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, 2022

OR

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

Commission File Number 1-39083

Vir Biotechnology, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**81-2730369**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
499 Illinois Street, Suite 500 **San Francisco, California**	**94158**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $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, 2022 was approximately $2.0 billion based upon the closing price of its Common Stock on June 30, 2022 of $25.47 per share, as reported by The Nasdaq Global Select Market.

The number of shares of the Registrant's Common Stock outstanding as of February 21, 2023 was 133,531,379.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement, or the Proxy Statement, for the Registrant's 2023 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, 2022.

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

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our strategy, future financial condition, future operations, research and development, potential of, and expectations for, our pipeline, planned clinical trials and preclinical studies, technology platforms, the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our product candidates, the potential benefits of collaborations, projected costs, prospects, plans, objectives of management, expected market growth, the timing of availability of clinical data, program updates and data disclosures, the ability of sotrovimab to treat and/or prevent COVID-19, our plans for sotrovimab, and our plans for our hepatitis B virus, hepatitis D virus, influenza, COVID-19 and human immunodeficiency virus portfolios, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions described in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report. Other sections of this report may include additional factors that could harm our business and financial performance. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements, or the scientific data presented. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

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

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.

RISK FACTOR SUMMARY

Investing in our securities involves a high degree of risk. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found under the heading "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

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 operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We may require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.
- Although we have an Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, for sotrovimab for the early treatment of COVID-19, the disease caused by the virus SARS-CoV-2, the FDA has excluded the use of sotrovimab in all U.S. regions, and sotrovimab has limitations on its use in some countries outside of the U.S. If the FDA does not reauthorize the use of sotrovimab in the U.S., the FDA revokes or terminates our EUA for sotrovimab, the federally-declared COVID-19 public health emergency ends, or countries outside of the U.S. continue to limit its use, we may be unable to sell sotrovimab in or outside of the U.S.
- We are committing substantial financial resources and personnel and making substantial capital commitments with third parties in connection with therapies for COVID-19. Market demand and utilization of any of our COVID-19 product candidates has been, and may continue to be, adversely impacted by factors such as the development of monoclonal antibodies, or mAbs, of other third parties, the rollout of oral antivirals and vaccines, the emergence of new variants or subvariants and the current challenges in the delivery and administration of mAbs to patients.
- Our near-term revenue is dependent on the continued sales and commercialization of sotrovimab for the early treatment of COVID-19, including our ability to enter into procurement contracts with government entities. If we are unable to continue to sell and/or commercialize sotrovimab in or outside of the U.S., our business, financial condition, results of operations and prospects may be adversely affected. In addition, sotrovimab may be rendered inferior or obsolete due to rapid changes in epidemiology and the emergence of new variants or subvariants.
- 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.
- Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals and marketing authorizations.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control.
- We are a party to strategic collaboration and license agreements pursuant to which we are obligated to make substantial payments upon achievement of milestone events and, in certain cases, have relinquished important rights over the development and commercialization of certain current and future product candidates. We also intend to explore additional strategic collaborations, which may never materialize or may require that we relinquish rights to and control over the development and commercialization of our product candidates.

- We rely on third parties to produce clinical and commercial supplies of our product candidates.
- If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.
- We are highly dependent on our key personnel, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.
- 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.

Item 1. Business.

Overview

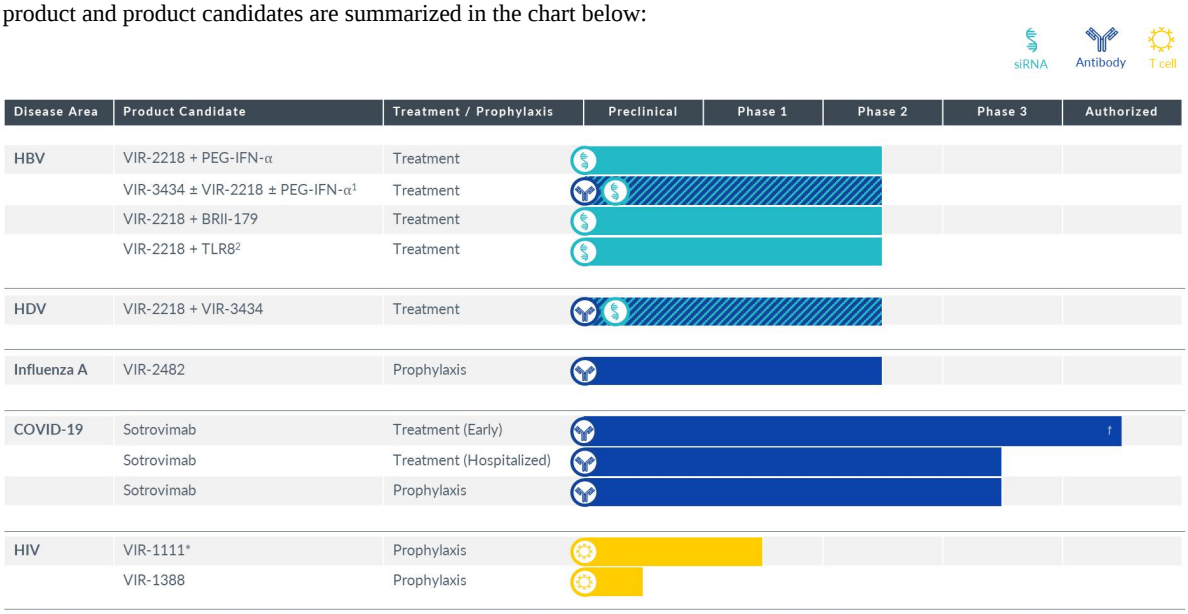
Our mission is to create a world without infectious disease.

We are a commercial-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Infectious diseases are among the leading causes of death worldwide and can cause trillions of dollars of direct and indirect economic burden each year – as evidenced by the coronavirus disease 2019, or COVID-19, pandemic. We believe that now is the time to apply the recent and remarkable advances in immunology to combat current and prepare for future infectious diseases. Our approach begins with identifying the limitations of the immune system in combating a particular pathogen, the vulnerabilities of that pathogen and the reasons why previous approaches have failed. We then bring to bear powerful technologies that we believe, individually or in combination, will lead to effective therapies.

Our current pipeline consists of sotrovimab (previously VIR-7831; and where marketing authorization has been granted, marketed under the brand name Xevudy®) and other product candidates targeting hepatitis B virus, or HBV, hepatitis D virus, or HDV, influenza A virus, COVID-19, and human immunodeficiency virus, or HIV. We have assembled four technology platforms, focused on antibodies, T cells, innate immunity and small interfering ribonucleic acid, or siRNA, through internal development, collaborations and acquisitions. We have built an industry-leading team that has deep experience in immunology, infectious diseases, and product development and commercialization. Given the global impact of infectious diseases, we are committed to developing cost-effective treatments that can be delivered at scale.

Our Pipeline

Our current product and product candidates are summarized in the chart below:



IFN-α: interferon alfa-2a; HBV: Hepatitis B Virus; HDV: Hepatitis D Virus; HIV: Human Immunodeficiency Virus
1: MARCH trial (Part B), PREVAIL platform trial (THRIVE/STRIVE sub-protocols); 2: GS-9688
**Vaccine designed to establish proof of concept in Phase 1 clinical trial to determine whether unique immune response observed in non-human primates can be replicated in humans; ultimately, any candidates we advance as a potential HIV vaccine will require modifications to VIR-1111 before further clinical development.*
†sotrovimab for early treatment by intravenous (IV) administration currently has marketing approval, temporary authorization or emergency authorization, supplying >40 countries. In April 2022, the FDA (as defined below) deauthorized sotrovimab's use in all U.S. regions.
Sotrovimab and VIR-2482 incorporate Xencor's Xtend™ technology. VIR-3434 incorporates Xencor's Xtend™ and other Fc technologies.

HBV: According to the Hepatitis B Foundation, approximately 300 million people globally are chronically infected with HBV and approximately 900,000 of them die from HBV-associated complications each year. There is a significant unmet medical need for more effective therapies that lead to life-long control of the virus after a finite duration of therapy, which is the definition of a functional cure. For a registrational trial to demonstrate a functional cure, the formal endpoint accepted by the U.S. Food and Drug Administration, or FDA, is undetectable hepatitis B virus surface antigen, or HBsAg, defined as less than 0.05 international units per milliliter, or IU/ml, as well as HBV deoxyribonucleic acid, or DNA, less than the lower limit of quantification, in the blood six months after the end of therapy. Currently, a year-long course of pegylated interferon-alpha, or IFN-α, is the best available curative therapy. It has a low functional cure rate of approximately 3% to 7%. Alternatively, suppressive therapy with nucleotide/nucleoside reverse transcriptase inhibitors, or NRTIs, is commonly used, but patients often require a lifetime of therapy.

We are developing VIR-2218 and VIR-3434 for the functional cure of HBV. Each of these product candidates has the potential to stimulate an effective immune response and also has direct antiviral activity against HBV. We believe that a functional cure for HBV will require an effective immune response in addition to antiviral activity based on the observation that severe immunosuppression can reactivate HBV disease. While monotherapy with VIR-2218 and VIR-3434 may provide a functional cure in some patients, we believe combination therapy will be necessary for a functional cure in many patients.

VIR-2218 is an investigational subcutaneously administered HBV-targeting siRNA. By targeting a conserved region of the HBV genome, it is designed to inhibit the production of all HBV proteins: X, polymerase, S, and core. Suppression of HBV proteins, particularly HBsAg, is hypothesized to remove the inhibition of T cell and B cell activity directed against HBV, allowing VIR-2218 to potentially result in a functional cure. VIR-2218 was the first siRNA in the clinic to include Alnylam Pharmaceuticals, Inc.'s, or Alnylam, Enhanced Stabilization Chemistry Plus, or ESC+, technology, which has the potential to enhance the therapeutic index.

Building on previously disclosed data, in November 2022, we announced initial end of treatment data from our ongoing Phase 2 clinical trial (NCT04412863) evaluating VIR-2218 in combination with IFN-α for 24 and up to 48 weeks. 30.8% (4/13) of the participants receiving up to 48 weeks of VIR-2218 plus IFN-α treatment achieved higher rates of HBsAg seroclearance with anti-HBs seroconversion by the end of treatment. Participants receiving longer duration of VIR-2218 plus IFN-α had the greatest mean declines from baseline HBsAg (log10 IU/mL) levels at week 48 (2.9 ± 1.36). Across all cohorts, 10 participants receiving VIR-2218 plus IFN-α for 24 or up to 48 weeks achieved HBsAg seroclearance by week 48, and nine achieved anti-HBs levels >10 mIU/mL. All patients were virally suppressed on NRTIs. The treatment regimens were generally well tolerated and resulted in no new safety signals. Additional data are expected in the first half of 2023.

VIR-2218 is also being evaluated in additional clinical trials with collaborators. Brii Biosciences Offshore Limited, or Brii Bio, continues to lead the Phase 2 trial (NCT04749368) of VIR-2218 in combination with BRII-179, an investigational T cell vaccine, for the treatment of chronic HBV infection. Treatment has completed in this trial. Interim safety and efficacy were presented at the Asian Pacific Association for the Study of the Liver (APASL) in February 2023. Treatment of VIR-2218 alone or in combination with BRII-179 with and without coadjuvant IFN-α was generally well tolerated. Although the combination of VIR-2218 and BRII-179 had greater anti-HBs responses and improved HBsAg-specific T-cell responses, comparable HBsAg reduction was observed in all cohorts at end of treatment (EOT) (-1.7-1.8 log10 IU/mL). In December 2021, we and Gilead Sciences, Inc., or Gilead, initiated a Phase 2 clinical trial (NCT04891770) of VIR-2218 in combination with GS-9688 (selgantolimod), Gilead's investigational TLR-8 agonist, and nivolumab, an approved PD-1 inhibitor, in both NRTI-suppressed patients and viremic patients. Patients with HBV treatment experience also may receive tenofovir alafenamide fumarate, or TAF. In February 2023, due to immune-related adverse events associated with nivolumab, which are consistent with the safety profile of the class, in the cohorts evaluating nivolumab in combination with VIR-2218 and GS-9688, nivolumab was discontinued.

VIR-3434 is an investigational subcutaneously administered HBV-neutralizing monoclonal antibody, or mAb. By targeting a conserved region of HBsAg, it is designed to block entry of all 10 genotypes of HBV into liver cells called hepatocytes and reduce the level of virions and subviral particles in the blood. VIR-3434, which incorporates Xencor, Inc.'s, or Xencor, Xtend and other Fc technologies, has been engineered to potentially function as a T cell vaccine against HBV in infected patients, as well as to have an extended half-life. These modifications are intended to enhance its potential to result in an HBV functional cure.

Building on previously disclosed data, in November 2022 we announced that a single dose of 75 mg or 300 mg of VIR-3434 to trial participants with chronic HBV infection with viremia resulted in rapid reductions in HBsAg and HBV DNA in the majority of participants not on NRTI therapy.

In July 2021, we initiated the Phase 2 Monoclonal Antibody siRNA Combination against Hepatitis B, or MARCH, trial (NCT04856085) to evaluate the combination of VIR-2218 and VIR-3434 as a functional cure regimen for chronic HBV infection. In April 2022, we announced initial results from MARCH Part A, demonstrating that the combination of VIR-3434 and VIR-2218 resulted in an approximate 3 log decline in HBsAg with no drug-related safety signals reported at that time. In November 2022, we announced end of treatment data for all MARCH Part A cohorts, including that the combination of VIR-3434 and VIR-2218 achieved

mean HBsAg reductions ≥2.7 log10 IU/mL in all cohorts, absolute HBsAg levels <10 IU/mL were achieved in most participants, and the combination was generally well tolerated with most adverse events being mild. All patients were virally suppressed on NRTIs. Additional MARCH Part A data are expected in the first half of 2023 and initial MARCH Part B data, evaluating VIR-2218 in combination with VIR-3434 for 24 and 48 weeks with and without interferon, are expected in the second half of 2023.

Initiation of the Phase 2 PREVAIL platform trial (NCT05612581) and its THRIVE/STRIVE sub-protocols of VIR-3434 and/or VIR-2218 and/or IFN-α in viremic patients with chronic HBV infection is expected in the first half of 2023. The THRIVE sub-protocol will evaluate inactive carriers defined as adults with chronic HBV that are hepatitis B virus e-antigen, or HBeAg, negative with HBV DNA ≤2000 IU/mL and alanine transaminase, or ALT, less than the upper limits of normal, or ULN. The STRIVE sub-protocol will evaluate immune active, treatment-naïve patients defined as adults with chronic HBV who have not received prior NRTI or IFN-α therapy and are HBeAg positive or negative with HBV DNA >2000 IU/mL, ALT > ULN and ≤ 5× ULN. Initial data are expected in the first half of 2024.

HDV: According to a 2020 article in the Journal of Hepatology, approximately 12 million people globally are infected with HDV, representing approximately 5% of the HBV population. HDV is considered the most severe and aggressive form of viral hepatitis leading to increased rates of cirrhosis, hepatocellular carcinoma, or HCC, hepatic decomposition, and liver failure. People with HDV are 3.9 times more likely to have hepatocellular carcinoma than people with HBV and have more rapid progression to liver-related death. There are no approved therapies for HDV in the U.S. and Hepcludex (bulevirtide), a once daily subcutaneous injection, has conditional approval in the European Union, or EU, and the U.K.

We are developing VIR-2218 and VIR-3434 for the chronic treatment and suppression of HDV. HBsAg is a critical component necessary for the HDV lifecycle. Both VIR-2218 and VIR-3434 act independently to inhibit the replication of HDV by targeting HBsAg. VIR-2218 inhibits the production of HBsAg by targeting a conserved region of the HBV genome and inhibiting production of all HBV proteins including HBsAg. VIR-3434 binds to a conserved region of HBsAg, which reduces the levels of HDV virions and also prevents the infection of hepatocytes with HDV.

In September 2022, we initiated the Phase 2 SOLSTICE trial (NCT05461170) evaluating once monthly subcutaneous injections of VIR-2218 and VIR-3434 as monotherapy and in combination for the chronic treatment of people living with HDV. The trial is assessing the safety and ability of the combination to reduce HDV viremia and normalize ALT, surrogate endpoints used for regulatory approval and endpoints that may improve clinical outcomes. Initial data are expected in the second half of 2023.

Influenza: According to the World Health Organization, or WHO, on average, each year the influenza virus is estimated to infect 1 billion people and to result in 290,000 to 650,000 deaths globally. According to the Centers for Disease Control and Prevention, or CDC, in the 2018-2019 flu season, despite the availability of the flu vaccine, approximately 36 million people were diagnosed with influenza, 500,000 people were hospitalized, and 34,000 people died from influenza in the United States alone. Influenza vaccines have historically had limited success, with an average efficacy of 40% overall, across all populations. This limited efficacy results from incomplete coverage against seasonal strains and the lack of an effective immune response in many individuals after receiving the vaccine.

We are developing VIR-2482 as a universal prophylactic for influenza A and have designed it to address the limitations of flu vaccines, which we believe will lead to meaningfully higher levels of protection against seasonal and pandemic strains of influenza A. We anticipate that the initial registration population for VIR-2482 will include individuals at high risk of influenza A complications, such as the elderly with chronic lung disease or congestive heart failure.

In May 2021, we signed a definitive collaboration agreement, or the 2021 GSK Agreement, with Glaxo Wellcome UK Limited to expand our existing collaboration to include the research and development of new therapies for influenza and other respiratory viruses. See the section titled “Our Collaboration, License and Grant Agreements—Collaboration Agreements with GSK” for a description of the 2021 GSK Agreement.

VIR-2482 is an investigational intramuscularly, or IM, administered influenza A-neutralizing mAb. In vitro, VIR-2482 has been shown to neutralize all major strains of influenza A that have arisen since the 1918 Spanish flu pandemic and is designed as a universal prophylactic for influenza A. We believe that VIR-2482 has the potential to address the limitation of current flu vaccines and be able to be used year after year because it has broad strain coverage as opposed to the limited strain coverage generated by current vaccines. We also believe that it provides passive immunity rather than relying on a person to generate active immunity via a functional immune response, an ability that is known to decline with age. VIR-2482, which incorporates Xencor’s Xtend technology, has been engineered to extend its half-life so that a single IM dose has the potential to last the entire flu season, which is typically five to six months long. VIR-2482 is estimated to have a half-life of 58 days based on preliminary data.

In August 2019, we initiated a Phase 1 clinical trial (NCT04033406) for VIR-2482. VIR-2482 was well-tolerated in the approximately 100 healthy volunteers under age 65 dosed in Phase 1. In September 2022, we initiated a Phase 1b prophylaxis trial evaluating the safety of VIR-2482 in elderly participants (aged 65 and older) receiving a flu vaccine. Initial data are expected in mid-2023. In October 2022, we initiated the Phase 2 PrevENtIoN of IllnesS DUe to InfLuenza A, or PENINSULA, trial (NCT05567783) in healthy volunteers aged 18 to 64 to evaluate the safety, tolerability and efficacy of two different IM administered doses of VIR-2482 in preventing illness due to influenza A. The primary efficacy endpoint is the proportion of trial participants with protocol-defined influenza illness, requiring one systemic symptom and one respiratory symptom, with PCR confirmed influenza A infection, compared to placebo. Other endpoints will evaluate the effect of VIR-2482 on the severity and duration of illness in trial participants with confirmed influenza A compared to placebo. Initial data are expected in mid-2023. The PENINSULA trial is being funded in part with federal funds from the U.S. Department of Health and Human Services, or HHS; the Administration for Strategic Preparedness and Response, or ASPR; and the Biomedical Advanced Research and Development Authority, or BARDA, under Other Transaction, or OT, number 75A50122C00081.

COVID-19: According to the John Hopkins Coronavirus Resource Center, as of February 27, 2023, there have been almost 675.1 million recorded infections and almost 6.9 million recorded deaths worldwide from COVID-19. The FDA has granted either Emergency Use Authorization, or EUA, or marketing approvals to multiple vaccines, drugs and/or antibodies to prevent or treat COVID-19. The ongoing efficacy of these medicines, however, particularly as the virus mutates while it infects more people and comes under increased immune pressure, is uncertain.

In response to the ongoing COVID-19 pandemic, we have moved rapidly to address this global health challenge. Our focus is on treating and preventing severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2 (the virus that causes COVID-19 illness), as well as potential future coronavirus outbreaks. To do so, together with our collaborator Glaxo Wellcome UK Limited and GlaxoSmithKline Biologicals S.A. (individually and collectively referred to as GSK), we are developing sotrovimab, as well as small molecules. Vir is also developing additional differentiated mAbs as well as vaccines.

Sotrovimab is a SARS-CoV-2-neutralizing mAb, based on a parent antibody, S309, which was derived from samples previously gathered for research on pan-coronavirus-neutralizing mAbs. Data suggest that sotrovimab has the potential for ‘dual-action’, or the ability to block viral entry into healthy cells and an enhanced ability to clear infected cells.

Early Treatment

In August 2020, we initiated the lead-in phase of our Phase 2/3 trial (NCT04545060) COVID-19 Monoclonal antibody Efficacy Trial - Intent to Care Early, or COMET-ICE, for the treatment of adults at high risk of hospitalization or death from COVID-19 via intravenous, or IV, administration. In May 2021, the FDA granted an EUA to 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 European Commission 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 March 2022, the FDA de-authorized sotrovimab’s use in all U.S. regions due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 subvariant. Sotrovimab has obtained emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®) for early treatment of COVID-19, supplying more than 40 countries. Sotrovimab is not authorized in the U.S. Over 2.1 million doses of sotrovimab have been delivered as of December 31, 2022.

We continue to conduct in vitro testing of sotrovimab against new variants and subvariants as they emerge, and to collect and evaluate real-world evidence, both of which are being shared with regulatory authorities.

Prophylaxis

In August 2022, sotrovimab entered the Phase 3 PROphylaxis for PaTiEnts at Risk of COVID-19 InfecTion, or PROTECT-V, platform trial (NCT04870333) sponsored by Cambridge University Hospitals National Health Service, or NHS, Foundation Trust assessing the use of a 2 g dose of sotrovimab administered IV in uninfected, high-risk immunocompromised individuals. Timing of initial data will depend on continued rate of enrollment.

Hospitalized treatment

In December 2021, sotrovimab entered the Randomized Evaluation of COVID-19 Therapy, or RECOVERY, trial, a Phase 3 trial (NCT04381936) in the U.K. evaluating standard of care alone versus usual standard of care plus a single 1 g dose of sotrovimab given IV. Timing of initial data will depend on continued rate of enrollment.

In addition to sotrovimab, we are preparing for future pandemics with coronavirus mAbs that have the potential to be even broader and more potent than sotrovimab, pan-coronavirus vaccines designed with the aim to be variant-proof (initial pre-clinical proof of concept achieved), and small molecules that have the potential to treat multiple respiratory diseases like COVID-19 and influenza (initial pre-clinical proof of concept achieved).

VIR-7832, which has similar properties to sotrovimab, but is also designed to potentially enhance virus-specific T cell function, was evaluated in the U.K.'s NHS-supported AGILE initiative. The Phase 1b portion of the trial (NCT04746183) assessed safety of VIR-7832 at 50 mg, 150 mg and 500 mg IV doses. The Phase 2 portion of the trial was designed to assess safety and efficacy at 500 mg IV dose. The Phase 2a was stopped early due to concerns about the evolving COVID landscape, including circulating SARS-CoV-2 variants. No safety signals were reported in the Phase 1b or 2a portions of the trial.

HIV: According to the Joint United Nations Programme on HIV/AIDS, or UNAIDS, each year there are approximately 1.5 million new cases of HIV and approximately 700,000 HIV-related deaths globally. Current prevention approaches such as behavioral modification and pharmacological intervention have had only a modest effect on HIV transmission globally, leaving a high unmet medical need for a safe and effective vaccine for the billions of individuals who are or may become sexually active.

We are developing VIR-1111 as a proof-of-concept HIV vaccine designed to elicit a type of immune response that is different from other vaccines. Learnings from VIR-1111 have informed the trial design for VIR-1388, which has additional modifications that have the potential to enhance immunogenicity compared to VIR-1111. We anticipate the initial registration population for our eventual HIV vaccine will be individuals at high risk of contracting HIV.

VIR-1111 is an investigational subcutaneously administered HIV T cell vaccine based on human cytomegalovirus, or HCMV. VIR-1111 has been designed to elicit T cells that recognize HIV epitopes that are different from those recognized by prior HIV vaccines and to stimulate a different and specific type of T cell immune response to HIV, known as an HLA-E restricted immune response. An HLA-E restricted immune response has been shown to be associated with protection of non-human primates, or NHPs, from simian immunodeficiency virus, or SIV, the NHP equivalent of HIV. VIR-1111 is a vaccine designed solely to establish proof of concept in a Phase 1 clinical trial to determine whether the unique immune response observed in NHPs can be replicated in humans.

In December 2020, we initiated a Phase 1 trial (NCT04725877) of VIR-1111. In November 2022, we announced that safety and immunology data from the initial two cohorts of the trial showed no safety signals and no vector shedding or viremia reported to date. In addition, no sustained HIV insert-specific T cell responses were observed in the lower dose cohorts 1 and 2. Safety and immunology data from the highest dose cohort 3 are expected in the first half of 2023. This trial is being funded in part by the Bill & Melinda Gates Foundation.

VIR-1388 is a preclinical subcutaneously administered HIV T cell vaccine based on HCMV. Like VIR-1111, VIR-1388 has been designed to elicit T cells that recognize HIV epitopes that are different from those recognized by prior HIV vaccines and to stimulate a different and specific type of T cell immune response to HIV, known as an HLA-E restricted immune response. VIR-1388 has additional modifications that have the potential to enhance immunogenicity compared to VIR-1111. We expect to initiate a Phase 1 trial of VIR-1388 in the second half of 2023. This trial will be funded in part by the Bill & Melinda Gates Foundation and the National Institutes of Health's Division of AIDS, through the HIV Vaccine Trials Network.

Additionally, in January 2022, we expanded our collaboration with the Bill & Melinda Gates Foundation to explore the development of broadly neutralizing antibodies designed to provide a "vaccinal effect" for the functional cure of HIV as well as the prevention of malaria.

Our Technology Platforms

Our four current technology platforms are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. We are using our platforms to advance sotrovimab and other current product candidates and generate additional product candidates for multiple indications.

Antibody Platform: We have established a robust method for capitalizing on unusually successful immune responses naturally occurring in people who are protected from, or have recovered from, infectious diseases. We identify rare antibodies from survivors that have the potential to treat and prevent rapidly evolving and/or previously untreatable pathogens via direct pathogen neutralization and immune system stimulation. The fully-human antibodies that we discover may also be modified to enhance their therapeutic potential. We have applied these methods to identify mAbs for a range of pathogens including SARS-CoV-2, HBV, HDV, influenza A and influenza B virus, Ebola, HIV, respiratory syncytial virus, or RSV, metapneumovirus, or MPV, malaria, rabies, *clostridium difficile*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, and *Acinetobacter spp*. Examples of the power of this platform are sotrovimab (previously VIR-7831; and where marketing authorization has been granted, marketed under the brand name Xevudy®),

our anti-SARS-CoV-2 mAb, and Ebanga (ansuvimab-zykl, formerly known as mAb114), the anti-Ebola virus mAb identified by our scientists in collaboration with the NIH and others and marketed by Ridgeback Biotherapeutics LP.

T Cell Platform: We are exploiting the unique immunology of HCMV, a commonly occurring virus in humans, as a vaccine vector to potentially treat and prevent infection by pathogens refractory to current vaccine technologies. This approach is based on fundamental observations made in NHPs, with rhesus cytomegalovirus, or RhCMV. HCMV is the most potent known inducer of T cell responses of any human virus and may induce potent and long-lasting T cell responses to a broader range of epitopes than observed for other viral vaccines. In addition, we can make proprietary modifications in the HCMV genome that we expect will elicit different types of pathogen-appropriate T cell responses. We term this approach "immune programming." We believe that this platform may also have applicability beyond infectious diseases, to areas such as cancer.

Innate Immunity Platform: Moving beyond more traditional approaches that are used to evoke adaptive immunity or that directly target pathogens, where the development of resistance can occur, we plan to target host proteins as a means of creating host-directed therapies with high barriers to resistance. We believe that by leveraging the power of innate immunity, we can create medicines that break the "one-drug-for-one-bug" paradigm by producing "one-drug-for-multiple-bugs." For example, we believe this platform can create a single product for respiratory viruses, such as SARS-CoV-2 and influenza. This is enabled using clustered regularly interspaced short palindromic repeats, or CRISPR, -based genomics, computational biology and machine learning to identify key host factors necessary for each pathogen's survival and the protective effects of the innate immune system. We then identify product candidates that may be able to safely target host proteins to block pathogen replication or induce innate immunity to control infection. We believe that this platform may also have applicability beyond infectious diseases.

siRNA Platform: We are harnessing the power of siRNA to inhibit pathogen replication, eliminate key host factors necessary for pathogen survival and remove microbial immune countermeasures. Our collaboration with Alnylam includes VIR-2218 for HBV and up to four additional programs for infectious diseases. This platform can leverage Alnylam's proprietary N-acetylgalactosamine, or GalNAc, delivery technology, for product candidates targeting the liver, allowing for subcutaneous administration and extended tissue half-life, as well as ESC+ technology to enhance stability and minimize off-target activity, which potentially can result in an increased therapeutic index.

Our Team

We have an industry-leading management team and board of directors with significant experience in immunology and infectious diseases and progressing product candidates from early-stage research to clinical trials, regulatory approval and ultimately commercialization.

Our Chief Executive Officer, George Scangos, Ph.D., has spent over 30 years developing treatments in infectious disease, neuroscience and oncology, among other fields, and was previously the Chief Executive Officer of Biogen Inc., or Biogen, the Chief Executive Officer of Exelixis, Inc. and the President of Bayer Biotechnology. Dr. Scangos notified us on January 19, 2023, that he will retire from his position as President and CEO, effective April 3, 2023. Upon his retirement as President and CEO, Dr. Scangos will transition to an advisory role through June 2, 2023 and will continue as a member of the Board of Directors. His appointed successor is Marianne De Backer, MSc, Ph.D., MBA, currently Executive Vice President, Head of Pharmaceuticals Strategy, Business Development and Licensing/Open Innovation, and member of the Executive Committee for Bayer Pharmaceuticals. Dr. De Backer brings deep scientific expertise to her new role, as well as more than two decades of broad international leadership experience, including a strong track record in global expansion, innovation technology licensing and multiple billion-dollar mergers and acquisitions. She will be appointed as a member of the Board of Directors on April 3, 2023. Our Chief Medical Officer and Interim Head of Research, Phil Pang, M.D., Ph.D., was previously Chief Medical Officer of Riboscience LLC, and before that was the Harvoni® project lead at Gilead, where he led the team responsible for worldwide regulatory approval. Our Senior Vice President and Senior Research Fellow, Antonio Lanzavecchia, M.D., is a Member of the National Academy of Sciences, was a co-founder of Humabs BioMed SA, or Humabs, which we acquired in 2017, and was the Director of the Institute for Research in Biomedicine in Bellinzona, Switzerland. Our Executive Vice President and Chief Operating Officer, Johanna Friedl-Naderer, was previously President of Europe, Canada & Partner Markets for Biogen, where she served on the company's Global Leadership Team. Our Chief Technology Officer, Aine Hanly, Ph.D., was previously Vice President of Process Development for Amgen Inc., where she was accountable for clinical manufacturing and global supply of clinical trial materials. Our Senior Vice President of Regulatory Affairs and Program Leadership & Management, Lynne Krummen, Ph.D., previously served in many roles at Genentech, Inc. and F. Hoffmann-La Roche AG, including Head of U.S. Technical Development, Global Head of Technical Regulatory for Biologics, Head of Process Development and Clinical Development Project Team Lead for Avastin®. Our Chief Corporate Affairs Officer, Bolyn Hubby, Ph.D., was previously Chief Scientific Officer at Agenovir Corporation, which we acquired in 2018, and before that was the Vice President of Vaccines and Antimicrobials at Synthetic Genomics, Inc. Our Chief Administrative Officer, Steven Rice, was previously Chief Human Resources Officer at the Bill & Melinda Gates Foundation, and before that was Executive Vice President of Global Human Resources at Juniper Networks, Inc. Our Chief Financial Officer, Howard Horn, was previously Vice President,

Business Planning at Biogen, and before that was a senior consultant at McKinsey & Company and an equity analyst at UBS Group AG. On February 13, 2023, the Board of Directors appointed Sung Lee as Executive Vice President and Chief Financial Officer of the Company, effective as of March 27, 2023. Mr. Horn will step down as Chief Financial Officer of the Company effective upon Mr. Lee's appointment on March 27, 2023, and will remain with the Company as Executive Vice President until April 28, 2023, to assist with the transition. Mr. Lee is currently the Chief Financial Officer and Management Board member of MorphoSys AG, a biopharmaceutical company. Mr. Lee brings a strong track record of driving financial performance, scaling global operations, leading large teams and communicating with investors around the world. Our Chief Data Officer, Amalio Telenti, was previously Chief Scientific Officer at Human Longevity, Inc., and before that was Chief Data Scientist at the Scripps Research Translational Institute and professor of genomics at Scripps Research.

Our board of directors is composed of leaders: from academia, Nobel laureate Phillip Sharp, Ph.D.; from the biopharmaceutical industry, Jeffrey Hatfield, Robert Perez, Saira Ramasastry, Elliott Sigal, M.D., Ph.D., and our Chairman Vicki Sato, Ph.D.; from the life science investment community, Robert More and Robert Nelsen (a co-founder); and from government, Janet Napolitano.

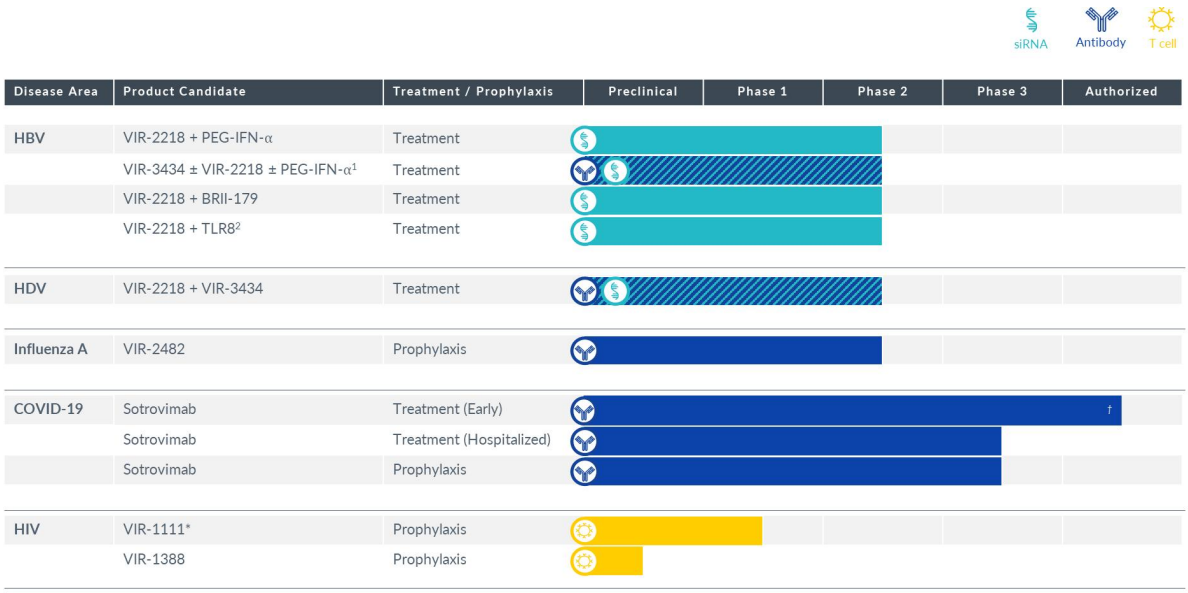
Our Strategy

We are a commercial-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. The core elements of our business strategy include:

- **Maximizing the impact of sotrovimab.** Sotrovimab has been granted emergency authorization, temporary authorization or marketing approval, supplying more than 40 countries. We and GSK will continue to work actively with governments and payors around the world to make sotrovimab available to patients in need.
- **Rapidly advancing our pipeline**. Currently underway are two Phase 3 clinical trials, seven Phase 2 clinical trials, and two Phase 1 clinical trials across five distinct therapeutic areas. We anticipate moving additional preclinical candidates into the clinic and initiating additional later-stage combination trials where applicable in the next 12-18 months.
- **Expanding our pipeline using our current technology platforms**. We are leveraging our four current technology platforms to discover and develop novel product candidates for HBV, HDV, influenza A virus, COVID-19, and HIV, as well as additional viral, bacterial, fungal and parasitic infections, and potentially cancers.
- **Acquiring or accessing new technology platforms and assets**. We continually evaluate external technology platforms and assets that may help us develop therapies to treat and prevent serious infectious diseases.
- **Scaling our capabilities**. We are investing in our people, processes and systems across all functions of our company to ensure that we are able to take full advantage of our multiple product candidates and multiple technology platforms.
- **Enabling global access to our future medicines**. We have established relationships with organizations seeking to make a global impact like the Bill & Melinda Gates Foundation, BARDA, the NIH, and the NHS to further enable and facilitate access to our future medicines and to support our clinical development efforts. We will continue to pursue additional relationships like these moving forward.

Pipeline

Our current pipeline consists of a product and product candidates that address unmet needs caused by HBV, HDV, influenza A virus, COVID-19, and HIV.



IFN-α: interferon alfa-2a; HBV: Hepatitis B Virus; HDV: Hepatitis D Virus; HIV: Human Immunodeficiency Virus
1: MARCH trial (Part B), PREVAIL platform trial (THRIVE/STRIVE sub-protocols); 2: GS-9688
**Vaccine designed to establish proof of concept in Phase 1 clinical trial to determine whether unique immune response observed in non-human primates can be replicated in humans; ultimately, any candidates we advance as a potential HIV vaccine will require modifications to VIR-1111 before further clinical development.*
†sotrovimab for early treatment by intravenous (IV) administration currently has marketing approval, temporary authorization or emergency authorization, supplying >40 countries. In April 2022, the FDA (as defined below) deauthorized sotrovimab's use in all U.S. regions. Sotrovimab and VIR-2482 incorporate Xencor's Xtend™ technology. VIR-3434 incorporates Xencor's Xtend™ and other Fc technologies.

Functional Cure for HBV

Summary

We are developing VIR-2218 and VIR-3434 for the functional cure of HBV. Each of these product candidates has the potential to stimulate an effective immune response and also has direct antiviral activity against HBV. We believe that a functional cure for HBV will require an effective immune response, in addition to antiviral activity, based on the observation that severe immunosuppression can reactivate HBV disease. While monotherapy with VIR-2218 and VIR-3434 may provide a functional cure in some patients, we believe combination therapy will be necessary for a functional cure in many patients.

VIR-2218, an HBV-targeting siRNA, is currently in several Phase 2 clinical trials. Initial data with VIR-2218 in healthy volunteers demonstrated that it was generally well tolerated up to 900 mg. In addition, durable, dose-dependent reductions in HBsAg were observed in patients with chronic HBV suppressed on NRTI therapy at doses ranging from 20 mg to 200 mg with durability out to at least 48 weeks. In November 2022, we announced initial end of treatment data from our ongoing Phase 2 clinical trial evaluating VIR-2218 in combination with IFN-α for 24 and up to 48 weeks. 30.8% (4/13) of the participants receiving up to 48 weeks of VIR-2218 plus IFN-α treatment achieved higher rates of HBsAg seroclearance with anti-HBs seroconversion by the end of treatment. Participants receiving longer duration of VIR-2218 plus IFN-α had the greatest mean declines from baseline HBsAg (log10 IU/mL) levels at week 48 (2.9 ± 1.36). Across all cohorts, 10 participants receiving VIR-2218 plus IFN-α for 24 or up to 48 weeks achieved HBsAg seroclearance by week 48, and nine achieved anti-HBs levels >10 mIU/mL. All patients were virally suppressed on NRTIs. The treatment regimens were generally well tolerated and resulted in no new safety signals. Additional data are expected in the first half of 2023.

VIR-2218 is also being evaluated in additional Phase 2 clinical trials with collaborators. Brii Bio continues to lead the Phase 2 trial of VIR-2218 in combination with BRII-179, an investigational T cell vaccine, for the treatment of chronic HBV infection. Treatment has completed in this trial. Interim safety and efficacy data was presented at the APASL in February 2023. Treatment of VIR-2218 alone or in combination with BRII-179 with and without coadjuvant IFN-α was generally well tolerated. Although the combination of VIR-2218 and BRII-179 had greater anti-HBs responses and improved HBsAg-specific T-cell responses, comparable

HBsAg reduction was observed in all cohorts at EOT (-1.7-1.8 log10 IU/mL). In December 2021, we and Gilead initiated a Phase 2 clinical trial of VIR-2218 in combination with GS-9688 (selgantolimod), Gilead's investigational TLR-8 agonist, and nivolumab in both NRTI-suppressed patients and viremic patients. Patients with HBV treatment experience also may receive TAF. In February 2023, due to immune-related adverse events associated with nivolumab, which are consistent with the safety profile of the class, in the cohorts evaluating nivolumab in combination with VIR-2218 and GS-9688, nivolumab was discontinued.

VIR-3434, an HBV-neutralizing mAb, is currently in a Phase 2 clinical trial. Two analyses from our Phase 1 trial showed no safety signals in healthy volunteers dosed with up to 3,000 mg. Single doses of VIR-3434 up to 300 mg demonstrated dose-dependent, rapid reductions in HBsAg in chronic HBV patients suppressed on NRTI therapy. In November 2022, we announced that a single dose of 75 mg or 300 mg of VIR-3434 to trial participants with chronic HBV with viremia not on NRTI therapy resulted in rapid reductions in HBsAg and HBV DNA in the majority of participants. In July 2021, we initiated the Phase 2 MARCH trial to evaluate the combination of VIR-2218 and VIR-3434 as a functional cure regimen for chronic HBV infection in patients suppressed on NRTI therapy.

