of oncology indications.

Under the Sanofi Agreement the Company made an upfront payment to Sanofi in the amount of $100.0 million and placed into escrow a $75.0 million milestone payment due to former shareholders of Amunix Pharmaceuticals, Inc., which is subject to VIR-5525 achieving "first in human dosing" by 2026. In July 2025, the first patient was dosed in phase 1 study evaluating VIR-5525. During the third quarter of 2025, the Company paid the $75.0 million milestone, which was recorded as part of research and development expenses in the Company's consolidated statement of operations for the year ended December 31, 2025.

Sanofi will also be eligible to receive up to an additional $323.0 million in future development and regulatory milestone payments, up to an additional $1.49 billion in commercial net sales-based milestone payments, and low single-digit to low double-digit tiered royalties on worldwide net sales. In addition, if, within a two-year period from the execution of the Sanofi Agreement, the Company executes a transaction that gives rise to Vir Bio receiving certain sublicense income related to the licenses obtained from the Sanofi Agreement, Sanofi may be eligible to receive a portion of such income.

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

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

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

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. 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 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, GSK entered into a collaboration agreement (the 2020 GSK Agreement), pursuant to which 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. On February 8, 2023, the Company and GSK entered into two amendments to the 2020 GSK Agreement, pursuant to which the Company and GSK agreed to reduce the scope of the collaboration to include only sotrovimab and VIR-7832, and certain variants thereof. 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. 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. The parties share all development costs, manufacturing costs, and costs and expenses for the commercialization of sotrovimab, with the Company bearing 72.5% of such costs, 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 and Taiwan at GSK's sole cost and expense, and equal sharing of such costs for the functional genomics products.

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. In periods when allowable expenses exceed amounts recognized for net product sales of sotrovimab, negative revenue is 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. For the year ended December 31, 2023, the Company released $35.7 million profit-sharing amount previously constrained for certain allowable manufacturing expenses related to excess sotrovimab supply and binding reserved manufacturing capacity not utilized.

During the years ended December 31, 2025, 2024, and 2023, the Company recorded profit-sharing amounts, profit-sharing amounts constrained, and profit-sharing amounts previously constrained, released as components of license and collaboration revenue in the consolidated statements of operations, as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
License and collaboration revenue under GSK 2020 Agreement			
Profit-sharing amount	$ (1,138)	$ 9,078	$ 1,536
Profit-sharing amount constrained	—	(699)	—
Profit-sharing amount previously constrained, released	—	—	35,730
Total license and collaboration revenue under GSK 2020 Agreement	$ (1,138)	$ 8,379	$ 37,266

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 $5.5 million, $7.7 million, and $23.4 million during the years ended December 31, 2025, 2024, and 2023, respectively.

2021 Expanded GSK Collaboration

In 2021, the Company and GSK entered into a collaboration agreement (the 2021 GSK Agreement) under which the parties agreed to expand the 2020 GSK Agreement to collaborate on three separate programs. One of three programs granted GSK the option to select up to three non-influenza target pathogens. GSK selected respiratory syncytial virus (RSV) as its first pathogen in 2022. 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 reduce the scope of collaboration to include only the RSV program. During the first quarter of 2024, the Company recognized $51.7 million deferred revenue as license and collaboration 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 years ended December 31, 2025 and 2024, the reimbursement of research and development expenses by GSK is not material. During the year ended December 31, 2023, the Company recognized additional net research and development expenses of $2.2 million.

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

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

The Company did not incur any expenses under the Alnylam Agreement during the year ended December 31, 2025 and 2024, respectively, and incurred expenses of $1.7 million during the year ended December 31, 2023.

Xencor

In August 2019, the Company entered into a patent license agreement, which was amended in February 2021, with Xencor. 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 and HBV, 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, 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.

7. *Balance Sheet Components*

Property and Equipment, net

Property and equipment, net consists of the following (in thousands). Depreciation expenses were $11.4 million, $14.2 million, and $18.9 million for the years ended December 31, 2025, 2024 and 2023, respectively.