In April 2022, we announced initial results from MARCH Part A that the combination of VIR-3434 and VIR-2218 resulted in an approximate 3 log decline in HBsAg with no safety signals reported to date. In November 2022, we announced end of treatment data for all MARCH Part A that the combination of VIR-3434 and VIR-2218 achieved mean HBsAg reductions >2.7 log10 IU/mL in all cohorts, absolute HBsAg levels <10 IU/mL were achieved in most participants, and no safety signals were reported to date. Additional MARCH Part A data are expected in the first half of 2023 and initial MARCH Part B data, evaluating VIR-2218 in combination with VIR-3434 for 24 and 48 weeks with and without interferon, are expected in the second half of 2023.

Initiation of the Phase 2 PREVAIL platform trial, which will evaluate the efficacy and safety of investigational therapies in participants with chronic HBV infection, is expected in the first half of 2023. The trial allows for a modular approach with a master protocol containing common elements shared across sub-protocol trials and interventions with an adaptive approach. Two sub-protocols are initially planned: the THRIVE sub-protocol in inactive carriers and the STRIVE sub-protocol in immune active, treatment naïve patients. Initial data are expected in the first half of 2024.

Disease Overview and Limitations of Current Standard of Care

HBV is a significant global health threat, characterized by high morbidity, mortality, and economic burden. According to the Hepatitis B Foundation, approximately 300 million people globally are chronically infected with HBV. In the United States, up to two million people are chronically infected with HBV. Up to 40% of patients with chronic HBV will develop significant clinical consequences including cirrhosis, decompensated cirrhosis, liver failure, and HCC. Globally, approximately 900,000 people die each year from HBV-associated complications.

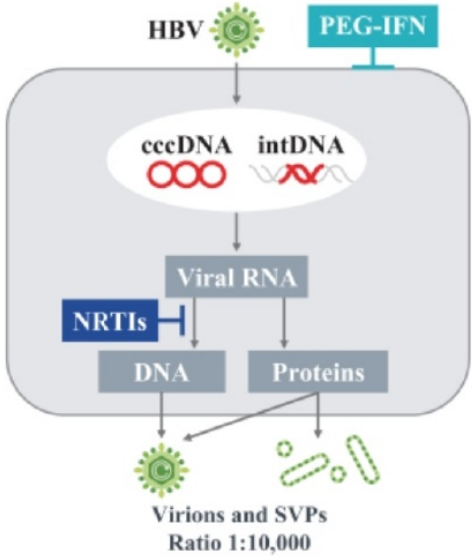
There is a significant unmet medical need for finite versus chronic therapies that achieve functional cure. The most commonly used therapy for chronic HBV is life-long suppressive therapy with NRTIs, like tenofovir or entecavir. However NRTIs rarely achieve functional cure , defined as the sustained loss (seroclearance) of detectable HBsAg and HBV DNA in serum, after a finite course of treatment NRTIs prevent HBV ribonucleic acid, or RNA, from being transcribed into HBV DNA, which is a process known as reverse transcription. NRTIs therefore have little to no direct impact on covalently closed circular DNA, or cccDNA, the reservoir for HBV. It has been reported that after a year of therapy with NRTIs, zero to 3% of patients experience a functional cure. Additionally, NRTIs reduce, but do not eliminate, the risk of HBV associated liver failure and liver cancer. Despite its low utilization rate, suppressive therapy with NRTIs for HBV represented over a billion-dollar market in 2021.

An alternative treatment option for chronic HBV is a year-long course of IFN-α therapy, which has poor tolerability and low functional cure approximately 3% to 7% of the time. The mechanisms by which IFN-α, an immune cytokine, achieves a functional cure are not known, but there is additional evidence supporting the need for immune stimulation to achieve a functional cure.

Of the hundreds of millions of people with chronic HBV worldwide, only about 10% are diagnosed, and of those diagnosed, only about 22% are treated. New, functional cure therapies have potential to increase diagnosis and treatment rates. The projected size of the global HBV functional cure market is >$10 billion annually.

HBV Life Cycle and Undetectable HBsAg as a Clinical Endpoint

The viral life cycle of HBV is shown in the figure below. After infecting a cell, the virus forms cccDNA. This form of HBV DNA is located in the nucleus of hepatocytes and acts like a mini-chromosome. HBV DNA can also integrate into the patient's DNA. This form of HBV DNA is known as integrated DNA, or intDNA.



HBV lifecycle with inhibition of processes by currently available therapies*. Arrows indicate viral life cycle process. Perpendicularly-ended lines indicate inhibition of viral process.*

HBV releases infectious virions and subviral particles, or SVPs, from infected cells. Both virions and SVPs include forms of an HBV protein called HBsAg, a blood biomarker that indicates that the HBV cccDNA and/or intDNA in that patient's hepatocytes are actively making HBV RNA and HBV proteins. For a registrational trial to demonstrate a functional cure, the formal endpoint accepted by the FDA, is undetectable HBsAg, defined as less than 0.05 IU/ml, as well as HBV DNA less than the lower limit of quantification, in the blood six months after the end of therapy. Achievement of this endpoint has been shown to predict improved clinical outcomes and the lack of need for further therapy.

VIR-2218 for HBV

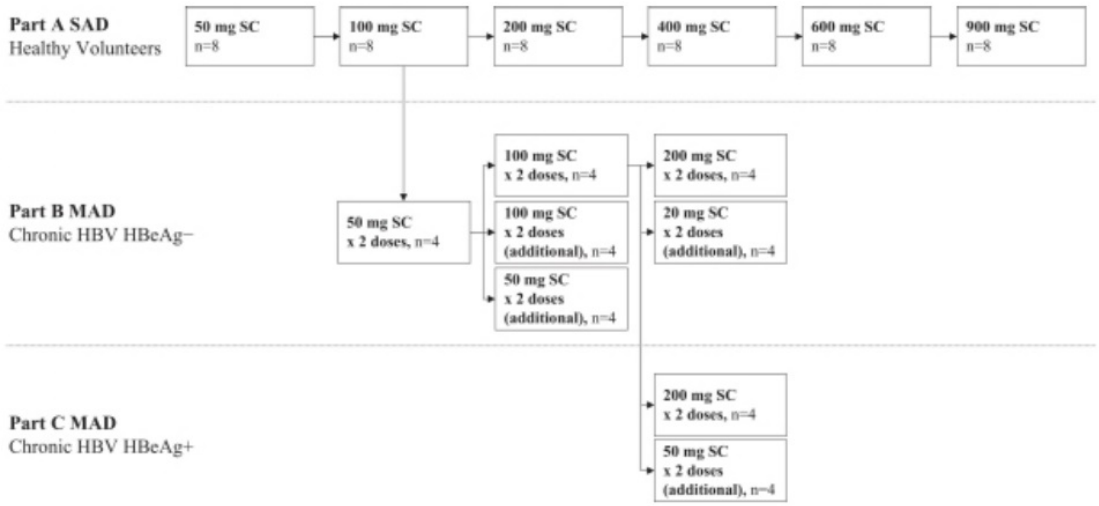
Molecular Characteristics. VIR-2218 is an investigational, single siRNA targeting a conserved sequence of HBV that allows for predicted activity against 99.7% of the strains of HBV, including all 10 HBV genotypes. Because this conserved sequence falls within a specific region of the X gene of HBV that exists within all four HBV RNA transcripts, VIR-2218 is able to degrade each transcript, and consequently decrease the expression of all proteins produced by the virus: X, polymerase, S, and core. VIR-2218 is thus potentially a broad-spectrum, potent antiviral.

HBV DNA can become integrated into human DNA as intDNA. Because VIR-2218 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 cccDNA.

We believe that the large amount of HBV protein that is transcribed in liver cells can suppress the immune system. There are at least two potential mechanisms by which suppression occurs. 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, VIR-2218 has the potential to decrease the ability of HBV to suppress the immune system—in effect removing a brake on the immune system. 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 such mice of HBV, suggesting that HBsAg suppression has the ability to enhance the immune response against HBV.

We believe that VIR-2218 is the only HBV-targeting siRNA currently in development that includes ESC+ technology. We believe this technology may be able to enhance the potential safety of VIR-2218.

Phase 1/2 Trial of VIR-2218. The trial was an adaptive clinical trial designed to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of VIR-2218. It evaluated single ascending doses of VIR-2218 in healthy volunteers and multiple ascending doses in adults with chronic HBV suppressed on NRTI therapy. The study design is shown below.

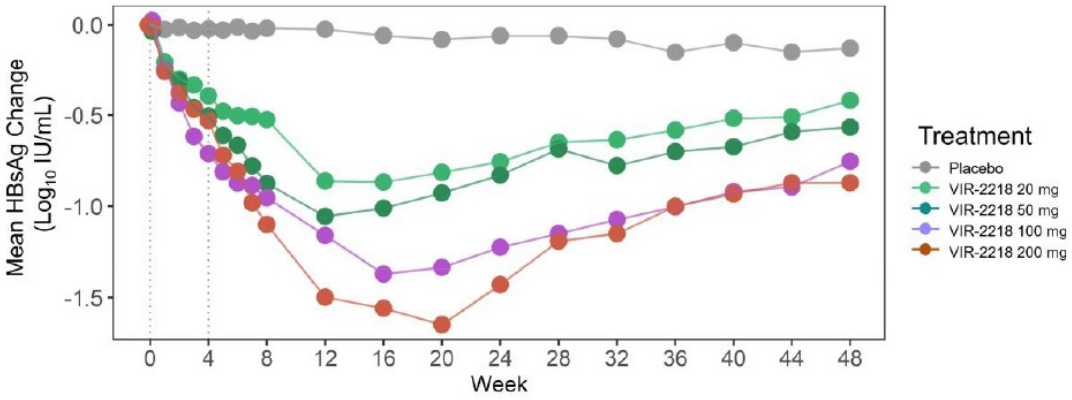


VIR-2218 trial in healthy volunteers and patients with chronic HBV infection*. Arrows indicate trial progression. HBeAg- = hepatitis B virus e-antigen negative; HBeAg+ = hepatitis B virus e-antigen positive; MAD = multiple ascending dose; SAD = single ascending dose; SC = subcutaneous.*

Across healthy volunteers and chronic HBV patients, VIR-2218 has been generally well-tolerated. No clinically significant ALT abnormalities, which are a marker of liver inflammation, have been observed. In the Part A 900 mg cohort, asymptomatic Grade 1 ALT elevations with no associated changes in bilirubin, or other markers of liver function, have been observed. Three serious adverse events, or SAEs, have been reported, all in Part B. The first, a Grade 2 headache, resolved with intravenous fluids and non-opioid pain medications. This patient had additional symptoms of fever, nausea, vomiting and dehydration, assessed by us as consistent with a viral syndrome. The second SAE, a Grade 4 depression, occurred over 50 days after the last drug dose was administered, and was assessed by us as not related to VIR-2218. The third SAE, a patient suicide, occurred 241 days after the last dose of study drug and was assessed by us as not related to VIR-2218. Three Grade 3 adverse events of upper-respiratory tract infection, chest pain and low phosphate levels in the blood have also been reported. We did not consider any of these Grade 3 events as related to VIR-2218.

The biologic activity of VIR-2218 was assessed by declines in HBsAg. The activity of VIR-2218 through Week 48 for each dose level is shown in the graph below. For Parts B and C, the average baseline HBsAg levels were 3.3 log10 IU/mL and 3.9 log10 IU/mL, respectively. The average decline in HBsAg across HBeAg negative and HBeAg positive subjects at Week 16 was 1.5 log10, or an approximately 32-fold reduction. The declines observed in HBsAg at Week 16 ranged from 0.97 log10 to 2.2 log10, or an approximately nine to 160-fold reduction, after two 200 mg doses of VIR-2218 given four weeks apart. The average HBsAg level at Week 16 was 314 IU/mL, with half of the patients achieving HBsAg values < 100 IU/mL and 5/6 achieving HBsAg values < 1000 IU/mL. Five of the 12 patients that achieved HBsAg values of <100 IU/mL maintained it through Week 48. Therefore, even though HBsAg levels gradually rebounded, overall, a durable effect was observed.

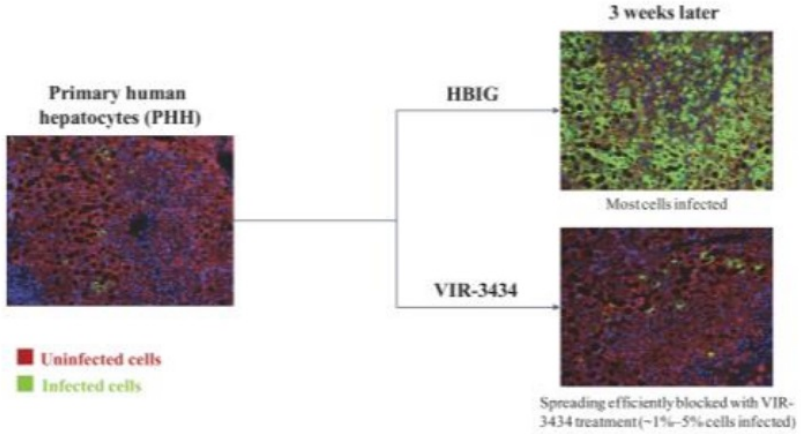
The ability of VIR-2218 to result in substantial and durable declines in HBsAg after only two doses suggests that VIR-2218 has the potential to play an important role in the functional cure of chronic HBV. We have initiated and plan to initiate additional clinical trials evaluating VIR-2218 in combination with other immunomodulatory agents.



Change from Baseline in HBsAg following administration of VIR-2218*. Each line represents the average decline from baseline in HBsAg for VIR-2218 for each dosing level or pooled placebo in Parts B and C.*

VIR-3434 for HBV

Molecular Characteristics and Preclinical Data. VIR-3434 is an investigational mAb targeting a conserved region on HBsAg that allows it to neutralize strains from all 10 HBV genotypes. VIR-3434 specifically targets the antigenic loop, or AGL, on HBsAg. The AGL helps the virus bind to hepatocytes and subsequently infect these liver cells. By binding to the AGL, VIR-3434 prevents viral entry, which prevents the spread of HBV to uninfected hepatocytes. VIR-3434, through a process called opsonization, also helps remove HBV virions and SVPs from the blood. Hepatitis B immunoglobulin, or HBIG, an approved therapy for preventing reinfection after transplantation and which consists of polyclonal antibodies against HBV, acts by similar mechanisms. In vitro, VIR-3434 demonstrates approximately 5000-fold greater potency than HBIG in neutralization assays. As shown in the figure below, VIR-3434 is better able to prevent the spread of HBV to uninfected cells in vivo compared to HBIG.

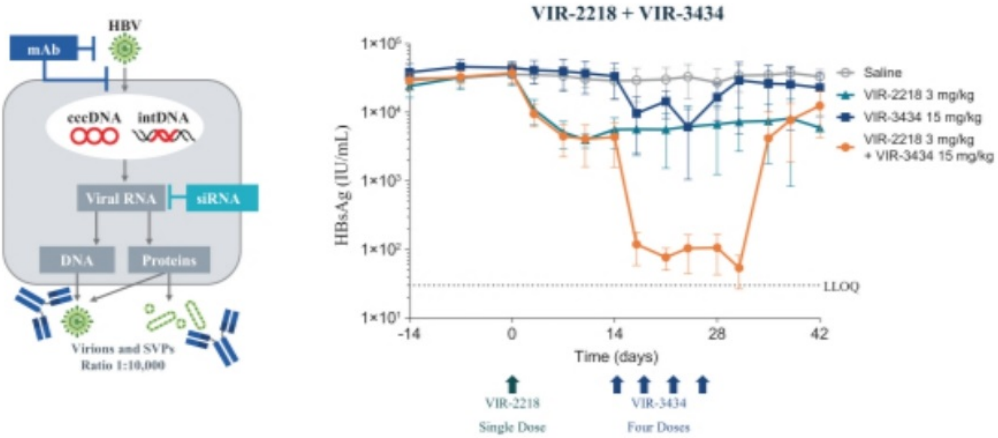


Progression of infection in primary human hepatocytes with hepatitis B immune globulin or VIR-3434 in vivo*. PHH = primary human hepatocytes.*

VIR-3434 also has the potential to activate the immune system, via three different processes. First, due to specialized mutations in the Fc domain of VIR-3434, it has the potential to act as a T cell vaccine. VIR-3434, which incorporates Xencor's Xtend™ and other Fc technologies, has been engineered with mutations that enhance binding to the FcR IIa activating receptor and diminish binding to the FcR IIb inhibitory receptor. As such, VIR-3434 is designed to capture virions and SVPs, deliver such virions and SVPs to dendritic cells, or DCs, and instruct these DCs to mature and stimulate T cells that can eliminate HBV infected hepatocytes.

Second, VIR-3434 has the potential to act via antibody-dependent cell cytotoxicity, or ADCC. In this process, by binding to HBsAg at the cell surface, VIR-3434 recruits natural killer cells to eliminate infected hepatocytes. The Fc domain of VIR-3434 has been engineered to promote ADCC. Third, by reducing the amount of HBsAg in the blood, VIR-3434 has the potential to remove a brake on the immune system by decreasing the ability of HBV to suppress it.

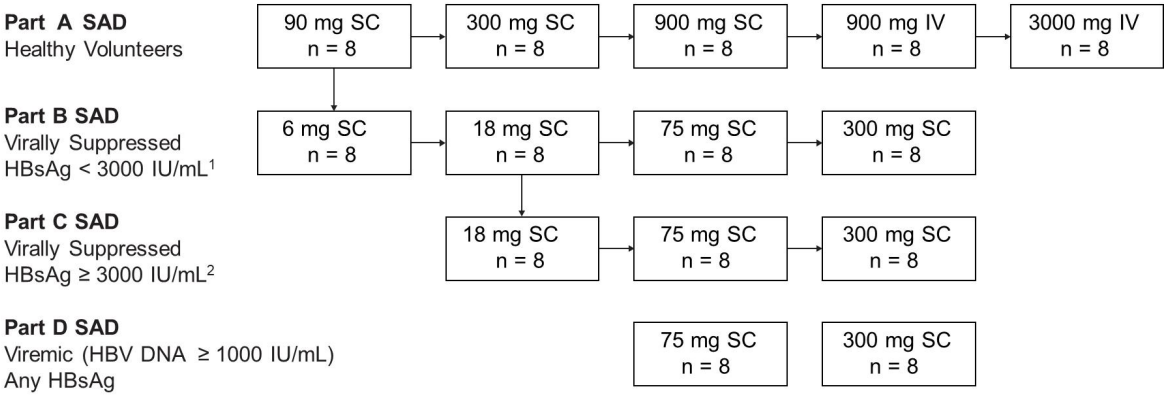
We have also evaluated the antiviral activity of the combination of VIR-2218 and VIR-3434 in an adeno-associated virus-HBV mouse model. As shown in the figure below, VIR-2218 and VIR-3434 work together to reduce the level of HBsAg.



VIR-2218 and VIR-3434, which was modified to have a mouse mAb backbone for this experiment, administered alone or together result in reduced HBsAg in a mouse model.

Phase 1 Trial of VIR-3434. The trial is an adaptive clinical trial designed to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of VIR-3434. The current trial design of VIR-3434-1002 is shown below.

The Phase 1 clinical trial has four parts. Part A is a single ascending dose design in healthy volunteers with Parts B and C as single ascending dose designs in adults with chronic HBV on NRTIs. Patients in Part B had HBsAg levels less than 1,000 IU/ml for the 6 mg cohort and less than 3,000 IU/mL for the other cohorts. It is possible that patients with lower HBsAg levels will have a more profound response to VIR-3434 than patients with higher HBsAg levels. Patients with HBsAg levels greater than or equal to 3,000 IU/ml were evaluated in an optional Part C. In Part D, patients with HBV DNA greater than or equal to 1,000 IU/mL who were not receiving NRTI therapy were evaluated.



VIR-3434-1002 is an adaptive clinical trial design in healthy volunteers and patients with chronic hepatitis B virus infection*. Arrows indicate trial progression. SC = subcutaneous.*
SAD = single ascending dose. IV = intravenous.

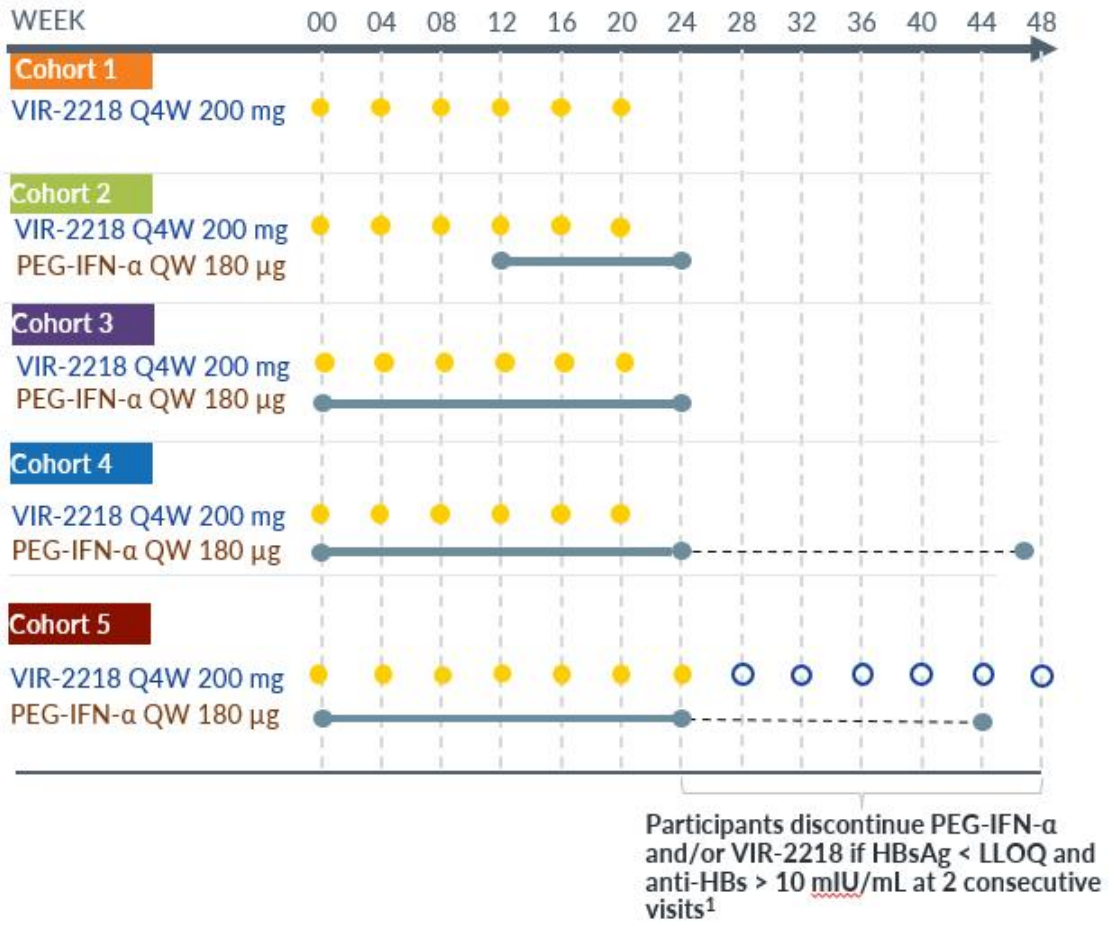
(1) *The six mg SC cohort in Part B enrolled participants with screening HBsAg less than 1,000 IU/ml.*
(2) *The 18 mg SC cohort in Part C enrolled participants with any screening HBsAg.*

The primary endpoints across all parts of the trial were safety and tolerability. The key secondary endpoint in Parts B and C is the maximum reduction of serum HBsAg from baseline. In Part D, an additional key secondary endpoint is the maximum change of HBV DNA from baseline.

All cohorts have completed dosing up to 3,000 mg administered intravenously. Data from Part A up to 3000 mg IV was generally well tolerated with no clinical safety concerns observed. In Part B, most participants achieved a ≥1 log10 IU/mL reduction from baseline in HBsAg within 1-3 days. Mean HBsAg reductions in the 6 mg, 18 mg, 75 mg, and 300 mg groups were 1.30, 1.27, 1.96, and 2.21 log10 IU/mL, respectively, at nadir. All participants who received 75 mg or 300 mg of VIR-3434 achieved HBsAg <100 IU/mL and 5/6 (83%) in the 300 mg group achieved HBsAg <10 IU/mL. In Part D, single doses of 75 mg or 300 mg was associated with rapid reductions in HBsAg and HBV DNA in the majority of participants. Across both cohorts, 11/12 participants receiving VIR-3434 achieved a >1 log10 IU/mL decline in HBsAg and 11/12 achieved a >1 log10 IU/mL decline in HBV DNA with the changes in HBsAg and HBV DNA showing similar kinetics. Across all parts of the study, VIR-3434 was generally well tolerated with the majority of adverse events being mild to moderate in severity.

HBV Combinations and New Product Candidates

Phase 2 Trial of VIR-2218 in combination with IFN-α. The trial is a clinical trial evaluating the safety, tolerability, pharmacokinetics and antiviral activity of VIR-2218 alone and in combination with IFN-α in adults with chronic HBV infection on NRTIs. The trial is evaluating multiple doses of VIR-2218 200 mg, alone or in combination with IFN-α for 24 to 48 weeks. The trial cohorts are shown below.



VIR-2218-1001 Parts D and F are evaluating multiple doses of VIR-2218 alone or in combination with IFN-α in patients with chronic hepatitis B virus infection.

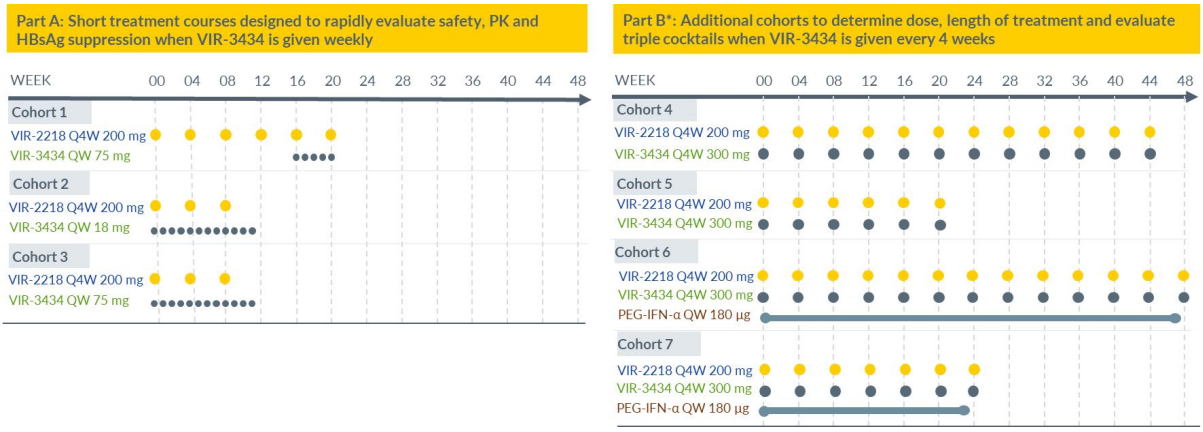
1. ***HBsAg assay LLOQ and LLOD are 0.05 IU/mL. LLOD, lower limit of detection; LLOQ, lower limit of quantitation. All participants are virally suppressed on NRTIs.***

VIR-2218 in combination with IFN-α for 24 weeks from Day 1 (Cohort 3) resulted in a more rapid and substantial decline in HBsAg compared to VIR-2218 alone (Cohort 1) and VIR-2218 lead-in followed by concomitant administration with IFN-α from Week 12-24 (Cohort 2). Through Week 24, mean HBsAg change from baseline were -1.9, -2.0, and -2.4 log10 IU/mL in Cohorts 1, 2, and 3, respectively, with greater than 1 log10 decline in HBsAg still at Week 48. Cohorts 4 and 5 evaluated treatment beyond 24 weeks. In both Cohorts 4 and 5, participants took VIR-2218 and IFN-α from Day 1 through Week 24. In Cohort 4, participants were eligible to continue IFN-α up to 48 weeks if they did not achieve HBsAg less than the lower limit of quantitation, or LLOQ, and participants in Cohort 5 were able to continue VIR-2218 and IFN-α up to Week 48 if they did not achieve HBsAg <LLOQ. If a participant in Cohorts 4 or 5 achieved HBsAg <LLOQ at 2 consecutive visits, they were eligible to stop therapy. Through Week 48, mean HBsAg change from baseline were -1.8 and -2.9 log10 IU/mL in Cohorts 4 and 5, respectively. Overall, 10 participants achieved HBsAg seroclearance by Week 48 across all cohorts with the majority occurring in Cohorts 4 and 5. Importantly, nine out of these 10 participants, including all four in Cohort 5, also achieved seroconversion defined as anti-HBsAb > 10 mIU/mL, which suggests the potential for durability of response after stopping therapy. The treatment regimens were generally well tolerated and resulted in no new safety signals.

Participants with HBsAg seroclearance, n (%)	Cohort 1 (n=15) VIR-2218 x6	Cohort 2 (n=15) VIR-2218 x 6 lead-in + PEG-IFNα x 12	Cohort 3 (n=18) VIR-2218 x 6 + PEG-IFNα x 24	Cohort 4 (n=18[1]) VIR-2218 x 6 + PEG-IFNα x ≤48	Cohort 5 (n=13) VIR-2218 x 13 + PEG-IFNα x ≤ 44
At any time up to Week 48	0 (0%)	1 (6.7%)	1 (5.6%)	4 (22.2%)	4 (30.8%)
At Week 48	0 (0%)	1 (6.7%)	0 (0%)	3 (16.7%)	4 (30.8%)
With Anti-HBs (>10 mIU/mL) at Week 48	0 (0%)	1 (6.7%)	0 (0%)	3 (16.7%)	4 (30.8%)

Preliminary 48-week safety and efficacy data from novel investigative cohorts of VIR-2218 alone and in combination with IFN-α in participants with chronic HBV infection. All participants are virally suppressed on NRTIs.

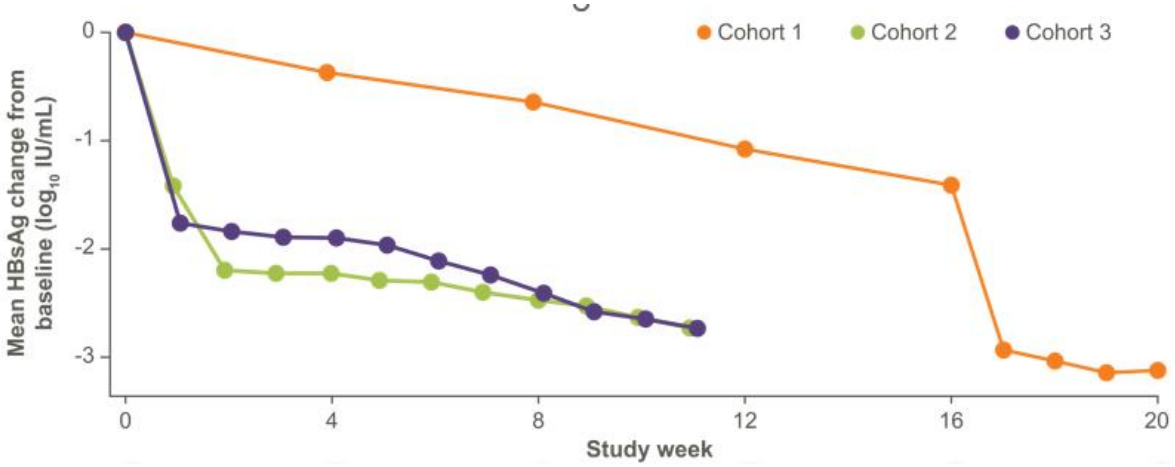
Phase 2 Trial of VIR-2218 and VIR-3434 with and without IFN--α. In July 2021, we initiated the Phase 2 MARCH trial to evaluate the combination of VIR-2218 and VIR-3434 as a functional cure regimen for chronic HBV infection. We believe VIR-2218 and VIR-3434 have the potential to act in concert by inhibiting virion production, removing potentially tolerogenic HBV proteins, and stimulating new HBV specific T cells. All patients were virally suppressed on NRTIs.



MARCH: Monoclonal Antibody siRNA Combination against Hepatitis B; QW: weekly; Q4W, every 4 weeks
****Not exhaustive – does not include mono therapy arms for VIR-3434. Additional cohorts may be added***

Part A of the MARCH trial evaluated the safety of the combination of VIR-2218 and VIR-3434. Cohort 1 was a lead-in with VIR-2218 followed by coadministration of VIR-3434 from Week 16-20. Cohort 2 and 3 evaluated the concomitant administration of VIR-2218 and VIR-3434 from Day 1 through Week 12, evaluating 18 mg and 75 mg VIR-3434 administered weekly. Cohort 1 demonstrated a mean 3.1 log10 decline in HBsAg at end of treatment while Cohorts 2 and 3 demonstrated a 2.7 log10 decline in

HBsAg. Although no participants achieved HBsAg <LLOQ, most participants achieved HBsAg <10 IU/mL. VIR-2218 in combination with VIR-3434 was generally well tolerated with most adverse events being mild.



Preliminary data from the ongoing open-label Phase 2 MARCH trial evaluating the safety, tolerability and antiviral activity of VIR-2218 in combination with VIR-3434 in virally suppressed participants with chronic HBV infection who received continuous NRTI therapy for two months or more. All participants are virally suppressed on NRTIs

Part B of the MARCH trial is currently enrolling and is evaluating the combination of VIR-2218 and VIR-3434 with and without IFN-α for 24 and 48 weeks. Initial data from Part B is expected in the second half of 2023.

Other Collaborators. In December 2021, we and Gilead initiated a multi-center, open-label Phase 2 clinical trial which is designed to evaluate the safety, tolerability and efficacy of various combinations of VIR-2218, GS-9688 (selgantolimod), Gilead's investigational TLR-8 agonist, nivolumab, an approved PD-1 inhibitor, and TAF in adults with chronic HBV. The trial will enroll approximately 120 patients ages 18 to 65 who are either viremic or are NTRI-suppressed. Patients who are HBeAg-positive (an indicator of acute viral replication), as well as those who are HBeAg-negative, will be enrolled. The primary efficacy endpoint is the proportion of patients who achieve a functional cure (defined as HBsAg loss and HBV DNA <20 IU/mL at follow-up week 24). In February 2023, due to immune-related adverse events associated with nivolumab, which are consistent with the safety profile of the class, in the cohorts evaluating nivolumab in combination with VIR-2218 and GS-9688, nivolumab was discontinued.

In April 2021, Brii Bio initiated a Phase 2 trial of VIR-2218 in combination with BRII-179, an investigational T cell vaccine, for the treatment of chronic HBV infection. Treatment has completed in this trial. Interim safety and efficacy data were presented at the APASL in February 2023. Treatment of VIR-2218 alone or in combination with BRII-179 with and without coadjuvant IFN-α was generally well tolerated. Although the combination of VIR-2218 and BRII-179 had greater anti-HBs responses and improved HBsAg-specific T-cell responses, comparable HBsAg reduction was observed in all cohorts at EOT (-1.7-1.8 log10 IU/mL).

Initiation of the Phase 2 PREVAIL platform trial (NCT05612581) and its THRIVE/STRIVE sub-protocols of VIR-3434 and/or VIR-2218 and/or IFN-α in viremic patients with chronic HBV infection is expected in the first half of 2023. The PREVAIL platform approach allows for a modular approach with a master protocol containing common elements shared across sub-protocol trials and interventions with an adaptive approach. Two sub-protocols are initially planned. The THRIVE sub-protocol will initially evaluate the safety and efficacy of regimens containing combinations of an NRTI with VIR-3434 and/or VIR-2218 in inactive carriers defined as adults with chronic HBV that are HBeAg negative with HBV DNA ≤2000 IU/mL and ALT ≤ULN. The STRIVE sub-protocol will evaluate the safety and efficacy of regimens containing combinations of an NRTI with VIR-3434 and/or VIR-2218 and/or IFN-α in adults with chronic HBV infection who have not received prior NRTI or IFN-α treatment. Participants will be HBeAg positive or negative with HBV DNA >2000 IU/mL, ALT>ULN and ≤ 5× ULN. Initial data from the PREVAIL platform trial are expected in the first half of 2024.

Furthermore, in parallel with the above development programs, research efforts are underway to use our innate immunity platform to identify and disrupt the host proteins necessary for HBV cccDNA formation and stability, which we believe could result in a complete cure. We also have an HBV therapeutic vaccine that leverages our T cell platform in preclinical development. This is an example of the potential value of combining outputs from our four technology platforms to complex infectious diseases.

Chronic Treatment for HDV

Summary

We are developing VIR-2218 and VIR-3434 for the chronic treatment and suppression of HDV. HBsAg is a critical component necessary for the HDV lifecycle and both VIR-2218 and VIR-3434 act independently to inhibit the replication of HDV by targeting HBsAg. VIR-2218 inhibits the production of HBsAg by targeting a conserved region of the HBV genome and inhibiting production of all HBV proteins including HBsAg. VIR-3434 binds to a conserved region of HBsAg, which reduces the levels of HDV virions and prevents the infection of hepatocytes with HDV. VIR-2218 and VIR-3434 as monotherapy have independently demonstrated reduction in HBsAg of greater than 1 log10 and initial data when VIR-2218 and VIR-3434 are given together have demonstrated an additive effect of almost 3 log10 decline in HBsAg through at least 20 weeks of treatment. As HBsAg is required for the lifecycle of HDV, both VIR-2218 and VIR-3434 are expected to suppress the replication of HDV and to potentially improve clinical outcomes.

Disease Overview and Limitations of Current Standard of Care

HDV is a replication-defective virus that uses HBsAg as its envelope protein and therefore only occurs with HBV co-infection. Approximately 12 million people globally are infected with HDV, representing approximately 5% of the HBV population. HDV is considered the most severe and aggressive form of viral hepatitis leading to significantly more rapid progression towards cirrhosis, hepatocellular carcinoma, hepatic decomposition, and liver failure. People with HDV are 3.9 times more likely to have hepatocellular carcinoma than people with HBV and 2 times more likely to die from HDV vs. HBV mono-infection. Despite this high disease severity, there are no approved therapies for HDV in the U.S. although pegylated interferon alpha has been used off label with limited success due to its tolerability profile and low rates of sustained virologic response. Hepcludex (bulevirtide), a once daily subcutaneous injection, has conditional approval in the EU and the U.K. for the chronic treatment of HDV but has not yet been approved in the U.S. The projected size of the global HDV treatment market is >$2 billion annually.

VIR-2218 + VIR-3434 for HDV

Phase 2 Trial of VIR-2218 in combination with VIR-3434. In September 2022, we initiated the Phase 2 SOLSTICE trial evaluating once monthly subcutaneous injections of VIR-2218 and VIR-3434 as monotherapy and in combination for the chronic treatment of people living with HDV. The trial is assessing the safety and ability of the combination to reduce HDV viremia and normalize ALT, surrogate endpoints used for regulatory approval and endpoints that may improve clinical outcomes. Initial data are expected in the second half of 2023.

Universal Prophylaxis for Influenza A

Summary

We are developing VIR-2482 as universal prophylaxis for influenza A. VIR-2482 is a mAb that targets a conserved region of the influenza A hemagglutinin protein and consequently has the potential to prevent illness from any strain of influenza A, including seasonal and pandemic strains. In vitro, VIR-2482 has been shown to cover all major strains of influenza A that have arisen since the 1918 Spanish flu pandemic. Since flu vaccines have incomplete strain coverage and limited efficacy, the broad coverage of VIR-2482 may allow it to achieve higher protection levels and for it to be used year after year. In addition, because VIR-2482 is an antibody that can directly confer protection, it does not rely on a person to create their own antibodies. Thus, we believe VIR-2482 has the potential to be effective even in a person with a compromised immune system. VIR-2482 has been half-life engineered so that a single dose has the potential to last the entire flu season, which is typically five to six months long. VIR-2482 is currently in a Phase 2 clinical trial. VIR-2482 was well-tolerated in the approximately 100 healthy volunteers dosed in Phase 1.

In May 2021, we signed the 2021 GSK Agreement to expand our existing collaboration to include the research and development of new therapies for influenza and other respiratory viruses. See the section titled “Our Collaboration, License and Grant Agreements—Collaboration Agreements with GSK” for a description of the 2021 GSK Agreement.

Disease Overview and Limitations of Current Standard of Care

Seasonal influenza is a significant medical and economic burden, even with vaccines. There are two major types of influenza virus: type A and type B. Influenza A has been associated with more severe illness and has been the source of all known influenza pandemics. According to the CDC, influenza A accounts for nearly 80% of infections and approximately 75-85% of influenza hospitalizations.

Seasonal influenza is a huge medical and economic burden, even with vaccines. According to the WHO, on average, each year the influenza virus is estimated to infect 1 billion people and results in approximately 6 million hospitalizations and 290,000 to 650,000 deaths globally. According to the CDC, there are approximately X infections, 500,000 hospitalizations and 34,000 deaths in

the U.S. alone each year due to flu. The large majority of these influenza-related deaths occurred in the elderly, defined as those 65 and older, and/or those with comorbidities at high risk for severe disease. These patients comprise a population with a high unmet need for better preventive measures. There are approximately 140 million people in the U.S., U.K., Germany, France, Spain, Italy and Japan who are 65 and older with a risk-factor for severe disease and between 21 and 42% of them are hospitalized each year if they get the flu.

According to the CDC, the efficacy of the seasonal flu vaccine has ranged from 10% to 60% over the past 16 years, with an average of 40%, overall, across all populations. The seasonal flu vaccine's efficacy in the elderly has been found to be notably lower, in some flu seasons as low as 10%. The limited success rate of current influenza vaccines has been attributed to two primary factors. First, flu vaccines have incomplete strain coverage and therefore often do not provide protection against all strains of influenza that circulate in a given season, despite being updated every year.

Second, flu vaccines are active immunizations that rely on a person's own immune system to create protective influenza virus antibodies, and many individuals do not generate an effective immune response. Clinical and technological advances in flu vaccines, such as cell-based manufacturing, mRNA-based vaccines and higher dose administration, do not address these fundamental limitations.

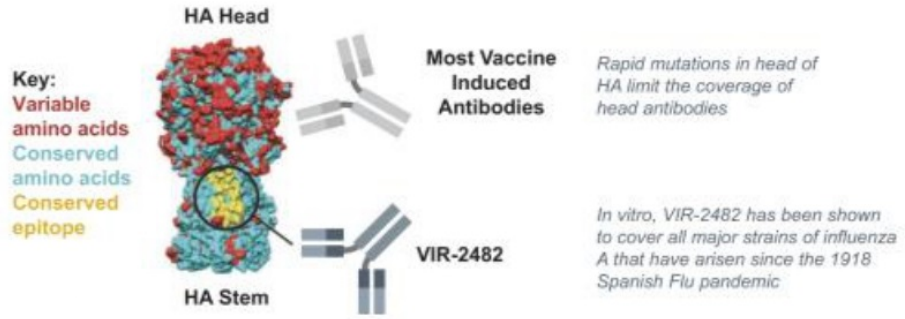
The projected size of the mAb flu prevention market is >$5 billion annually.

VIR-2482 for Influenza A

Molecular Characteristics and Preclinical Data. VIR-2482 is an investigational mAb targeting a functionally conserved epitope on the influenza A hemagglutinin protein located within the stem region. We believe that all strains of influenza, past and future, have and likely will contain this conserved epitope within the stem region. In preclinical studies, we have demonstrated that, in vitro, VIR-2482 covers all the major strains of influenza A that have arisen since 1918. Thus, unlike flu vaccines, whose incomplete strain coverage results in limited efficacy despite being updated every year, the broad coverage of VIR-2482 may allow it to achieve higher protection levels and to be used year after year. In addition, because VIR-2482 is an antibody that can directly confer protection, it does not rely on a person to create their own antibodies. Thus, we believe VIR-2482 has the potential to be effective irrespective of the status of a person’s immune system.

Notably, in a 2019 clinical epidemiology study, it was observed that the presence of rare, stem-binding influenza antibodies correlated with protection from influenza infection. While other stem-binding influenza A antibodies have been identified, we have demonstrated that VIR-2482 has the broadest coverage when compared to a large representative panel of stem-binding mAbs. In prophylactic lethal challenge studies of influenza A in mice, VIR-2482 was able to protect mice from death at VIR-2482 exposures we believe to be clinically relevant.

We engineered the parent form of VIR-2482 to extend its half-life to create VIR-2482, which incorporates Xencor’s Xtend™ technology. This half-life extension potentially allows for a single injection of VIR-2482 given at the start of the influenza season to maintain a protective concentration in the respiratory tract for the duration of the influenza season.



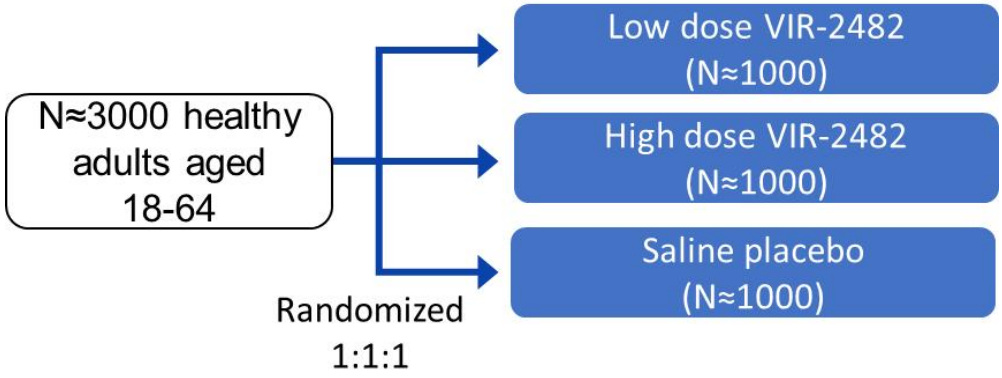
VIR-2482 targets a highly conserved region of the influenza virus and exhibits potency against the last century of influenza viruses*. Following vaccination, most anti-influenza antibodies target the variable head region. VIR-2482 binds to the stem region which is highly conserved over time. HA = hemagglutinin.*

Phase 1 and 2 Trials of VIR-2482.

VIR-2482-3001 was a Phase 1 first-in-human, randomized, double-blinded, placebo-controlled single ascending dose trial in healthy adult volunteers with endpoints of safety, tolerability, and pharmacokinetics, or PK, when VIR-2482 is administered IM in four different doses: 60 mg, 300 mg, 1200 mg, and 1800 mg. This trial initiated in August 2019 and is now complete. The trial showed VIR-2482 was well-tolerated up to 1800 mg and is estimated to have a half-life of 58 days based on preliminary clinical data.

In September 2022, we initiated VIR-2482-4004, a Phase 1b prophylaxis trial evaluating the safety of VIR-2482 in elderly participants (aged 65 and older) receiving a flu vaccine. The trial is ongoing and initial data are expected in mid-2023.

In October 2022, we initiated PENINSULA, a Phase 2 randomized, double-blind, placebo-controlled, dose-ranging trial in healthy adult volunteers aged 18 to 64 to evaluate the safety, tolerability and efficacy of two different intramuscularly administered doses of VIR-2482 in preventing illness due to influenza A. The primary efficacy endpoint is the proportion of trial participants with protocol-defined influenza illness, requiring one systemic symptom and one respiratory symptom, with PCR confirmed influenza A infection, compared to placebo. Other endpoints will evaluate the effect of VIR-2482 on the severity and duration of illness in trial participants with confirmed influenza A compared to placebo. Enrollment is complete and initial data are expected in mid-2023. The PENINSULA trial is being funded in part with federal funds from the HHS; the ASPR; and the BARDA, under OT number 75A50122C00081.



In addition to VIR-2482, we are developing next generation antibodies that have the potential to be even broader, treating both influenza A and B, and more potent.

Treatment and Prophylaxis for COVID-19

Summary

In response to the ongoing COVID-19 pandemic, we have moved rapidly to address this global health challenge. Our focus is on treating and preventing COVID-19, as well as potential future coronavirus outbreaks. To do so, together with our collaborator GSK, we are developing the mAb sotrovimab, as well as small molecules. Vir is also developing additional differentiated mAbs as well as vaccines.

We are developing sotrovimab for the treatment and prophylaxis of COVID-19. Sotrovimab is based on a parent antibody, S309, which was derived from samples previously gathered for research on pan-coronavirus-neutralizing mAbs. Data suggest that sotrovimab and VIR-7832 have the potential for ‘dual-action’, or the ability to block viral entry into healthy cells and an enhanced ability to clear infected cells.

In May 2021, the FDA granted an EUA to 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 European Commission 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 March 2022, the FDA de-authorized sotrovimab’s use in all U.S. regions due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 subvariant.

Sotrovimab has obtained emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®) for early treatment of COVID-19, supplying more than 40 countries. Sotrovimab is not authorized in the U.S. Over 2.1 million doses of sotrovimab have been delivered as of December 31, 2022.

We continue to conduct in vitro testing of sotrovimab against new variants and subvariants as they emerge, and to collect and evaluate real-world evidence, both of which are being shared with regulatory authorities.

We are also evaluating the use of sotrovimab in two additional indications: (1) to determine if sotrovimab can prevent symptomatic COVID-19 infection in uninfected immunocompromised adults, and (2) to evaluate if sotrovimab treatment can improve clinical outcomes in patients hospitalized with COVID-19.

In addition to sotrovimab, we are preparing for future pandemics with coronavirus mAbs that have the potential to be even broader and more potent than sotrovimab, pan-coronavirus vaccines designed with the aim to be variant-proof (initial pre-clinical proof of concept achieved), and small molecules that have the potential to treat multiple respiratory diseases like COVID-19 and influenza (initial pre-clinical proof of concept achieved).

VIR-7832, which has similar properties to sotrovimab, but is also designed to potentially enhance virus-specific T cell function, was evaluated in the U.K.'s NHS-supported AGILE initiative. The Phase 1b portion of the trial assessed safety of VIR-7832 at 50 mg, 150 mg and 500 mg IV doses. The Phase 2 portion of the trial was designed to assess safety and efficacy at 500 mg IV dose. The Phase 2a was stopped early due to concerns about the evolving COVID landscape, including circulating SARS-CoV-2 variants. No safety signals were reported in the Phase 1b or 2a portions of the trial.

Disease Overview and Limitations of Current Standard of Care

According to the John Hopkins Coronavirus Resource Center, as of February 27, 2023, there were almost 675.1 million recorded infections and almost 6.9 million recorded deaths worldwide from COVID-19. The FDA has granted either EUAs or marketing approvals to multiple vaccines, drugs and/or antibodies to prevent or treat COVID-19 in the U.S.

For prophylaxis, despite the high efficacy of the COVID-19 vaccines, there are still populations in whom vaccine immunogenicity is suboptimal, such as the elderly with comorbidities, immunocompromised persons, or those who may not want or be able to tolerate vaccines.

For early treatment, both mAbs and small molecules have shown strong efficacy data and have pros and cons around convenience and compliance. For example, for some patients and their physicians, IM or IV mAbs may be preferred to small molecules due to administration in a single treatment visit ("one and done"), concerns about compliance with small molecules (multiple pills, multiple times per day, over multiple days), and concerns about oral treatment initiation requirements.

For hospitalized patients, there is still significant unmet need. Preliminary data suggest that COVID-19 mAbs may have a role in improving clinical outcomes such as decreasing intensive care unit stays and/or mortality in hospitalized patients who have severe or critical COVID-19.

Importantly, the ongoing durability of current vaccines, small molecules, and mAbs in the setting of the continued emergence of variants is uncertain.

The size of the COVID-19 prevention and treatment market is projected to continue to be double-digit billions of dollars annually.

Sotrovimab for COVID-19

Molecular Characteristics. Sotrovimab is an investigational engineered human IgG1 neutralizing anti-SARS-CoV-2 monoclonal antibody that has Fc modifications that are designed to improve bioavailability in the respiratory mucosa and increase half-life, and incorporates Xencor's Xtend™ technology. Sotrovimab binds with high affinity to the receptor binding domain of the SARS-CoV-2 spike protein. It is designed to have dual-actions of neutralizing the virus by blocking viral entry into healthy cells, while also enhancing the ability to clear infected cells. Sotrovimab potently neutralizes live SARS-CoV-2 in vitro and in vivo, and binds to a highly conserved epitope that is shared with SARS-CoV-1, thus potentially leading to a wide breadth of sarbecovirus coverage and a higher barrier to resistance.

Phase 2/3 Trials of Sotrovimab.

COMET-ICE: Sotrovimab was evaluated as a treatment in adults with mild to moderate COVID-19 at high risk of hospitalization or death. This trial was a Phase 2/3, randomized, double-blind, multi-center, placebo-controlled trial investigating IV infusion of 500 mg of sotrovimab in adults with mild to moderate COVID-19 at high-risk of progression to severe disease, who were not hospitalized and did not require oxygen. The trial included a lead-in phase to evaluate the safety and tolerability of sotrovimab, followed by an expansion phase with 1:1 randomization of sotrovimab and placebo. The final COMET-ICE trial results in the full trial population of 1,057 participants demonstrated an adjusted relative risk reduction of 79% ($p<0.001$) in all-cause hospitalization for more than 24 hours or death due to any cause by Day 29 compared to placebo, meeting the primary endpoint of the trial.

PROTECT-V: Sotrovimab is being evaluated in a Phase 3 platform trial sponsored by Cambridge University Hospitals NHS Foundation Trust assessing the use of a 2 g IV dose of sotrovimab in uninfected, high-risk individuals. This is a randomized, double-blinded, placebo-controlled trial that is currently enrolling participants. The primary endpoint is PCR-confirmed symptomatic COVID-19 infection at three months. Key secondary endpoints include PCR-confirmed symptomatic COVID-19 infection at subsequent timepoints, time to confirmed SARS-CoV2 infection, safety, mortality and disease severity. Due to significant uncertainty in the anticipated infection rate, the sample size will be monitored and reviewed regularly by the independent Data Monitoring Committee (IDMC). Timing of initial data will depend on continued rate of enrollment.

RECOVERY: Sotrovimab is being evaluated in a randomized, controlled, open-label, platform trial assessing several possible treatments in patients hospitalized with COVID-19 in the U.K. Trial participants who are hospitalized with COVID-19 are eligible for random assignment in a 1:1 ratio to usual standard of care alone versus usual standard of care plus a single dose of sotrovimab given IV. Timing of initial data will depend on continued rate of enrollment.

Vaccine for HIV Prophylaxis

Summary

We are developing a vaccine to prevent HIV. We have designed VIR-1111 and VIR-1388 to elicit T cells that recognize HIV epitopes that are different from those recognized by prior HIV vaccines and to stimulate a different and specific type of T cell immune response to HIV, known as an HLA-E restricted immune response. An HLA-E restricted immune response has been shown to be associated with protection of NHPs from SIV. In December 2020, we initiated a Phase 1 trial for VIR-1111. VIR-1111 is a proof of concept vaccine, because, at minimum, changes to the vaccine antigen from HIV will be required before starting subsequent phases of clinical development. VIR-1388 has incorporated modifications that have the potential to enhance immunogenicity compared to VIR-1111 and provide broader coverage against circulating strains of HIV. We expect to initiate a Phase 1 trial of VIR-1388 in the second half of 2023.

Disease Overview and Limitations of the Current Standard of Care

According to UNAIDS, each year there are approximately 1.5 million new cases of HIV and approximately 700,000 HIV-related deaths globally. Unless treated, infection with HIV results in an almost universally fatal disease, acquired immune deficiency syndrome, or AIDS. According to the WHO, almost 36 million people have died from HIV-related illnesses globally.

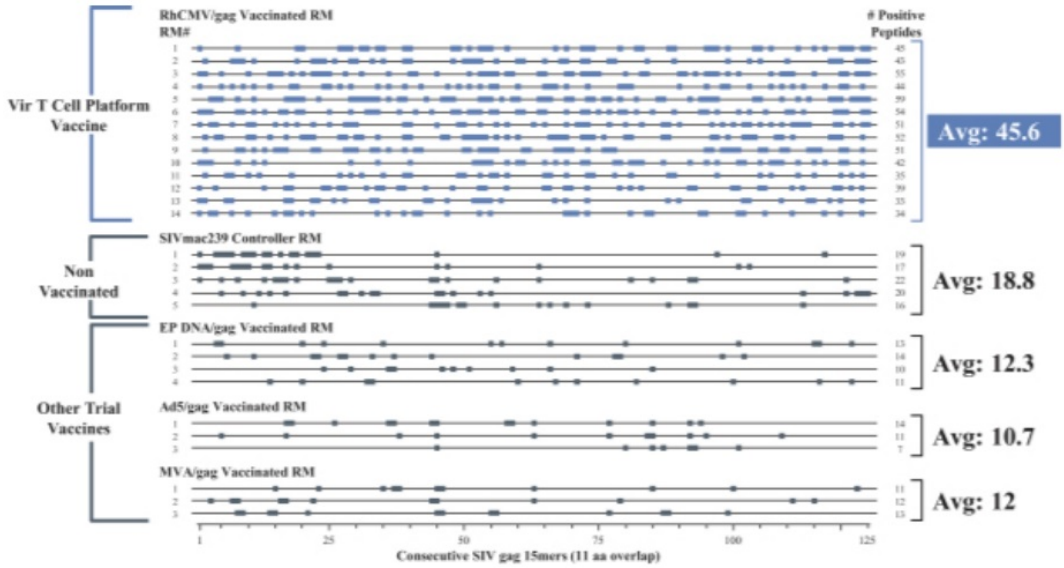
Highly effective HIV treatments are now available, but these medicines only suppress HIV and are not curative. They require life-long administration and carry the risk for viral breakthrough and resistance. Furthermore, while HIV prevention programs based on behavioral modification, pharmacological intervention, use of barrier devices and other methods continue to be developed, such approaches have had at most a modest effect on HIV transmission globally in high-risk populations. Therefore, we believe the most effective means of curbing the worldwide HIV epidemic would be a safe and effective vaccine for individuals who are or may become sexually active. We believe that the target population for an HIV vaccine is comprised of billions of individuals and is potentially larger than the target population for Gardasil®, a vaccine to prevent human papillomavirus and the cancers human papillomavirus cause, due to the higher lethality associated with HIV. In 2022, Gardasil® revenue approximated $6.9 billion. Despite nearly 30 years of intensive efforts, no vaccine for HIV has been successfully developed.

The projected size of the HIV functional cure and prevention market is >$40 billion annually.

VIR-1111 and VIR-1388 for HIV

Molecular Characteristics and Preclinical Data. VIR-1111 is a proof-of-concept T cell vaccine based on HCMV that is designed to elicit T cells that recognize parts of HIV epitopes that are different from those recognized by prior HIV vaccines, and to stimulate a different and specific type of T cell immune response to HIV, known as an HLA-E restricted immune response. VIR-1388 contains modifications to enhance its immunogenicity and provide broader coverage against circulating strains of HIV compared to VIR-1111. In NHP models, T cell vaccines based on an RhCMV elicited T cells that recognized 3-4 times the number of epitopes

compared to other vaccine platforms; the specific epitopes recognized were also different, as shown in the figure below. SIV is the NHP equivalent of HIV.

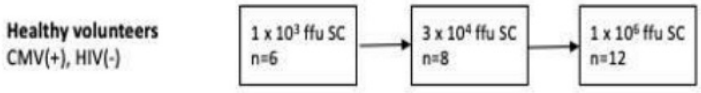


Number of epitopes recognized by T cells using RhCMV compared to other vaccine vector technologies or NHPs naturally achieving SIV control*. Each line represents a different NHP. Each box denotes the relative location of the epitope within the antigen that is recognized by the T cells elicited by that vaccine vector or SIV. The total number of epitopes recognized is shown on the right. RM = rhesus macaque; SIVmac239-controller = infected with a virulent strain of SIV; EP DNA/gag = electroporation of DNA expressing the SIV gag protein; Ad5/gag = Adenovirus type 5 expressing the SIV gag protein; MVA/gag = Modified vaccinia virus Ankara expressing the SIV gag protein.*

Further, in such NHP models, introducing different mutations to RhCMV allows the vector to be programmed to elicit an HLA-E restricted immune response. An HLA-E restricted immune response has been shown to be associated with protection of NHPs from SIV. In these series of experiments, large groups of NHPs were given an RhCMV-based vaccine, which protected more than 50% of the NHPs from repeated exposure to SIV.

Preliminary data suggest the ability to predict which NHPs will be protected from SIV after administration of the RhCMV-based vaccine. This is made possible using transcriptomic signatures, a blood test that evaluates how cells in the body respond to the vaccine. Transcriptomic signatures will be analyzed in human clinical trials. If protection effectiveness is found to be less than 100%, such data may allow us to predict who will be protected as well as to generate next-generation vaccines.

Phase 1 Trial of VIR-1111. The trial is a multiple ascending dose clinical trial designed to evaluate the safety, tolerability, reactogenicity and immunogenicity of VIR-1111 in CMV-positive healthy adult volunteers. The immunogenicity evaluation includes an assessment of the breadth and nature of the T cell response to the vaccine. The current trial design of VIR-1111-2001 is shown below. We initiated a Phase 1 clinical trial for VIR-1111 in December 2020. In November 2022, we announced that safety and immunology data from the initial two cohorts of the trial showed no safety signals and no vector shedding or viremia reported to date. In addition, no sustained HIV insert-specific T cell responses were observed in the first two cohorts. Safety and immunology data from the highest dose cohort is expected in the first half of 2023. The manufacture and early clinical development of VIR-1111 is funded by the Bill & Melinda Gates Foundation. Modifications to VIR-1111 will be required before subsequent phases of clinical development, as VIR-1111 is a proof of concept vaccine and will not in its current format result in a commercial product.



VIR-1111-2001 is a multiple ascending dose escalation trial in CMV seropositive, HIV uninfected healthy adult volunteers. *Arrows indicate trial progression. CMV = cytomegalovirus, HIV = human immunodeficiency virus, SC = subcutaneous, ffu = focus forming units*

Phase 1 Trial of VIR-1388. Learnings from VIR-1111 have informed the trial design of VIR-1388. We expect to initiate a Phase 1 trial of VIR-1388 in the second half of 2023. This trial will be funded in part by the Bill & Melinda Gates Foundation and the NIH's Division of AIDS, through the HIV Vaccine Trials Network.

Technology Platforms

Platforms for the Creation of Transformative Medicines for Infectious Diseases

We have purposefully assembled a portfolio of technology platforms that we believe will, individually or in combination, allow us to stimulate and enhance the immune system in innovative ways and to exploit the vulnerabilities of pathogens. Our current platforms are focused on antibodies, T cells, the innate immune response and siRNAs. We have assembled these platforms through internal development, collaborations and acquisitions. We are using our platforms, and continue to evaluate others, to advance our current product candidates and generate additional product candidates for multiple indications.

We follow the science to select the modality, or combination of modalities, that gives us the highest chance of success for a specific infection in a given patient population. The diversity of our different platforms allows us to select the best modality or modalities for a given clinical need.

Antibody Platform

Overview

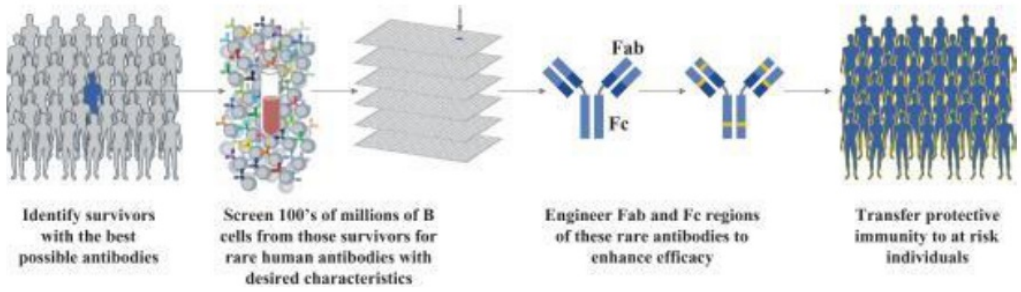
We are using specialized mAbs to treat or prevent rapidly evolving and/or previously untreatable pathogens. These mAbs act in a variety of ways, including direct pathogen neutralization and immune system stimulation. We combine high-throughput, rapid isolation of rare, highly potent, broad-spectrum and fully human antibodies with targeted engineering to enhance their therapeutic potential. We expect that these specialized mAbs can be administered to transfer protective immunity to all at-risk individuals.

We expect the following benefits from our antibody platform:

- Effective regardless of an individual's ability to generate their own immune response
- Diminished likelihood of self-reactivity because they are selected in humans
- Broad coverage of most or all strains of a pathogen, or even multiple pathogens
- High affinity binding to conserved pathogen antigens, resulting in a high barrier to resistance
- Longer half-life than naturally occurring antibodies
- Potential to induce a vaccinal effect, i.e., to elicit continued protection even after the mAb is no longer present

Sotrovimab (previously VIR-7831), VIR-3434 and VIR-2482 were generated using our antibody platform.

Our Approach



We use a proprietary antibody screening technology that allows us to characterize the antibodies produced from hundreds of millions of B cells derived from survivors of an infection to identify those rare antibodies that have the characteristics needed to create an effective medicine. Rare characteristics include, for example, the ability to bind to a highly conserved antigen within a pathogen and the ability to neutralize multiple different pathogens. We refer to this technology as High Throughput Isolation since we are able to screen hundreds of millions of B cells to find rare antibodies in just weeks.

Following isolation, we clone the antibody genes and express the resulting fully human antibody for further trials, engineering and development.

We have applied these methods to identify mAbs for a range of pathogens including SARS-CoV-2, HBV, HDV, influenza A and influenza B virus, Ebola, HIV, RSV, MPV, malaria, rabies, clostridium difficile, Staphylococcus aureus, Klebsiella pneumoniae, and Acinetobacter spp. Examples of the power of this platform are sotrovimab (previously VIR-7831; and where marketing authorization has been granted, marketed under the brand name Xevudy®), our anti-SARS-CoV-2 mAb, and Ebanga (ansuvimab-zykl, formerly known as mAb114), the anti-Ebola virus mAb identified by our scientists in collaboration with the NIH and others and marketed by Ridgeback Biotherapeutics LP.

Precision Antibody Engineering to Create the Best Medicines

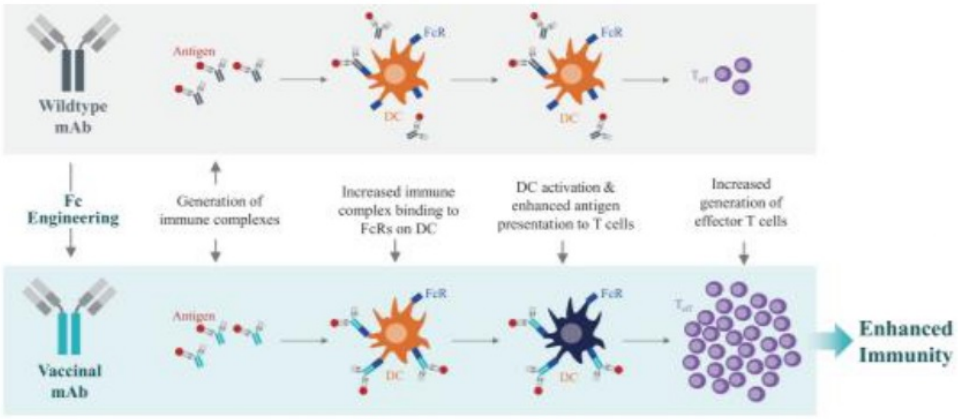
Our strategy is to optimize both the Fab and Fc domains of a mAb to generate the best medicine to treat or prevent infection. Having isolated a rare, fully human antibody via High Throughput Isolation, we then engineer as desired both parts of the mAb, the Fab and Fc domains, to enhance efficacy, potency and manufacturability. The Fab portion binds to the protective antigen on the pathogen. The Fc portion binds to effector proteins and cells in the body to engage the immune system in killing and clearing the infection.

Fab engineering is performed to further increase mAb potency and breadth of coverage. mAb potency and breadth are based on the epitope bound, affinity of binding and valency. In some cases, it may be valuable to create mAbs that bind to more than one epitope, so-called “multi-specific” mAbs, by engineering the Fab region. There are many approaches to creating multi-specific antibodies, and we are exploring a number of them, including some that naturally occur in people. We believe that naturally occurring multi-specific antibodies can be leveraged to create new and potent therapeutics and to enhance antibody prophylaxis of disease, and have the potential for higher manufacturing yields and better pharmacokinetics in patients, as compared to artificial multi-specific formats currently being developed.

Fc engineering selects and optimizes the specific ways in which mAbs engage Fc receptors, or FcRs, which in turn govern “effector functions” such as the half-life of the antibody and the way that the immune system is recruited by the mAb to fight infection. Effector functions can be enhanced or reduced via Fc mutations that alter the binding affinity of the Fc domain of a mAb to the various FcRs, based on a detailed understanding of the role of individual FcRs in half-life and immunity. Examples of immunity that can be altered in this way include the recruitment of serum proteins to infected areas, phagocytosis and destruction of viruses and viral particles, the killing of virus-infected cells through a process known as ADCC and the presentation of antigens to elicit B and T cell immunity.

Antibodies as T Cell Vaccines

We are using Fc engineering to create antibodies that are designed to not only directly treat or prevent infection but also to immunize an infected individual against future infections. We refer to this property as a vaccinal effect, i.e., eliciting continued protection even after the mAb is no longer present. This technology benefits from the fact that FcRs on specialized antigen-presenting cells, which are called dendritic cells, or DCs, internalize complexes of antibody and antigen. Our strategy leverages the observation that different FcRs on antigen presenting cells can bind different parts of the Fc portion of the mAb. By engineering the Fc region, we can select which FcRs interact with the antibody-antigen complex to generate activated DCs that we believe can effectively induce T cell immunity.



Design and mechanism of vaccinal antibodies intended to induce enhanced immunity through induction of T cells. *The Fc portion of mAbs interacts with FcRs on DCs to trigger uptake of antigen and induction of T cells. Engineering of the Fc portion of the mAb is predicted to increase the induction of T cells by these DCs.*

Specific vaccinal mutations in the Fc domain can enhance immune responses to a pathogen in two ways. First, the mAb can deliver increased amounts of antigen to DCs. Second, FcRs deliver signals that activate DCs. In turn, activated DCs can stimulate T cells specific to the delivered antigen, resulting in T cell immunity. In this way, an antibody with vaccinal mutations can potentially actively immunize infected patients. The in vivo data supporting enhancement of the vaccinal effect through Fc mutants has been demonstrated by others in a CD20 positive tumor model, using mice with humanized Fc receptors. In this experiment, anti-CD20 mAbs and CD20 tumor cells were administered to mice months before being later rechallenged with a lethal dose of CD20 tumor cells. 80% of the mice who received a mAb with Fc mutants that enhanced binding to activating FcRs IIa and IIIa survived. Conversely, 70% or more mice who received a mAb without the enhancing Fc mutations died. This durable protection is believed to be the result of the induction of a T-cell response. We have also generated similarly compelling animal data in influenza. We are testing this technology in chronic HBV infection with VIR-3434, and if it performs as expected, we believe it may have applicability to multiple other infections including influenza and HIV.

T Cell Platform

Overview

T cells can prevent or control infection and cancer. T cells are diverse in how they sense pathogens and cancer cells, the tissues that they protect and the effector functions that they use to control infection or cancer. Our approach is to use HCMV as a vaccine vector to potentially treat and prevent infection by pathogens refractory to current vaccine technologies because HCMV may induce potent and long-lasting T cell responses to a broader range of epitopes than observed for other viral vaccines. In addition, we can make proprietary modifications in the HCMV genome that we expect will elicit different types of pathogen-appropriate T cell responses. Experiments in NHPs demonstrate the ability of vaccine vectors based on the closely related RhCMV to protect against SIV, a close relative of HIV, and TB, two of the most challenging infections for which to create effective vaccines.

HCMV infects a large proportion of the human population and causes a life-long asymptomatic infection that typically causes no harm. This is due to millions of years of co-evolution between the virus and host in which the virus evades sterilizing immunity using specialized viral genes, while at the same time allowing the generation of certain T cell responses that prevent HCMV infection from becoming lethal.

We expect the following benefits from our T cell platform:

- Highly potent and long-lived T cell responses throughout the body
- Induction of high numbers of specialized T cells, known as effector memory cells, that allow control of disease in the first few days after infection
- Immune responses to three- to four-fold more antigenic epitopes in a target protein than other viral vectors
- Programmable T cell responses allowing selection of the type of T cells elicited

- Generation of universal T cells that may be active in most or all people despite high genetic variability between people in immune response genes
- Opportunity for repeated vaccination using the same backbone HCMV vector against different infections
- Opportunity to use the same vaccine to protect against multiple pathogens
- Potential to induce responses even to proteins that the host is tolerant of, such as self-proteins expressed in a tumor

VIR-1111 and VIR-1388 were generated using our T cell platform.

Our Approach

We believe that the type of T cell response elicited by an HCMV-based vaccine vector can be selected by mutating certain genes in HCMV. We term this approach “immune programming.” We believe that immune programming is critical to combatting infections such as HIV and TB that have proven intractable, to date, for other vaccine technologies.

Immune programming is best understood in the context of the normal processes that elicit T cell immunity. T cells that fight infection and cancer are elicited by DCs, as well as other types of cells. The elicited T cells detect small peptide fragments from antigens on the surface of DCs and other antigen presenting cells, which have been captured in grooves found within specialized proteins encoded by major histocompatibility complex, or MHC, genes.

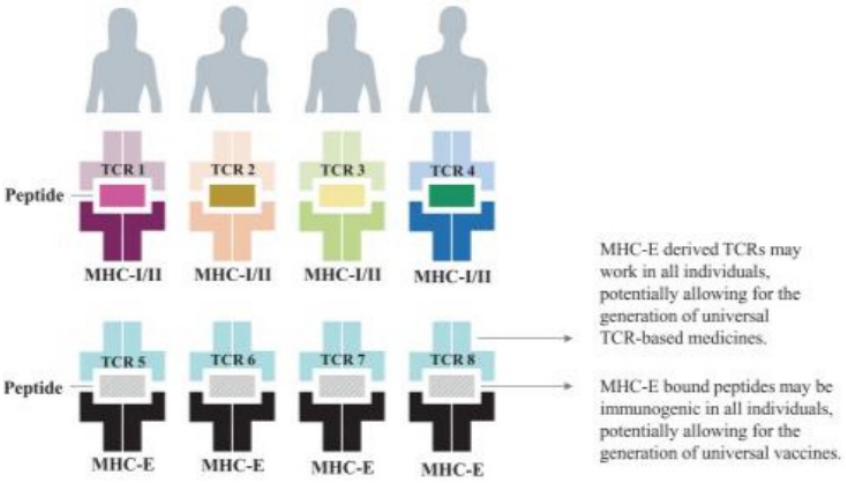
The unique immunology of HCMV depends on the virus’s ability to regulate the normal immune processes of antigen presentation by MHC genes. HCMV contains multiple genes that regulate many of the steps in antigen presenting cells that elicit T cell immunity by altering antigen presenting cell biology, the types of antigen presenting cells infected by the viral vaccine and the mechanisms responsible for the ability of a T cell to recognize antigens together with MHC molecules. Through manipulation of the HCMV genome, we believe we can program different types of pathogen-appropriate T cell responses.

MHC-E as a Near-Universal Target for Medicines that Leverage T Cell Receptors

T cells need to be able to recognize a highly diverse set of pathogen proteins to be effective. This diversity comes from the use of multiple different host immune response MHC genes to present foreign antigens to T cells. Some immune response MHC genes are highly variable between individuals, while others are less variable between individuals as illustrated below. The immune response MHC genes that are highly variable between individuals are responsible for most T cell responses. These MHC molecules enable T cells to recognize foreign proteins through the use of a highly specialized T cell receptor, or TCR, on the T cell surface.

An important consequence of the inter-individual variation in some immune response MHC genes is that a TCR that recognizes an antigenic peptide associated with one person’s MHC molecules could attack even normal tissues of a person with different MHC genes. As a result, identifying universal TCRs and universal T cell antigens that work in all people has been very challenging.

Our T cell platform may enable us to create vaccines or other types of medicines that are near universal in their effects on human immunity. The programmed T cell responses elicited by engineered HCMV vectors are predicted to use immune response MHC genes that vary minimally between people, instead of the highly variable immune response MHC genes targeted by other types of vaccines. As demonstrated by the graphic below, TCRs recognizing antigenic peptides together with MHC-E may be functional in all individuals, potentially allowing for the generation of universal TCR-based medicines, such as off-the-shelf cancer cell therapy. The peptides presented by MHC-E may be immunogenic in all individuals, potentially allowing for the generation of universal infectious disease and cancer vaccines.



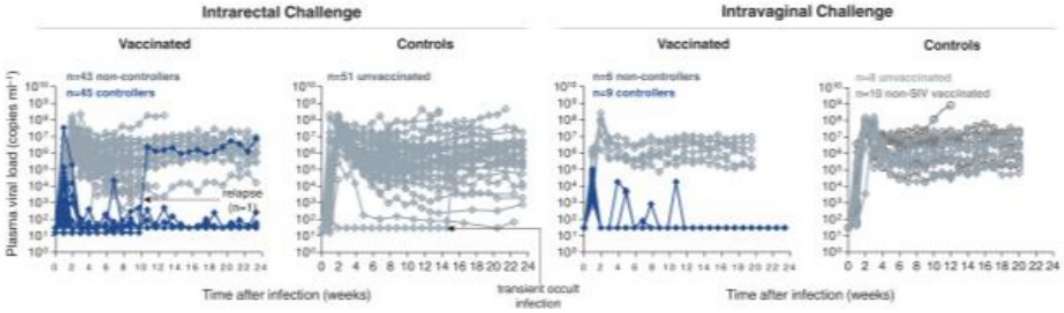
Comparison of standard T cell responses to MHC-E responses*. Peptides that are bound to MHC-I, -II or -E proteins are expressed on cell surfaces where they are recognized by T cell receptors on T cells (TCRs). This interaction results in the expansion of T cells that can recognize diverse antigen peptides (top row) and that carry out functions that protect the host. Since MHC-I and MHC-II molecules are highly variable between people, peptide presentation to TCRs has a high degree of individual specificity, as illustrated by the different colors of each peptide in the top row. In contrast to MHC-I and MHC-II, MHC-E proteins (bottom row) are conserved in the human population.*

Specifically programmed RhCMV vectors can elicit strong T cell responses that target MHC molecules which vary minimally between NHPs. One such protein is MHC-E. The fundamental discovery, by some of our founders, that enables this part of our T cell platform is that RhCMV responses can be programmed to generate abundant MHC-E-restricted T cells.

We believe that using our T cell programming approach will allow us to select vaccine antigens and to identify TCRs that work across the human population. An example of a use of such a TCR would be creating a biological product that specifically recognizes infected cells in all individuals.

Programming T Cell Responses to Create HIV and TB Vaccines

Two of the most challenging infections for vaccine development are HIV and TB. Preclinical studies have demonstrated that programmed RhCMV vectors can be used to vaccinate against either SIV or TB in NHPs. For example, as shown in the figure below, in an NHP study, an MHC-E programmed RhCMV vaccine effectively protected more than half of NHPs from infection when challenged with a highly virulent form of SIV, under conditions in which all animals in the control group became infected. SIV vaccines programmed in other ways were not protective, demonstrating the potential value of having a programmable T cell vaccine platform.



Primary data for the protective effects of RhCMV-derived T cell vaccines on SIV infection*. Rhesus monkeys were vaccinated with an RhCMV vaccine that elicits CD8 T cells recognizing SIV peptides presented by MHC-E and MHC-II or a control before challenge with SIV by rectal or vaginal routes. SIV genome copies were measured in peripheral blood (vertical axis) at intervals*

after challenge (horizontal axis). SIV infection was cleared in approximately 51% of intrarectal challenged animals and approximately 60% of intravaginal challenged animals while the infection was progressive in all unvaccinated controls.

Protection has also been observed against TB in preclinical studies of NHPs after immunization with either of two different RhCMV vaccines. One of the protective vaccines was programmed to elicit MHC-II and MHC-E responses, while the other was programmed to elicit a response depending on MHC-I genes. This shows the potential significance of being able to specifically program a T cell vaccine to target a given infection, as the programming of a vaccine to protect against SIV can be different from the programming of a vaccine to protect against TB. These preclinical data support our plans to use our T cell platform to vaccinate against HIV and TB.

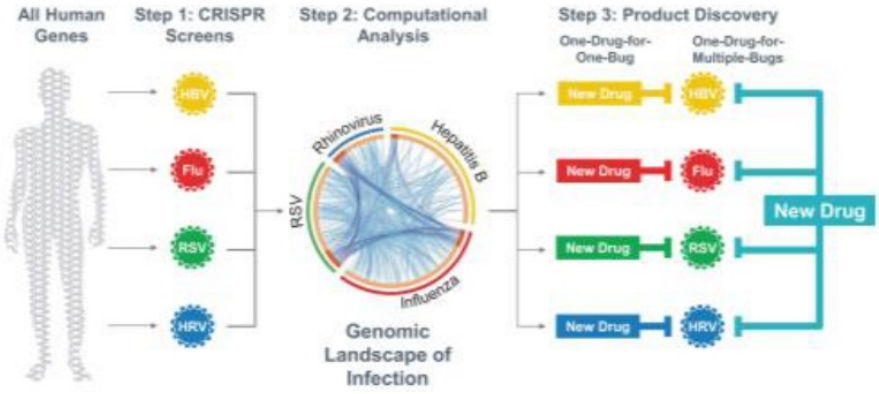
The Bill & Melinda Gates Foundation is providing funds for the process development and manufacturing and early clinical development of our HIV and TB vaccine programs. If proof of concept for the potential efficacy of our T cell vaccine platform is obtained in currently planned clinical trials, we plan to apply this T cell platform for treating additional types of infections, as well as potentially even cancers.

Innate Immunity Platform

Overview

Innate immunity protects us during the early stages of infection until antibodies and T cells can be generated by the immune system. Importantly, innate immunity is not pathogen-specific. We believe that we can target innate immunity to create medicines that break the “one-drug-for-one-bug” paradigm by producing “one-drug-for-multiple-bugs.” We term this concept “host-directed therapy” because the medicine would target a host protein instead of pathogen proteins, which are the target of standard antibiotics and antivirals. We can also identify proteins that are critical for a high priority infection, such as HBV, for which host-directed therapy might be part of a functional cure or complete cure. This platform may also identify targets relevant to diseases outside of infection.

Our scientists have developed and applied cutting-edge CRISPR-based genetic technologies to identify host genes that regulate innate immunity and/or pathogen replication. We have built internal capacity to systematically extend such trials to multiple pathogens and multiple aspects of innate immunity. We have joined the Broad Institute’s Functional Genomics Consortium, which provides us access to cutting-edge CRISPR reagents and computational services for whole-genome and custom-designed genetic screens.



Design of steps in our innate immunity platform*. We are systematically mapping the genes that regulate pathogen control across a diverse set of pathogens. To accomplish this, advanced gene editing technology (CRISPR) is used to create cell libraries in which individual genes are either knocked out or activated. By exposing these cell libraries to pathogens of interest, under different screening conditions, we can systematically create genomic maps that identify genes that could lead to pathogen control. By computationally comparing these genomic maps, genes or pathways that are common to multiple pathogens can be identified and could lead to the development of products that could treat more than a single pathogen. Human rhinovirus = HRV.*

We expect the following benefits from our innate immunity platform:

- Enhancement of the potency of innate immunity, allowing for control of multiple unrelated pathogens
- High barrier to resistance since the targeted host protein is not likely to mutate
- Identification of key host targets in areas outside of infectious disease

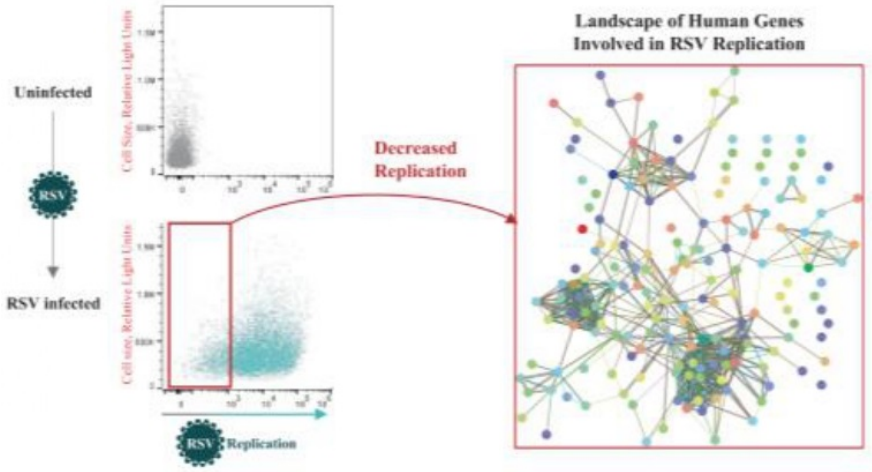
Our Approach

Our innate immunity platform envisions three steps leading to new medicines, as illustrated in the figure above.