		December 31,	
	Useful life (in years)	2025	2024
Leasehold improvements	8 - 12	$ 56,180	$ 53,992
Laboratory equipment	5	40,961	39,428
Furniture and fixtures	5	2,836	2,696
Computer equipment	3	2,689	2,778
Construction in progress	NA	114	1,074
Property and equipment, gross		102,780	99,968
Less: accumulated depreciation and amortization		(47,160)	(36,785)
Total property and equipment, net		$ 55,620	$ 63,183

Accrued and Other Liabilities

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

	December 31,	
	2025	2024
Research and development expenses	$ 35,299	$ 29,225
Payroll and related expenses	28,724	31,165
Operating lease liabilities, current	8,798	7,752
Excess funds payable under grant agreements	1,825	11,589
Other professional and consulting expenses	3,327	2,268
Deferred revenue, current	—	12,648
Other accrued expenses	5,039	3,874
Total accrued and other liabilities	$ 83,012	$ 98,521

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 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). The actions related to 2023 Restructuring Plan and 2024 Restructuring Plan were substantially completed by the end of 2024.

	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

[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,		
	2025	2024	2023
Operating lease cost	$ 10,444	$ 11,446	$ 13,934
Variable lease cost	8,007	10,306	10,996
Total lease cost	$ 18,451	$ 21,752	$ 24,930
Other Information			
Weighted average remaining lease term (in years)	8.1	9.0	8.9
Weighted average incremental borrowing rate (%)	5.4	5.2	5.1
Cash paid for amounts included in the measurement of operating lease liabilities	$ 13,603	$ 28,566	$ 19,584

The maturity of the Company's operating lease liabilities as of December 31, 2025 was as follows (in thousands):

	Amounts
2026	$ 13,792
2027	14,079
2028	14,432
2029	14,702
2030	15,071
Thereafter	49,321
Total lease payments	121,397
Less: imputed interest	(23,545)
Present value of operating lease liabilities	$ 97,852

The following amounts were recorded in the consolidated balance sheets as of December 31, 2025 and 2024 (in thousands) for various operating leases:

	December 31,	
	2025	2024
Operating ROU assets	$ 62,099	$ 59,680
Accrued and other liabilities	$ 8,798	$ 7,752
Operating lease liabilities, noncurrent	89,054	90,139
Total operating lease liabilities	$ 97,852	$ 97,891

10. *Commitments and Contingencies*

Manufacturing and Supply Agreements

The Company has entered into various scopes of work with third-party contract development and manufacturing organizations (CDMOs) to support the advancement of its pipeline programs. As of December 31, 2025, the Company had unaccrued unpaid commitments of approximately $24 million under manufacturing agreements related to tobevibart and elebsiran and unaccrued unpaid commitments of approximately $20 million under manufacturing agreements related to its TCE programs.

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. Awards granted typically vest over a four-year period but may be granted with different vesting terms. As of December 31, 2025, there are 27,326,711 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. Awards 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, 2025, 645,752 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, 2024	9,605,591	$ 25.03	6.9	
Granted	2,476,000	$ 9.06		
Exercised	(298,260)	$ 4.53		
Forfeited	(3,148,820)	$ 28.06		
Outstanding at December 31, 2025	8,634,511	$ 20.05	7.2	$ 834
Vested and expected to vest at December 31, 2025	8,634,511	$ 20.05	7.2	$ 834
Vested and exercisable at December 31, 2025	4,793,030	$ 27.00	5.9	$ 633

The aggregate intrinsic value of options exercised during the years ended December 31, 2025, 2024 and 2023 was $0.8 million, $2.4 million, and $5.9 million, respectively. During the years ended December 31, 2025, 2024, and 2023, the estimated weighted-average grant date fair value of the options granted was $6.90, $7.40, and $19.13 per share, respectively. As of December 31, 2025, the Company expects to recognize the remaining unamortized stock-based compensation expense of $30.0 million related to stock options, over an estimated weighted average period of 2.1 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,		
	2025	2024	2023
Expected term of options (in years)	5.5 – 6.1	5.5 – 6.1	5.5 – 6.1
Expected stock price volatility	86.1% – 89.9%	89.2% – 91.8%	99.0% – 101.5%
Risk-free interest rate	3.7% – 4.5%	3.5% – 4.6%	3.4% – 4.9%
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,		
	2025	2024	2023
Expected term of ESPP (in years)	0.5	0.5	0.5
Expected stock price volatility	63.5% - 95.4%	56.6% - 64.4%	41.2% - 95.1%
Risk-free interest rate	3.7% - 4.3%	4.3% - 5.2%	4.5% - 5.2%
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, 2025, 2024 and 2023 was $2.07, $2.99 and $4.93 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, 2024	4,981,082	$ 16.73
Granted	3,467,457	$ 9.17
Vested	(1,571,517)	$ 20.21
Forfeited	(1,187,014)	$ 12.94
Unvested as of December 31, 2025	5,690,008	$ 11.95