Step 1: CRISPR Screens to Map the Genomic Landscape of Infection and Innate Immunity

Multiple types of proteins participate in innate immunity and infection, as they may be required for entry, replication, gene expression, pathogenicity and/or innate immune control of an infectious agent.

To identify such proteins, we screen CRISPR-derived cell libraries after infection, treatment with cytokines that trigger innate immunity, or both, and then select cells with desired properties. Using next-generation sequencing, we identify genes responsible for the desired property. By combining these data across screens and across pathogens, our team has created, and is continuously expanding, a proprietary database of the genomic landscape of infection and innate immunity.



CRISPR screen for genes involved in RSV replication*. A CRISPR cell library was prepared in cells in which RSV can replicate. After a period of infection with an RSV strain expressing a fluorescent protein which serves as a surrogate for viral replication, cells were separated using flow cytometry into populations in which RSV replication was decreased or increased. Deep sequencing of the population exhibiting decreased replication compared to control revealed candidate genes required for efficient replication. Computational analysis represented on the right panel revealed that some of these genes fall into nodes that function in specific cellular processes. These nodes are represented as dots interconnected with a dense network of lines.*

As an example, to identify genes required for RSV growth, we performed a screen in which a CRISPR-generated cell library was infected with RSV, as shown in the figure above. We then purified and sequenced populations exhibiting low or high RSV growth. Sequencing of the RSV low population revealed genes potentially required for RSV infection. When analyzed computationally, these genes fell into sets involved in specific cellular processes. These genes are potential targets for product candidates. We performed a similar screen with the influenza A virus and HRV and found that certain genes are shared between RSV, influenza A virus and HRV. Targeting such proteins might result in a pan-respiratory virus product candidate capable of treating RSV, influenza A virus and HRV.

The result from this step of the innate immune platform is a continuously updated database of the genomic landscape of pathogen replication and innate immunity. We have already performed multiple screens, and additional screens and target validation trials are in progress.

Step 2: Computational Analysis for Identification of Product Targets

Results from CRISPR screens provide the critical data that helps identify host targets necessary for a given pathogen. When creating a single drug for multiple pathogens, host targets in common among multiple pathogens are identified. After having identified the critical set of host targets necessary for a pathogen or pathogens, the specific target for a new medicine is selected by computationally integrating diverse data sets that account for tissue gene expression, human genetic variation, redundancies in cellular pathways and protein-protein interaction networks, among other factors.

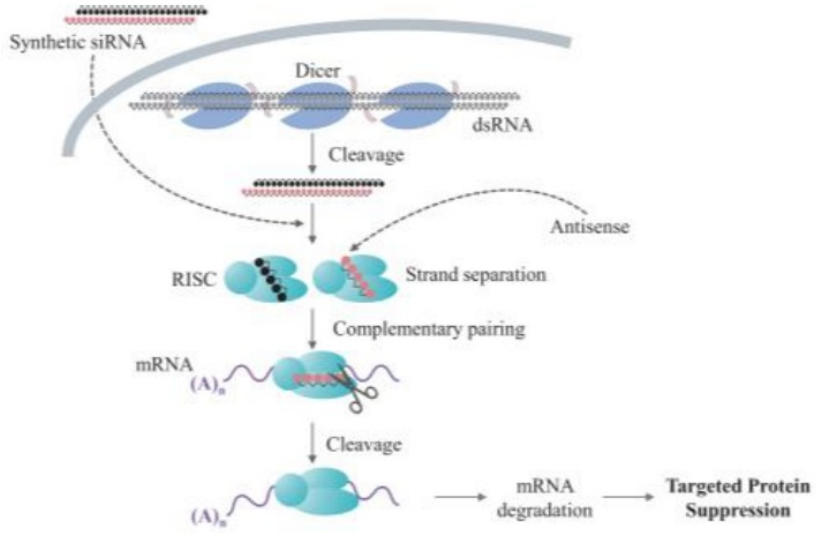
Step 3: Product Discovery

Once a specific target has been chosen, the modality used to disrupt the function of the target is then selected. Potential modalities may include small molecules, antibodies or siRNAs. Standard drug discovery efforts are then applied to identify a lead product candidate. Alternatively, machine learning and database mining can be used to identify pre-existing chemical matter that is already known to inhibit an identified host target. This chemical matter can then be verified as having anti-pathogen activity, and serve as a lead compound. There are two potential outcomes from Step 3: one-drug-for-one-bug and one-drug-for-multiple-bugs.

siRNA Platform

Overview

Gene expression can be altered by two main types of synthetic oligonucleotides: (i) antisense oligonucleotides; and (ii) siRNAs. We believe that our current approach leveraging siRNAs may have safety and potency advantages over antisense oligonucleotides. The first FDA-approved siRNA in the United States was ONPATTRO® (patisiran), which was developed by our collaborator, Alnylam.



Mechanism of siRNA action to regulate gene expression*. Intracellular double stranded RNA, or dsRNA, is processed by the "dicer" complex to produce siRNAs that become integrated into a multi-subunit protein complex, the RNA-induced silencing complex, or RISC, which guides the siRNAs to the target messenger RNA, or mRNA, sequence. The siRNA duplex unwinds, and the antisense strand remains bound to RISC and directs site-specific cleavage of the target complementary mRNA sequence, resulting in mRNA degradation and reduced expression of the target protein. (A)n = polyadenylation.*

siRNAs act via an RNA interference, or RNAi, mechanism involving sequence-specific knockdown of target RNAs. Our bodies create their own so-called endogenous siRNAs, which act via the RNAi mechanism. This RNAi mechanism can be exploited by chemically synthesizing synthetic siRNAs that are introduced as medicines to knock down target RNAs that express pathogen or host proteins of interest. Pursuant to our collaboration and license agreement with Alnylam, we have an option to license Alnylam's siRNA technology for use in up to four other infectious disease targets in addition to VIR-2218 for HBV. See the section titled "Our Collaboration, License and Grant Agreements" for a description of the collaboration and license agreement.

We expect the following benefits from our siRNA platform and siRNAs generally:

- Cutting-edge siRNA design, through collaboration with Alnylam
- Direct anti-pathogen activity and potential for immunomodulation
- Diminished off-target siRNA effects via use of next generation ESC+ technology as a differentiator compared to other siRNA approaches, which has the potential to increase the therapeutic index
- Efficient targeting of siRNAs to the liver using GalNAc technology

- Extended effects of siRNA may last for weeks to months in humans

VIR-2218 was generated using our siRNA platform.

Our Approach

We have elected to develop modified siRNAs initially for infectious diseases of the liver because these product candidates can be administered subcutaneously, are highly stable in the blood stream and are efficiently delivered into hepatocytes via GalNAc sugar modification. Once in a liver cell, the siRNA can act to reduce pathogen or host gene expression. Such siRNAs can be further modified to reduce off-target activity, and potentially increase the therapeutic index. Since October 2017, we have collaborated with Alnylam to leverage this validated technology, with the goal of eliminating key host factors necessary for pathogen survival and removing microbial immune countermeasures.

We believe that HBV persists in part due to the expression of viral proteins such as HBsAg, which potentially inhibit antibody, T cell, and innate immune responses. This prevents the immune response from clearing HBV. By inhibiting the expression of these viral proteins, we envision enhancing immune function in persistently infected individuals. Furthermore, we believe that combining siRNA therapy with products derived from our other platforms, including antibodies, T cells and innate immune modulators, may allow us to rapidly advance a functional cure for HBV and a chronic treatment for HDV as well.

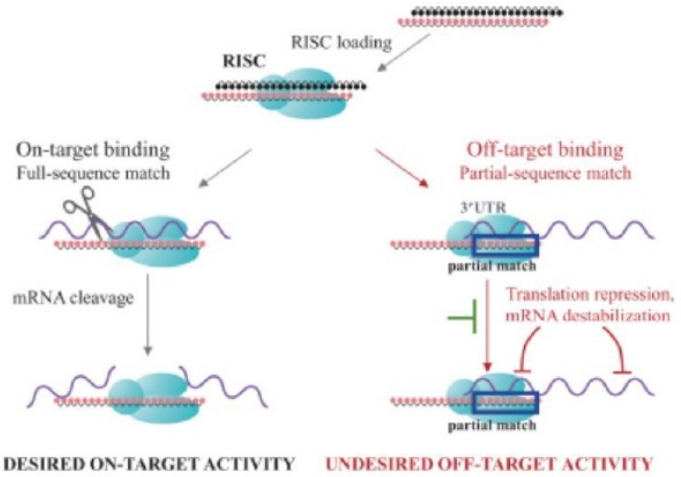
siRNA Delivery Mechanism

Since unmodified synthetic siRNAs can be unstable in the blood stream, methods to stabilize synthetic siRNAs have been pioneered by Alnylam including using their ESC technology.

An approach that has been used successfully to deliver siRNA to liver cells is to conjugate siRNAs to a specific sugar known as a GalNAc, whose receptor is exclusively expressed at high levels on hepatocytes, allowing for uptake of large quantities of siRNA into hepatocytes. Importantly, a GalNAc-conjugated siRNA can be delivered to the liver by subcutaneous injection, making administration relatively simple.

Potentially Enhancing the Therapeutic Index by Diminishing Off-Target Activity of siRNAs

A distinguishing characteristic of VIR-2218 siRNA, and of future siRNAs that we may develop with Alnylam, is the application of a new approach to diminish off-target effects of RNAi. siRNAs may cause unwanted alterations to non-target host RNAs, a process known as off-target activity, which can result in short- or long-term toxicity. To reduce off-target activity, which is thought to be due in part to microRNA, or miRNA, activity, it is necessary to preserve the RNAi activity of an siRNA while simultaneously decreasing its miRNA activity, as shown in the figure below. Alnylam scientists have pioneered placement of a modified nucleotide called a glycol nucleic acid, or GNA, into the part of the siRNA that generates miRNA-like activity. GNA modification has been shown to reduce miRNA activity, while preserving the RNAi activity of siRNA. The combination of GNA modification and other chemical modifications that enhance siRNA stability is called ESC+ technology. In animal models, reducing off-target miRNA activity can result in an increased therapeutic index of approximately five-fold. A higher therapeutic index has the potential to allow for higher siRNA doses and/or a longer duration of therapy, while maintaining a favorable safety profile. VIR-2218 was the first siRNA to enter the clinic with ESC+ technology.



On-Target and Off-Target Activity of siRNA*. siRNAs can have off-target activity when siRNA binds to mRNA with a partial sequence match, leading to translation repression or mRNA destabilization of unrelated messages (right side). This contrasts with the intended on-target activity of an siRNA, which binds to an mRNA through a match to the entire sequence, leading to mRNA cleavage (left side). mRNA = messenger ribonucleic acid; RISC = ribonucleic acid-induced silencing complex.*

Our Collaboration, License and Grant Agreements

Collaboration Agreements with GSK

2020 Collaboration Agreement with GSK

In June 2020, we entered into a definitive collaboration agreement with GSK, or the 2020 GSK Agreement, pursuant to which we agreed to collaborate to research, develop and commercialize products for the prevention, treatment and prophylaxis of diseases caused by SARS-CoV-2, the virus that causes COVID-19, and potentially other coronaviruses. The collaboration initially focused on the development and commercialization of three types of collaboration products under three programs: (1) antibodies targeting SARS-CoV-2, and potentially other coronaviruses, or the Antibody Program; (2) vaccines targeting SARS-CoV-2, and potentially other coronaviruses, or the Vaccine Program, and (3) products based on genome-wide CRISPR screening of host targets expressed in connection with exposure to SARS-CoV-2, and potentially other coronaviruses, or the Functional Genomics Program. The initial antibodies under the Antibody Program are sotrovimab (previously VIR-7831) and VIR-7832.

The original 2020 GSK Agreement contained the following key terms. For a period of four years beginning April 2020, the parties agreed to conduct certain research and development activities under mutually agreed development plans and associated budgets for each of the three programs, and under the oversight of a joint steering committee, or JSC. During such period, generally, subject to certain rights granted to WuXi Biologics (Hong Kong) Limited, or WuXi Biologics, under then existing agreements between us and WuXi Biologics, the parties would have an exclusive research collaboration with respect to antibody products directed to SARS-CoV-2 or to any other coronavirus, and in connection with functional genomics CRISPR screens for drug discovery and development in connection with SARS-CoV-2 or other coronaviruses. We are primarily responsible for the development and clinical manufacturing activities for the Antibody Program, and for conducting the initial development activities directed to a vaccine in the Vaccine Program. GSK is primarily responsible for the commercialization activities for the Antibody Program (except in connection with sales of antibody products licensed to WuXi Biologics in mainland China, Hong Kong, Macau and Taiwan), the later-stage development, manufacturing and commercialization activities for the Vaccine Program and the development, manufacturing and commercialization activities for the Functional Genomics Program. We and GSK are required to use commercially reasonable efforts to conduct the activities assigned to each party under each development plan and to seek and obtain regulatory approval for collaboration products that arise from such activities in the United States and specified major markets. Subject to an opt-out mechanism, we and GSK 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 the antibody products, 27.5% of such costs for the vaccine products, and we and GSK sharing equally all such costs for the functional genomics products, and all profits will be shared in the same ratios. If we and GSK elect to conduct a technology transfer of manufacturing technology under our agreement with WuXi Biologics (as further described below), we will bear 72.5% of the costs related to such manufacturing technology transfer and for commercial manufacturing of the antibody products under such agreement with WuXi Biologics, and GSK will bear 27.5% of such costs. The parties will also share the committed costs for the reservation of manufacturing capacity for the drug substance for antibody products in the foregoing ratio under our agreement

with Samsung as well as such costs relating to committed manufacturing capacity for antibody products as are approved by the JSC from time to time.

On a collaboration product-by-collaboration product basis, each party has the one-time right, at specified points in development, to opt out of its co-funding obligations, and the other party may, at its election, either pursue such program unilaterally, or also cease research and development activities and funding of such collaboration product. If the opt-out provisions are not exercised by either party subject to the terms of the 2020 GSK Agreement, the parties share all profits and losses arising from any collaboration product in the same ratios in which the parties bore development costs for such collaboration program. For each collaboration product as to which a party exercises its opt-out right, the commercializing party pays to the opt-out party royalties on net sales of the applicable collaboration product at rates based on factors such as the stage of development of such collaboration product at the time the opt-out party exercises such right, and whether the opt-out party is the lead party, or a portion of the sublicense revenue if the commercializing party chooses to sublicense or otherwise divest rights to such collaboration product. On an antibody product-by-antibody product basis, we have a co-promotion right for such antibody product in the United States, under which we have the right to perform up to 20% of details in connection with such antibody product. GSK will lead commercialization and book all sales and is required to use commercially reasonable efforts to commercialize each collaboration product following regulatory approval in the United States and specified major markets. This definitive agreement superseded and replaced the April 2020 preliminary agreement with GSK. 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, or GGL, an affiliate of GSK, at a price per share of $37.73, for an aggregate purchase price of approximately $250.0 million.

The 2020 GSK Agreement as amended will remain in effect with respect to each collaboration program for as long as there is a collaboration product being developed or commercialized by the lead party, or the non-opt-out party, in such program. Either party has the right to terminate the 2020 GSK Agreement in the case of the insolvency of the other party, an uncured material breach of the other party with respect to a collaboration program or collaboration product, or as mutually agreed by the parties.

In December 2021, Beecham S.A. assigned and transferred all its rights, title, interest, and benefit in the 2020 GSK Agreement to GlaxoSmithKline Biologicals S.A., including all its rights to bring claims under such agreement.

On May 27, 2022, we entered into Amendment No. 1 to the 2020 GSK Agreement, or Amendment No. 1. Pursuant to Amendment No. 1, we and GSK acknowledged that the antibody products that had been licensed to WuXi Biologics in mainland China, Hong Kong, Macau and Taiwan and had reverted to us pursuant to the Termination Agreement (described below) and agreed with GSK that they are now included in and governed by the 2020 GSK Agreement, subject to certain amendments relating to sotrovimab.

Under the terms of Amendment No. 1, GSK has the sole right to develop (including to seek, obtain or maintain regulatory approvals), manufacture and commercialize sotrovimab in and for mainland China, Hong Kong, Macau and Taiwan at GSK's sole cost and expense (other than certain payments for which we remain responsible under certain of our existing agreements with third parties). GSK paid us a one-time upfront payment of $7.0 million in consideration for the rights and licenses granted to GSK under Amendment No. 1. In addition, GSK will be obligated to pay us tiered royalties on net sales of sotrovimab in mainland China, Hong Kong, Macau and Taiwan in percentages ranging from the high teens to the low thirties. Such royalties are payable to us during the term of the 2020 GSK Agreement applicable to the Antibody Program.

On February 8, 2023, we and GSK entered into Amendment No. 2 and Amendment No. 3 to the 2020 GSK Agreement. Pursuant to Amendment No. 2 to the 2020 GSK Agreement, effective as of March 31, 2022, or the Effective Date, we and GSK agreed to remove the Vaccine Program from the 2020 GSK Agreement, and to wind down and terminate the cost-sharing arrangements and all ongoing activities in relation to the Vaccine Program. As of the Effective Date, the Vaccine Program had not yet advanced to its predefined development candidate stage. We retain 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, subject to certain deductions in certain circumstances. Pursuant to Amendment No. 3 to the 2020 GSK Agreement, we and GSK agreed to modify the Antibody Program to remove from the collaboration all coronavirus antibodies other than sotrovimab and VIR-7832, and certain variants thereof. Sotrovimab and VIR-7832, and certain variants thereof, remain subject to the terms of the 2020 GSK Agreement, and we retain 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, and subject to certain deductions in certain circumstances.

2021 Expanded GSK Collaboration

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

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. The 2021 GSK Agreement superseded and replaced the preliminary agreement entered into with GSK in February 2021, or the 2021 Preliminary Agreement.

For a period of three years following the effective date of the 2021 GSK Agreement, or the Research Term, the parties will conduct certain research and development activities under mutually agreed development plans and associated budgets for the programs within the expanded collaboration. Subject to certain exceptions, we will exclusively collaborate with respect to (a) all of our mAbs that the parties agree to develop for the prevention, treatment or prophylaxis of the influenza virus, until such time there are none of our mAbs being developed under the expanded collaboration, (b) functional genomic screens for targets associated with respiratory viruses during the Research Term, and compounds or products developed through the Expanded Functional Genomics Program directed to a collaboration target for five years following the target selection (unless either party elects to opt-out earlier), and (c) products directed to Selected Pathogens during the Research Term. We will be responsible for continuing the development and clinical manufacturing activities for VIR-2482 unless and until GSK exercises the Option. If GSK does not exercise the Option for VIR-2482, then, in general, we have the right to continue the development and/or commercialization of VIR-2482 by itself or with a third party. GSK will be the lead party for development, clinical and commercial manufacturing, and commercialization activities for products under the Influenza Program (other than VIR-2482 unless and until GSK exercises the Option, if applicable). We will mutually agree upon the allocation of responsibility for the development of products under the Expanded Functional Genomics Program, and for the development and early-stage manufacturing of products under the Additional Programs if and when GSK decides which Selected Pathogens to pursue. GSK will be primarily responsible for commercial manufacturing and commercialization activities for products under the Expanded Functional Genomics Program and Additional Programs, if and when selected by GSK. For each collaboration program, upon execution of the definitive agreement, we will grant GSK certain license rights related to the development, manufacturing and commercialization of products arising from the program.

The parties will share 50% of all development costs in accordance with the budget for each of the collaboration programs (other than for the Selected Pathogens and VIR-2482, unless GSK exercises the Option), with each party having the right (on a target-by-target, or collaboration product-by-collaboration product basis, as applicable) to opt-out of its co-funding obligations at specified points in development. In such case, the party continuing with the program will pay to the opt-out party a royalty on net sales of products arising from such program at specified rates based on the stage of development at which the opt-out is exercised. Following the exercise of an opt-out right by a party the other party may, at its election, either pursue development and commercialization of such product or program unilaterally, or also cease the conduct and funding of such collaboration product or program. In the absence of any opt-out, the parties will also share 50% of all profits and losses arising from any collaboration product. Each party is required to use commercially reasonable efforts to conduct the activities assigned to it under each development plan and, where applicable, to seek and obtain regulatory approval for collaboration products that arise from such activities in the United States and specified major markets. GSK will lead commercialization and book all sales, and is required to use commercially reasonable efforts to commercialize each collaboration product following regulatory approval in the United States and specified major markets.

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

In September 2022, GSK exercised its first Selected Pathogen Right, selecting RSV as its first pathogen under the Additional Programs of the 2021 GSK Agreement. GSK agreed to retroactively share the research and development costs that we had incurred under its RSV program since April 2022 in accordance with the applicable provisions of the 2021 GSK Agreement.

With respect to the Influenza Program and each Additional Program, unless earlier terminated, the 2021 GSK Agreement will remain in effect for as long as there is a product from such collaboration program being developed or commercialized by the lead party in the collaboration program or by the non-opt-out party, if applicable. With respect to the Expanded Functional Genomics Program, unless earlier terminated, the 2021 GSK Agreement will remain in effect (a) until the end of the Research Term, if no targets are selected for the Expanded Functional Genomics Program prior to the end of the Research Term, or (b) if at least one target is selected for the Expanded Functional Genomics Program prior to the end of the Research Term, for as long as there is a product from the Expanded Functional Genomics Program being developed or commercialized by the lead party in the Expanded Functional Genomics Program or by the non-opt-out party, if applicable. Either party has the right to terminate the 2021 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 a collaboration product, or as mutually agreed by the parties.

Collaboration and License Agreement with Alnylam

In October 2017, we entered into a collaboration and license agreement with Alnylam, or the Alnylam Agreement, for the development of siRNA products for the treatment of HBV and following the exercise of certain program options, the development and commercialization of siRNA products directed to up to four other infectious disease targets selected by us. The technology licensed under the Alnylam Agreement forms the basis of our siRNA technology platform.

Pursuant to the Alnylam Agreement, we obtained a worldwide, exclusive license to develop, manufacture and commercialize the HBV siRNA product candidates, including VIR-2218, for all uses and purposes other than agricultural, horticultural, forestry, aquaculture and other residential applications, such excluded fields, the Excluded Fields. In addition, Alnylam granted us an exclusive option, for each of the infectious disease siRNA programs directed to our selected targets, to obtain a worldwide, exclusive license to develop, manufacture and commercialize siRNA products directed to the target of each such program for all uses and purposes other than the Excluded Fields. Our options are each exercisable during a specified period following selection of candidates for each program, or two years following the initiation of certain activities under an agreed-upon development plan, if earlier. On a product-by-product basis for each product arising from the HBV and, following our option exercise, the infectious disease programs, Alnylam has an exclusive option, exercisable during a specified period prior to the initiation of a Phase 3 clinical trial for each such product, to negotiate and enter into a profit-sharing agreement for such product.

We and Alnylam were jointly responsible for funding the initial research and development activities for VIR-2218 through completion of proof of concept trials. Prior to the exercise of our option for each siRNA program directed to one of our selected infectious disease targets, Alnylam is responsible for conducting all development activities, at our expense, in accordance with an agreed-upon development plan. Following our exercise of an option for a program and payment of the program option exercise fee and any outstanding program costs due to Alnylam, we are solely responsible, at our expense, for conducting all development, manufacture and commercialization activities for products arising from each such program unless Alnylam exercises its profit-sharing option. We are required to use commercially reasonable efforts to develop and commercialize one siRNA product directed to HBV and one siRNA product directed to the target of each other infectious disease program for which we exercise our option, in each of the major markets. If Alnylam exercises a profit-sharing option for a product, we will negotiate the terms of such profit-sharing agreement, which will include sharing equally with Alnylam all subsequent costs associated with the development of such product, as well as the profits and losses in connection with such product, subject to reimbursement by Alnylam of a portion of specified development costs in certain circumstances.

We retain final decision-making authority with respect to which infectious disease product candidates we advance and the development programs for the HBV and infectious disease product candidates, subject to certain limitations. During the term of the Alnylam Agreement, neither we nor Alnylam may develop or commercialize any gene-silencing, oligonucleotide-based product directed to the same target as any product candidate under the Alnylam Agreement, other than pursuant to the Alnylam Agreement, subject to certain exceptions.

Pursuant to the Alnylam Agreement, we paid Alnylam an upfront fee of $10.0 million and issued to Alnylam 1,111,111 shares of our common stock. Upon the achievement of a certain development milestone, as further discussed below, we were obligated to issue shares of our common stock equal to the lesser of (i) 1,111,111 shares or (ii) a certain number of shares based on our stock price at the time such milestone was achieved. We will be required to pay Alnylam up to $190.0 million in the aggregate for the achievement of specified development and regulatory milestones by the first siRNA product directed to HBV, and up to $115.0 million for the achievement of specified development and regulatory milestones for the first product directed to the target of each infectious disease siRNA program for which we exercised our option. Following commercialization, we will be required to pay to Alnylam up to $250.0 million in the aggregate for the achievement of specified levels of net sales by siRNA products directed to HBV and up to $100.0 million for the achievement of specified levels of net sales by products directed to the target of each infectious disease siRNA program for which we exercised our option. We will also be required to pay Alnylam tiered royalties at percentages ranging from the low double-digits to mid-teens on annual net sales of HBV products, and tiered royalties at percentages ranging from

the high single-digits to the sub-teen double-digits on annual net sales of licensed infectious disease products, in each case subject to specified reductions and offsets. The royalties are payable on a product-by-product and country-by-country basis until the later of the expiration of all valid claims of specified patents covering such product in such country and 10 years after the first commercial sale of such product in such country. Alnylam is also entitled to receive a portion of any consideration we receive as a result of granting a sublicense under the licenses granted to us by Alnylam under the Alnylam Agreement or an option to acquire such a sublicense, determined based on the timing of the grant of such sublicense. In November 2018, in connection with the inclusion of the HBV siRNA program as the subject of a potential grant of a sublicense to Brii Bio under the Brii Agreement, as defined under the section titled "—Collaboration, Option and License Agreement with Brii Bio," which triggered certain payment obligations under the Alnylam Agreement, we entered into a letter agreement with Alnylam, or the Alnylam Letter, making certain modifications to the payments due to Alnylam as a result of the grant of the option and potential payments that would result from Brii Bio's exercise of rights under such sublicense. As a result of the rights granted under the Brii Agreement and pursuant to the Alnylam Letter, in February 2020 we transferred to Alnylam a specified percentage of the equity consideration allocable to the HBV siRNA program that we received from Brii Bio and its affiliated companies in connection with the entry into the Brii Agreement.

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

In March 2020, we achieved one of the specified development milestones relating to VIR-2218 pursuant to the Alnylam Agreement, as amended. As such, we paid Alnylam $15.0 million in April 2020, and issued Alnylam 1,111,111 shares of our common stock in May 2020.

In March and April 2020, we entered into two further amendments to the Alnylam Agreement, or the Amended Alnylam Agreement, to expand our existing collaboration to include the development and commercialization of siRNA products targeting SARS-CoV-2 and potentially other coronaviruses, and up to three targeting human host factors for SARS-CoV-2, or collectively, the COVID Collaboration Targets.

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

License Agreements with MedImmune

2012 Sub-License and Collaboration Agreement with MedImmune

In March 2012, our subsidiary Humabs entered into a sub-license and collaboration agreement with MedImmune, LLC, or MedImmune, as amended, or the 2012 MedImmune Agreement, pursuant to which Humabs conducted certain activities under a mutually agreed research plan for the development of therapeutic antibodies directed to influenza viruses (including influenza A and influenza B) and to Klebsiella bacteria. The 2012 MedImmune Agreement was amended in April 2013, April 2015, December 2015, August 2016, July 2017, and September 2018 to designate Klebsiella as an extra target, to extend the term of the research program and provide for related payments, and to incorporate certain research activities funded by MedImmune under a specified government grant. Under the 2012 MedImmune Agreement, as amended, MedImmune obtained a worldwide exclusive license from Humabs to develop and commercialize products directed to such targets for all uses in humans and animals except for active vaccination. MedImmune is obligated to use commercially reasonable efforts to develop at least one product directed to influenza viruses.

In consideration for the grant of the license, MedImmune made certain upfront payments to Humabs. MedImmune is obligated to pay Humabs development, regulatory and commercial milestone payments of up to $96.5 million in the aggregate for the first product directed to influenza viruses to achieve the applicable milestones, and up to $12.0 million for the first product directed to

Klebsiella to achieve the applicable milestones. MedImmune will also be obligated to pay royalties based on net sales of products directed to influenza viruses or Klebsiella at certain fixed percentages in the low to mid-single-digits, with the rate determined based on the specific target to which the product is directed, in each case subject to specified reductions and a royalty floor. The royalties are payable, on a product-by-product and country-by-country basis, until the later of the last to expire valid claim that would, but for the licenses granted under the 2012 MedImmune Agreement, be infringed by the sale of such product in such country, and 10 years from the first commercial sale of the first product in such country. MedImmune also made certain payments to Humabs in consideration for Humabs' conduct of the research program. We will be obligated to pass through the milestone payments and royalty payments that we receive under the 2012 MedImmune Agreement, following deduction of certain expenses incurred by us or Humabs thereunder, to Humabs' securities holders pursuant to the Humabs SPA, as defined under the section titled "—Securities Purchase Agreement with Humabs."

The 2012 MedImmune Agreement will remain in force until MedImmune has fulfilled all of its obligations to make milestone and royalty payments. MedImmune may terminate the 2012 MedImmune Agreement in its entirety, or on a product-by-product, license-by-license or country-by-country basis, for convenience, upon 90 days' notice. Either MedImmune or Humabs may terminate the 2012 MedImmune Agreement for the other party's uncured material breach or in the event of bankruptcy of the other party.

2018 License Agreement with MedImmune

In September 2018, we entered into a license agreement with MedImmune, or the 2018 MedImmune Agreement, pursuant to which we obtained a worldwide, exclusive license to develop and commercialize half-life extended versions of two specified antibodies under development by MedImmune that target influenza A and influenza B, respectively, for all uses in humans and animals. The license from MedImmune includes the grant of a sublicense under MedImmune's license to certain intellectual property controlled by Humabs that was granted to MedImmune pursuant to the 2012 MedImmune Agreement. Under certain circumstances and during certain periods of time we have the right to nominate up to two variants of each of these antibodies for inclusion under the license. MedImmune retained the rights to continue to develop and to commercialize the two specified antibodies that target influenza A and influenza B, in each case that are not the half-life extended versions that are licensed to us. Additionally, we obtained a worldwide, exclusive license under MedImmune's antibody half-life extension technology to develop and commercialize half-life extended antibodies directed to up to two additional targets selected by us for all uses in humans or animals for the prevention, treatment or diagnosis of infectious diseases and had the right to nominate such additional targets during a specified period following the effective date of the 2018 MedImmune Agreement.We are solely responsible, at our sole cost, for the development of products containing half-life extended versions of antibodies directed to the influenza targets and any additional selected targets, and are obligated to use commercially reasonable efforts to develop and obtain regulatory approval for at least one product containing half-life extended versions of antibodies directed to each of influenza A, influenza B and any additional targets, if applicable, in the United States and specified markets in Europe and Asia. We are also obligated to use commercially reasonable efforts to commercialize products containing half-life extended versions of antibodies directed to such targets in such markets. We are developing VIR-2482 using technology licensed under the 2018 MedImmune Agreement.

In consideration for the grant of the licenses under the 2018 MedImmune Agreement, we made an upfront payment to MedImmune of $10.0 million. We will be obligated to make development and regulatory milestone payments to MedImmune of up to $92.0 million, of which $5.0 million was paid in the third quarter of 2019, in the aggregate for products containing half-life extended versions of antibodies directed to influenza A that we licensed, up to an additional $39.2 million in the aggregate for such products directed to influenza B that we licensed, and up to $250,000 in the aggregate for certain specified products directed to the additional selected targets, if applicable. We will also be required to make sales-related milestone payments to MedImmune following commercialization up to an aggregate of $200.0 million for the achievement of specified levels of aggregate annual net sales of products containing half-life extended versions of antibodies directed to influenza A and/or influenza B. MedImmune will also be entitled to receive tiered royalties based on net sales of products containing half-life extended versions of antibodies directed to influenza A and/or influenza B at percentages ranging from the mid-single-digits to sub-teen double-digits and a royalty based on net sales of products containing half-life extended versions of antibodies directed to any additional selected targets, if applicable, at a percentage in the low single-digits, in each case subject to specified reductions. These royalties are payable, on a product-by-product and country-by-country basis, until the latest to occur of expiration of the last to expire valid claim covering such product in such country, expiration of regulatory exclusivity for such product in such country, and 12 years after the first commercial sale of such product in such country. Additionally, we are responsible for paying any royalties due under the 2012 MedImmune Agreement as a result of our commercialization of products under the 2018 MedImmune Agreement.

The 2018 MedImmune Agreement will remain in force until the expiration on a country-by-country and product-by-product basis of all of our obligations to pay royalties to MedImmune. We may terminate the 2018 MedImmune Agreement in its entirety or on a product-by-product basis, for convenience, upon 120 days' notice. Either party may terminate the 2018 MedImmune Agreement for cause for the other party's uncured material breach on 60 days' notice or immediately in the event of bankruptcy of the other party.

Additionally, MedImmune may terminate the 2018 MedImmune Agreement for cause on 30 days' written notice if we challenge the validity or enforceability of the patents to which we have obtained a license under the 2018 MedImmune Agreement.

Master Exclusive License Agreement with OHSU

In June 2012, our subsidiary TomegaVax, Inc., or TomegaVax, entered into a master exclusive license agreement, or the OHSU Agreement, with Oregon Health & Science University, or OHSU. The OHSU Agreement was revised and restated in August 2014 and again in August 2019, at which time we assumed TomegaVax's rights and obligations as licensee under the OHSU Agreement. Under the OHSU Agreement, we obtained a worldwide exclusive license under certain patent rights and a non-exclusive license under certain know-how to make, have made, use, offer to sell, sell, have sold and import certain products relating to CMV vectors in all fields of use. The OHSU Agreement provides for us to include within the license grant additional patent or know-how rights covering certain inventions arising at OHSU and relating to the use of CMV vaccine vectors through the execution of technology addenda, each such addendum, a Technology Addendum. Each Technology Addendum relates to one or more invention disclosures and their corresponding patent family or know-how rights. During the term of the OHSU Agreement to date, we have entered into 17 such Technology Addenda. We must use reasonably diligent efforts to develop and commercialize the CMV vector products consistent with its reasonable business practices and judgment, including by achieving certain specified development and regulatory milestones within certain periods. We use technology licensed under the OHSU Agreement in our T cell platform and in our product candidate VIR-1111.

Pursuant to the initial entry into the OHSU Agreement and certain of the Technology Addenda, TomegaVax issued a specified percentage of its then outstanding common stock to OHSU, which was subsequently exchanged for shares of our common stock as a result of our acquisition of TomegaVax in September 2016. In connection with the second revision and restatement of the OHSU Agreement in August 2019, we issued an additional specified number of shares of our common stock to OHSU. We are obligated to pay OHSU up to $1.3 million upon the achievement of certain development and regulatory milestones for each CMV vector product, and up to $2.0 million upon the achievement of certain aggregate annual net sales milestones for all CMV vector products. We will also be required to pay OHSU a royalty in the low single-digits on net sales of licensed products on a product-by-product basis, subject to specified reductions and offsets, and specified minimum annual royalty payments. The royalties are payable, on a product-by-product and country-by-country basis, until the later of (a) the expiration of all valid claims in the licensed patents covering such product in the country of sale or country of manufacture, as applicable, and (b) 10 years after the first commercial sale of such product in the country of sale. OHSU is also entitled to receive a specified percentage of any consideration received by us as a result of the grant of a sublicense under the rights granted under the OHSU Agreement, with the applicable percentage based on the development stage of the applicable program at the time of the grant of the sublicense.

The OHSU Agreement will remain in force until the expiration of all licensed patent rights or 10 years after the effective date of the last Technology Addendum, whichever is the later. Each individual Technology Addendum remains in force until the expiration of the patent rights to which it applies, or 10 years after the effective date of such Technology Addendum, whichever is later. Either party may terminate the OHSU Agreement, or any individual Technology Addendum, for the other party's uncured material breach on 60 days' written notice, which may be extended by an additional 120 days under certain conditions. The OHSU Agreement and each Technology Addendum also terminate in the event of bankruptcy of either party. We may also terminate the OHSU Agreement in its entirety, or any Technology Addendum individually, upon 60 days' notice. OHSU may immediately terminate the OHSU Agreement if we or our sublicensees bring any action or proceeding against OHSU, subject to certain exceptions.

Exclusive License Agreement with the Institute for Research in Biomedicine

In December 2011, Humabs Holdings GmbH, or Humabs Holdings, the former parent company of our subsidiary Humabs, entered into an exclusive license agreement, or the IRB Agreement, with the Institute for Research in Biomedicine, or IRB. The IRB Agreement amended and restated an original 2004 exclusive license agreement between the parties in connection with IRB's proprietary technologies relating to human monoclonal antibodies and the discovery of unique epitopes recognized by such antibodies. In May 2008, Humabs entered into an exclusive license agreement with IRB, or 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. Following the entry into the Humabs IRB Agreement, in February 2012, Humabs and IRB entered into a research agreement, or the IRB Research Agreement, concurrently with the termination of an original research agreement dated July 2004 between Humabs Holdings and IRB, 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. In August 2017, we acquired all of the share capital of Humabs as described further below. Prior to the closing of such acquisition, Humabs Holdings was consolidated into Humabs, such that Humabs Holdings ceased to exist as a separate

legal entity, and Humabs became the successor-in-interest to Humabs Holdings' rights under the IRB Agreement. As a result, Humabs is the licensee under each of the Current IRB License Agreements.

We use technology licensed under the Current IRB License Agreements in our antibody platform and in our product candidates VIR-2482 and VIR-3434.

Pursuant to the Current IRB License Agreements, IRB granted to Humabs an exclusive, worldwide, royalty-bearing, sublicensable license under patent and know-how rights covering or associated with IRB's proprietary technology platform relating to antibody discovery, as well as rights in certain antibodies, including as a result of activities under the IRB Research Agreement, in each case for all purposes, including to practice the licensed technology platform, and to develop, manufacture and commercialize any drug, vaccine or diagnostic product containing such licensed antibodies. Humabs is required to use commercially reasonable efforts to develop and commercialize licensed products, and must 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. A single royalty stream is payable on products that include the licensed antibodies (including antibodies that are owned by Humabs, but developed using the licensed technology), irrespective of whether a given product is covered by patents under both of the Current IRB License Agreements. Humabs' obligation to pay royalties to IRB, on a country-by-country basis, is reduced upon the expiration of the relevant patents in such country, and expires 10 years after the date of first commercialization of a licensed product in such country. Humabs is also required to pay to IRB a specified percentage in the sub-teen double-digits of consideration received in connection with the grant of a sublicense to a non-affiliate third party, subject to a specified maximum dollar amount for the first up front or milestone payment received under such sublicense for each licensed product, and a lower specified maximum dollar amount for subsequent up front or milestone payments for such licensed product.

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

Exclusive License Agreement with The Rockefeller University

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

We use technology licensed under the Rockefeller Agreement in our antibody platform and in our product candidates VIR-3434 and VIR-7832.

We paid Rockefeller an upfront fee of $0.3 million for entry into the Rockefeller Agreement, and are required to pay annual license maintenance fees of $1.0 million, which will be creditable against royalties following commercialization. In addition, for the 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 to Rockefeller a tiered royalty at a low single-digit percentage rate on net sales of licensed products, subject to certain adjustments. Our obligation to pay royalties to Rockefeller will terminate, on a product-by-product and jurisdiction-by-jurisdiction basis, upon the latest of the expiration of the last valid claim of a licensed patent in such jurisdiction, the expiration of all regulatory exclusivity in such jurisdiction or 12 years following the first commercial sale of the applicable licensed product in such jurisdiction. If we grant a sublicense to a non-affiliate third party under the Rockefeller technology, we will be required to pay to Rockefeller a specified percentage of the consideration received from such sublicensee for the grant of the sublicense, depending on the date of receipt of the applicable sublicense income from such sublicensee.

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

Collaboration, Option and License Agreement with Brii Bio

In May 2018, we entered into a collaboration, option and license agreement with Brii Biosciences Limited (previously named BiiG Therapeutics Limited), or Brii Bio Parent, 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 (excluding mAbs in Vir's active research and development program against coronaviruses), an exclusive option to obtain exclusive rights to develop and commercialize compounds and products arising from such programs in China, Taiwan, Hong Kong and Macau, or collectively the China Territory, for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection, or the Field of Use. Our HBV siRNA program being developed under the Amended Alnylam Agreement (described above) is included within the Brii Agreement as a program for which Brii Bio may exercise one of its options. Brii Bio may exercise each of its options following the achievement by us of proof of concept for the first product in such program. In partial consideration for the options granted by us to Brii Bio, Brii Bio Parent and Brii Bio granted us, with respect to up to four of Brii Bio Parent's or Brii Bio's programs, an exclusive option to be granted exclusive rights to develop and commercialize compounds and products arising from such Brii Bio programs in the United States for the Field of Use. The number of options that we may exercise for a Brii Bio program is limited to the corresponding number of options that Brii Bio exercises for a Vir program. All options granted to Brii Bio under the Brii Agreement that are not exercised will expire no later than seven years following the effective date, or two years earlier than such date if Brii Bio has not undergone an initial public offering within such shorter period. All options granted to us under the Brii Agreement that are not exercised will expire no later than two years following the expiration of all options granted to Brii Bio.

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

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

With respect to programs for which Brii Bio exercises its options, Brii Bio will be required to pay us an option exercise fee for each such Vir program ranging from the mid-single-digit millions up to $20.0 million, determined based on the commercial potential of the licensed program. Brii Bio will also be required to pay regulatory milestone payments on a licensed product-by-licensed product basis ranging from the mid-single-digit millions up to $30.0 million, also determined based on the commercial potential of such program. Following commercialization, Brii Bio will be required to make sales milestone payments based on certain specified levels of aggregate annual net sales of products arising from each licensed program in the China Territory, up to an aggregate of $175.0 million per licensed program. Brii Bio also will pay us royalties that range from the mid-teens to the high-twenties, as described below. 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 VIR-2218 in the China Territory. Brii Bio paid us a $20.0 million option exercise fee in connection with the option exercise. We separately paid $10.0 million, half of the option proceeds, to Alnylam in connection with the Amended Alnylam Agreement. In July 2022, Brii Bio notified us of the exercise of its option to obtain exclusive rights to develop and commercialize compounds and products arising from VIR-3434 in the China Territory. Brii Bio paid us a $20.0 million option exercise fee in connection with the option exercise. We are also eligible to receive the following payments related to VIR-3434 in the China Territory: a $30.0 million regulatory milestone payment, up to $175.0 million in sales-based milestone payments, and royalties on net sales ranging from mid-teens to mid-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 our HBV siRNA program, under the terms of the Amended Alnylam Agreement, in February 2020 we transferred to Alnylam a specified percentage of such equity consideration allocable to such program. In July 2021, Brii Bio Parent completed its initial public offering, or the Brii Bio Parent IPO, on the Stock Exchange of Hong Kong Limited. Upon completion of the Brii Bio Parent IPO, our Class A ordinary shares held at Brii Bio Parent converted into the same single class of ordinary shares issued in the Brii Bio Parent IPO.

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

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

Patent License Agreements with Xencor

In August 2019, we entered into a patent license agreement, which was amended in February 2021, or the 2019 Xencor Agreement, with Xencor, pursuant to which we obtained a non-exclusive, sublicensable (only to our affiliates and subcontractors) license to incorporate Xencor's licensed technologies into, and to evaluate, antibodies that target influenza A and HBV, and a worldwide, non-exclusive, sublicensable license to develop and commercialize products containing such antibodies incorporating such technologies for all uses, including the treatment, palliation, diagnosis and prevention of human or animal diseases, disorders or conditions. We are obligated to use commercially reasonable efforts to develop and commercialize an antibody product that incorporates Xencor's licensed technologies, for each of the influenza A and HBV research programs. These technologies are used in our VIR-2482, incorporating Xencor's Xtend technology, and VIR-3434, incorporating Xencor's Xtend and other Fc technologies.

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

In March 2020, we entered into a patent license agreement, which was amended in February 2021, or the 2020 Xencor Agreement, with Xencor pursuant to which we obtained a non-exclusive license to Xencor's licensed technologies into, and to evaluate, antibodies that target any component of a coronavirus, including SARS-CoV-2, SARS-CoV and MERS-CoV, and a worldwide, non-exclusive, sublicensable license to develop and commercialize products containing such antibodies incorporating such technologies for all uses, including the treatment, palliation, diagnosis and prevention of human or animal diseases, disorders or conditions. We are obligated to use commercially reasonable efforts to develop and commercialize an antibody product that incorporates Xencor's licensed technologies, for each of the coronavirus research programs. These technologies are used in sotrovimab, incorporating Xencor's Xtend technology, and VIR-7832, incorporating Xencor's Xtend and other Fc technologies.

In consideration for the grant of the license, we are obligated to pay royalties based on net sales of licensed products at the mid-single-digits. The royalties are payable, on a product-by-product and country-by-country basis, until the later of the expiration of the last to expire valid claim in the licensed patents covering such product in such country or 12 years.

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

Amended and Restated Letter Agreement with the Bill & Melinda Gates Foundation

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

If we fail to comply with (i) our obligations to use the proceeds of the Bill & Melinda Gates Foundation's investment for the purposes described in the paragraph above and to not use such proceeds for specified prohibited uses, (ii) specified reporting requirements or (iii) specified applicable laws, or if we materially breach our specified global access commitments (any such failure or material breach, a Specified Default), we will be obligated to redeem or arrange for a third party to purchase all of our stock purchased by the Bill & Melinda Gates Foundation under the Gates Agreement at the Bill & Melinda Gates Foundation's request, at a price equal to the greater of (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 Bill & Melinda Gates Foundation will receive compensation equal to the excess of what it would have received in such transaction if it still held the stock redeemed or sold at the time of such sale transaction over what it actually received in the Gates Foundation Redemption. Additionally, if a specified default occurs, if we are unable or unwilling to continue the HIV program, TB program, vaccinal antibody program or, if applicable, the mutually agreed additional program (except for scientific or technical reasons), or if we institute bankruptcy or insolvency proceedings, then the Bill & Melinda Gates Foundation will have the right to exercise a non-exclusive, fully-paid license (with the right to sublicense) under our intellectual property to the extent necessary to use, make and sell products arising from such programs, in each case solely to the extent necessary to benefit people in the developing countries in furtherance of the Bill & Melinda Gates Foundation's charitable purpose.

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 Bill & Melinda Gates Foundation's investment, such third party is required to assume our specified global access commitments on terms that are reasonably acceptable to the Bill & Melinda Gates Foundation. Additionally, we will not grant to any third party any rights or enter into any agreement with any third party that would restrict the Bill & Melinda 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 Bill & Melinda Gates Foundation. Consistent with the foregoing restriction, we also specifically will not enter into any such agreement negotiated in connection with a decision by us not to pursue the technology platform controlled by us as a result of our acquisition of TomegaVax. The global access commitments will continue for as long as the Bill & Melinda Gates Foundation continues to be a charitable entity.

In connection with the purchase of $40.0 million of shares of our common stock in January 2022, we entered into a stock purchase agreement, or the Gates Stock Purchase Agreement, with the Bill & Melinda Gates Foundation. The Bill & Melinda Gates Foundation purchased the shares of our common stock at $45.3841 price per share, which is the average of the volume weighted average price of a share of our common stock for the 30 trading day period prior to the date of the Gates Stock Purchase Agreement. We have agreed to register the shares for resale following expiration of the one-year lock-up period if Rule 144 under the Securities Act of 1933, as amended, is not available for such resale without any volume or manner of sale restrictions.

Separately, in January 2018, March 2018 and January 2022, we entered into three grant agreements with the Bill & Melinda Gates Foundation, pursuant to which the Bill & Melinda Gates Foundation agreed to grant additional funding to us for our HIV, TB and vaccinal antibody programs, respectively, through the award of three research grants totaling in the aggregate up to $12.2 million with respect to the HIV program, up to $14.9 million with respect to the TB program, and up to $10.0 million with respect to the vaccinal antibody program if we achieve all the specified research and development milestones or reporting deliverables under the grants. In February 2020, we amended the HIV grant agreement pursuant to which we were awarded with a supplemental grant of $8.6 million. In addition, the term of the HIV grant agreement was extended through October 31, 2022, and we entered another amendment in September 2022 to further extend the term through September 2023. The TB grant agreement remained in effect until March 31, 2022 and was amended to extend the term through December 31, 2023. As of December 31, 2022, we had received $29.7 million with respect to the HIV program and $12.2 million with respect to the TB program.

In November 2021, we entered into a grant agreement with the Bill & Melinda Gates Foundation under which we were awarded a grant totaling up to $10.0 million to support the manufacturing and clinical activities of our HIV and TB vaccine programs. This grant agreement will remain in effect until August 30, 2023. As of December 31, 2022, we had received $6.5 million under this grant agreement.

The grant agreements may be terminated early by the Bill & Melinda 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 Bill & Melinda Gates Foundation reasonably believes may threaten the success of the applicable project.

Our Acquisition Agreements

Agreement and Plan of Merger with TomegaVax

In September 2016, we entered into an agreement and plan of merger with TomegaVax, or the TomegaVax Merger Agreement, pursuant to which we purchased all equity interests of TomegaVax, a preclinical private biotechnology company. The primary asset purchased in the acquisition was a CMV vector-based vaccine platform for the development of products directed to HBV, HIV and TB.

In connection with the entry into the TomegaVax Merger Agreement, we also entered into a letter agreement with TomegaVax, or the TomegaVax Letter Agreement, which provides for certain payments to TomegaVax's former stockholders prior to September 2024, in each case so long as we are continuing to pursue the development of the TomegaVax technology. Under the terms of the TomegaVax Letter Agreement, we will be required to pay to the former stockholders of TomegaVax milestone payments of up to an aggregate of $30.0 million if the per-share price of our publicly traded common stock, or implied price per share of our Series A-1 convertible preferred stock (or common stock upon conversion) upon a certain asset sale, merger or stock sale, is at least $45 (as adjusted in the case of any stock dividend, stock split or other similar recapitalization), with the amount of such payments determined by the share price and/or the stage of our clinical development at the time of the relevant event triggering the payment. The share price of our publicly traded common stock will be determined using the average of the daily volume-weighted average trading price of our common stock for each trading day during a consecutive 90-day period. The foregoing payments are payable (i) during any date after the completion of an initial public offering by the company or any successor or affiliate controlling the TomegaVax technology, provided that no payment will be due before the first anniversary of the initial public offering, (ii) upon the sale of all assets related to the TomegaVax technology or (iii) upon a merger or stock sale of the company or any successor or affiliate controlling the TomegaVax technology, in each case subject to certain conditions with respect to the timing of the payments. The payments under the TomegaVax Letter Agreement can be made in cash or shares of our common stock, at the discretion of our board of directors.

The TomegaVax Letter Agreement may be amended, modified or terminated and the observance of any term may be waived only with the written consent of the stockholders' representative (as such term is defined in the TomegaVax Merger Agreement) and us.

In February 2021, we achieved one of the milestones related to the specified per-share price of our common stock, which resulted in a $10.0 million payable to TomegaVax's former stockholders. In July 2021, we made the milestone payment to the former TomegaVax stockholders through a combination of $8.1 million in cash and the issuance of 42,737 shares of common stock with a total fair value of $1.9 million. The remaining milestone payments of up to $20.0 million in the aggregate will be triggered if (i) the

per-share price of our publicly traded common stock is at least $45 (as adjusted in the case of any stock dividend, stock split or other similar recapitalization) and upon the achievement of a certain milestone related to the stage of our clinical development at the time of the relevant event triggering the payment and/or (ii) the per-share price of our publicly traded common stock is at least $90 (as adjusted in the case of any stock dividend, stock split or other similar recapitalization).

Securities Purchase Agreement with Humabs

In August 2017, we entered into a securities purchase agreement with Humabs and its securities holders, or the Humabs SPA, pursuant to which we purchased all equity interests of Humabs. Pursuant to the Humabs SPA, we are required to pay up to $135.0 million upon the first achievement of certain clinical, regulatory and commercial milestones for an HBV product, or the HBV Milestones, and up to $105.0 million upon the first achievement of certain clinical, regulatory and commercial milestones for another product. Pursuant to the Humabs SPA, we are required to use commercially reasonable efforts to achieve such milestones during a specified period following the closing of the Humabs acquisition. In addition, Humabs' securities holders are also entitled to receive certain pass-through payments that Humabs receives under certain license agreements, including the 2012 MedImmune Agreement, following deduction of certain expenses incurred by us or Humabs thereunder.

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to build a commercial infrastructure to support sales of our product candidates. We expect to manage sales, marketing and distribution through internal resources and third-party relationships. While we may commit significant financial and management resources to commercial activities, we will also consider collaborating with one or more pharmaceutical companies to enhance our commercial capabilities.

Manufacturing

We are currently manufacturing product candidates from three of our platforms: antibodies, T cells and siRNAs. We have established our own internal process development, manufacturing and quality capabilities and are working with contract development and manufacturing organizations, or CDMOs, to supply our early- and late-stage product candidates in the near term. We continue to expand our internal capabilities and resources in process development, analytical development, quality, manufacturing and supply chain, which are supported by our San Francisco, California, and Portland, Oregon facilities that include laboratories for process development, production of HCMV research viral seed stock and selected quality control testing for our product candidates.

We have established relationships with multiple CDMOs and have produced material to support preclinical studies and Phase 1, 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. For example, for our COVID-19 program, we and our collaborator GSK have executed manufacturing agreements with CDMOs having large-scale capacity to support future scale-up and product supply, particularly for commercialization. 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 COVID-19 therapies will be able to satisfy demand in a timely manner or not have supply chain disruptions due to COVID-19 related shutdowns, stock-outs due to raw material shortages, extended lead times, and/or greater than anticipated demand or quality issues given the operational challenges and raw material shortages that have been experienced during the COVID-19 pandemic.

Production Modalities

Antibody Platform

The technology and industrial processes for producing mAbs are well-established across the biopharmaceutical industry. Over the last 30 years, process optimization and standardization has enabled process portability and facilitated manufacturing with high success rates at most biologic CDMOs, as well as the partnered use of excess capacity with other biopharmaceutical companies. We rely on the mAb process platforms and manufacturing facilities of our CDMOs and strategic collaborators for all of our product candidate clinical supplies. For sotrovimab, we and our collaborator GSK have executed manufacturing agreements with large-scale CDMOs to support future scale-up and capacity, particularly for potential commercialization.

T Cell Platform

Our T cell platform is based on genetically engineered HCMV. We have attenuated the HCMV for the purpose of patient safety, but this attenuation also reduces its yield in production. To improve manufacturing efficiency and scale-up, we have made significant internal investments in process development, largely funded by the Bill & Melinda Gates Foundation. We have established a

reproducible current Good Manufacturing Practices, or cGMP, manufacturing process in support of Phase 1 and Phase 2 clinical trials that has been successfully transferred to and executed at CDMOs specializing in live virus manufacturing.

siRNA Platform

We assumed responsibility for all manufacturing of Phase 2 and 3 clinical supplies for VIR-2218 in the first half of 2022 as well as for all commercial manufacturing in advance of any Phase 3 clinical trial. In addition to the current CDMOs supplying our clinical trials, other CDMOs as well as Alnylam are capable of producing kilogram-scale batches of siRNA and we may contract for scale-up and Phase 3 manufacturing at one of these qualified facilities.

Manufacturing Agreements

In connection with the ongoing COVID-19 pandemic, we have entered into the following agreements to date in support of our COVID-19 program:

Letter Agreement, Assignment and Master Services Agreement with Samsung

In April 2020, we entered into a binding letter agreement with Samsung pursuant to which Samsung will perform process development and manufacturing services for our SARS-CoV-2 mAbs. Under the terms of the letter agreement, we had committed to purchase a firm and binding capacity reservation for a specified number of drug substance manufacturing slots in 2021 and 2022. Samsung will reserve such manufacturing slots on a non-cancellable, non-adjustable basis and will not offer such manufacturing slots under our capacity reservation to third parties. We were obligated to pay a total of approximately $362.0 million for such capacity reservation on a take-or-pay basis regardless of whether such manufacturing slots are utilized by us, subject to annual adjustment based on the Korean Consumer Price Index. The amounts were to be payable during 2021 and 2022 and invoiced on a per-batch basis, with shortfalls invoiced at the end of the year in which such shortfall occurs.

In August 2020, we entered into an Assignment and Novation Agreement with GlaxoSmithKline Trading Services Limited, or GSKTSL, and Samsung effective as of July 31, 2020 pursuant to which we assigned and transferred to GSKTSL all of our right, title, and interest in, to and under the letter agreement, and GSKTSL became our successor in interest in and to all of our rights, duties, and obligations in, to and under the letter agreement. On August 4, 2020, GSKTSL entered into a Master Services Agreement with Samsung effective as of July 31, 2020, or the Samsung MSA, thereby superseding the letter agreement, and pursuant to which, among other things, Samsung will perform technology transfer, development, and manufacturing services for clinical and commercial supply of antibody products under our SARS-CoV-2 antibody program.

Development and Manufacturing Collaboration Agreement with WuXi Biologics

In February 2020, we entered into a development and manufacturing collaboration agreement with WuXi Biologics, or the WuXi Biologics Collaboration Agreement, for the clinical development, manufacturing, and commercialization of our proprietary antibodies developed for SARS-CoV-2. Under the WuXi Biologics Collaboration Agreement, WuXi Biologics conducted cell-line development, process and formulation development, and initial manufacturing for clinical development. WuXi Biologics had the right to commercialize products incorporating such SARS-CoV-2 antibodies in mainland China, Hong Kong, Macau and Taiwan pursuant to an exclusive license granted for the selected SARS-CoV-2 antibodies that were developed. We had the right to commercialize such products in all other markets worldwide.

On May 16, 2022, we and WuXi Biologics entered into a Termination Agreement, or the Termination Agreement, pursuant to which we and WuXi Biologics terminated the WuXi Biologics Collaboration Agreement. Other existing agreements between us and WuXi Biologics remain in effect. Under the terms of the Termination Agreement, all licenses granted under the WuXi Biologics Collaboration Agreement were terminated and all rights to the SARS-CoV-2 antibody products in mainland China, Hong Kong, Macau and Taiwan reverted to us. We made a one-time termination payment to WuXi Biologics of $7.0 million in consideration for WuXi Biologics' development activities under the WuXi Biologics Collaboration Agreement. Under the terms of the Termination Agreement, we are obligated to pay WuXi Biologics tiered royalties on net sales of sotrovimab in mainland China, Hong Kong, Macau and Taiwan ranging from low single digits to low double digits. Royalties are payable to WuXi Biologics for a specified royalty term and are subject to reduction in certain circumstances.

Letter Agreement, Assignment and Master Services Agreement with WuXi Biologics

In June 2020, we entered into a binding letter of intent with WuXi Biologics, or WuXi Biologics Letter of Intent, pursuant to which WuXi Biologics performs certain development and manufacturing services for our SARS-CoV-2 antibody program. Under the terms of the WuXi Biologics Letter of Intent, we had committed to purchase a firm and binding capacity reservation for the manufacture of a specified number of batches of drug substance of our SARS-CoV-2 antibody in 2020 and 2021. In addition, we had the right to order an additional specified number of batches of drug substance, provided we make such election by a specified date in the fourth calendar quarter in 2020. WuXi Biologics is obligated to reserve such manufacturing slots on a non-cancellable basis, and will manufacture the agreed number of batches of drug substance in accordance with an agreed manufacturing schedule. We were obligated to pay a total of approximately $130.0 million for such capacity reservation, if all batches are manufactured, inclusive of estimated raw material costs, with between 70% and 80% of the batch production fees owed to WuXi Biologics on a take-or-pay basis regardless of whether we utilize such manufacturing slots. The amounts were to be payable during 2020 and 2021 and invoiced on a per-batch basis. The SARS-CoV-2 antibody drug substance contemplated to be manufactured in accordance with the terms of the WuXi Biologics Letter of Intent will be utilized in connection with progressing the development and commercialization of the SARS-CoV-2 antibody product under our collaboration with GSK.

In August 2020, we entered into an Assignment and Novation Agreement with GSKTSL and WuXi Biologics effective as of July 29, 2020 pursuant to which we assigned and transferred to GSKTSL all of our right, title, and interest in, to and under the WuXi Biologics Letter of Intent, and GSKTSL became our successor in interest in and to all of our rights, duties, and obligations in, to and under the WuXi Biologics Letter of Intent. On August 4, 2020, GSKTSL entered into a non-exclusive Master Services Agreement for Commercial Manufacture of Drug Substance with WuXi Biologics effective as of July 29, 2020, or the WuXi Biologics MSA, thereby superseding the WuXi Biologics Letter of Intent, and pursuant to which, among other things, WuXi Biologics will perform development and manufacturing services for clinical and commercial supply of antibody products under our SARS-CoV-2 antibody program.

GSKTSL entered into the WuXi Biologics MSA and Samsung MSA in connection with the performance of GSK and our obligations pursuant to the 2020 GSK Agreement. In accordance with the terms of the 2020 GSK Agreement, we will continue to be responsible for 72.5% of the costs under each of the WuXi Biologics MSA and Samsung MSA, and GSK will bear 27.5% of such costs under each of the Samsung MSA and the WuXi Biologics MSA, subject to certain conditions and exceptions.

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. For example, the industry and competitive landscape for COVID-19 treatments is rapidly changing, which could result in more competition from new and existing therapies 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.

COVID-19

There are limited FDA-approved treatments and prophylactic vaccines for COVID-19 and several treatments, and a prophylactic vaccine are available under EUA. An IV administered antiviral, remdesivir, marketed by Gilead, is FDA-approved for treatment in the hospitalized and early-treatment settings. Currently, there are no mAbs available in the U.S. for use as treatment or prophylaxis against COVID-19. For example, in February 2022, the FDA approved an EUA for Eli Lilly and Company's, or Eli Lilly, antibody, bebtelovimab, for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms) with positive results of direct SARS-CoV-2 testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death and when alternative treatment options are not accessible or clinically appropriate; however, in November 2022 the FDA announced that bebtelovimab is no longer authorized in any U.S. region due to lack of activity against recent Omicron subvariants. AstraZeneca plc's, or AstraZeneca . EVUSHELD™, a cocktail of two mAbs, was previously approved under an EUA for pre-exposure prophylaxis of COVID-19 in adults and pediatric individuals over the age of 12 at risk for severe disease progression of COVID-19, but was deauthorized by the FDA in January 2023. EVUSHELD™ currently remains authorized in other countries where it is approved for COVID-19 pre-exposure prophylaxis and treatment, including the EU and Japan. Oral antiviral therapies from Merck & Co, Inc., or Merck, and Pfizer Inc., or Pfizer (molnupiravir and nirmatrelvir/ritonavir, respectively), are available under EUA in the mild to moderate early treatment setting. Additionally, Pfizer's COVID-19 vaccine, Comirnaty®, was approved by the FDA for individuals 12 years of age or older, Moderna, Inc.'s COVID-19 vaccine, Spikevax®, was approved by the FDA for individuals 18 years of age or older and a COVID-19 vaccine is available in the United States under EUA from Janssen Biotech, Inc. Numerous large and small pharmaceutical and biotechnology companies are developing programs with various mechanisms of actions, including prophylactic vaccines, oral antivirals, immunomodulators, and antibodies, some of which are further along in the development process than we are. Companies with antibodies in clinical development include Invivyd, Inc., or Invivyd, AstraZeneca, Brii Bio, Celltrion Healthcare Co., Ltd., Eli Lilly and Regeneron Pharmaceuticals, Inc. Companies with oral antivirals in clinical development include Shionogi Inc., Gilead, Pardes Biosciences, Inc., Enanta Pharmaceuticals, Inc. and others. Companies with prophylactic vaccines in clinical development include AstraZeneca, GSK, Novavax, Inc. and Sanofi S.A. In addition, COVID-19 treatment standards are susceptible to rapid changes in epidemiology and the emergence of new variants, thus, sotrovimab may be rendered inferior or obsolete in the future.

HBV

Current FDA-approved treatments for chronic HBV infection include IFN-α, marketed by Roche Holding AG, or Roche, and oral antiviral agents such as NRTIs, marketed by Gilead and Bristol-Myers Squibb Company. These treatments do not lead to either a functional or a complete cure in the vast majority of patients, and in the case of NRTIs, require life-long therapy. Several large and small pharmaceutical companies are developing programs with various mechanisms of action, to be used alone or in combination, with the goal of achieving an HBV functional or complete cure. Companies with RNAi agents in clinical development include Arbutus Biopharma Corporation, GSK, Janssen Pharmaceuticals, Inc., or Janssen (part of Johnson & Johnson, in partnership with Arrowhead Pharmaceuticals, Inc.), and Roche (in partnership with Dicerna Pharmaceuticals, Inc.) In addition, several companies are developing antibodies against surface antigen including GC Pharma, Bluejay Therapeutics & Huahui Health. Several companies, including Gilead, GSK, Janssen, and Vaccitech plc have therapeutic vaccines in late-preclinical or early-clinical development.

Influenza

There are numerous approved seasonal flu vaccines, including trivalent, quadrivalent, high-dose, and adjuvanted products, marketed by GSK, Sanofi Pasteur, and Seqirus (owned by CSL Limited). In addition, there are approved antiviral agents to treat influenza, such as Xofluza and Tamiflu, marketed by Roche, as well as other neuraminidase inhibitors. Cidara Therapeutics, Inc. (in partnership with Janssen) is working to develop an antiviral conjugate which could be a novel method for long-acting prophylaxis.

While several companies, including Janssen and SAB Biotherapeutics, Inc., have conducted clinical trials of antibodies for the treatment of influenza, to our knowledge, there are no other prophylactic antibodies currently in clinical development. Invivyd has stated that it intends to develop prophylactic antibodies for influenza.

Several vaccines are in clinical development from large and small pharmaceutical companies including GSK (in partnership with CureVac N.V.), Moderna, Inc., Novavax, Inc., Pfizer (in partnership with BioNTech SE) and Sanofi S.A. (in partnership with Translate Bio). Some aim to improve efficacy or convenience over existing seasonal vaccines, and others are pursuing a universal flu vaccine approach with broad strain coverage and at least one year of protection.

HIV

No FDA-approved vaccine is currently available for the prevention of HIV. Several pharmaceutical companies, including GSK, Moderna Inc., and Worcester HIV Vaccine are actively engaged in vaccine research and development in this area. These and other companies are developing vaccines using viral vectors, nanoparticles, DNA, RNA, or formulations, with the goal of stimulating T cell-mediated and/or neutralizing antibody responses against HIV. To our knowledge, none are using a CMV-based vector. Numerous clinical trials of these vaccines are ongoing with support from the NIH Vaccine Research Center, the Bill & Melinda Gates Foundation, the U.S. military, the International AIDS Vaccine Initiative, the European Vaccine Initiative, the South African AIDS Initiative, and their academic and industry partners. In addition, many of these institutions, as well as pharmaceutical companies like Gilead and Viiv Healthcare Limited, or Viiv, are also studying the passive transfer of broadly neutralizing antibodies against HIV for prophylactic and therapeutic applications.

We may also compete with oral or long-acting antiretroviral therapies for pre-exposure prophylaxis of HIV. Truvada, marketed by Gilead, is a once-daily therapy approved for this indication. Viiv recently received FDA approval for long-acting antiretroviral therapy, cabotegravir for pre-exposure prophylaxis of HIV. Gilead, Janssen, Merck and Viiv have additional long-acting formulations in development.

Intellectual Property

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

Our patent portfolio includes patents and patent applications that are licensed from a number of collaborators and other third parties, including Alnylam, OHSU, MedImmune, IRB, Rockefeller and Xencor, and patents and patent applications that are owned by us. Our patent portfolio includes patents and patent applications that cover our product candidates sotrovimab (previously VIR-7831), VIR-7832, VIR-2218, VIR-3434, VIR-2482, VIR-1111 and VIR-1388, and the use of these candidates for therapeutic purposes. Our proprietary technology has been developed primarily through acquisitions, relationships with academic research centers and contract research organizations.

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

In total, our patent portfolio, including patents licensed from our collaborators and other third parties, comprises over 100 different patent families as of December 31, 2022, filed in various jurisdictions worldwide. Our patent portfolio includes issued patents and patent applications in the United States and in many international countries. Our patent portfolio for our product candidates and technology platforms is outlined below:

Patent Portfolio by Product Candidate

Sotrovimab

Licensed Patents

Our sotrovimab intellectual property portfolio includes patents and patent applications that we have non- exclusively licensed from Xencor. As of December 31, 2022, these patents and applications include five issued patents in the United States directed to composition of matter claims, methods of extending antibody serum half-life claims, pharmaceutical composition claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire in 2025, absent any available patent

term adjustments or extensions. Additionally, as of December 31, 2022, these patents and applications include 90 issued patents in Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, South Korea, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the U.K. directed to composition of matter claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2025 and 2028, absent any available patent term adjustments or extensions.

The patents and applications we have non-exclusively licensed from Xencor also include, as of December 31, 2022, one patent application pending in the United States directed to composition of matter claims. The 20-year term of any patents issuing from this application is estimated to expire in 2025, absent any available patent term adjustments or extensions.

Patents Owned by Us

Additionally, we own four patent families relating to sotrovimab. These families collectively include, as of December 31, 2022, two issued patents in the United States directed to composition of matter claims and method of treatment claims. The 20-year term of these patents is presently estimated to expire in 2041, absent any available patent term adjustments or extensions. Additionally, as of December 31, 2022, these families collectively include two patent applications and three provisional patent applications in the United States, one pending international Patent Cooperation Treaty, or PCT, application and 50 patent applications in Algeria, Argentina, Australia, Bahrain, Brazil, Canada, Chile, China, Colombia, Egypt, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Kuwait, Malaysia, Mexico, New Zealand, Nigeria, Oman, Philippines, Qatar, Russia, Saudi Arabia, Singapore, South Korea, Taiwan, Ukraine, United Arab Emirates, and Vietnam. The applications in these families 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 pending patent applications in these families is presently estimated to expire between 2041 and 2043, absent any available patent term adjustments or extensions.

We also co-own two patent families that collectively include, as of December 31, 2022, two pending PCT applications. These applications include 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.

We also co-own one patent family that includes, as of December 31, 2022, one pending PCT application. This application includes method of 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.

We also co-own one patent family that includes, as of December 31, 2022, one pending PCT application related to delivery of sotrovimab. This application includes composition of matter claims, pharmaceutical composition claims and method of 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.

VIR-7832

Licensed Patents

Our VIR-7832 intellectual property portfolio includes a patent family that we have exclusively licensed from Rockefeller, which includes, as of December 31, 2022, issued patents in Nigeria and Organisation Africaine de la Propriété Intellectuelle (OAPI) (Africa), one pending patent application in the United States and 31 pending patent applications in the African Regional Intellectual Property Organization (ARIPO) (Africa), Algeria, Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, the Dominican Republic, Ecuador, Eurasia, Europe, Guatemala, Hong Kong, Indonesia, Israel, India, Japan, Malaysia, Mexico, New Zealand, Panama, Peru, Philippines, Singapore, South Africa, South Korea, Thailand, the Ukraine and Vietnam. The applications in this family include composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. 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.

Our VIR-7832 intellectual property portfolio also includes patents and patent applications that we have non-exclusively licensed from Xencor. As of December 31, 2022, these patents and applications include 10 issued patents in the United States directed to

composition of matter claims, methods of extending antibody serum half-life claims, pharmaceutical composition claims, methods of treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2023 and 2026, absent any available patent term adjustments or extensions.

Additionally, as of December 31, 2022, these patents and applications include 119 issued patents in Australia, Austria, Belgium, Bulgaria, Brazil, Canada, China, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, South Korea, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the U.K. directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2023 and 2028, absent any available patent term adjustments or extensions.

The patents and applications we have non-exclusively licensed from Xencor also include, as of December 31, 2022, one patent application pending in the United States directed to composition of matter claims, and one patent application pending in India. The 20-year term of any patents issuing from these patent applications is presently estimated to expire between 2023 and 2025, absent any available patent term adjustments or extensions.

Patents Owned by Us

Additionally, we own three patent families relating to VIR-7832. These families collectively include, as of December 31, 2022, two issued patents in the United States directed to composition of matter claims and method of treatment claims. The 20-year term of these patents is presently estimated to expire in 2041, absent any available patent term adjustments or extensions. Additionally, as of December 31, 2022, these families collectively include two patent applications in the United States, one pending international PCT application and s50 patent applications in Algeria, Argentina, Australia, Bahrain, Brazil, Canada, Chile, China, Colombia, Egypt, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Kuwait, Malaysia, Mexico, New Zealand, Nigeria, Oman, Philippines, Qatar, Russia, Saudi Arabia, Singapore, South Korea, Taiwan, Ukraine, United Arab Emirates, and Vietnam. The applications in these families 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 pending patent applications in these families is presently estimated to expire between 2041 and 2042, absent any available patent term adjustments or extensions.

We also co-own two patent families that collectively include, as of December 31, 2022, two pending PCT patent applications. These applications include 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.

We also co-own one patent family that includes, as of December 31, 2022, one pending PCT application. This application includes method of 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.

We also co-own one patent family that includes, as of December 31, 2022, one pending PCT application related to delivery of VIR-7832. This application includes composition of matter claims, pharmaceutical composition claims and method of 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.

VIR-2218

Licensed Patents

Our VIR-2218 intellectual property portfolio includes three different patent families that we have exclusively licensed from Alnylam.

One of these families includes, as of December 31, 2022, two issued patents in the United States directed to composition of matter claims, pharmaceutical composition claims and method of treatment claims. This family also includes 52 issued patents in Albania, Australia, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, China, Croatia, Cyprus, Czechia, Denmark, Estonia, Eurasia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, India, Ireland, Italy, Japan, Jordan, Latvia, Lebanon, Lithuania, Luxembourg, Macao, Monaco, North Macedonia, Malta, Mexico, Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Taiwan, Turkey, the U.K. and Vietnam directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims. The 20-year term of these patents is presently estimated to expire in 2035, absent any available patent term adjustments or extensions. A third party filed a

request for invalidation of the patent issued in China with the China National Intellectual Property Administration on December 31, 2021 and this invalidation proceeding has now concluded in favor of Vir and the subject China patent was held valid as amended.

Another of these families includes, as of December 31, 2022, one issued patent in the United States directed to method of treatment claims. This family also includes three issued patents in ARIPO (Africa), Nigeria and OAPI (Africa) directed to method of treatment claims and composition for use in treatment claims. The 20-year term of these patents is presently estimated to expire in 2038, absent any available patent term adjustments or extensions.

Another of these families includes, as of December 31, 2022, one issued patent in the United States directed to composition of matter claims, pharmaceutical composition claims and method of treatment claims. This family also includes two issued patents in Nigeria and OAPI (Africa) directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims. The 20-year term of these patents is presently estimated to expire in 2039, absent any available patent term adjustments or extensions.

The three licensed families also collectively include, as of December 31, 2022, three patent applications in the United States and 82 patent applications in ARIPO (Africa), Algeria, Argentina, Australia, Brazil, Canada, China, Eurasia, Europe, Gulf Cooperation Council (GCC), Hong Kong, India, Indonesia, Israel, Japan, Jordan, Malaysia, Mexico, New Zealand, OAPI (Africa), Pakistan, Paraguay, Philippines, Singapore, South Africa, South Korea, Taiwan, Thailand, Ukraine, Venezuela and Vietnam directed to 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 pending patent applications in these families is presently estimated to expire between 2035 and 2039, absent any available patent term adjustments or extensions.

Patents Owned by Us

In addition, we own four different patent families that are directed to VIR-2218 in combination with one or more other therapeutics. One of these families includes, as of December 31, 2022, one issued patent in OAPI (Africa) directed to composition for use in treatment claims. The 20-year term of this patent is presently estimated to expire in 2040, absent any available patent term adjustments or extensions. The four families also collectively include, as of December 31, 2022, three pending provisional patent applications in the United States, two patent applications in the United States and 46 patent applications in ARIPO (Africa), Algeria, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Malaysia, Mexico, New Zealand, Philippines, Singapore, South Africa, South Korea, Taiwan, Thailand, Ukraine and Vietnam. The applications in these families include method of treatment claims and composition for use in treatment claims for VIR-2218 in combination as a second therapeutic. The 20-year term of any patents issuing from pending patent applications in these families is presently estimated to expire between 2039 and 2043, absent any available patent term adjustments or extensions.

We also co-own another patent family directed to VIR-2218 in combination with another therapeutic. This family includes a pending PCT application and patent applications in Argentina and Taiwan, directed to method of treatment claims. The 20-year term of any patents issuing from pending patent applications in these families is presently estimated to expire in 2042, absent any available patent term adjustments or extensions.

VIR-3434

Licensed Patents

Our VIR-3434 intellectual property portfolio includes a patent family that we have exclusively licensed from Rockefeller, which includes, as of December 31, 2022, issued patents in Nigeria and OAPI (Africa), one pending patent application in the United States and 31 pending patent applications in ARIPO (Africa), Algeria, Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, the Dominican Republic, Ecuador, Eurasia, Europe, Guatemala, Hong Kong, Indonesia, Israel, India, Japan, Malaysia, Mexico, New Zealand, Panama, Peru, Philippines, Singapore, South Africa, South Korea, Thailand, the Ukraine and Vietnam. The applications in this family include composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. 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.

Our VIR-3434 intellectual property portfolio also includes patents and patent applications that we have non-exclusively licensed from Xencor. As of December 31, 2022, these patents and applications include 10 issued patents in the United States directed to composition of matter claims, methods of extending antibody serum half-life claims, pharmaceutical composition claims, method of treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2023 and 2026, absent any available patent term adjustments or extensions. Additionally, as of December 31, 2022, these

patents and applications include 119 issued patents in Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, South Korea, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the U.K. directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2023 and 2028, absent any available patent term adjustments or extensions.

The patents and applications we have non-exclusively licensed from Xencor also include, as of December 31, 2022, one patent application pending in the United States directed to composition of matter claims, and one patent application pending in India. The 20-year term of any patents issuing from these patent applications is presently estimated to expire between 2023 and 2025, absent any available patent term adjustments or extensions.

Patents Owned by Us

We also own two different patent families that include, as of December 31, 2022, one pending PCT patent application, one patent application in the United States and 19 patent applications in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Indonesia, Israel, Japan, Mexico, New Zealand, Singapore, South Africa, South Korea, Taiwan, Thailand, and Ukraine. These applications include composition of matter claims, pharmaceutical composition claims and method of treatment claims. The 20-year term of any patents issuing from patent applications in this family is presently estimated to expire between 2040 and 2042, absent any available patent term adjustments or extensions.

In addition, through our subsidiary Humabs, we own two different patent families related to VIR-3434. One of these families includes, as of December 31, 2022, two issued patents in the United States directed to composition of matter claims, pharmaceutical composition claims and method of treatment claims. This family also includes, as of December 31, 2022, 47 issued patents in Albania, ARIPO (Africa), Austria, Belgium, Bulgaria, China, Croatia, Cyprus, Czechia, Denmark, Estonia, Eurasia, Finland, France, Germany, Greece, Hong Kong, Hungry, Iceland, Indonesia, Ireland, Israel, Italy, Japan, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mexico, Monaco, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Turkey and the U.K. that include composition of matter claims, pharmaceutical composition claims and composition for use in treatment claims. The 20-year term of these patents is presently estimated to expire in 2036, absent any available patent term adjustments or extensions.

The other patent family owned through our subsidiary Humabs that relates to VIR-3434 includes, as of December 31, 2022, two issued patents in Nigeria and OAPI (Africa), directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire in 2039, absent any available patent term adjustments or extensions.

These two families owned by Humabs also collectively include, as of December 31, 2022, two pending patent applications in the United States and 50 pending patent applications in ARIPO (Africa), Australia, Bahrain, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Kuwait, Macao, Malaysia, Mexico, Nigeria, New Zealand, OAPI (Africa), Oman, the Philippines, Qatar, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan, Thailand, Ukraine, United Arab Emirates and Vietnam. The applications in these families include composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of any patents issuing from patent applications in these families is presently estimated to expire between 2036 and 2039, absent any available patent term adjustments or extensions.

VIR-2482

Licensed Patents

Our VIR-2482 intellectual property patent portfolio includes two different patent families that we have exclusively licensed from MedImmune, which collectively include, as of December 31, 2022, two issued patents in the United States directed to composition of matter claims, pharmaceutical composition claims and method of treatment claims. These families also collectively include, as of December 31, 2022, 55 issued patents in Albania, Australia, Austria, Belgium, Bulgaria, China, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Gibraltar, Greece, Guernsey, Hong Kong, Hungry, Iceland, Ireland, Italy, Japan, Jersey, Latvia, Lithuania, Luxembourg, Malta, Mexico, Monaco, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, San Marino, Serbia, Singapore, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey and the U.K. that include composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2034 and 2037, absent any available patent term adjustments or extensions.

The two families licensed from MedImmune also collectively include, as of December 31, 2022, three patent applications in the United States and 25 patent applications in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, Japan, Mexico, Russia, Singapore, South Korea and Taiwan. The applications in these families include composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of any patents issuing from patent applications in these families is presently estimated to expire between 2034 and 2037, absent any available patent term adjustments or extensions.

Our VIR-2482 intellectual property portfolio also includes patents and patent applications that we have non-exclusively licensed from Xencor. As of December 31, 2022, these patents and applications include five issued patents in the United States directed to composition of matter claims, methods of extending antibody serum half-life claims, pharmaceutical composition claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire in 2025, absent any available patent term adjustments or extensions. Additionally, as of December 31, 2022, these patents and applications include 90 issued patents in Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, South Korea, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the U.K. directed to composition of matter claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2025 and 2028, absent any available patent term adjustments or extensions.

The patents and applications we have non-exclusively licensed from Xencor also include, as of December 31, 2022, one patent application pending in the United States directed to composition of matter claims. The 20-year term of any patents issuing from this application is estimated to expire in 2025, absent any available patent term adjustments or extensions.

Patents Owned by Us

We also own one patent family that includes, as of December 31, 2022, one pending application in the United States and 18 patent applications in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Indonesia, Israel, Japan, Mexico, New Zealand, Singapore, South Africa, South Korea, Thailand and Ukraine. 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 2040, absent any available patent term adjustments or extensions.

Through our subsidiary Humabs, we co-own a patent family (with MedImmune) that includes, as of December 31, 2022, two issued patents in the United States directed to composition of matter claims, pharmaceutical composition claims and method of treatment claims. This family also includes 54 issued patents in Albania, Australia, Austria, Belgium, Bulgaria, China, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Gibraltar, Greece, Guernsey, Hong Kong, Hungry, Iceland, Ireland, Italy, Japan, Jersey, Latvia, Lithuania, Luxembourg, Malta, Mexico, Monaco, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, San Marino, Serbia, Singapore, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey and the U.K. that include composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire in 2034, absent any available patent term adjustments or extensions.

This co-owned family also includes, as of December 31, 2022, one patent application in the United States and 15 patent applications in Australia, Brazil, Canada, China, Europe, Hong Kong, Japan, South Korea, Mexico, Russia, Singapore and Taiwan. The applications in this family include composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of any patents issuing from patent applications in this family is presently estimated to expire in 2034, absent any available patent term adjustments or extensions.

In addition, through our subsidiary Humabs, we own a patent family that includes, as of December 31, 2022, one pending application in the United States and 34 pending applications in Algeria, Australia, Bahrain, Brazil, Canada, Chile, China, Colombia, Egypt, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Kuwait, Malaysia, Mexico, New Zealand, Nigeria, Oman, Philippines, Qatar, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan, Thailand, Ukraine, United Arab Emirates and Vietnam. The application in this family includes 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 the patent application in this family is presently estimated to expire in 2040, absent any available patent term adjustments or extensions.