The unvested shares of RSUs have not been included in the shares issued and outstanding. As of December 31, 2025, there was $47.4 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 2.4 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,		
	2025	2024	2023
Research and development	$ 25,071	$ 43,917	$ 62,745
Selling, general and administrative	24,001	34,540	48,571
Total stock-based compensation	$ 49,072	$ 78,457	$ 111,316

12. *Net Loss Per Share*

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

	Years ended December 31,		
	2025	2024	2023
Net loss attributable to Vir Bio	$ (437,987)	$ (521,960)	$ (615,061)
Weighted-average shares outstanding, basic and diluted	138,520,419	136,246,865	134,130,924
Net loss per share attributable to Vir Bio, basic and diluted	$ (3.16)	$ (3.83)	$ (4.59)

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

	Years ended December 31,		
	2025	2024	2023
Options issued and outstanding	8,634,511	9,605,591	11,124,181
Restricted shares subject to future vesting	5,690,008	4,981,082	5,260,229
Total	14,324,519	14,586,673	16,384,410

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 $3.4 million, $4.3 million, and $4.6 million for the years ended December 31, 2025, 2024, and 2023, respectively.

14. *Income Taxes*

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

	Years Ended December 31,		
	2025	2024	2023
Domestic	$ (448,370)	$ (499,680)	$ (608,134)
Foreign	10,600	(23,425)	(20,060)
Total loss before (provision for) benefit from income taxes	$ (437,770)	$ (523,105)	$ (628,194)

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

	Years Ended December 31,		
	2025	2024	2023
Current:			
Federal	$ (162)	$ (965)	$ 12,774
State	(12)	1,254	(685)
Foreign	261	(2,093)	(75)
	87	(1,804)	12,014
Deferred:			
Federal	(302)	2,105	406
State	—	900	598
Foreign	(2)	(56)	59
	(304)	2,949	1,063
(Provision for) benefit from income taxes	$ (217)	$ 1,145	$ 13,077

Income taxes paid consists of following (in thousands):

	Year Ended December 31 2025
Federal	$ —
State	73
Foreign (Switzerland)	2,347
Total	$ 2,420

A reconciliation between the U.S. federal statutory income tax provision and rate and the reported effective income tax provision and rate for the year ended December 31, 2025 is as follows (in thousands, except for percentages). The Company's effective tax rate of (0.03)% for the year ended December 31, 2025 is primarily due to the movement of valuation allowance and nondeductible stock compensation expense.

	Year Ended December 31 2025	
Provision at US federal statutory rate	$ (91,933)	21.00 %
State and local income taxes, net of federal income tax effect	9	—
Foreign tax effects	(2,224)	0.51
Effect of cross-border tax laws: GILTI	3,559	(0.81)
Tax credits: research and development credit	(3,904)	0.89
Change in valuation allowance	76,305	(17.43)
Nontaxable or nondeductible items		
Stock-based compensation	15,335	(3.50)
Other permanent items	3,169	(0.72)
Changes in unrecognized tax benefits	1,025	(0.23)
Other adjustments	(1,124)	0.26
Income tax provision and effective tax rate	$ 217	(0.03%)

As previously disclosed for the years ended December 31, 2024 and 2023, prior to the adoption of ASU 2023-09, the effective income tax rate differs from the statutory federal income tax rate as follows.

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

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, 2025, and 2024, are related to the following (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 294,591	$ 180,130
Capitalized research and development	118,473	175,835
Intangible assets	61,266	40,593
Research and development tax credit carryforward	35,578	30,549
Equity compensations	14,779	23,776
Lease liabilities	18,274	20,502
Reserves and accruals	6,712	7,543
Valuation allowance	(527,114)	(453,394)
Deferred tax assets	22,559	25,534
Deferred tax liabilities:		
ROU assets	(10,916)	(12,219)
Property and equipment	(9,004)	(10,628)
IPR&D	(1,928)	(1,928)
Other	(257)	—
Deferred tax liabilities	(22,105)	(24,775)
Net deferred tax assets	$ 454	$ 759

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, 2025, the Company recorded a valuation allowance increase of $73.7 million. As of December 31, 2025, the Company has net operating loss carryforwards of $1.2 billion for federal purposes and $446.4 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, 2025, the Company also has net operating loss carryforwards of $34.2 million for Australian tax purposes, which have an indefinite carryforward period, and $16.0 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, 2025, 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, 2025, the Company has research and development tax credit carryforwards of $16.4 million and $30.5 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.