In addition, through our subsidiary Humabs, we own a patent family that includes, as of December 31, 2022, two pending provisional applications in the United States. These applications include pharmaceutical composition claims, method of treatment

claims and composition for use in treatment claims. The 20-year term of any patents issuing from the patent application in this family is presently estimated to expire in 2043, absent any available patent term adjustments or extensions.

VIR-1111

Licensed Patents

Our VIR-1111 intellectual property patent portfolio includes three different patent families that we have exclusively licensed from OHSU. These patent families are generally directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims.

The three families collectively include, as of December 31, 2022, five issued patents in the United States directed to composition of matter claims, pharmaceutical composition claims and method of treatment claims. The 20-year term of these patents is presently estimated to expire between 2031 and 2035, absent any available patent term adjustments or extensions. Additionally, the three patent families collectively include, as of December 31, 2022, 180 issued patents in Albania, ARIPO (Africa), Australia, Austria, Belgium, Bulgaria, Canada, China, Croatia, Cyprus, Czechia, Denmark, Estonia, Eurasia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Latvia, Lithuania, Luxembourg, Macao, Monaco, North Macedonia, Malta, Mexico, New Zealand, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Singapore, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey, Ukraine and the U.K. The 20-year term of these patents is presently estimated to expire between 2025 and 2035, absent any available patent term adjustments or extensions.

The three licensed families also collectively include, as of December 31, 2022, three patent applications in the United States and 20 patent applications in ARIPO (Africa), Australia, Brazil, Canada, China, Europe, Hong Kong, Indonesia, India, Japan, Mexico, New Zealand, Singapore, South Africa and Thailand. The 20-year term of any patents issuing from patent applications in these families is presently estimated to expire between 2025 and 2035, absent any available patent term adjustments or extensions.

VIR-1388

Licensed Patents

Our VIR-1388 intellectual property patent portfolio includes four different patent families that we have exclusively licensed from OHSU. These patent families are generally directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims.

Two of these four families collectively include, as of December 31, 2022, three issued patents in the United States directed to composition of matter claims, pharmaceutical composition claims and method of treatment claims. The 20-year term of these patents is presently estimated to expire in 2035, absent any available patent term adjustments or extensions. Additionally, three of the four patent families collectively include, as of December 31, 2022, 33 issued patents in ARIPO (Africa), Australia, Canada, China, Eurasia, France, Germany, Israel, Japan, Macao, Mexico, New Zealand, Netherlands, Singapore, South Korea, Switzerland, Ukraine and the U.K. The 20-year term of these patents is presently estimated to expire between 2025 and 2035, absent any available patent term adjustments or extensions.

The four licensed families also collectively include, as of December 31, 2022, five patent applications in the United States and 77 patent applications in ARIPO (Africa), Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, Dominican Republic, Ecuador, Eurasia, Europe, Guatemala, Hong Kong, Indonesia, India, Israel, Japan, Mexico, Malaysia, New Zealand, Nigeria, OAPI (Africa), Panama, Peru, Philippines, Singapore, South Africa, South Korea, Thailand, Ukraine and Vietnam. The 20-year term of any patents issuing from patent applications in these families is presently estimated to expire between 2025 and 2040, absent any available patent term adjustments or extensions.

Patents Owned by Us

We co-own a patent family that includes, as of December 31, 2022, one issued patent in the United States directed to composition of matter claims and method of treatment claims. Additionally, this patent family includes, as of December 31, 2022, two issued patents in Eurasia and Mexico, directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims. The family also includes two patent applications in the United States and 28 patent applications in ARIPO (Africa), Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Indonesia, Israel, India, Japan, Mexico, New Zealand, Singapore, South Africa, South Korea, Thailand and the Ukraine directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims. The 20-year term of the issued patents and any patents issuing from patent applications in this family is presently estimated to expire in 2035, absent any available patent term adjustments or extensions.

Additionally, we own a family that includes, as of December 31, 2022, a pending PCT application and patent applications in Argentina and Taiwan, directed to 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.

Patent Portfolio by Technology Platform

siRNA Platform

Licensed Patents

Our siRNA intellectual property portfolio includes three additional different patent families that we have exclusively licensed from Alnylam. Two of the three families collectively include, as of December 31, 2022, 10 issued patents in the United States directed to composition of matter claims, pharmaceutical composition claims and method of treatment claims. The 20-year term of these patents is presently estimated to expire between 2024 and 2031, absent any available patent term adjustments or extensions. Additionally, the three patent families collectively include, as of December 31, 2022, 79 issued patents in Albania, Australia, Belgium, Canada, China, Croatia, Denmark, Finland, France, Germany, Hungary, Iceland, India, Indonesia, Ireland, Japan, Latvia, Lithuania, Luxembourg, Macao, Monaco, Netherlands, North Macedonia, Norway, Russia, Singapore, Slovenia, South Korea, Sweden, Switzerland and the U.K. directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims. The 20-year term of these patents is presently estimated to expire between 2024 and 2031, absent any available patent term adjustments or extensions.

The three licensed families also collectively include, as of December 31, 2022, two patent applications in the United States and seven patent applications in Canada, Europe, Hong Kong, India, Japan, and Thailand directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims and composition for use in treatment claims. The 20-year term of the issued patent and any patents issuing from pending patent applications in these families is presently estimated to expire between 2024 and 2031, absent any available patent term adjustments or extensions.

We have also exclusively licensed from Alnylam, as of December 31, 2022, three issued patents in the United States directed to composition of matter claims, pharmaceutical composition claims and method of treatment claims. The 20-year term of these patents is presently estimated to expire between 2022 and 2028, absent any available patent term adjustments or extensions.

We also have an exclusive license to additional Alnylam platform technology for HBV licensed products.

Antibody Platform

Licensed Patents

We have exclusively licensed from Rockefeller a patent family that includes, as of December 31, 2022, issued patents in Nigeria and OAPI (Africa), one pending patent application in the United States and 31 pending patent applications in ARIPO (Africa), Algeria, Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, the Dominican Republic, Ecuador, Eurasia, Europe, Guatemala, Hong Kong, Indonesia, Israel, India, Japan, Malaysia, Mexico, New Zealand, Panama, Peru, Philippines, Singapore, South Africa, South Korea, Thailand, the Ukraine and Vietnam. The applications in this family include composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. 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. One of these families includes, as of December 31, 2022, two issued patents in the United States directed to process (methods of producing) claims, and 23 issued patents in Austria, Australia, Belgium, Czechia, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Netherlands, Portugal, Romania, Singapore, Spain, Sweden, Switzerland, Turkey and the U.K. directed to process (methods of producing) claims. The two families also collectively include, as of December 31, 2022, two pending patent applications in the United States directed to process (methods of producing) claims, as well as one patent application in the United States and 19 patent applications in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Mexico, New Zealand, Singapore, South Africa, South Korea, Thailand and Ukraine directed to composition of matter claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of the issued patents and any patent issuing from the pending patent applications in these families is presently estimated to expire between 2024 and 2038, absent any available patent term adjustments or extensions.

In addition, we have non-exclusively licensed a group of patents and applications from Xencor. As of December 31, 2022, these patents and applications include 10 issued patents in the United States directed to composition of matter claims, methods of extending antibody serum half-life claims, pharmaceutical composition claims, method of treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2023 and 2026, absent any available patent term adjustments or extensions. Additionally, as of December 31, 2022, these patents and applications include 119 issued patents in Australia, Austria, Belgium, Bulgaria, Canada, China, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, South Korea, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the U.K. directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treatment claims and process (methods of producing) claims. The 20-year term of these patents is presently estimated to expire between 2023 and 2028, absent any available patent term adjustments or extensions.

The patents and applications we have non-exclusively licensed from Xencor also include, as of December 31, 2022, two patent applications pending in the United States directed to composition of matter claims and process (methods of producing) claims, and one patent application pending in India. The 20-year term of any patents issuing from these patent applications is presently estimated to expire between 2023 and 2025, 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, 2022, one pending PCT application and one patent application in Taiwan. 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.

T Cell Platform

Licensed Patents

We have exclusively licensed from OHSU 10 different patent families related to our T cell portfolio.

Eight of the 10 families collectively include, as of December 31, 2022, 15 issued patents in the United States, directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims and process (methods of producing) claims. The 20-year term of the issued patents in these families is presently estimated to expire between 2031 and 2037, absent any available patent term adjustments or extensions. In addition, nine of the 10 families collectively include, as of December 31, 2022, 259 issued patents in Albania, ARIPO (Africa), Australia, Austria, Belgium, Bulgaria, Canada, China, Croatia, Cyprus, Czechia, Denmark, Germany, Estonia, Eurasia, Finland, France, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Latvia, Lithuania, Luxembourg, North Macedonia, Malta, Macao, Mexico, Monaco, Netherlands, Norway, New Zealand, OAPI (Africa), Poland, Portugal, Romania, San Marino, Serbia, Singapore, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Tunisia, Turkey, Ukraine and the U.K. directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treating claims and process (methods of producing) claims. The 20-year term of the issued patents in these families is presently estimated to expire between 2025 and 2037, absent any available patent term adjustments or extensions.

The 10 patent families also collectively include, as of December 31, 2022, nine patent applications in the United States, and 100 patent applications in Algeria, ARIPO (Africa), Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, the Dominican Republic, Ecuador, Eurasia, Europe, Guatemala, Hong Kong, Indonesia, Israel, India, Japan, Malaysia, Mexico, New Zealand, Nigeria, OAPI (Africa) Panama, Peru, Philippines, Singapore, South Africa, South Korea, Thailand, the Ukraine and Vietnam directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treating claims and process (methods of producing) claims. The 20-year term of any patents issuing from pending patent applications in these families is presently estimated to expire between 2025 and 2040, absent any available patent term adjustments or extensions.
Patents Owned by Us

In addition, we own two patent families that include, as of December 31, 2022, two pending PCT applications and three patent applications in Argentina and Taiwan directed to composition of matter claims, pharmaceutical composition claims, method of treatment claims, composition for use in treating claims and process (method of producing) claims. The 20-year term of any patent issuing in these families is presently estimated to expire in 2042, absent any available patent term adjustments or extensions.

Innate Immunity Platform

We have know-how relating to our innate immunity platform and are continually developing our intellectual property in this area, as well as evaluating external technologies and assets that may also help grow this platform.

We do not currently license or own any patents related to our innate immunity platform.

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 U.S. Patent and Trademark Office's, or the USPTO, delay 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.

Our patents and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. 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. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors, commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For more information, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, 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, or the FDCA. Biological products, or biologics, are licensed for marketing under the Public Health Service Act, or the PHSA, and regulated under the FDCA. A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products is typically referred to as a sponsor. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or trials or seek approval or licensure of our product candidates.

U.S. Biopharmaceuticals Regulation

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

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

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. These studies are typically referred to as IND-enabling studies. 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. In such a case, the IND may be placed on clinical hold and the IND sponsor, and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, 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. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. 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 and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

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

- *Phase 1.* The investigational product is initially introduced into patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- *Phase 2.* The investigational product is administered to a limited patient population to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- *Phase 3.* The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 trials may be made a condition to approval of the application. Concurrent with clinical trials, companies may complete additional animal trials and develop additional information about the characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability trials must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

In December 2022, with the passage of the Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan for each phase 3 clinical trial or any other “pivotal study” of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, action plans must include the sponsor’s goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on diversity action plans.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research patients or patients are being exposed to an unacceptable health risk. Similarly, an institutional review board can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the institutional review board’s requirements or if the product candidate has been associated with unexpected serious harm to patients.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived by the FDA. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee and seeking and receiving informed consent from subjects.

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. The failure to submit clinical trial information to clinicaltrials.gov, as required, is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to $10,000 for each day the violation continues. Although the FDA has historically not enforced these reporting requirements due to HHS’s long delay in issuing final implementing regulations, those regulations have now been issued and the FDA has issued several Notices of Noncompliance to manufacturers since April 2021.

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. The application must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product’s chemistry, manufacturing, controls, and proposed labeling, among other things. The

submission of an application requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies. The FDA has sixty days from the applicant's submission to either issue a refusal to file letter, or RTF, or accept the application for filing, indicating that it is sufficiently complete to permit substantive review.

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

Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug or biologic undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States. Additionally, before approving an application, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. With passage of FDORA, Congress clarified the FDA's authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct or analysis of clinical and non-clinical studies submitted to the FDA as well as other persons holding study records or involved in the study process.

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 Complete Response letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the application, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the application in condition for approval, including requests for additional information or clarification, which may include the potential requirement for additional clinical trials. The FDA may delay or refuse approval of an application if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

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 REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. 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.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

With the passage of FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded; require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to the FDA every six months until the study is completed; and use expedited procedures to withdraw accelerated approval of an NDA or BLA after the confirmatory trial fails to verify the product's clinical benefit. Further, FDORA requires the agency to publish on its website "the rationale for why a post-approval study is not appropriate or necessary" whenever it decides not to require such a study upon granting accelerated approval.

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.

Emergency Use Authorization

In emergency situations, such as a pandemic, and with a declaration of a public health emergency by the Secretary of the U.S. Department of Health and Human Services, or HHS, the FDA has the authority to allow unapproved medical products or unapproved uses of cleared or approved medical products to be used to diagnose, treat or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear warfare threat agents when there are no adequate, approved, and available alternatives.

Under this authority, the FDA may issue an EUA if the following four statutory criteria have been met: (1) a serious or life-threatening condition exists; (2) evidence of effectiveness exists; (3) a risk-benefit analysis shows that the benefits of the product outweigh the risks; and (4) no other alternatives exist for diagnosing, preventing or treating the disease or condition. The "may be effective" standard for EUAs requires a lower level of evidence than the "effectiveness" standard that FDA uses for product clearances or approvals in non-emergency situations. The FDA assesses the potential effectiveness of a possible EUA product on a case-by-case basis using a risk-benefit analysis. In determining whether the known and potential benefits of the product outweigh the known and potential risks, the FDA examines the totality of the scientific evidence to make an overall risk-benefit determination. Such evidence, which could arise from a variety of sources, may include (but is not limited to) results of domestic and foreign clinical trials, in vivo efficacy data from animal models, in vitro data, as well as the quality and quantity of the available evidence.

Once granted, an EUA will remain in effect and generally terminate on the earlier of (1) the determination by the Secretary of HHS that the public health emergency has ceased or (2) a change in the approval status of the product such that the authorized use(s) of the product are no longer unapproved. After the EUA is no longer valid, the product is no longer considered to be legally marketed

and one of the FDA's non-emergency premarket pathways would be necessary to resume or continue distribution of the subject product.

The FDA also may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect public health or safety.

On January 31, 2020, the Secretary of HHS issued a declaration of a public health emergency related to COVID-19. On February 4, 2020, HHS determined that COVID-19 represents a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and, subsequently, declared on March 24, 2020, that circumstances exist to justify the authorization of emergency use of certain medical products, during the COVID-19 pandemic, subject to the terms of any authorization as issued by the FDA. The declaration of the Secretary of HHS has been further updated and the FDA has issued numerous guidance to sponsors seeking to obtain EUAs to diagnose and treat COVID-19. The declaration of a public health emergency related to COVID-19 was most recently renewed on January 11, 2023.

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. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Among the benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application fee.

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.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective. In September 2021, the Court of Appeals for the 11th Circuit held that, for the purpose of determining the scope of market exclusivity, the term "same disease or condition" in the statute means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved.

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, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA or BLA. Biopharmaceutical manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must

continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

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. Moreover, with passage of the Pre-Approval Information Exchange Act, or PIE Act, in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patients access upon product approval. Previously, such communications were permitted under FDA guidance, but the new legislation explicitly provides protection to sponsors who convey certain information about products in development to payors, including unapproved uses of approved products.

The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. In September 2021, the FDA published final regulations which describe the types of evidence that the FDA will consider in determining the intended use of a drug or biologic.

Biosimilars and Regulatory Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or 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 approved a number of biosimilars and the first interchangeable biosimilar product was approved on July 30, 2021, and a second product previously approved as a biosimilar was designated as interchangeable in October 2021.

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

December 2022, Congress clarified through FDORA that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the first day on which such a product is approved as interchangeable with the reference product.

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. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. Since passage of the BPCIA, many states have passed laws or amendments to laws that address pharmacy practices involving biosimilar products.

Generic Drugs and Regulatory Exclusivity

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant 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, or 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. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo or other testing. 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. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, 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 or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA 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 or 505(b)(2) NDA 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 or 505(b)(2) NDA 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 or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

The FDA also cannot approve an ANDA or 505(b)(2) application 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 of a new chemical entity, or NCE, which is a drug containing an active moiety that has not been approved by FDA in any other NDA. This interpretation was confirmed with enactment of the Ensuring Innovation Act in April 2021. An "active moiety" is defined as the molecule responsible for the drug substance's physiological or pharmacologic action. During that five-year exclusivity period, the FDA cannot accept for filing (and therefore cannot approve) any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA that relies on the FDA's approval of the drug, provided that the FDA may accept an ANDA four years into the NCE exclusivity period if the ANDA applicant also files a paragraph IV certification.

Pediatric Exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of exclusivity. For drug products, the six-month exclusivity may be attached to the term of any existing patent or regulatory exclusivity, including the orphan exclusivity and regulatory exclusivities available under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. For biologic products, the six-month period may be attached to any existing regulatory exclusivities but not to any patent terms. The conditions for pediatric exclusivity include the FDA's determination that information relating to 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. This six-month exclusivity may be granted if a sponsor submits pediatric data that fairly responds to a written request from the FDA for such data. 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. Assuming grant of the patent for which the extension is sought, 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, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension in consultation with the FDA.

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. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. 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.

A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act or the civil monetary penalties laws.

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

been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses.

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

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or 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 state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing, and state and local laws that require the registration of biopharmaceutical sales representatives.

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, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, implementation of corporate compliance programs, and reporting of payments or transfers of value to healthcare professionals.

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 generally decide which products they will pay for and establish reimbursement levels for those products. 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 are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for products. For example, federal and state governments reimburse products at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of products. Third-party payors may limit coverage to

specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Similarly, because certain of our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of products, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic trials in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party payor reimbursement may not be available to enable us to realize an appropriate return on our investment in product development. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our product candidates, if approved, or exclusion of our product candidates from coverage and reimbursement. The cost containment measures that third-party payors and providers are instituting and any healthcare reform could significantly reduce our revenue from the sale of any approved product candidates.

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.

There have been several U.S. government initiatives over the past few years to fund and incentivize certain comparative effectiveness research, including creation of the Patient-Centered Outcomes Research Institute under the ACA. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates.

The ACA became law in March 2010 and substantially changed the way healthcare is financed by third-party payors, and significantly impacts the U.S. biopharmaceutical industry. Among other measures that may have an impact on our business, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increased the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Additionally, the ACA extended manufacturers' Medicaid rebate liability, expands eligibility criteria for Medicaid programs, and expanded entities eligible for discounts under the PHSA. At this time, we are unsure of the full impact that the ACA will have on our business.

In March 2010, the United States Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for pharmaceutical products under government healthcare programs. Other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031. Pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, and subsequent legislation, these Medicare sequester reductions were suspended and reduced through the end of June 2022, with the full 2% cut resuming thereafter.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, or the Tax Act, which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court heard this case on November 10, 2020 and, on June 17, 2021, dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Pharmaceutical Prices

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. Congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020 President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. The final rule is currently the subject of ongoing litigation, but at least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada with the intent of developing SIPs for review and approval by the FDA. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule would eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager, or PBM, service fees. It originally was set to go into effect on January 1, 2022, but with passage of the Inflation Reduction Act has been delayed by Congress to January 1, 2032.

More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, 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.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. 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. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or “catastrophic period” of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. 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.

Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

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. Whether or not we obtain FDA approval for a drug, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. 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.

Further, some countries outside of the United States, including the EU member states, Switzerland and the U.K., have also adopted data protection laws and regulations, which impose significant compliance obligations. In the EU, the collection and use of personal health data is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR, together with the national legislation of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to process personal data, including health data from clinical trials and adverse event reporting. For additional information regarding the GDPR, see the section titled “Business—Government Regulation and Product Approval —Privacy Laws.”

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. We are subject to numerous domestic and foreign laws and regulations regarding privacy and data security, the scope of which is changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules.

At the federal level, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specific requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. HITECH, among other things, also increased the civil and criminal penalties that may be imposed for non-compliance with the law, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney’s fees and costs associated with pursuing federal civil actions. Penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include significant civil monetary penalties and, in certain circumstances, criminal penalties and/or imprisonment.

Various states, such as California and Texas, have implemented privacy laws and regulations similar to HIPAA, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. 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.

Additionally, in 2018, California passed into law the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020, and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities. In addition, other states, including Virginia, Colorado, Utah, and Connecticut already have passed state privacy laws. Virginia's privacy law also went into effect on January 1, 2023, and the laws in the other three states will go into effect later in the year. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Regulation of privacy, data protection and data security has also become more stringent in foreign jurisdictions. For example, the EU adopted the GDPR, which 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 and include fines in the amount of the greater of €20 million or 4% of global turnover and restrictions or prohibitions on data processing, which could hinder our ability to do business in the EU, reduce demand for our services and adversely impact our business and results of operations. The GDPR also provides that EU member states may implement further laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use and share European data, or could cause our compliance costs to increase, require us to change our practices, adversely impact our business, and harm our financial condition. Assisting parties with whom we exchange personal data in complying with the GDPR, or complying with the GDPR ourselves, may cause us to incur substantial operational costs or require us to change our business practices.

Furthermore, European privacy, data protection, and data security laws, including the GDPR, generally restrict the transfer of personal information from the U.K., European Economic Area, or EEA, and Switzerland to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. There is uncertainty as to how to implement such safeguards and how to conduct such transfers in compliance with the GDPR, 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. One of the primary safeguards allowing U.S. companies to import personal information from Europe was certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks. However, the EU-U.S. Privacy Shield framework was invalidated in July 2020 in a decision by the Court of Justice of the European Union and the Swiss-U.S. Privacy Shield Framework was declared as inadequate by the Swiss Federal Data Protection and Information Commissioner. The decision by the Court of Justice and the announcement by the Swiss Commissioner both raised questions about whether one of the primary alternatives to the Privacy Shield frameworks, the European Commission's Standard Contractual Clauses, can lawfully be used for personal information transfers from Europe to the United States or most other countries. Since that time, EU regulators have adopted a new set of Standard Contractual Clauses, which impose additional obligations and requirements with respect to the transfer of EU personal data to other jurisdictions and may increase the legal risks and liabilities under the GDPR and local EU laws associated with cross-border data transfers, and result in material increased compliance and operational costs. If we are unable to implement a valid mechanism for personal information transfers to the United States and other countries, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal information from Europe, and we may be required to increase our data processing capabilities in Europe at significant expense. Inability to import personal information from Europe to the United States or other countries may limit our ability to conduct clinical trials in Europe and collaborate with other entities subject to European data protection laws. At present, there are few, if any, viable alternatives to the Standard Contractual Clauses. Other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

This data transfer issue is also continually evolving. In October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-US Privacy Shield. The European Commission initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022. It is unclear if and when the framework will be finalized and whether it will be challenged in court (and whether such a court challenge will further affect the viability of the new Standard Contractual Clauses). The uncertainty around this issue may further impact our business operations in the EU.

There are also relevant data transfer issues in the U.K. that we must address as part of our business operations. The European Commission and U.K. regulators have both adopted adequacy decisions that permit data transfers between the EEA and the U.K. in light of Brexit. However, the U.K. has its own guidance for data transfers to other jurisdictions that are not covered by an "adequacy" decision (which includes the United States) and recently adopted the international data transfer agreement, which can serve as a basis for companies to lawfully transfer outside of the U.K. We must also account for these requirements as part of addressing our compliance obligations.

Compliance with U.S. and foreign privacy, data protection, and data security laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. 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 to comply with U.S. and foreign privacy, data protection, and data security laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with privacy, data protection, and data security laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, and results of operations.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Human Capital Management

Employees

As of December 31, 2022, we had 576 full-time employees, 424 of whom were primarily engaged in research and development activities. Substantially all of our employees are located in San Francisco, California; St. Louis, Missouri; Portland, Oregon; and Bellinzona, Switzerland. None of our employees are represented by a labor union and we consider our employee relations to be good.

As the clinical development of our product candidates progresses, we expect to continue to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. In addition, we also expect to hire additional personnel in order to sustain operations as a public company.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purpose of our equity incentive plan is to attract, retain, and motivate our employees, non-employee directors, and consultants through the granting of stock-based compensation and performance cash awards.

Response to COVID-19

We have implemented a number of plans and policies designed to address and mitigate the impact of the COVID-19 pandemic on our employees and our business. We continue to closely monitor the COVID-19 situation and will evolve our plans and policies as needed going forward. As a result of these developments, in March 2020, we implemented work-from-home policies for most of our employees. We now offer all of our employees the choice of working full time in the office, a hybrid approach, or full-time remote. As a result, we expect to continue to be subject to the challenges and risks of having a remote workforce, as well as new challenges and risks from operating with a hybrid workforce. We are also working to provide our employees with the support they need to ensure continuity of business operations.

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 499 Illinois Street, Suite 500, 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, some of which have manifested and any of which may occur in the future, as well as the other information in this Annual Report on Form 10-K, including our audited consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and/or prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. You should consider all the risk factors described when evaluating our business.

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 income of $515.8 million and $528.6 million for the years ended December 31, 2022, and 2021, respectively. As of December 31, 2022, we had retained earnings of $377.2 million.

We expect to continue to incur significant expenses and will continue to incur net losses in the foreseeable future. Since inception, we have devoted substantially all of our efforts to identifying, researching and conducting preclinical and clinical activities of our product candidates, acquiring and developing our technology platforms and product candidates, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio.

We received an Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, for sotrovimab (previously VIR-7831). In March and April 2022, the FDA amended the EUA fact sheet to exclude sotrovimab use in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information, including variant susceptibility to these drugs and regional variant frequency. With this EUA revision, sotrovimab is not currently authorized for use in any U.S. region. In light of these developments, we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future. In addition, there can be no assurance with respect to how long the EUA will remain in effect or whether the EUA will be further revised or revoked by the FDA based on the determination by the Secretary of the U.S. Department of Health and Human Services, or HHS, that the underlying health emergency no longer exists or warrants such authorization or other reasons. Furthermore, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and Glaxo Wellcome UK Limited and GlaxoSmithKline Biologicals S.A. (individually and collectively referred to as GSK) do not plan to file a Biologics License Application, or BLA, for sotrovimab at this time.

We received a positive scientific opinion from the Committee for Human Medicinal Products, or CHMP, in the European Union, or EU, for sotrovimab and to date, sotrovimab has obtained emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®) for early treatment of COVID-19, supplying more than 40 countries. However, foreign regulatory authorities may impose similar limitations to the FDA on the use of sotrovimab in jurisdictions where sotrovimab has been granted EUA, temporary authorization or marketing approval. For example, certain countries outside of the U.S., such as Canada and Japan, continue to maintain access to sotrovimab 500 mg intravenous, or IV, while noting that it is unlikely to maintain efficacy against certain Omicron subvariants. We cannot predict whether other countries will further limit the use of sotrovimab.

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

It could be several years, if ever, before we are able to commercialize any of our other product candidates. Any net losses we incur may fluctuate significantly from quarter to quarter and year to year. To remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our current and future product candidates, obtaining regulatory approval, procuring commercial-scale manufacturing and marketing and selling any products for which we obtain regulatory approval (including through third parties), as well as discovering or acquiring and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may not be able to continue to generate revenue that is sufficient to offset our expenses and maintain profitability.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses, or if we will be able to maintain profitability. If we are required by regulatory authorities to perform studies and trials in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

We could be required to perform additional studies and trials on sotrovimab based on any additional feedback we may receive from the regulatory and health authorities. For example, we and GSK continue to conduct *in vitro* testing of sotrovimab against new variants and subvariants as they emerge, and to collect and evaluate real-world evidence, both of which are being shared with regulatory authorities.

We may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

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

We are a commercial-stage company founded in April 2016 and our operations to date have been largely focused on identifying, researching and conducting preclinical and clinical activities of our product candidates, acquiring and developing our technology platforms and product candidates, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio. Sotrovimab has received marketing authorization in the EU and has been granted emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®), supplying more than 40 countries. Although certain countries outside of the U.S., such as Canada and Japan, continue to maintain access to sotrovimab 500 mg IV while noting that it is unlikely to maintain efficacy against certain Omicron subvariants, we cannot predict whether other countries will further limit the use of sotrovimab.

Furthermore, although we have an EUA from the FDA for sotrovimab, the FDA has excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. With this EUA revision, sotrovimab is not currently authorized for use in any U.S. region. In light of these developments, we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future. In addition, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA for sotrovimab at this time. Moreover, even if we were to file a BLA or marketing applications in other jurisdictions, it is possible that the FDA and other regulatory authorities may not grant sotrovimab full marketing approval for the treatment of COVID-19, or that any such marketing approvals, if granted, may have similar or other significant limitations on its use. As an organization, we have not yet demonstrated an ability to successfully manufacture a BLA-approved, commercial-scale product or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We currently have four technology platforms and eight product candidates in our development pipeline. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives, including with respect to our technology platforms and product candidates.

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

As of December 31, 2022, we had cash, cash equivalents and investments of $2.4 billion. Based upon our current operating plan, we believe that the $2.4 billion as of December 31, 2022, will fund our current operating plans for at least the next 12 months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional financing to fund our long-term operations sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future revenue and expenses given the dynamic and rapidly evolving nature of our business and the COVID-19 pandemic environment generally. We may also need to raise additional capital to complete the development and commercialization of our product candidates and fund certain of our existing manufacturing and other commitments. We expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. Our future capital requirements will depend on many factors, including:

- the timing, progress and results of our ongoing preclinical studies and clinical trials of our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;

- our ability to establish and maintain collaboration, license, grant and other similar arrangements, and the financial terms of any such arrangements, including timing and amount of any future milestones, royalty or other payments due thereunder;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of commercialization activities, including product manufacturing, marketing, sales and distribution, for our product candidates for which we receive marketing approval;
- the amount of revenue received from commercial sales of any product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- any expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other companies' product candidates and technologies.

General economic conditions, both inside and outside the U.S., including heightened inflation, capital market volatility, interest rate and currency rate fluctuations, and economic slowdown or recession as well as the COVID-19 pandemic, including the evolution of new and existing variants of COVID-19, and geopolitical events, including civil or political unrest (such as the ongoing war between Ukraine and Russia), have resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. In addition, market volatility, high levels of inflation and interest rate fluctuations may increase our cost of financing or restrict our access to potential sources of future liquidity. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether terminate our research and development programs or commercialization efforts, which may adversely affect our business, financial condition, results of operations and prospects. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest in our company may be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

If we raise additional capital through future collaborations, strategic alliances or licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Although we have an EUA from the FDA for sotrovimab for the early treatment of COVID-19, the disease caused by the virus SARS-CoV-2, the FDA has excluded the use of sotrovimab in all U.S. regions, and sotrovimab has limitations on its use in some countries outside of the U.S. If the FDA does not reauthorize the use of sotrovimab in the U.S., the FDA revokes or terminates our EUA for sotrovimab, the federally-declared COVID-19 public health emergency ends, or countries outside of the U.S. continue to limit its use, we may be unable to sell sotrovimab in or outside of the U.S.

Sotrovimab received an EUA from the FDA on May 26, 2021, 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 who are at risk for progression to severe COVID-19, including hospitalization or death. In March and April 2022, the FDA amended the EUA fact sheet to exclude sotrovimab use in geographic regions where infection is likely to have been caused by a non-susceptible

SARS-CoV-2 variant based on available information, including variant susceptibility to these drugs and regional variant frequency. With these EUA revisions, sotrovimab is not currently authorized for use in any U.S. region. In light of these developments, we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future.

In addition, there can be no assurance with respect to how long the EUA will remain in effect or whether the EUA will be further revised or revoked by the FDA based on the determination by the Secretary of HHS that the underlying health emergency no longer exists or warrants such authorization or other reasons. Any such revision or revocation of our EUA by the FDA could adversely impact our business in a variety of ways, including having to absorb related manufacturing and overhead costs as well as potential inventory write-offs. Furthermore, if we or our collaborators experience inventory revaluation adjustments, lower of cost or market inventory adjustments, and excess inventory, it may be necessary to write down or write-off inventory or incur an impairment charge with respect to the facility where such product is manufactured, which could adversely affect our operating results. For example, during the year ended December 31, 2022, we recorded a non-cash charge for potential write-offs related to excess supply and unused binding manufacturing capacity of $369.7 million related to sotrovimab against uncertain future pandemic demand, which has not been reported by GSK as cost-sharing amounts.

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

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

The FDA may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect public health or safety. An EUA may also be terminated upon a declaration by the Secretary of HHS that the public health emergency has ended. We cannot predict how long our EUA will remain in effect, and we may not receive advance notice from the FDA regarding revocation of our EUA or withdrawal of the public health emergency declaration. If our EUA is terminated or revoked, sotrovimab will no longer be available in the United States unless and until we have obtained FDA approval of a BLA for the product. Changing policies and regulatory requirements could limit, delay or prevent further commercialization of sotrovimab and could adversely impact our business, financial condition, results of operations and prospects.

We are committing substantial financial resources and personnel and making substantial capital commitments with third parties in connection with therapies for COVID-19. Market demand and utilization of any of our COVID-19 product candidates has been, and may continue to be, adversely impacted by factors such as the development of monoclonal antibodies, or mAbs, of other third parties, the rollout of oral antivirals and vaccines, the emergence of new variants or subvariants and the current challenges in the delivery and administration of mAbs to patients.

In response to the COVID-19 pandemic, we continue to pursue various potential therapies to address the disease, including through mAbs using our antibody platform (in collaboration with several partners), such as sotrovimab and VIR-7832. To prepare for new waves of variants and future pandemics, we are also actively pursuing multiple next-generation mAbs as well as small molecules aimed at treating COVID-19.

We are committing substantial financial resources, both internally and externally, and personnel to the development of therapies for COVID-19. There are no assurances that there will be sufficient market demand for our COVID-19 product candidates or that the FDA and other regulatory authorities will grant us full marketing approvals. For example, market demand and utilization for sotrovimab has been, and may continue to be adversely impacted by factors such as the development of mAbs of other third parties, the rollout of oral antivirals and vaccines, the emergence of new variants and subvariants, such as certain Omicron subvariants, and the current challenges in the delivery and administration of mAbs to patients. There are no assurances that these factors will not adversely impact our other COVID-19 product candidates. In addition, COVID-19 treatment standards are susceptible to rapid changes in epidemiology and the emergence of new variants or subvariants, which may render sotrovimab or any of our future COVID-19 product candidates inferior or obsolete in the future. For example, although we have an EUA from the FDA for sotrovimab, the FDA has excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. In addition, certain countries outside of the U.S., such as Canada and Japan, continue to maintain access to sotrovimab 500 mg IV, while noting that it is unlikely to maintain efficacy against certain Omicron subvariants. We

cannot predict whether other countries will further limit the use of sotrovimab. Any of these developments may adversely affect our financial condition and business.

Our ability to develop a successful therapy will also depend on the success of our manufacturing capabilities, for which we are dependent on third-party manufacturing organizations, and which will require significant additional funding. Although our current estimated aggregate commitment to GSK under a master services agreement with Samsung Biologics Co., Ltd. for sotrovimab drug substance, drug product and raw material has been substantially recognized on our balance sheet as part of the profit-sharing amount constrained as of December 31, 2022, under the definitive collaboration agreement dated June 9, 2020, between the Company and GSK, or the 2020 GSK Agreement, any future commitments for sotrovimab or any of our other future COVID-19 product candidates, may, in the future, exceed our available cash and cash equivalents and investments. We may also need to enter into additional manufacturing agreements in the future in order to create an effective supply chain for our other COVID-19 product candidates that will adequately support demand. In the event that there is not enough demand for the manufacturing capacity that we have already secured or regulatory approval of our product candidates is delayed or unsuccessful, we may remain obligated to pay for such excess manufacturing capacity and/or related costs under the agreements, which could adversely affect our business, financial condition, results of operations and prospects. For example, during the year ended December 31, 2022, we recorded a non-cash charge for potential write-offs related to excess supply and unused binding manufacturing capacity of $369.7 million related to sotrovimab against uncertain future pandemic demand, which has not been reported by GSK as cost-sharing amounts.

We may need to raise substantial additional capital to fund the development of our product candidates and meet our capital commitments to our manufacturing partners in connection therewith. There can be no assurance that sufficient funds will be available to us on attractive terms or at all and our ability to obtain additional capital could be adversely affected if there is a significant decline in the demand for our products or other significantly unfavorable changes in economic conditions. If we are unable to obtain additional funding from these or other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Furthermore, there are no assurances that we will secure additional supply commitments from governments, which may be material to the commercial success of our product candidates.

Product candidates that we successfully develop and commercialize may compete with existing therapies, including competing antibody therapies, oral antivirals, prophylactic vaccines, and new therapies that may become available in the future. In addition, one or more of our competitors may be successful in producing a more efficacious therapy for SARS-CoV-2 and current and future variants, such as certain Omicron subvariants, or in producing a therapy that is easier to deliver and administer to patients in a timelier manner. For example, in February 2022, the FDA approved an EUA for Eli Lilly Company's, or Eli Lilly, antibody, bebtelovimab, for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms) with positive results of direct SARS-CoV-2 testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death and when alternative treatment options are not accessible or clinically appropriate; however, in November 2022 the FDA announced that bebtelovimab is no longer authorized in any U.S. region due to lack of activity against recent Omicron subvariants. Merck & Co., Inc., or Merck, Pfizer Inc., or Pfizer, and Eli Lilly have all been successful in securing government support and funding. AstraZeneca plc's, or AstraZeneca, EVUSHELD™, a cocktail of two mAbs, showed topline efficacy of 50% reduction in risk for hospitalization or death risk in early treatment clinical trials and currently has an EUA for use as pre-exposure prophylaxis of COVID-19 in adults and pediatric individuals over the age of 12. EVUSHELD has also been approved in Japan and the EU for use in treatment of adults and adolescents over the age of 12 at risk of severe disease progression of COVID-19. There are several other manufacturers exploring options for pre-exposure and post-exposure prophylaxis such as Invivyd, Inc.'s, or Invivyd, adintrevimab.

There are FDA-approved treatments for COVID-19 including an intravenously administered antiviral, remdesivir, marketed by Gilead Sciences, Inc., or Gilead, which is FDA approved for the treatment of COVID-19 in both outpatient and hospitalized settings, and several treatments and a prophylactic vaccine are available under EUA. In December 2021 the FDA approved EUAs for the oral antiviral, molnupiravir, from Merck for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate, which has shown topline efficacy of 30% reduction in risk for hospitalization or death risk in early treatment clinical trials, and the oral antiviral, PAXLOVID™, from Pfizer for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms) with positive results of direct SARS-CoV-2 testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, which has demonstrated an 89% reduction in risk of COVID-19-related hospitalization or death. Additionally, Pfizer's COVID-19 vaccine, Comirnaty®, is approved by the FDA for individuals 5 years of age or older, Moderna, Inc.'s, or Moderna, COVID-19 vaccine, Spikevax®, is approved by the FDA for individuals 18 years of age or older and a COVID-19 vaccine is available in the United States under EUA from Janssen Biotech, Inc., or Janssen. These other entities may be more successful at developing, manufacturing or commercializing a therapy for COVID-19. Several of these other

organizations are much larger than we are and have access to larger pools of capital, including U.S. government funding, and broader manufacturing infrastructure. There are no assurances that there will be sufficient market demand for our COVID-19 therapies, that we will secure additional U.S. government funding, that our manufacturing and supply chain infrastructure will remain uninterrupted and reliable, or that the third parties we rely on to manufacture our COVID-19 therapies will be able to satisfy demand in a timely manner and not have supply chain disruptions, all of which could negatively impact or eliminate demand for our COVID-19 therapies.

Our near-term revenue is dependent on the continued sales and commercialization of sotrovimab for the early treatment of COVID-19, including our ability to enter into procurement contracts with government entities. If we are unable to continue to sell and/or commercialize sotrovimab in or outside of the U.S., our business, financial condition, results of operations and prospects may be adversely affected. In addition, sotrovimab may be rendered inferior or obsolete due to rapid changes in epidemiology and the emergence of new variants or subvariants.

Our near-term revenue is dependent on the continued sales and commercialization of sotrovimab, which is our only currently available commercial product. Our ability to sell and commercialize sotrovimab will depend on a number of factors, some of which are outside of our control, including the following:

- the ability of sotrovimab to be effective in patients with COVID-19 and its variants;
- our ability to comply with all regulatory requirements applicable to sotrovimab;
- the reauthorization of EUA in the U.S. and/or the receipt of additional marketing authorizations and approvals from the FDA and other similar regulatory authorities;
- whether we are required by the FDA or other similar regulatory authorities to conduct additional clinical trials or required to modify the design of our current trials to support the approval of sotrovimab;
- our expectations for future sales of sotrovimab and our ability to secure supply commitments from governments;
- limitation on use or warnings required by the FDA and other similar regulatory authorities;
- our ability to achieve and maintain compliance with all regulatory requirements applicable to sotrovimab;
- perceptions by the public and members of the medical community, including physicians, as to the safety and efficacy of sotrovimab as well as the accuracy and sufficiency of clinical evidence supporting its performance;
- demand from the public and members of the medical community for sotrovimab;
- the availability, perceived advantages, relative cost, relative convenience and relative efficacy of sotrovimab compared to other COVID-19 therapies as well as the accuracy and sufficiency of clinical evidence supporting its performance;
- positive or negative media coverage of sotrovimab;
- our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of sotrovimab;
- the ability to enter into procurement contracts with government entities, and our ability to meet our obligations under any such contracts;
- our reliance on GSK and other collaborators for development, commercialization and manufacturing of sotrovimab;
- our ability to obtain, maintain and enforce our intellectual property rights;
- our ability to maintain a continued supply of sotrovimab that meets our quality control requirements;
- the ability of third-party manufacturing partners to meet demand in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements;
- our current and future arrangements with healthcare providers, physicians and third-party payors; and
- availability of, or changes in, coverage or reimbursement rates for sotrovimab from government or other commercial or healthcare payors.

In addition, COVID-19 treatment standards are susceptible to rapid changes in epidemiology and the emergence of new variants or subvariants, which may render sotrovimab inferior or obsolete. In March and April 2022, the FDA amended the EUA fact sheet to exclude sotrovimab use in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information, including variant susceptibility to these drugs and regional variant frequency. With this EUA revision, sotrovimab is not currently authorized for use in any U.S. region. In light of these developments, we cannot predict whether (if at all)

or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future. Given the EUA revision by the FDA, it is possible that other regulatory authorities may not grant sotrovimab full marketing approval for the treatment of COVID-19, or that any such marketing approvals, if granted, may have similar or other significant limitations on its use. In addition, there can be no assurance with respect to how long the EUA will remain in effect or whether the EUA will be further revised or revoked by the FDA based on the determination by the Secretary of HHS that the underlying health emergency no longer exists or warrants such authorization or other reasons. Furthermore, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA for sotrovimab at this time.

Although certain countries outside of the U.S., such as Canada and Japan, continue to maintain access to sotrovimab 500 mg IV while noting that it is unlikely to maintain efficacy against certain Omicron subvariants, we cannot predict whether other countries will further limit the use of sotrovimab. If we are unable to sell or commercialize sotrovimab, our business, financial condition, results of operations and prospects may be adversely affected.

Risks Related to the Development and Commercialization

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

We have invested a significant portion of our time and financial resources in the development of our product candidates and have initiated clinical trials for multiple product candidates. Our business is dependent on our ability to successfully complete development of, obtain regulatory approval for, and successfully commercialize our product candidates, if approved, in a timely manner. We may face unforeseen challenges in our product development strategy, and we can provide no assurances that our product candidates will be successful in clinical trials or will ultimately receive regulatory approval.

Sotrovimab has received marketing authorization in the EU and has been granted emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®), supplying more than 40 countries. Although certain countries outside of the U.S., such as Canada and Japan, have maintained access to sotrovimab 500 mg IV while noting that it is unlikely to maintain efficacy against certain Omicron subvariants, we cannot predict whether other countries will limit the use of sotrovimab. Furthermore, although we have an EUA from the FDA for sotrovimab, the FDA has excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. With this EUA revision, sotrovimab is not currently authorized for use in any U.S. region. In light of these developments, we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future. In addition, there can be no assurance with respect to how long the EUA will remain in effect or whether the EUA will be further revised or revoked by the FDA based on the determination by the Secretary of HHS that the underlying health emergency no longer exists or warrants such authorization or other reasons. Furthermore, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA for sotrovimab at this time. We have not obtained BLA approval in the U.S. for any product candidate to date. We operate in a highly regulated field, and it is possible that none of our product candidates will obtain regulatory approval.

Prior to obtaining approval to commercialize any product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidate is safe and effective for its intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe that the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval for further development, manufacturing or commercialization of our product candidates by the FDA and other regulatory authorities. The FDA or other regulatory authorities may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program, requiring their alteration.

Even if we eventually complete clinical testing and receive approval of a new drug application, or NDA, BLA, or foreign marketing application for our product candidates, the FDA or the comparable foreign regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

In addition, the FDA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under

development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain applicable regulatory approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Furthermore, even if we obtain regulatory approval for our product candidates, we may still need to develop a commercial organization, establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors, including government health administration authorities. If we are unable to successfully commercialize our product candidates or if there is an insufficient demand for our product candidates, we may not be able to generate sufficient revenue to continue our business.

The development of additional product candidates is risky and uncertain, and we can provide no assurances that we will be able to replicate our approach for other diseases.

A core element of our business strategy is to expand our product candidate pipeline. Efforts to identify, acquire or in-license, and then develop product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our efforts may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development, approved products or commercial revenue for many reasons.

We have limited financial and management resources and, as a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, strategic alliances, licensing or other royalty arrangements in circumstances under which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, we may not be successful in replicating our approach to development for other disease indications. If we are unsuccessful in identifying and developing additional product candidates or are unable to do so, our business may be harmed.

Furthermore, we intend to seek approval to market our product candidates outside of the United States, and may also do so for future product candidates. If we market approved products outside of the United States, we expect that we will be subject to additional risks in commercialization. We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in which we may operate, with which we will need to comply. Many biopharmaceutical companies have found the process of marketing their products in foreign countries to be challenging.

We are developing, and in the future may develop, other product candidates in combination with other therapies, which exposes us to additional risks.

We are developing VIR-2218 and VIR-3434 for the functional cure of hepatitis B virus, or HBV, and for the chronic treatment of hepatitis D virus, or HDV. Each of these product candidates has the potential to stimulate an effective immune response and has direct antiviral activity against HBV. We believe that a functional cure for HBV will require an effective immune response, in addition to antiviral activity, based on the observation that severe immunosuppression can reactivate HBV disease. Monotherapy with each of these agents may provide a functional cure in some patients, while combination therapy may be necessary for others. We have an ongoing Phase 2 clinical trial that combines VIR-2218 with pegylated interferon-alpha and a Phase 2 clinical trial that combines VIR-2218 with VIR-3434. We are also evaluating additional combinations with other immunotherapy agents and direct acting antiviral agents. We also have a Phase 2 clinical trial evaluating VIR-2218 and VIR-3434 as a monotherapy or in combination for the treatment of chronic HDV. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate. There is also a risk that safety, efficacy, manufacturing or supply issues could arise with these other existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals and market authorizations.

Success in preclinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Success in preclinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired characteristics in clinical development sufficient to obtain regulatory approval, despite positive results in preclinical studies or having successfully advanced through earlier clinical trials.

A trial design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. If we do not conduct clinical trials with a large enough patient sample size, we may not achieve statistically significant results or the same level of statistical significance, if any, that would have been possible to achieve in a larger trial.

As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval, which could mean we will suffer setbacks. Any such setbacks could negatively impact our business, financial condition, results of operations and prospects.

Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, "top-line" or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data is available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

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

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA or comparable foreign regulatory authority, and we may never receive such approvals. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. We do not know whether our planned clinical trials will begin or enroll on time, need to be redesigned or be completed on schedule, if at all. For example, the availability of superior or competitive therapies coupled with changing standards of care could limit our ability to perform placebo-controlled trials and/or require us to enroll a larger number of subjects to address competing treatments. A failure of one or more clinical trials can occur at any stage of testing. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We may experience numerous unforeseen events prior to, during, or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales or other sources. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring competing products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

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

- be delayed in obtaining marketing approval, or not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all. For example, enrollment and retention of patients in clinical trials could be disrupted by geopolitical events, including civil or political unrest (such as the ongoing war between Ukraine and Russia), terrorism, insurrection or war, man-made or natural disasters, or public health pandemics or epidemics or other business interruptions, including the current COVID-19 pandemic and future outbreaks of the disease.

Furthermore, our product candidates are based on certain innovative technology platforms, which makes it even more difficult to predict the time and cost of product candidate development and obtaining necessary regulatory approvals, particularly for our small interfering ribonucleic acid, or siRNA, and cytomegalovirus, or CMV, vector technologies. In addition, the compounds we are developing may not demonstrate in patients the chemical and pharmacological properties ascribed to them in preclinical studies, and they may interact with human biological systems in unforeseen, ineffective or harmful ways.

As part of our T cell platform, our approach is to use human CMV, or HCMV, as a vaccine vector to potentially treat and prevent pathogens refractory to current vaccine technologies because HCMV may induce potent and long-lasting T cell responses to a broader range of epitopes than observed for other viral vaccines. Safety and toxicity trials for this technology have so far only been conducted in animal species, in which HCMV has limited ability to replicate. If our first clinical trial for VIR-1111 causes unexpected side effects that are not tolerable in the treatment of the relevant patient group, the further development of the product candidates and any other potential products based on HCMV-vector technology may be significantly limited or become impossible. Also, because our HCMV-vector technology is novel, regulatory agencies may lack experience with product candidates such as VIR-1111, which may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. In addition, our HCMV-vector technology utilizes live-attenuated, genetically-modified organisms for which the FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities and other public health authorities, such as the Centers for Disease Control and Prevention and hospitals involved in clinical trials, have established additional safety and contagion rules and procedures, which could establish additional hurdles for the development, manufacture or use of our vectors. These hurdles may lead to delays in the conduct of clinical trials or in obtaining regulatory approvals for further development, manufacturing or commercialization of our product candidates.

Further, we, the FDA, a foreign regulatory authority or an institutional review board may place a full or partial hold on our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA or foreign regulatory authority finds deficiencies in our investigational new drug, or IND, applications or clinical trial applications, respectively, or the conduct of these trials. Moreover, we may not be able to file INDs to commence additional clinical trials on the timelines we expect because our filing schedule is dependent on further preclinical and manufacturing progress. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenue from our product candidates may be delayed.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. In particular, clinical trials for prophylaxis are impacted by many factors including competing therapies that tend to require enrollment of a larger number of subjects than clinical trials for treatments. We may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our product candidates. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depend on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data, changing standards of care, the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the trial. The enrollment and retention of patients in the clinical trials for sotrovimab and VIR-7832 for the treatment of COVID-19 may be disrupted or delayed as a result of regulatory feedback, clinicians' and patients' perceptions as to the potential advantages of sotrovimab and VIR-7832 in relation to other available therapies, including products that have been recently authorized under EUAs or approved and licensed through NDAs and BLAs to treat COVID-19 as well as any other new products that may be approved in the future for the treatment of COVID-19. In addition, enrollment and retention of patients in clinical trials could be disrupted by geopolitical events, including civil or political unrest (such as the ongoing war between Ukraine and Russia), terrorism, insurrection or war, man-made or natural disasters, or public health pandemics or epidemics or other business interruptions, including, the current COVID-19 pandemic and future outbreaks of the disease.

Our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. Any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we may rely on contract research organizations, or CROs, and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to ensure their actual performance.

The continued spread of COVID-19 globally, or the evolution of new variants or subvariants of COVID-19 that are more contagious, have more severe effects or are resistant to treatments or vaccinations, could adversely impact our preclinical or clinical trial operations in the United States, including our ability to enroll and retain patients as well as CROs and clinical trial site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. In response to the COVID-19 pandemic, the FDA issued guidance on March 18, 2020, and subsequently updated it, to address the conduct of clinical trials during the pandemic. The guidance sets out a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical study report (or as a separate document) contingency measures implemented to manage the study, and any disruption of the study as a result of COVID-19; a list of all study participants affected by COVID-19-related study disruptions by a unique subject identifier and by investigational site, and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study. On January 30, 2023, the Biden administration announced that it will end the public health emergency declarations related to COVID-19 on May 11, 2023. On January 31, 2023, the FDA indicated that it would soon issue a Federal Register notice describing how the termination of the public health emergency will impact the FDA's COVID-19 related guidance, including the clinical trial guidance and updates thereto. An inability to enroll a sufficient number of patients for the clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether.

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

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

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

We are a party to strategic collaboration and license agreements pursuant to which we are obligated to make substantial payments upon achievement of milestone events and, in certain cases, have relinquished important rights over the development and commercialization of certain current and future product candidates. We also intend to explore additional strategic collaborations, which may never materialize or may require that we relinquish rights to and control over the development and commercialization of our product candidates.

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

A core element of our business strategy also includes continuing to acquire or in-license additional technologies or product candidates for the treatment and prevention of serious infectious diseases. As a result, we intend to periodically explore a variety of possible strategic collaborations or licenses in an effort to gain access to additional product candidates, technologies or resources.

At this time, we cannot predict what form such strategic collaborations or licenses might take in the future. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations and licenses can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations or licenses because of the numerous risks and uncertainties associated with establishing them. Any delays in entering into new strategic collaborations or licenses related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

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

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- disputes may arise between us and our strategic collaborators that result in costly litigation or arbitration that diverts management’s attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Furthermore, license agreements we enter into in the future may not provide exclusive rights to use intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

If the market opportunities for our product candidates are smaller than we believe they are or any approval we obtain is based on a narrower definition of the patient population, our business may suffer.

We currently focus our product development on product candidates for the treatment and prevention of serious infectious diseases. Our eligible patient population, pricing estimates and available coverage and reimbursement may differ significantly from the actual market addressable by our product candidates. Our estimates of the number of people who have these diseases, the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, and the market demand for our product candidates are based on our beliefs and analyses. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of the diseases we are targeting. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be receptive to treatment with our product candidates, and new patients may become increasingly difficult to identify or access. Additionally, the availability of superior or competitive therapies from our competitors could negatively impact or eliminate market demand for our product candidates. If the market opportunities for our product candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and an emphasis on proprietary products. We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions.

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

In addition, regulatory incentives to develop products for treatment of infectious diseases have increased interest and activity in this area and may lead to increased competition for clinical investigators and clinical trial subjects, as well as for future prescriptions, if any of our product candidates are successfully developed and approved.

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

Since the beginning of the COVID-19 pandemic, and even before, there has been substantial research in the development of new drugs and biologics to address diseases caused by the coronavirus. Numerous large and small pharmaceutical and biotechnology companies are developing COVID-19 therapy programs with various mechanisms of actions, including prophylactic vaccines, oral antivirals, immunomodulators, and antibodies, some of which are further along in the development process than we are. Other parties may be successful in producing a more efficacious therapy for SARS-CoV-2 or in producing a therapy that is easier to deliver and administer to patients in a timelier manner, which may also lead to the diversion of funding away from us and toward other companies or lead to decreased demand for our potential therapies. Companies with antibodies in clinical development include Invivyd, AstraZeneca, Brii Biosciences Offshore Limited, Celltrion Healthcare Co., Ltd., Eli Lilly and Regeneron Pharmaceuticals, Inc. Companies with oral antivirals in clinical development include Shionogi Inc., Gilead, Pardes Biosciences, Enanta Pharmaceuticals and others. Companies with prophylactic vaccines in clinical development include AstraZeneca, GSK, Novavax, Inc. and Sanofi S.A. The industry and competitive landscape for COVID-19 treatments is rapidly changing, and we could have more competition in the future. Although certain countries outside of the U.S., such as Canada and Japan, continue to maintain access to sotrovimab 500 mg IV while

noting that it is unlikely to maintain efficacy against certain Omicron subvariants, we cannot predict whether other countries will further limit the use of sotrovimab.

The availability of superior or competitive therapies, or preventative measures such as vaccines, coupled with the unpredictable nature of pandemics and the prevalence of new variants or subvariants of COVID-19, such as certain Omicron subvariants, could negatively impact or eliminate demand for our COVID-19 therapies. For example, in March and April 2022, the FDA amended the EUA fact sheet to exclude sotrovimab use in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information, including variant susceptibility to these drugs and regional variant frequency. With these EUA revisions, sotrovimab is not currently authorized for use in any U.S. region. In light of these developments, we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future. In addition, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA for sotrovimab at this time.

Product candidates that we successfully develop and commercialize may compete with existing therapies, including prophylactic vaccines, competing antibody therapies, oral antivirals, and new therapies that may become available in the future. In addition, one or more of our competitors may be successful in producing a more efficacious therapy for SARS-CoV-2 and current and future variants, such as certain Omicron subvariants, or in producing a therapy that is easier to deliver and administer to patients in a timelier manner. For example, there are FDA-approved treatments for COVID-19 including an intravenously administered antiviral, remdesivir, marketed by Gilead, which is FDA approved for the treatment of COVID-19 in both outpatient and hospitalized settings, and several treatments and a prophylactic vaccine are available under EUA. Additionally, Pfizer's COVID-19 vaccine, Comirnaty®, is approved by the FDA for individuals 5 years of age or older, Moderna's COVID-19 vaccine, Spikevax®, is approved by the FDA for individuals 18 years of age or older and a COVID-19 vaccine is available in the United States under EUA from Janssen. In December 2021 the FDA approved EUAs for the oral antiviral, molnupiravir, from Merck for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate, which has shown topline efficacy of 30% reduction in risk for hospitalization or death risk in early treatment clinical trials, and the oral antiviral, PAXLOVID™, from Pfizer for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms) with positive results of direct SARS-CoV-2 testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, which has demonstrated an 89% reduction in risk of COVID-19-related hospitalization or death. Currently, there are no mAbs available in the U.S. for use as treatment or prophylaxis against COVID-19. For example, in February 2022, the FDA approved an EUA for Eli Lilly's antibody, bebtelovimab, for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms) with positive results of direct SARS-CoV-2 testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death and when alternative treatment options are not accessible or clinically appropriate; however, in November 2022 the FDA announced that bebtelovimab is no longer authorized in any U.S. region due to lack of activity against recent Omicron subvariants. AstraZeneca's EVUSHELD™, a cocktail of two mAbs, was previously approved under an EUA for pre-exposure prophylaxis of COVID-19 in adults and pediatric individuals over the age of 12 at risk for severe disease progression of COVID-19, but was deauthorized by the FDA in January 2023. EVUSHELD currently remains authorized in other countries where it is approved for COVID-19 pre-exposure prophylaxis and treatment, including the EU and Japan. There are several other manufacturers exploring options for pre-exposure and post-exposure prophylaxis such as Invivyd's adintrevimab.

As a result of these factors, our competitors may achieve patent protection or obtain regulatory approval or authorization of their products before we are able to, which may limit our ability to develop or commercialize our product candidates. Our competitors may also develop therapies that are safer, more effective, more widely accepted or less expensive than ours, and may also be more successful than we are in manufacturing and marketing their products. These advantages could render our product candidates obsolete or non-competitive before we can recover the costs of such product candidates' development and commercialization. For additional information regarding our competitors, see the section titled "Business—Competition".

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

To date, sotrovimab has been granted emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®), supplying more than 40 countries. Although certain countries outside of the U.S., such as Canada and Japan, have maintained access to sotrovimab 500 mg IV while noting that it is unlikely to maintain efficacy against certain Omicron subvariants, we cannot predict whether other countries will further limit the use of sotrovimab. Furthermore, although we have an EUA from the FDA for sotrovimab, the FDA has excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. With this EUA revision, sotrovimab is not currently authorized for use in any U.S. region. In light of these developments, we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future. In addition, there can be no assurance with respect to how long the EUA will remain in

effect or whether the EUA will be further revised or revoked by the FDA based on the determination by the Secretary of HHS that the underlying health emergency no longer exists or warrants such authorization or other reasons. In addition, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA for sotrovimab at this time. Moreover, even if we were to file a BLA or marketing applications in other jurisdictions, itis possible that the FDA and certain other regulatory authorities may not grant sotrovimab full marketing approval for the treatment of COVID-19, or that any such marketing approvals, if granted, may have similar or other significant limitations on its use.

Even if any of our product candidates receive marketing approval, they may fail to achieve adoption by physicians, patients, third-party payors and others in the medical community. If such product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the convenience and ease of administration compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the efficacy and potential advantages compared to alternative treatments and therapies;
- the effectiveness of sales and marketing efforts;
- acceptance in the medical and patient communities of our product candidates as a safe and effective treatments;
- the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments;
- our ability to offer such product for sale at competitive prices;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement;
- the products' safety profile; and
- any restrictions on the use of the product together with other medications.

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

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

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

If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Moreover, product labeling, advertising and promotion for any approved product will be subject to regulatory requirements, continuing regulatory review and review by other government agencies and third parties. For example, a company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved or authorized label in the United States or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and comparable foreign regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued.

Failure to comply with such requirements, when and if applicable, could subject us to a number of actions ranging from warning letters to product seizures or significant fines or monetary penalties, among other actions. The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the marketing and promotion of products to ensure that they are

marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we market our medicines for uses other than their respective approved indications, we may be subject to DOJ-led enforcement actions for off-label marketing. Violations of the Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws, which violations may result in the imposition of significant administrative, civil and criminal penalties. Any government investigation of alleged violations of laws or regulations could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue. For additional information regarding regulatory approval and ongoing regulatory oversight, see the section titled "Business—Government Regulation and Product Approval".

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing them, if and when they are approved.

To successfully commercialize any product candidate that may result from our development programs, we will need to build out our sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market any product candidate we may develop will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability, and we have no experience as a company in commercializing products. Establishing sales and marketing capabilities will be particularly important to the commercial success of our product candidates that target diseases with large patient populations throughout the world. We may seek to enter into collaboration agreements with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. For example, GSK is primarily responsible for the commercialization of sotrovimab. If any current or future collaborators, including GSK, do not commit sufficient time or resources to commercialize our product candidates, or we are unable to develop the necessary capabilities on our own, we may be unable to generate sufficient revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel, and will have to compete with those companies to recruit, hire, train and retain any of our own marketing and sales personnel. We will likely also face competition if we seek third parties to assist us with the sales and marketing efforts of our product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval outside of the United States, which would limit our market opportunities.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable foreign regulatory authorities also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside of the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any product candidates, if approved, is also subject to approval. Obtaining approval for our product candidates in the EU from the European Commission following the opinion of the EMA if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a product candidate is approved, the EMA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Approval of certain product candidates outside of the United States, particularly those that target diseases that are more prevalent outside of the United States will be particularly important to the commercial success of such product candidates. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

In addition, following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. After lapse of a transition period, the U.K. is no longer part of the European Single Market and European Union Customs Union as of January 1, 2021. A trade and cooperation agreement that outlines the future trading relationship between the U.K. and the EU was agreed to in December 2020 and entered into force on May 1, 2021. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or the MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to EU rules under

the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law of the body of EU law instruments governing medicinal products that pre-existed prior to the U.K.'s withdrawal from the EU. Since a significant proportion of the regulatory framework for pharmaceutical products in the U.K. covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit may have a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. For example, the U.K. is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA, and a separate marketing authorization will be required to market our product candidates in the U.K. Until December 31, 2023, it is possible for the MHRA to rely on a decision taken by the European Commission on the approval of a new marketing authorization via the centralized procedure. However, it is unclear whether the MHRA in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive after such time. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the U.K. for our product candidates, which could significantly and materially harm our business. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for our product candidates may be withdrawn. If we fail to comply with the applicable regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects could be harmed.

Negative developments and negative public opinion of new technologies on which we rely may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

The clinical and commercial success of our product candidates will depend in part on public acceptance of the use of new technologies for the prevention or treatment of human diseases. For example, we use CMV, a commonly occurring virus in humans, as a vaccine vector to prevent and treat pathogens refractory to current vaccine technologies. We also use CRISPR gene-editing technology as a research tool to systematically identify human genes that control infection.

Public perception may be influenced by claims that CMV technology is unsafe and products incorporating this technology may not gain the acceptance of the public or the medical community, or that CRISPR gene-editing technology is unethical or immoral. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in our targeted diseases prescribing, and their patients being willing to receive, our product candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments for which greater clinical data may be available. Any increase in negative perceptions of the technologies that we rely on may result in fewer physicians prescribing our products or may reduce the willingness of patients to utilize our products or participate in clinical trials for our product candidates.

Increased negative public opinion or more restrictive government regulations in response thereto, would have a negative effect on our business, financial condition, results of operations or prospects and may delay or impair the development and commercialization of our product candidates or demand for such product candidates. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing similar technologies, even if not ultimately attributable to product candidates we may discover and develop, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we may identify and develop, stricter labeling requirements for those product candidates that are approved, a decrease in demand for any such product candidates and a suspension or withdrawal of approval by regulatory authorities of our product candidates.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop. In addition, our insurance policies may be inadequate and potentially expose us to unrecoverable risks.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;

- withdrawal of clinical trial participants;
- increased insurance costs;
- the inability to commercialize any product candidate that we may develop; and
- injury to our reputation and significant negative media attention.

Any such outcomes could negatively impact our business, financial condition, results of operations and prospects. Furthermore, although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify such as cybersecurity-related issues; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Conditions in the insurance markets relating to nearly all areas of traditional corporate insurance change rapidly and may result in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

Risks Related to Regulatory Compliance

The regulatory pathways for our product candidates targeting SARS-CoV-2, the virus that causes COVID-19, are continually evolving, and may result in unexpected or unforeseen challenges.

Our product candidates targeting SARS-CoV-2, the virus that causes COVID-19, are in various development and approval stages. To date, sotrovimab has been granted emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®), supplying more than 40 countries. Although certain countries outside of the U.S., such as Canada and Japan, have maintained access to sotrovimab 500 mg IV while noting that it is unlikely to maintain efficacy against certain Omicron subvariants, we cannot predict whether other countries will further limit the use of sotrovimab. Furthermore, although we have an EUA from the FDA for sotrovimab, the FDA has excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. With this EUA revision, sotrovimab is not currently authorized for use in any U.S. region. In light of these developments, we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future. In addition, there can be no assurance with respect to how long the EUA will remain in effect or whether the EUA will be further revised or revoked by the FDA based on the determination by the Secretary of HHS that the underlying health emergency no longer exists or warrants such authorization or other reasons. In addition, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA for sotrovimab at this time.

Evolving or changing plans or priorities within the FDA, including changes based on new knowledge of COVID-19, variants and subvariants of the disease, and how the disease affects the human body, may significantly affect the regulatory timelines for our COVID-19 product candidates. Results from our continued development and planned clinical trials may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. As part of these ongoing discussions, the FDA may require us to conduct additional preclinical studies and/or clinical trials than we originally anticipated, which could result in significant delay in our development program for these product candidates. For example, we and GSK continue to conduct *in vitro* testing of sotrovimab against new variants and subvariants as they emerge, and to collect and evaluate real-world evidence, both of which are being shared with regulatory authorities.

If any of our future small molecule drug product candidates obtain regulatory approval, competitors could enter the market with generic or follow-on versions of such products, which may result in a material decline in sales of affected products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic version of an approved, small molecule innovator drug product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that references the FDA's prior approval of the small molecule innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book, see the section titled "—Risks Related to Our Intellectual Property— Patent terms may be inadequate to protect our competitive position on our product candidates or any products approved in the future for an adequate amount of time and additional competitors could enter the market with generic or biosimilar versions of such products."

Accordingly, if any of our future small molecule drug product candidates are approved, competitors could file ANDAs following the expiration of regulatory exclusivity for generic versions of these products or 505(b)(2) NDAs that reference our products. If competitors are able to obtain marketing approval for generics referencing our small molecule drug product candidates, such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval. They may also be prescribed by healthcare providers for off-label uses that are otherwise protected by regulatory exclusivity. For additional information regarding competition, see the section titled "Business—Competition".

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

If we are successful in achieving regulatory approval to commercialize any biologic product candidate faster than our competitors, such product candidates may face competition from biosimilar products. In the United States, biologic product candidates are subject to approval and licensure under the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated pathway for the approval of biosimilar and interchangeable biologic products following the approval of an original BLA. For additional information regarding biosimilars and exclusivity, see the section titled "Business—Government Regulation and Product Approval—Biosimilars and Regulatory Exclusivity".

If competitors are able to obtain marketing approval for biosimilars referencing our biologic product candidates, if approved and after the expiration of regulatory exclusivity, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval. In addition, the extent to which any regulatory exclusivity may apply to competing products authorized under an EUA is unclear and may not apply. For additional information regarding competition, see the section titled "Business—Competition".

In addition, we may also face competition from product candidates that receive EUA approval, which could negatively impact sales of our product candidates. For example, numerous large and small pharmaceutical and biotechnology companies are developing COVID-19 therapy programs, including prophylactic vaccines, oral antivirals, immunomodulators, and antibodies, some of which have received full approval or EUAs from the FDA. For additional information regarding competition, see the section titled "—Risks Related to the Development and Commercialization — We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do."

Our relationships with customers, physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, such as the U.S. federal Anti-Kickback Statute, federal civil and criminal false claims laws, the healthcare fraud provisions of the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the Physician Payments Sunshine Act.

These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any product candidates, if approved. For additional information regarding these

laws, see the section titled “Business—Government Regulation and Product Approval”. Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant civil, criminal or administrative sanctions, including exclusions from government-funded healthcare programs. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace.

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

Even if we obtain BLA approval in the United States, market acceptance and sales of any product candidates that we commercialize may depend in part on the extent to which reimbursement for these product and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. While no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Therefore, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor’s decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy and on what tier of its formulary it will be placed. The position on a payor’s list of covered drugs and biological products, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. In addition, because certain of our product candidates are physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used.

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

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

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

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future product candidates or additional pricing pressures. It is possible that additional governmental action is taken in response to the COVID-19 pandemic. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Additionally, in August 2011, the President signed into law the Budget Control Act of 2011, as amended, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and, following passage of subsequent legislation, including the Bipartisan Budget Act of 2018, will continue through 2031.

Additionally, as a result of litigation challenging the interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, on December 27, 2021, the Centers for Medicare & Medicaid Services, or CMS, published a final rule that rescinds the Most Favored Nation Model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to President Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, with passage of the Inflation Reduction Act in August 2022, Congress authorized Medicare, beginning in 2026, to negotiate lower prices for certain high Medicare expenditure single-source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year, and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition and for which the only approved indication is for such disease are categorically excluded from price negotiation. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, 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. In addition, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference.

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. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or "catastrophic period" of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. 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.

Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

For additional information regarding other healthcare legislative reform measures, see the section titled "Business—Government Regulation and Product Approval—Healthcare Reform".

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

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

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act and other anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption and anti-bribery laws have been enforced aggressively in recent years and are interpreted broadly to generally prohibit companies and their employees and third-party intermediaries from authorizing, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of government agencies and government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad or to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, collaborators and agents, even if we do not explicitly authorize such activities.

While we have policies and procedures to address compliance with such laws in the United States, we cannot assure you that all of our employees and agents will not take actions in violation of our policies and applicable law, for which we may be ultimately held responsible. Detecting, investigating and resolving actual or alleged violations can require a significant diversion of time, resources and attention from senior management. In addition, noncompliance with anti-corruption, anti-bribery or anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, financial condition, results of operations and prospects could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Enforcement actions and sanctions could further harm our business, reputation, financial condition, results of operations and prospects.

Risks Related to Our Dependence on Third Parties

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

We are currently conducting process development and manufacturing material for product candidates of three different modalities: mAbs, HCMV-based vaccines and siRNAs. Except for limited process development and quality control testing capabilities in certain of our facilities, we do not own or operate facilities for full process development or product manufacturing, storage and distribution, or testing. We are dependent on third parties to develop the manufacturing process and manufacture the clinical supplies of our current and any future product candidates. We have established relationships with multiple contract development and manufacturing organizations, or CDMOs, that have produced material to support our preclinical, Phase 1, 2, and 3 clinical trials. We have limited experience manufacturing our product candidates on a commercial scale, and we do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our future product candidates. Certain of our product candidates may have to compete with existing and future products, such as the annual flu vaccine or any current or future COVID-19 vaccine, that may have a lower price point. The actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates.

The facilities used by third parties to develop and manufacture our product candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after we submit our NDA or BLA to the FDA or foreign marketing application to the appropriate regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with the cGMP requirements. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

We also intend to rely on third-party manufacturers to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization. There is, however, no assurance that our third-party manufacturers will meet our working assumptions of manufacturing titer and yield per batch of our product candidates or consistently manufacture product meeting our quality requirements. Any reduction in anticipated manufacturing titer, yield per batch or batch success rates may adversely impact

our ability to meet market demand for any approved product. Furthermore, if we are not able to produce supply at low enough costs, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business, financial condition, results of operations and prospects.

In addition, we currently rely on strategic collaborators and foreign CDMOs, including a CDMO in China, which we, in part, rely on for the clinical development, manufacturing, and commercialization of our proprietary antibodies developed for SARS-CoV-2, and will likely continue to rely on foreign CDMOs in the future. Foreign CDMOs may be subject to trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies.

Additionally, the biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our collaborators in China which could have an adverse effect on our business, financial condition, results of operations and prospects. Evolving changes in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the U.K., could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs.

Further, our reliance on third-party suppliers and manufacturers entails risks to which we would not be exposed to or that may be reduced if we conducted process development or manufactured product candidates ourselves, including:

- delay or inability to procure or expand sufficient manufacturing capacity;
- delays in process development;
- issues related to scale-up of manufacturing;
- excess manufacturing capacity due to insufficient market demand for our product candidates and responsibility for the associated costs;
- costs and validation of new equipment and facilities required for scale-up;
- inability of our third-party manufacturers to execute process development, manufacturing, technology transfers, manufacturing procedures and other logistical support requirements appropriately or on a timely basis;
- inability to negotiate development and manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of development and manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for product raw materials or components;
- lack of qualified backup suppliers for those raw materials or components that are currently purchased from a sole or single-source supplier;
- lack of ownership to the intellectual property rights to any improvements made by our third parties in the manufacturing process for our product candidates;
- price increases or decreased availability of product raw materials or components;
- disruptions to operations of our third-party manufacturers or suppliers by conditions unrelated to our business or operations, including supply chain issues, capacity constraints, transportation and labor disruptions, global competition for resources, the bankruptcy of the manufacturer and/or general economic conditions, heightened inflation, interest rate and currency rate fluctuations, and economic slowdown or recession;
- disruptions caused by geopolitical events, including civil or political unrest (such as the ongoing war between Ukraine and Russia), terrorism, insurrection or war, man-made or natural disasters or public health pandemics or epidemics, including, for example, the COVID-19 pandemic; and
- carrier disruptions or increased costs that are beyond our control, including increases in material, labor or other manufacturing-related costs or higher supply chain logistics costs.

We may be unable to obtain product raw materials or components for an indeterminate period of time if any of third-party suppliers and manufacturers were to cease or interrupt production or otherwise fail to supply these materials or components to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier or manufacturer, failure by the supplier or manufacturer to comply with cGMPs, contaminations, business interruptions, or labor shortages or disputes. Suppliers may extend lead times, limit supplies or increase prices due to capacity constraints or other factors beyond our control. We cannot be sure that single source suppliers for our product raw materials or components will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these raw materials or components for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in manufacturing delays, additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results.

Furthermore, there are a limited number of suppliers and manufacturers that supply synthetic siRNAs. We currently rely on a limited number of suppliers and CDMOs for our supply of synthetic siRNAs. There are risks inherent in pharmaceutical manufacturing that could affect the ability of our CDMOs to meet our delivery time requirements or provide adequate amounts of synthetic siRNAs to meet our needs. Included in these risks are potential extended lead times, delays or shortages of raw materials and component including as a result of the COVID-19 pandemic, synthesis and purification failures and/or contamination during the manufacturing process, as well as other issues with the CDMO's facility and ability to comply with the applicable manufacturing requirements, including cGMP requirements which could result in unusable product. This would cause delays in our manufacturing timelines and ultimately delay our clinical trials and potentially put at risk commercial supply, as well as result in additional expense to us. To fulfill our siRNA supply requirements, we may need to secure alternative suppliers of synthetic siRNAs and/or key raw materials and components, and such alternative suppliers are limited and may not be readily available, or we may be unable to enter into agreements with them on reasonable terms and in a timely manner.

In addition, manufacturers may have little or no experience with viral vector products and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our HCMV vector-based product candidates. The challenges to HCMV-based vaccine manufacturing include the large size of the virus, which precludes terminal sterile filtration, and that some vectors have a restricted growth phenotype in cells that reduces yields during manufacturing. To address these challenges, we have made significant internal investments in process development and scale-up, largely funded by grants from the Bill & Melinda Gates Foundation. We have established a cGMP process in support of Phase 1 and Phase 2 clinical trials that has been successfully transferred and executed at a CDMO specializing in live vaccine manufacturing. However, the existing process will require additional process development and scale-up for later stages of clinical development and commercial supply. To fulfill our HCMV supply requirements, we may need to secure alternative suppliers of viral vector products and/or key raw materials and components, and such alternative suppliers may not have the manufacturing experience or capacity required for HCMV-based vaccine manufacturing, or we may be unable to enter into agreements with them on reasonable terms and in a timely manner.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future product candidates once approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure or total or partial suspension of production. Any such recall, seizure or suspension could adversely impact our business in a variety of ways, including having to absorb related manufacturing and overhead costs as well as potential inventory write-offs.

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

The U.S. government has made statements and taken actions that have led to certain changes and may lead to additional changes to U.S. and international trade policies, including imposing several rounds of tariffs affecting certain products manufactured in China. In addition, the Chinese government took certain actions, including tariffs, which affect certain products manufactured in the U.S. It is unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry. Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may affect the demand for our product candidates, the competitive position of our product candidates, and import or export of raw materials and product used in our drug development activities and commercial manufacturing, particularly with respect to raw materials and product that we import from China, including pursuant to our development and manufacturing arrangements with WuXi Biologics. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

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

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

We rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our preclinical studies and clinical trials, and we expect to have limited influence over their actual performance. We rely on CROs to monitor and manage data for our clinical programs, as well as the execution of future preclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the good laboratory practices, or GLPs, and GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our reliance on third parties to conduct clinical trials will result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with CROs and other third parties can be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines or fail to comply with regulatory requirements, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. While we will have agreements governing their activities, our CROs will not be our employees and we will not control whether or not they devote sufficient time and resources to our future clinical and preclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology.

If our relationship with any of these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. While we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, financial condition, results of operations and prospects.

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

Risks Related to Our Intellectual Property

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

We license a number of technologies to form our antibody platform and T cell platform, and the technology we use in our siRNA platform is licensed from Alnylam Pharmaceuticals, Inc. We have also developed certain product candidates using intellectual property licensed from third parties. A core element of our business strategy includes continuing to acquire or in-license additional technologies or product candidates for the treatment and prevention of serious infectious diseases.

If we fail to meet our obligations under these agreements, our licensors may have the right to terminate our licenses. If any of our license agreements are terminated, and we lose our intellectual property rights under such agreements, this may result in a complete termination of our product development and any commercialization efforts for the product candidates which we are developing under such agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under such agreements, we may not be able to do so in a timely manner, at an acceptable cost or at all. We may also be subject to risks related to disputes between us and our licensors regarding the intellectual property subject to a license agreement.

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

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate. Furthermore, if third parties have filed such patent applications with a priority date before March 16, 2013, an interference proceeding in the United States can be initiated by such third party, or by the U.S. Patent and Trademark Office, or USPTO, itself, to determine who was the first to invent any of the subject matter covered by the claims of our patent applications or issued patents.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or patents at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In addition, changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the term, enforcement or defense of issued patents. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future.

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

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

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

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our owned and in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third

parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will have to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our service providers or our licensors to pay these fees. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or technologies, including as a result of geopolitical events such as civil or political unrest (including the ongoing war between Ukraine and Russia), we may not be able to use such patents and patent applications or stop a competitor from marketing products that are the same as or similar to our product candidates, which would have an adverse effect on our business. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

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

Patent terms may be inadequate to protect our competitive position on our product candidates or any products approved in the future for an adequate amount of time and additional competitors could enter the market with generic or biosimilar versions of such products.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent and the protection it affords is limited. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our business and results of operations could be adversely affected.

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

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

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 sotrovimab and other product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that sotrovimab and other product candidates may give rise to claims of infringement of the patent rights of others. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technology, including interference proceedings, derivation proceedings, post grant review and inter partes review before the USPTO. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all, and if such an instance arises, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Parties making claims against us may also seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have an adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. We may also have to redesign our products, which may not be commercially or technically feasible or require substantial time and expense. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could harm our business. Even if we are successful in defending against such claims, litigation can be expensive and time-consuming and would divert management's attention from our core business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim

proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications as a result of the work they performed on our behalf. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities.

In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our owned or licensed patents at risk of being invalidated or interpreted narrowly and could put our owned or licensed patent applications at risk of not issuing. The initiation of a claim against a third party might also cause the third party to bring counterclaims against us, such as claims asserting that our patent rights are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, post-grant review, or oppositions or similar proceedings outside of the United States, in parallel with litigation or even outside the context of litigation. Third parties may also challenge inventorship through a derivation proceeding or other litigation proceeding challenging inventorship, which can include claims of misappropriation of intellectual property, filing a patent application without authorization of the true inventor, not listing inventors, or listing non-inventors as inventors. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is or will be no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license, or if the license offered as a result is not on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail and, even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our current and any future product candidates and technology platforms in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Some countries do not enforce patents related to medical treatments, or limit enforceability in the case of a public emergency. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

The intellectual property systems in other countries can be destabilized or unpredictable as a result of geopolitical events such as civil or political unrest (including the ongoing war between Ukraine and Russia). Therefore, during such geopolitical events, the ability to obtain, retain and enforce intellectual property protection in the affected countries may be uncertain and evolve during the course of such geopolitical event. For example, as a result of the ongoing war between Ukraine and Russia, Russian officials have suggested that they may treat patents or patent applications owned by parties from certain countries, including the United States, as unenforceable and/or provide for zero compensation compulsory licenses to such patents or patent applications. Recent court decisions in Russia have raised questions about the strength of trademark protections in Russia. The U.S. government’s response to geopolitical events may also negatively affect our ability to obtain, retain and enforce intellectual property protection in the affected countries. For example, the U.S. government has issued sanctions against Russia related to the ongoing war in Ukraine, and as a result of these sanctions, it may not be possible to pay fees necessary for prosecution and maintenance of Russian patent applications and patents,

including Russian patent rights based on Eurasian patents, in the absence of licenses or exclusions set forth by the U.S. government authorizing transactions in connection with intellectual property. Payments for trademark protection may be similarly restricted. Failure to make such payments can result in the loss of intellectual property protection in Russia. The U.S. Department of the Treasury has issued General License No. 31, authorizing such transactions to allow filing, prosecution and maintenance of Russian patents and trademarks. Uncertainties regarding geopolitical events, including the ongoing war between Ukraine and Russia, as well as any resulting losses of intellectual property protection, could harm our business.

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

On June 17, 2022, the WTO adopted a Ministerial Decision to waive certain intellectual property rights for COVID-19 vaccines. The waiver allows certain developing countries to permit the manufacture and use of COVID-19 vaccines without the consent of the patent holder(s) to the extent necessary to address the COVID-19 pandemic. The waiver is also expected to allow certain developing countries to permit compulsory licensing for the export of COVID-19 vaccines to certain other developing countries. The waiver is in effect initially for five years from the date of the Ministerial Decision and will be reviewed annually. The WTO is considering whether to extend the waiver to diagnostics and therapeutics. The WTO may consider additional waivers, the ultimate timing and scope of which, if approved, are unknown. The scope and timing of such extensions and/or additional waivers will likely be subject to extensive negotiations given the complexity of the matter, which may result in prolonged uncertainty, which could adversely affect our business. If a waiver covering COVID-19 treatments or prophylactics, such as sotrovimab and VIR-7832, is approved, our ability to successfully commercialize our COVID-19 product candidates and protect our related technology could be adversely affected.

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

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking intellectual property protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Because we rely on third parties to help us discover, develop and manufacture our current and any future product candidates, or if we collaborate with third parties for the development, manufacturing or commercialization of our current or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development collaborations or similar agreements.