On July 4, 2025, legislation formally titled An Act to Provide for Reconciliation Pursuant to Title II of H. Con. Res. 14, commonly referred to as the One Big Beautiful Bill Act (OBBBA), was signed into law by President Trump. The application of the OBBBA did not have a material impact on the Company's financial statements during the year ended December 31, 2025.

Uncertain Tax Positions

As of December 31, 2025, and 2024, the Company had an unrecognized tax benefit balance of $17.3 million and $17.9 million, respectively, primarily related to transfer pricing and research and development tax credits. A portion of the unrecognized tax benefits as of December 31, 2025, if recognized, would increase the Company's effective tax rate by 2.3%. Other unrecognized tax benefits as of December 31, 2025, 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. 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 $1.3 million expense for interest and penalties related to uncertain tax positions during 2025, all of which was recorded as accrued and other liabilities as of December 31, 2025. 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, 2025, 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,		
	2025	2024	2023
Gross unrecognized tax benefits at January 1	$ 17,946	$ 13,583	$ 10,638
Addition for tax positions taken in the prior years	—	2,014	29
Reduction for tax positions taken in the prior years	(2,221)	(20)	—
Addition for tax positions taken in current year	1,611	2,369	2,916
Gross unrecognized tax benefits at December 31	$ 17,336	$ 17,946	$ 13,583

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 that also is reported on the consolidated statements of operations as consolidated net loss. The measure of segment assets is reported on the balance sheet as total consolidated assets. The CODM uses segment net loss to monitor spending, assess performance for the Company and management, evaluate the progress of completing corporate goals, decide how to allocate resources among the Company's clinical and pre-clinical portfolios, and make strategic decisions about business development opportunities.

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

	Years Ended December 31,		
	2025	2024	2023
Segment revenue	$ 68,556	$ 74,205	$ 86,180
Less: Segment expenses [1]			
Cost of revenue	26	845	2,765
Research and development			
Personnel [2]	125,274	162,960	189,418
Licenses, collaborations and contingent consideration	125,058	129,846	30,215
Clinical costs	87,173	57,624	121,422
Contract manufacturing	47,622	40,081	114,262
Other R&D [3]	70,839	115,988	124,403
Selling, general and administrative [2]	92,074	119,031	174,441
Restructuring, long-lived assets impairment and related charges, net	(182)	34,995	13,559
Plus: Other segment items [4]	41,341	65,205	69,188
Segment and consolidated net loss	$ (437,987)	$ (521,960)	$ (615,117)

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

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

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

[4] Other segment items include change in fair value of equity investments, interest income, other expense, net, and (provision for) benefit from 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 license and collaboration revenues recognized under the Company's license agreement with Norgine and collaboration agreements with GSK (refer to Note 6 *Collaboration and License Agreements* for further details), 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:	2025	2024	2023
U.S. customers	$ 2,036	$ 11,525	$ 47,138
Foreign customers			
Norgine	64,268	—	—
GSK	(1,138)	60,309	37,265
Other	3,390	2,371	1,777
Total segment and consolidated revenue	$ 68,556	$ 74,205	$ 86,180

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

16 *Subsequent Event*

On February 19, 2026, the Company and Astellas US LLC (together with its subsidiaries and affiliates (including its indirect parent, Astellas Pharma Inc.), Astellas) entered into a Collaboration and License Agreement (the Astellas Agreement). Upon closing of the transaction contemplated by the Astellas Agreement, the Company and Astellas will enter into a global strategic collaboration to co-develop and co-commercialize VIR-5500, an investigational PRO-XTEN® dual-masked CD3 TCE targeting PSMA (Prostate-Specific Membrane Antigen) for the treatment of prostate cancer that is currently in Phase 1 development, through a sharing of expenses and revenues. The Company has agreed to grant to Astellas, subject to certain intellectual property rights of Sanofi, an exclusive license to develop, manufacture, commercialize and otherwise exploit VIR-5500 and certain related derivative compounds throughout the world for therapeutic, prophylactic, palliative and diagnostic uses.

Under the terms of the Astellas Agreement, in the U.S., the Company will share profits and losses from future sales of VIR-5500 equally with Astellas, should VIR-5500 receive regulatory approval, and the Company will have the option to co-promote VIR-5500. Outside of the U.S., Astellas will obtain exclusive rights to commercialize VIR-5500 and be responsible for all commercialization costs. The Company and Astellas will jointly develop VIR-5500, with global clinical development costs shared 40% by the Company and 60% by Astellas, while costs of U.S.-specific studies will be shared equally, and Astellas will be solely responsible for costs of ex-U.S.-specific studies. In addition, the Company has the option to opt out of development cost sharing responsibilities and U.S. profit sharing, and in such case, Astellas will pay the Company royalties on net sales made in the U.S., as described below.

The Company will receive $335 million in upfront and near-term milestone payments, including $240 million in cash, a $75 million equity investment pursuant to a separate Stock Purchase Agreement (the Astellas SPA, described further below), and a near-term $20 million milestone payment upon completion of manufacturing technology transfer, anticipated in the second quarter or third quarter of 2027. The Company will also be eligible to receive up to $1.37 billion in future development, regulatory and ex-U.S. sales milestones, along with tiered, double-digit royalties on ex-U.S. net sales, which royalties are subject to reduction under certain specified circumstances. If the Company elects to opt out of development cost sharing responsibilities and U.S. profit sharing, it would be eligible to receive up to $1.37 billion (or $1.60 billion if the Company has met a pre-defined limited funding threshold at the time of the opt-out) in future development, regulatory and global sales milestones, along with tiered, double-digit royalties on global net sales, which royalties are subject to reduction under certain specified circumstances. Further, certain opt-out milestones, if met, will include reimbursement of a portion of the Company's previously expensed development and commercialization spend. The closing of the transaction is subject to the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

Under the terms of the Sanofi Agreement, the Company will share with Sanofi 20% of certain future collaboration proceeds, including the upfront payment, equity premium and the portion of milestones, profit-share and royalties that exceed amounts already owed to Sanofi.

Concurrently with the execution of the Astellas Agreement, the Company also entered into the Astellas SPA, pursuant to which Astellas has agreed to purchase 7,239,382 shares of the Company's common stock for an aggregate purchase price of approximately $75 million, subject to customary closing conditions and the closing of the Astellas Agreement. The purchase price per share of the Company's common stock of $10.36 is equal to a 50% premium of the 30-day volume weighted average price of a share of the Company's common stock as of February 17, 2026. The Astellas SPA includes standstill, voting and lockup provisions, with customary exceptions, that expire one year after the date of the anticipated closing of the Astellas SPA. One year after the anticipated closing of the Astellas SPA, Astellas will have, under certain circumstances, a customary right to require the Company to register the resale of the shares purchased pursuant to the Astellas SPA.

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, 2025.

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, 2025.

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, 2025 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, 2025, 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, 2025, 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, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes and our report dated February 23, 2026 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 23, 2026

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 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 December 19, 2025, for estate and financial planning purposes, Brent Sabatini, MBA, our Senior Vice President, Finance and Chief Accounting Officer, adopted a Rule 10b5-1 trading plan for the sale of our common stock that is intended to satisfy the affirmative defense conditions of Exchange Act Rule 10b5-1(c) (the Sabatini Trading Plan). The Sabatini Trading Plan provides for sales of RSU and Employee Stock Purchase Plan (ESPP) shares pursuant to market orders, which orders will be in effect from March 23, 2026 to June 12, 2026. The RSU share sales are intended to generate funds to satisfy Mr. Sabatini's tax obligations in connection with RSU shares that will vest in 2026 pursuant to RSU awards granted to him. The total number of RSU shares that will be sold under this arrangement is not currently determinable as the number will vary based on the extent to which vesting conditions are satisfied and the number of RSU shares that are sold upon vesting pursuant to the mandatory sell to cover tax withholding arrangements. The total number of ESPP shares that will be sold under this arrangement also is not currently determinable as the number will vary based upon how many ESPP shares are purchased by Mr. Sabatini in May 2026 in accordance with the Company's ESPP provisions. Under the Company's 10b5-1 plan guidelines, Mr. Sabatini is prohibited from selling more than 50,000 shares in a single trading day. The Sabatini Trading Plan will expire upon the earlier of (i) the date all sales contemplated by the Sabatini Trading Plan have been executed, or (ii) June 12, 2026.

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 2026 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	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+	Vir Biotechnology, Inc. 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 Restricted Stock 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	DEF 14A	001-39083	Appendix A	04/17/2025	
10.9+	Vir Biotechnology, Inc. Discretionary Bonus Plan	10-K	001-39083	10.9	02/26/2025	
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	10-K	001-39083	10.12	02/26/2025	
10.13+	Offer Letter between the Company and Mark Eisner, dated May 20, 2024	10-K	001-39083	10.13	02/26/2025	
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	10-K	001-39083	10.15	02/26/2025	

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit Reference	Filing Date	
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†	Amended and Restated Collaboration and License Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated March 7, 2025	10-Q	001-39083	10.2	05/07/2025	
10.19†	License Agreement between the Company and MedImmune, LLC, dated September 7, 2018	S-1	333-233604	10.20	09/03/2019	
10.20†	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	
10.21†	Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated January 26, 2018	S-1	333-233604	10.26	09/03/2019	
10.22†	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	
10.23†	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	
10.24†	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	
10.25†	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	
10.26†	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	
10.27†	Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated March 16, 2018	S-1	333-233604	10.27	09/03/2019	
10.28†	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	
10.29†	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	
10.30†	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	
10.31†	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	
10.32†	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	
10.33†	Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated November 5, 2021	10-K	001-39083	10.44	02/28/2022	
10.34†	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	
10.35	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	
10.36†	Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated January 12, 2022	10-K	001-39083	10.47	02/28/2022	

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit Reference	Filing Date	
10.37†	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	
10.38†	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	
10.39†	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	
10.40	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	
10.41†	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	
10.42†	Exclusive License Agreement between the Company and The Rockefeller University, dated July 31, 2018	S-1	333-233604	10.33	09/03/2019	
10.43†	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	
10.44†	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	
10.45†	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	
10.46†	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	
10.47†	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	
10.48†	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	
10.49†	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	
10.50†	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	
10.51†	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	
10.52†	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	
10.53	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	
10.54	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	
10.55†	Lease Agreement between the Company and KRE Exchange Owner LLC, dated December 16, 2021	10-K	001-39083	10.66	02/28/2022	

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit Reference	Filing Date	
10.56†	Patent License Agreement between the Company and Xencor, Inc., dated August 15, 2019	S-1	333-233604	10.44	09/03/2019	
10.57†	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	
10.58†	Patent License Agreement between the Company and Xencor, Inc., dated March 25, 2020	8-K	001-39083	99.1	06/19/2020	
10.59†	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	
10.60†	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	
10.61	Stock Purchase Agreement between the Company and Glaxo Group Limited, dated April 5, 2020	S-1	333-239689	10.55	07/06/2020	
10.62†	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	
10.63†	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	
10.64†	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	
10.65†	License Agreement between the Company and Amunix Pharmaceuticals, Inc., dated July 31, 2024	10-Q	001-39083	10.1	11/04/2024	
10.66†	First Amendment to the License Agreement between the Company and Amunix Pharmaceuticals, Inc., dated April 14, 2025	10-Q	001-39083	10.1	11/05/2025	
10.67†	License Agreement between the Company and Norgine Pharma UK Limited, dated December 15, 2025					X
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

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit Reference	Filing Date	
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
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 23, 2026

By: /s/ Marianne De Backer

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

Date: February 23, 2026

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 23, 2026
/s/ Jason O'Byrne Jason O'Byrne, MBA	Executive Vice President and Chief Financial Officer *(Principal Financial Officer)*	February 23, 2026
/s/ Brent Sabatini Brent Sabatini, CPA, MBA	Senior Vice President and Chief Accounting Officer *(Principal Accounting Officer)*	February 23, 2026
/s/ Vicki Sato Vicki Sato, Ph.D.	Chairman of the Board of Directors	February 23, 2026
/s/ Norbert Bischofberger Norbert Bischofberger, Ph.D.	Director	February 23, 2026
/s/ Ramy Farid Ramy Farid, Ph.D.	Director	February 23, 2026
/s/ Jeffrey S. Hatfield Jeffrey S. Hatfield, MBA	Director	February 23, 2026
/s/ Robert More Robert More, MBA	Director	February 23, 2026
/s/ Janet Napolitano Janet Napolitano, J.D.	Director	February 23, 2026
/s/ Saira Ramasastry Saira Ramasastry, M.S., M.Phil.	Director	February 23, 2026
/s/ Elliott Sigal Elliott Sigal, M.D., Ph.D.	Director	February 23, 2026