We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of these parties to use or disclose our confidential information, including our trade secrets. We also enter into invention or patent assignment agreements with our employees, advisors and consultants. Despite our efforts to protect our trade secrets, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally or unlawfully obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes less willing to protect trade secrets.

In addition, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using

that technology or information to compete with us. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business, financial condition, results of operations and prospects.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. Additionally, the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our work-from-home policies for most of our employees, which provides our employees the choice of working full time in the office, a hybrid approach, or full-time remote. A remote working environment may be less secure and more susceptible to hacking attacks. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

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

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

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

We entered into an amended and restated letter agreement with the Bill & Melinda Gates Foundation, or the Gates Agreement, in January 2022, which amends and restates the letter agreement with the Bill & Melinda Gates Foundation that we entered into in December 2016. In connection with the Gates Agreement, the Bill & Melinda Gates Foundation purchased $20.0 million of shares of our convertible preferred stock which converted to shares of our common stock after our initial public offering and purchased $40.0 million of shares of our common stock. We are obligated to use the proceeds of the Bill & Melinda Gates Foundation's investment in furtherance of its charitable purposes to perform certain activities set forth in the Gates Agreement. For additional information regarding our obligations under the Gates Agreement, see the section titled "Business—Our Collaboration, License and Grant Agreements—Amended and Restated Letter Agreement with the Bill & Melinda Gates Foundation".

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

Bill & Melinda Gates Foundation will have the right to exercise a non-exclusive, fully-paid license (with the right to sublicense) under our intellectual property to the extent necessary to use, make and sell products arising from such programs, in each case solely to the extent necessary to benefit people in the developing countries in furtherance of the Bill & Melinda Gates Foundation's charitable purpose.

The exercise by the Bill & Melinda Gates Foundation of any of its non-exclusive licenses to certain of our intellectual property (or its right to obtain such licenses), and its development and commercialization of product candidates and products that we are also developing and commercializing, could have an adverse impact on our market position.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

We are highly dependent on our key personnel, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

We are highly dependent on our management, scientific and medical personnel. Our key personnel may currently terminate their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

We announced a Chief Executive Officer transition in January 2023 that will be effective April 3, 2023 and announced a Chief Financial Officer transition in February 2023 that will be effective March 27, 2023. Management transitions may create uncertainty and involve a diversion of resources and management attention, be disruptive to our daily operations or impact public or market perception, any of which could negatively impact our ability to operate effectively or execute our strategies.

Recruiting and retaining other senior executives, qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Macroeconomic conditions, specifically labor shortages, increased competition for employees and wage inflation, could also have a material impact on our ability to attract and retain talent, our turnover rate and the cost of operating our business. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations.

We have in the past and may in the future acquire or invest in other companies or technologies, which could divert our management's attention, result in dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results.

We have in the past and may in the future seek to acquire or invest in additional businesses and/or technologies that we believe complement or expand our product candidates, enhance our technical capabilities or otherwise offer growth opportunities in the United States and internationally. The pursuit of potential acquisitions and investments may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. In addition, we are exposed to market risks related to our investments, including changes in fair value of equity securities we hold, which is discussed in greater detail under Item 7A. Quantitative and Qualitative Disclosures About Market Risk in this Annual Report on Form 10-K.

For example, we acquired TomegaVax, Inc., or TomegaVax, in September 2016, Humabs BioMed SA, or Humabs, in August 2017, Agenovir Corporation, or Agenovir, in January 2018 and Statera Health, LLC, or Statera, in February 2018. Realizing the benefits of these acquisitions will depend upon the successful integration of the acquired technology into our existing and future

product candidates. We also may not realize the anticipated benefits from any acquired business. We face many risks in connection with acquisitions and investments, whether or not consummated. A significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. If our acquisitions do not yield expected returns, we may in the future be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our business, financial condition, results of operations and prospects.

In addition, in connection with our acquisitions of TomegaVax, Humabs and Agenovir, we are required to make future contingent payments upon the achievement of certain milestones. We may in the future be required to make these payments, which could adversely affect our financial condition. For additional information regarding our obligations under these agreements, see the section titled "Business—Our Acquisition Agreements".

Furthermore, acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our business, financial condition, results of operations and prospects may suffer. We cannot assure you that we will be successful in integrating the businesses or technologies we may acquire. The failure to successfully integrate these businesses could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We have experienced significant growth in the number of our employees and the scope of our operations in recent years at both our sites and remote locations, particularly in the areas of research, development and regulatory affairs, and we expect to continue to experience growth as the clinical development of our product candidates progresses. In addition, if any of our product candidates receives marketing approval, we will need to build out our sales and marketing capabilities, either on our own or with others. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. As a result of the global pandemic, the majority of our workforce has been working from home since March 2020. Despite this, we must continue to effectively integrate, develop and motivate a growing number of new employees, and maintain the beneficial aspects of our corporate culture. In April 2022, we reopened our offices to allow employees to return to work and we now offer all our employees the choice of working full-time in the office, a hybrid approach, or full-time remote. Although the reopening of our offices is consistent with local government requirements, is focused on employee safety, and contemplates returning to remote work should the COVID-19 situation change, there is uncertainty regarding the long-term impact that the COVID-19 pandemic has had on the nature of the office environment and remote working, which could present operational and workplace culture challenges as we seek to expand our organization. The expansion of our operations may lead to significant costs and may divert our management and business development resources. We may not be able to effectively manage the expansion of our operations, recruit and train additional qualified personnel, or succeed at effectively integrating employees that have joined during the global pandemic. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CDMOs, CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health pandemics or epidemics (including, for example, the COVID-19 pandemic), geopolitical events, including civil or political unrest (such as the ongoing war between Ukraine and Russia), terrorism, insurrection or war, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our ability to develop our product candidates could be disrupted if our operations or those of our suppliers are affected by geopolitical events, man-made or natural disasters or other business interruptions. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Our business could be materially adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic and future pandemics.

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

The COVID-19 pandemic resulted in travel restrictions, quarantines orders and other restrictions by governments to reduce the spread of the disease. The effects of the restrictions related to the COVID-19 pandemic and our hybrid work policies, discussed below, may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of any future restrictions and other limitations on our ability to conduct our business in the ordinary course. Quarantines, shelter-in-place and similar government orders, or the perception that such orders or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. In particular, some of our CDMOs that we use to supply our early-stage product candidates are located in China, where there continue to government-imposed quarantines. While many of these materials may be obtained by more than one supplier, including suppliers outside of China, port closures and other restrictions resulting from the COVID-19 outbreak in the region or other regions may disrupt our supply chain or limit our ability to obtain sufficient materials for our product candidates.

In addition, our clinical trials have been affected by the COVID-19 pandemic. Site initiation and patient enrollment has been and may be further delayed due to prioritization of hospital resources toward the COVID-19 pandemic, and some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, has been delayed or disrupted, which has adversely impacted our clinical trial operations.

Since March 2020, due to the COVID-19 pandemic, the majority of our workforce has been working from home. We now offer all of our employees the choice of working full time in the office, a hybrid approach, or full-time remote. Coming into the office remains 100% voluntary, unless a person's role requires them to be on site to do their job. As a result, we expect to continue to be subject to the challenges and risks of having a remote workforce, as well as new challenges and risks from operating with a hybrid workforce. For example, our employees are accessing our servers remotely through home or other networks to perform their job responsibilities. Such security systems may be less secure than those used in our offices, which may subject us to increased security risks, including cybersecurity-related events, and expose us to risks of data or financial loss and associated disruptions to our business operations. Additionally, employees who access company data and systems remotely may not have access to technology that is as robust as that in our offices, which could place additional pressure on our user infrastructure and third parties that are not easily mitigated. We may also be exposed to risks associated with the locations of remote employees, including compliance with local laws and regulations or exposure to compromised internet infrastructure. Allowing our employees to work remotely may create intellectual property risk if employees create intellectual property on our behalf while residing in a jurisdiction with unenforced or uncertain intellectual property laws. Further, if employees fail to inform us of changes in their work location, we may be exposed to additional risks without our knowledge.

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

The continued spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic, may be difficult to assess or predict, it has already resulted in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 and the evolution of new and existing variants or subvariants that are resistant to existing treatments or vaccinations continue to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. These effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

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

Our computer and information technology systems, cloud-based computing services and those of our current and any future collaborators, service providers and other parties upon whom we rely are potentially vulnerable to malware, computer viruses, denial-of-service attacks (such as credential stuffing), ransomware attacks, user error or malfeasance, data corruption, cyber-based attacks, natural disasters, public health pandemics or epidemics (including, for example, the COVID-19 pandemic), geopolitical events, including civil or political unrest (such as the ongoing war between Ukraine and Russia), terrorism, war and telecommunication and electrical failures that may result in damage to or the interruption or impairment of key business processes, or the loss or corruption of our information, including intellectual property, proprietary business information and personal information. We may also experience server malfunction, software or hardware failures, supply-chain cyber-attacks, loss of data or other computer assets and other similar issues. We have experienced security breaches of our information technology systems, such as through business email compromises. The techniques used to sabotage or to obtain unauthorized access to information systems, and networks in which cyber threat actors store data or through which they transmit data change frequently and we may be unable to implement adequate preventative measures. Any significant system failure, accident or security breach could have a material adverse effect on our business, financial condition and operations.

We may be required to expend significant resources (including financial), fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security breaches and to detect (including performing required forensics), mitigate and remediate actual and potential vulnerabilities. Relevant laws, regulations, industry standards and contractual obligations may require us to implement specific security measures or use industry-standard or reasonable measures to protect against security breaches. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs, security breaches and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, data loss or corruption, delays, cessation of service and other harm to our business and our competitive position. If the information technology systems of our third-party vendors become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Although we maintain cybersecurity insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. Furthermore, if a security breach were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions.

For example, we, our third-party vendors, and our partners' third-party vendors have experienced social engineering efforts (including phishing attacks) designed to gain unauthorized access to our systems and information, including recent business email and system compromises. Similarly, we and our partners' third-party vendors may be a target of other phishing attacks, social engineering attacks and other cyber-attacks in the future. If a data security breach affects our or third parties' systems upon which we rely, corrupts our data or results in the unauthorized disclosure or release of personally identifiable information, our reputation could be materially damaged or our operations disrupted. In addition, such a breach may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media, individuals, collaborators or others pursuant to various federal, state and foreign data protection, privacy and security laws, regulations and guidelines, industry standards, our policies and our contracts, if applicable. Such laws may include HIPAA and the Health Information Technology for Economic and Clinical Health Act, or HITECH, and General Data Protection Regulation. Under these laws specifically, notice of certain security breaches must be made to affected individuals, the Secretary of HHS, applicable Supervisory Authority, and for extensive breaches, to the media or state attorneys general. Such a notice could further harm our reputation and our ability to compete. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to a material adverse effect on our reputation, business, or financial condition. Furthermore, a data security breach could result in fines, increased costs or loss of revenue and we could incur liability (such as through regulatory fines and penalties as well as private claims), our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Additionally, federal, state and foreign laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, EU and the U.K. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In 2018 California passed into law the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020, and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the General Data Protection Regulation, or GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In November 2020 California voters passed a ballot initiative for the California Privacy Rights Act, or CPRA, which went into effect on January 1, 2023, and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities. In addition, other states, including Virginia, Colorado, Utah and Connecticut, already have passed state privacy laws. Virginia's privacy law also went into effect on January 1, 2023, and the laws in the other three states will go into effect later in the year. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

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

The GDPR places restrictions on the cross-border transfer of personal data from the EU to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the EU to other countries. In July 2020 the Court of Justice of the European Union, or CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. While we were not self-certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States generally and increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.

Additionally, in October 2022 President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-U.S. Privacy Shield. The European Commission initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022. It is unclear if and when the framework will be finalized and whether it will be challenged in court. The uncertainty around this issue may further impact our business operations and activities in the EU.

Following the withdrawal of the U.K. from the EU, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the U.K. and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the U.K. and the EU have determined, through separate "adequacy" decisions, that data transfers between the two jurisdictions are in compliance with the U.K. Data Protection Act and the GDPR, respectively. Any changes or updates to these adequacy decisions have the potential to impact our business.

Beyond the GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow the GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and the sale and distribution of commercial products, if approved, through increased compliance costs, costs associated with contracting and potential enforcement actions.

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

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures, reckless and/or negligent conduct or unauthorized activities that violates (i) the laws and regulations of FDA and other regulatory authorities, including those laws requiring the reporting of true,

complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad, (iii) laws that require the true, complete and accurate reporting of financial information or data and (iv) insider trading laws that restrict the buying and selling of shares of our common stock while in possession of material non-public information. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. In addition, during the course of our operations, our directors, executives and employees may have access to material non-public information regarding our business, our results of operations or potential transactions we are considering. We may not be able to prevent a director, executive or employee from violating our insider trading policies and buying or selling, or "tipping" others who might buy or sell, shares of our common stock on the basis of, or while having access to, material non-public information. If a director, executive or employee was to be investigated, or an enforcement action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price.

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

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

As of December 31, 2022, we had net operating loss carryforwards of $20.9 million for federal tax purposes and $111.4 million for state tax purposes. If not utilized, federal carryforwards will begin expiring in 2037 and state carryforwards will begin expiring in 2031. Our ability to use our federal and state NOLs to offset potential future taxable income is dependent upon our generation of future taxable income before any expiration dates of the NOLs, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs.

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

In addition, under Sections 382 and 383 of the Code, a corporation that undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We may have experienced ownership changes in the past or as a result of our initial public offering and may experience ownership changes as a result of future offerings and/or subsequent changes in our stock ownership (some of which shifts are outside our control). In addition, Agenovir has experienced at least one ownership change in the past resulting in a limitation under Section 382 of the Code, which has been accounted for in calculating our available NOL carryforwards. As a result, if, and to the extent that we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations.

The Tax Cuts and Jobs Act of 2017 and the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, include, among other things, changes to U.S. federal tax rates and the rules governing NOL carryforwards. For example, NOLs arising in tax years ending after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of current year taxable income for tax years beginning on or after January 1, 2021. Deferred tax assets for NOLs will need to be measured at the applicable tax rate in effect when the NOL is expected to be utilized. The changes in the carryforward periods, as well as the new limitation on use of NOLs may impact our ability to utilize our NOLs to offset taxable income in the future.

Risks Related to Ownership of Our Common Stock

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

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

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

In addition, our collaboration revenue and certain assets and liabilities are subject to foreign currency exchange rate fluctuations due to the global nature of our operations. As a result, currency fluctuations among our reporting currency, the U.S. dollar, and other currencies in which we do business will affect our operating results, often in unpredictable ways. Currency exchange rates have been especially volatile in the recent past, and these currency fluctuations have affected, and may continue to affect, our assets and liabilities denominated in foreign currency. We are also exposed to market risks related to our investments, including changes in fair value of equity securities we hold which may fluctuate from quarter to quarter and year to year. For additional information, see 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. From October 11, 2019, our first day of trading on The Nasdaq Global Select Market, or Nasdaq, through February 21, 2023, the closing price of our stock ranged from $11.83 per share to $83.07 per share. As a result of the volatility in our stock price, our stockholders could incur substantial losses.

The stock market in general and the market for biopharmaceutical and pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The COVID-19 pandemic, for example, has negatively affected some sectors of the stock market and investor sentiment and has resulted in significant volatility. In

addition, economic trends and other external factors including, but not limited to, heightened inflation, interest rate and currency rate fluctuations, economic slowdown or recession, capital markets volatility, foreign market trends, national crisis, and disasters, may impact the market price of our common stock and result in volatility. As a result of this volatility, you may not be able to sell your common stock at or above the price you paid for your shares. Market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock.

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

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock beneficially own a significant percentage of our outstanding common stock. If these persons acted together, they may be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in the management of our company in ways with which other stockholders disagree.

If research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or financial analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if the clinical trials and operating results fail to meet the expectations of analysts, our stock could decline. If analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain in the foreseeable future.

We have incurred and we will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and we will continue to incur significant legal, accounting, investor relations and other expenses. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the Securities and Exchange Commission, or SEC, and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act was enacted, pursuant to which the SEC adopted rules and regulations related to corporate governance and executive compensation, such as "say on pay" and proxy access.

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

As a public company, we may also be subject to more stringent state law requirements, such as California Senate Bill 826, which generally requires public companies with principal executive offices in California to have a minimum number of females on the company's board of directors, and California Assembly Bill 979, which generally requires public companies with principal executive offices in California to include specified numbers of directors from "underrepresented communities." We are currently compliant with the requirements, but there are no assurances that we will be compliant in the future. Both Senate Bill 826 and Assembly Bill 979 have been challenged in legal proceedings and there is uncertainty whether the courts will uphold Senate Bill 826 or Assembly Bill 979. If we fail to comply with either Senate Bill 826 or Assembly Bill 979, we could be fined by the California Secretary of State, with a $100,000 fine for the first violation and a $300,000 for each subsequent violation, and our reputation may be adversely affected.

If we fail to develop or maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in us and the trading price of our common stock may decline.

Effective internal control over financial reporting are necessary for us to provide reliable financial reports and effectively prevent fraud and operate successfully as a public company. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If our internal control over financial reporting is not effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting could also restrict our future access to the capital markets.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the Sarbanes-Oxley Act, the requirements of being a reporting company under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and any complex accounting rules in the future, we may need to upgrade our information technology systems;

implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. We are currently in the process of hiring additional accounting and finance staff as we grow our business. If we are unable to hire the additional accounting and finance staff necessary to comply with these requirements, we may need to retain additional outside consultants.

Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.

Generally accepted accounting principles in the United States are subject to interpretation by the Financial Accounting Standards Board or the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results, may retroactively affect previously reported results, could cause unexpected financial reporting fluctuations and may require us to make costly changes to our operational processes and accounting systems.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. For a summary of these provisions, see the section titled “Anti-Takeover Provisions of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws—Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws” in Exhibit 4.3 Description of Capital Stock filed as part of this Annual Report on Form 10-K.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and
- any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act of 1933, as amended, or the Securities Act, creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, unless we consent in writing to the selection of an alternative forum. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated

certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the exclusive-forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters are located in San Francisco, California, where we lease approximately 179,566 square feet of office, research and development, engineering, and laboratory space pursuant to three lease agreements that expire at various dates through 2033, two of which are renewable for additional one and five years, respectively.

We also have several other locations, including St. Louis, Missouri, where we lease approximately 60,649 square feet of office, research and development, and laboratory space pursuant to two lease agreements that expire at various dates through 2028; Portland, Oregon, where we lease approximately 7,536 square feet of office, research and development, engineering, and laboratory space pursuant to two lease agreements that expire at various dates through 2027, one of which is renewable for an additional five years; and Bellinzona, Switzerland, where we lease approximately 15,642 square feet of office, research and development, engineering, and laboratory space pursuant to a lease agreement which expires on December 31, 2028, with an option to extend for five years.

We believe that our existing facilities are adequate for our near-term needs, but expect to need additional space as we grow, and we believe that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

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 21, 2023, there were approximately 133,531,379 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.

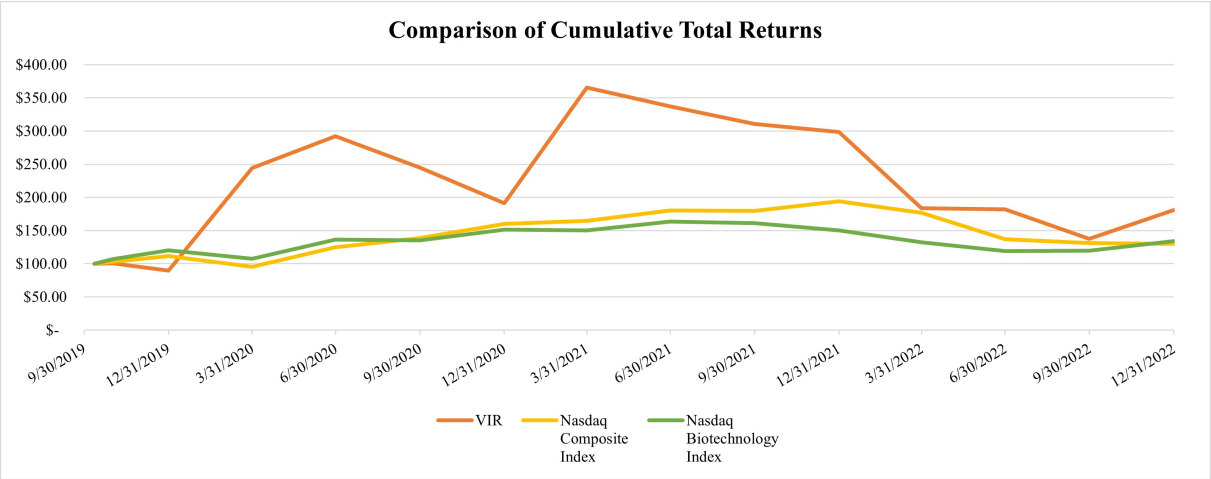
Dividend Policy

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 October 11, 2019 (the first day of trading of our common stock), through December 31, 2022 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 of 1933, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



Date	VIR	Nasdaq Composite Index	Nasdaq Biotechnology Index
10/11/2019	$ 100.00	$ 100.00	$ 100.00
10/31/2019	$ 100.57	$ 102.92	$ 106.95
12/31/2019	$ 89.69	$ 111.36	$ 120.19
3/31/2020	$ 244.44	$ 95.57	$ 107.67
6/30/2020	$ 292.23	$ 124.84	$ 136.40
9/30/2020	$ 244.86	$ 138.61	$ 135.11
12/31/2020	$ 191.01	$ 159.96	$ 151.06
3/31/2021	$ 365.69	$ 164.41	$ 149.97
6/30/2021	$ 337.23	$ 180.02	$ 163.40
9/30/2021	$ 310.41	$ 179.33	$ 161.40
12/31/2021	$ 298.64	$ 194.18	$ 150.10
3/31/2022	$ 183.45	$ 176.50	$ 132.24
6/30/2022	$ 181.67	$ 136.88	$ 118.99
9/30/2022	$ 137.52	$ 131.26	$ 119.59
12/31/2022	$ 180.53	$ 129.90	$ 133.73

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," "we," "us" and "our" 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, 2022 and 2021, including year-over-year comparisons of our financial performance and condition for these years. Discussion and analysis of the year ended December 31, 2020 specifically, as well as the year-over-year comparison of our financial performance and condition for the years ended December 31, 2021 and 2020, 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, 2021, as filed with the SEC on February 28, 2022. 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 commercial-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Infectious diseases are among the leading causes of death worldwide and can cause trillions of dollars of direct and indirect economic burden each year – as evidenced by the coronavirus disease 2019, or COVID-19, pandemic. We believe that now is the time to apply the recent and remarkable advances in immunology to combat current and prepare for future infectious diseases. Our approach begins with identifying the limitations of the immune system in combating a particular pathogen, the vulnerabilities of that pathogen and the reasons why previous approaches have failed. We then bring to bear powerful technologies that we believe, individually or in combination, will lead to effective therapies.

Our current pipeline consists of sotrovimab (previously VIR-7831; and where marketing authorization has been granted, marketed under the brand name Xevudy®) and other product candidates targeting hepatitis B virus, or HBV, hepatitis D virus, or HDV, influenza A virus, COVID-19, and human immunodeficiency virus, or HIV. We have assembled four technology platforms, focused on antibodies, T cells, innate immunity and small interfering ribonucleic acid, or siRNA, through internal development, collaborations and acquisitions. We have built an industry-leading team that has deep experience in immunology, infectious diseases, and product development and commercialization. Given the global impact of infectious diseases, we are committed to developing cost-effective treatments that can be delivered at scale.

HBV

VIR-2218 is an investigational HBV-targeting siRNA, and VIR-3434 is an investigational HBV-neutralizing mAb that incorporates Xencor's Xtend and other Fc technologies.

- In November 2022, at the American Association for the Study of Liver Diseases, or AASLD, The Liver Meeting®, we presented new data from multiple ongoing trials evaluating the potential for VIR-2218 and VIR-3434 to achieve a functional cure for chronic HBV, as well as health outcomes research. Highlights included:
  - Initial Phase 2 end-of-treatment data demonstrated that 30.8% of participants receiving 48 weeks of VIR-2218 plus IFN-α achieved hepatitis B surface antigen, or HBsAg seroclearance and each of those participants also achieved seroconversion, suggesting an improvement in those participants' immune function (anti-HBs levels >10mIU/mL). No safety signals have been reported to date. Additional data are expected in the first half of 2023.
  - Initial end-of-treatment results from Part A of the Phase 2 Monoclonal Antibody siRNA Combination against Hepatitis B, or MARCH, trial demonstrated mean HBsAg reductions of ≥2.7 $\log_{10}$ IU/mL across all three cohorts. These data show that VIR-2218 and VIR-3434 are additive in reducing HBsAg. No safety signals have been reported to date. Additional data from Part A are expected in the first half of 2023. Initial data from Part B, evaluating VIR-2218 in combination with VIR-3434 for 24 and 48 weeks, and in triple combination with VIR-3434 and IFN-α for 24 and 48 weeks, are expected in the second half of 2023.
- Initiation of the Phase 2 PREVAIL platform trial and its THRIVE/STRIVE sub-protocols of VIR-3434 and/or VIR-2218 and/or IFN-α in viremic patients is expected in the first half of 2023. The THRIVE sub-protocol will evaluate inactive carriers defined as adults with chronic HBV that are HBeAg negative with HBV DNA ≤2000 IU/mL and ALT ≤ ULN. The STRIVE sub-protocol will evaluate immune active, treatment-naïve patients defined as adults with chronic HBV who have not received prior NRTIs, or IFN-α therapy and are HBeAg positive or negative with HBV DNA >2000 IU/mL, ALT > ULN and ≤ 5× ULN. Initial data are expected in the first half of 2024.

- In February 2022, initial data from the Phase 2 trial led by Brii Biosciences evaluating VIR-2218 in combination with BRII-179, an investigational T cell vaccine, for the potential treatment of chronic HBV infection were presented at the Asian Pacific Association for the Study of the Liver. Although the combination of VIR-2218 and BRII-179 had greater anti-HBs responses and improved HBsAg-specific T-cell responses, comparable HBsAg reduction was observed in all cohorts at end of treatment (-1.7-1.8 log10 IU/mL). The combination of VIR-2218 and BRII-179 was generally well tolerated.

HDV

- Initial data from the Phase 2 SOLSTICE trial, which began in September 2022, evaluating VIR-2218 and VIR-3434 as monotherapy and in combination for the treatment of people living with chronic HDV, the most aggressive form of viral hepatitis, are expected in the second half of 2023.

Influenza A virus

VIR-2482 is an investigational influenza A-neutralizing mAb.

- In October 2022, we initiated the groundbreaking Phase 2 Prevention of Illness Due to Influenza A (PENINSULA) trial evaluating VIR-2482, and in December 2022, we achieved the target enrollment of approximately 3,000 participants. This is the first Phase 2 outpatient trial to evaluate the role of a mAb in the prevention of influenza A illness. The primary efficacy endpoint is the proportion of trial participants with protocol-defined influenza illness, requiring one systemic symptom and one respiratory symptom, with confirmed influenza A infection compared to placebo. Other endpoints will evaluate the effect of VIR-2482 on the severity and duration of illness in trial participants with confirmed influenza A compared to placebo. Initial data are expected in mid-2023. The PENINSULA trial is being supported in part with federal funds from the Department of Health and Human Services, or HHS; Administration for Strategic Preparedness and Response, or ASPR; and Biomedical Advanced Research and Development Authority, or BARDA, under Other Transaction Number: 75A50122C00081.
- In August 2022, we initiated the Phase 1b prophylaxis trial evaluating the safety of VIR-2482 in adults aged 65 and older receiving a flu vaccine, and initial data are expected in mid-2023.

COVID-19

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

- In 2022, a total of approximately 1.5 million doses were delivered worldwide.
- Sotrovimab has obtained emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®) for early treatment of COVID-19, supplying more than 40 countries. Sotrovimab is not authorized in the U.S.
- In February 2023, the U.K.’s National Institute for Health and Care Excellence (NICE) provided positive final draft guidance recommending the use of sotrovimab in adults who do not need supplemental oxygen for COVID-19 and who have an increased risk for progression to severe COVID-19 where nirmatrelvir/ritonavir (Paxlovid) is contraindicated or unsuitable.
- In February of 2022, Vir and GSK amended their existing agreement to reflect that:
    - We will continue to discover, develop and advance next-generation solutions for COVID-19 and other potential coronavirus outbreaks, independently or with other partners.
    - We and GSK will continue working together to ensure ongoing access to sotrovimab for patients around the world, where authorized, and to develop new therapies for influenza and other respiratory diseases.

HIV

VIR-1111 is an investigational HIV T cell vaccine based on human cytomegalovirus, or HCMV, and VIR-1388 is a preclinical HIV T cell vaccine based on HCMV.

- Safety and immunology data from the initial two cohorts of the proof-of-concept Phase 1 trial of VIR-1111 show no safety signals and no vector shedding or viremia reported to date. No sustained HIV insert-specific T cell responses have been observed in the lower dose cohorts 1 and 2. Safety and immunology data from the highest dose cohort 3 of the proof-of-concept Phase 1 trial of VIR-1111 are anticipated in the first half of 2023. This trial is being funded in part by the Bill & Melinda Gates Foundation.
- Initiation of a Phase 1 trial of VIR-1388, a novel vector that has the potential to have enhanced immunogenicity, is expected in the second half of 2023. This trial is being funded in part by the Bill & Melinda Gates Foundation and the National Institutes of Health's Division of AIDS through the HIV Vaccine Trials Network.

Financial Overview

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

We have financed our operations primarily through sales of our common stock from our initial public offering, subsequent follow-on offering and convertible preferred securities, and payments received under our grant and collaboration agreements. As of December 31, 2022, we had $2.4 billion in cash, cash equivalents, and investments. Based upon our current operating plan, we believe that the $2.4 billion will enable us to fund our operations for at least the next 12 months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional financing to fund our long-term operations sooner than planned. See the section titled "Liquidity, Capital Resources and Capital Requirements—Future Funding Requirements" below for additional information.

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. To date, sotrovimab has been granted emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®), supplying more than 40 countries. Although we have an EUA from the FDA for sotrovimab, the FDA has excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. With this EUA revision, sotrovimab is not currently authorized for use in any U.S. region. In light of these developments, we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future. Furthermore, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA for sotrovimab at this time. Although certain countries outside of the U.S., such as Canada and Japan, continue to maintain access to sotrovimab 500 mg IV while noting that it is unlikely to maintain efficacy against certain Omicron subvariants, we cannot predict whether other countries will further limit the use of sotrovimab. We have not obtained regulatory approval for any other product candidates, and we do not expect to generate significant revenue from the sale of our other product candidates until we complete clinical development, submit regulatory filings and receive approvals from the applicable regulatory bodies for such product candidates, if ever.

Our net income was $515.8 million and $528.6 million for the years ended December 31, 2022 and 2021, respectively. Our net loss was $298.7 million for the year ended December 31, 2020. As of December 31, 2022, we had retained earnings of $377.2 million. Our primary use of our capital resources is to fund our operating expenses, which consist primarily of expenditures related to identifying, acquiring, developing, manufacturing and in-licensing our technology platforms and product candidates, and conducting preclinical studies and 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. Although we began recognizing revenue for sotrovimab and have substantial deferred revenue under our definitive collaboration agreement with GSK executed in May 2021, or the 2021 GSK Agreement, we may continue to incur net operating losses for at least the next several years as the extent of future revenue remains uncertain. In particular, we expect our expenses and losses to increase as we continue our research and development efforts, advance our product candidates through preclinical and clinical development, seek regulatory approval, and prepare for commercialization, as well as hire additional personnel, protect our intellectual property and incur additional costs associated with being a public company. We also expect to increase the size of our administrative functions to support the growth of our business. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We are currently manufacturing product candidates from three of our platforms: antibodies, T cells and siRNAs. We have established our own internal process development, manufacturing and quality capabilities and are working with contract development and manufacturing organizations, or CDMOs, to supply our early- and late-stage product candidates in the near term. We continue to expand our internal capabilities and resources in process development, analytical development, quality, manufacturing and supply chain, which are supported by our San Francisco, California, and Portland, Oregon facilities that include laboratories for process development, production of HCMV research viral seed stock and selected quality control testing for our product candidates. We have established relationships with multiple CDMOs and have produced material to support preclinical studies and Phase 1 through Phase 3 clinical trials. Material for Phase 3 clinical trials and commercial supply will generally require large-volume, low-cost-of-goods production. For example, for sotrovimab, we and our collaborator GSK have executed manufacturing agreements with CDMOs having large-scale capacity to support future scale-up and product supply, particularly for potential commercialization.

COVID-19 Business Update and Macroeconomic Uncertainties

We have implemented a number of plans and policies designed to address and mitigate the impact of the COVID-19 pandemic on our employees and our business. We continue to closely monitor the COVID-19 situation and will evolve our plans and policies as needed going forward. As a result of these developments, in March 2020, we implemented work-from-home policies for most of our employees. We now offer all our employees the choice of working full time in the office, a hybrid approach, or full-time remote. As a result, we expect to continue to be subject to the challenges and risks of having a remote workforce, as well as new challenges and risks from operating with a hybrid workforce. We are working closely with our CDMOs to manage our supply chain activities and mitigate any potential disruptions to our clinical trial supplies as a result of the COVID-19 pandemic. However, there are no assurances that our manufacturing and supply chain infrastructure will remain uninterrupted and reliable, or that the CDMOs will be able to satisfy demand in a timely manner and not have supply chain disruptions due to COVID-19 related shutdowns, stock-outs due to raw material shortages and/or greater than anticipated demand or quality issues given the operational challenges and raw material shortages that have been experienced during the COVID-19 pandemic. In addition, we rely on contract research organizations or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic.

In addition to the impacts described above, the global economy, including the financial and credit markets, has recently experienced extreme volatility and disruptions, including increases to inflation rates, rising interest rates, declines in consumer confidence, declines in economic growth, and uncertainty about economic stability. The severity and duration of the impact of these conditions on our business cannot be predicted.

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 6—Grant Agreements and Note 7—Collaboration and License Agreements to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Components of Operating Results

Revenues

To date, sotrovimab has been granted emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®), supplying more than 40 countries. Although we have previously recognized revenue from our profit-share under our definitive collaboration agreement with GSK executed in June 2020, or the 2020 GSK Agreement, related to sotrovimab, we may continue to incur net operating losses for at least the next several years as the extent of future revenue from the sale of sotrovimab remains uncertain. Although we have an EUA from the FDA for sotrovimab, the FDA has excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. With this EUA revision, sotrovimab is not currently authorized for use in any U.S. region. Although certain countries outside of the U.S., such as Canada and Japan, continue to maintain access to sotrovimab 500 mg IV while noting that it is unlikely to maintain efficacy against certain Omicron subvariants, we cannot predict whether other countries will further limit the use of sotrovimab. In addition, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA for sotrovimab at this time. In light of these developments, we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future. In addition, we have not obtained regulatory approval for any other product candidates, and we do not expect to generate any significant revenue from the sale of our other product candidates until we complete clinical development, submit regulatory filings and receive approvals from the applicable regulatory bodies for such product candidates, if ever.

Our revenues consist of the following:

Collaboration revenue includes recognition of our profit-share from the sales of sotrovimab pursuant to the 2020 GSK Agreement. Our contractual share of 72.5% from the sales of sotrovimab is applied to the net sales reported in the period by GSK, net of cost of goods sold and allowable expenses from both GSK and us (e.g., manufacturing, distribution, medical affairs, selling, and marketing expenses). In order to record collaboration revenue, we utilize certain information from our collaboration partner, including actual net product sales and costs incurred for sales activities, and make key judgments based on business updates related to commercial and clinical activities such as expected commercial demand, commercial supply plan, manufacturing commitments, risks related to expired or obsolete inventories, and risks related to potential product returns or contract terminations.

Constraint on variable consideration

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

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

As of December 31, 2022, GSK held certain potentially excess binding supply manufacturing commitments of sotrovimab and reserved certain binding manufacturing capacity potentially not expected to be utilized, which have not yet been reported to us as allowable manufacturing expenses for the cumulative profit-sharing amounts to date. We expect GSK to adjust allowable manufacturing expenses for our share of the potential charge for excess supply write-offs and unused binding manufacturing capacity and report to us as cost-sharing amounts in future periods. We evaluated the latest available facts and circumstances to determine whether any portion of profit-sharing amounts should be constrained. In doing so, as of December 31, 2022, based on the current state of the COVID-19 pandemic, including the continued proportion of cases caused by certain Omicron subvariants, discussions with the FDA and other regulatory authorities, and our expectations for future sales in light of these factors, we revised our estimates and determined that $369.7 million should be constrained from profit-sharing revenues earned in relation to our anticipated contractual share of potential future adjustments to manufacturing expenses and recorded such amount as adjustments to profit-sharing amounts recognized in the year ended December 31, 2022 and accrued and other liabilities. We will re-assess these estimates each reporting period. Actual results could materially differ from this estimate.

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

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

License revenue from a related party is comprised of revenue related to Brii Bio's exercise of its option to obtain exclusive rights to develop and commercialize compounds arising from VIR-3434 in mainland China, Hong Kong, Macau and Taiwan recognized in the year ended December 31, 2022.

Operating Expenses

Cost of Revenue

Cost of revenue currently represents royalties earned by third-party licensors on net sales of sotrovimab by us or our collaborators. We recognize these royalties as cost of revenue when we recognize the corresponding revenue that gives rise to payments due to our licensors.

Research and Development

To date, our research and development expenses have related primarily to discovery efforts and preclinical and clinical development of our product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. We do not track research and development expenses by product candidate.

Research and development expenses consist primarily of costs incurred for our product candidates in development and prior to regulatory approval, which include:

- expenses related to license and collaboration agreements, and change in fair value of certain contingent consideration obligations arising from business acquisitions;
- personnel-related expenses, including salaries, benefits and stock-based compensation for personnel contributing to research and development activities;
- expenses incurred under agreements with third-party contract manufacturing organizations, contract research organizations, and consultants;
- clinical costs, including laboratory supplies and costs related to compliance with regulatory requirements; and
- other allocated expenses, including expenses for rent and facilities maintenance, and depreciation and amortization.

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance our product candidates into and through preclinical studies and clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors including: the safety and efficacy of our product candidates, early clinical data, investment in our clinical programs, the ability of collaborators to successfully develop our licensed product candidates, competition, manufacturing capability and commercial viability. To date, sotrovimab has been granted emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®), supplying more than 40 countries. Although we have an EUA from the FDA for sotrovimab, the FDA has excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. With this EUA revision, sotrovimab is not currently authorized for use in any U.S. region. In light of these developments, we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future. In addition, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA for sotrovimab at this time. Although certain countries outside of the U.S., such as Canada and Japan, continue to maintain access to sotrovimab 500 mg IV while noting that it is unlikely to maintain efficacy against certain Omicron subvariants, we cannot predict whether other countries will further limit the use of sotrovimab. Furthermore, COVID-19 treatment standards are susceptible to rapid changes in epidemiology and the emergence of new variants or subvariants, which may render sotrovimab inferior or obsolete in the future.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate significant revenue from the commercialization and sale of any of our product candidates. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments, our ongoing assessments as to each product candidate's commercial potential and the impact of public health epidemics, such as the COVID-19 pandemic. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured (if at all) and to what degree such arrangements would affect our development plans and capital requirements.

Our clinical development costs may vary significantly based on factors such as:

- whether a collaborator is paying for some or all of the costs;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- enrollment and retention of patients in trials in countries disrupted by geopolitical events, including civil or political unrest;
- the length of time required to enroll eligible patients;

- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates; and
- the efficacy and safety profile of our product candidates.

Selling, General and Administrative

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

We expect our selling, general and administrative expenses to increase substantially in absolute dollars in the foreseeable future as we continue to support our research and development activities, and commercialization activities for any of our product candidates, if approved, and to grow our business. We also anticipate incurring additional expenses associated with operating as a public company, including increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, and standards applicable to companies listed on a national securities exchange, additional insurance expenses, investor relations activities and other administrative and professional services.

Change in Fair Value of Equity Investments

Change in fair value of equity investments consists of the remeasurement of our investment in Brii 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 Income (Expense), Net

Other income (expense), net consists of gains and losses from foreign currency transactions and the remeasurement of contingent consideration related to our acquisition of TomegaVax, Inc., or TomegaVax.

Provision for Income Taxes

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

Results of Operations

Comparison of Years Ended December 31, 2022 and 2021

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

	Year Ended December 31,		
	2022	2021	Change
		(in thousands)	
Revenues:			
Collaboration revenue	$ 1,505,469	$ 917,194	$ 588,275
Contract revenue	52,714	169,874	(117,160)
License revenue from a related party	22,289	—	22,289
Grant revenue	35,325	8,347	26,978
Total revenues	1,615,797	1,095,415	520,382
Operating expenses:			
Cost of revenue	146,319	65,865	80,454
Research and development	474,648	448,006	26,642
Selling, general and administrative	161,762	160,793	969
Total operating expenses	782,729	674,664	108,065
Income from operations	833,068	420,751	412,317
Other income (expense):			
Change in fair value of equity investments	(111,140)	138,049	(249,189)
Interest income	28,092	439	27,653
Other income (expense), net	4,260	(9,437)	13,697
Total other income (expense)	(78,788)	129,051	(207,839)
Income before provision for income taxes	754,280	549,802	204,478
Provision for income taxes	(238,443)	(21,218)	(217,225)
Net income	$ 515,837	$ 528,584	$ (12,747)

Revenues

The increase in collaboration revenue for the year ended December 31, 2022 compared to the same period in 2021 was due to our profit-sharing arrangement with GSK for the sale of sotrovimab under the 2020 GSK Agreement. Our contractual share of 72.5% from the sales of sotrovimab is applied to the profit-sharing amounts, 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, and any amount constrained in relation to our anticipated contractual share of potential future adjustments to manufacturing expenses.

The decrease in contract revenue for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to $168.3 million related to the license granted to GSK upon execution of the 2021 GSK Agreement, partially offset by $39.8 million recognized in 2022 related to GSK's selection of respiratory syncytial virus, or RSV, as its first pathogen under the additional programs to develop neutralizing mAbs under the 2021 GSK Agreement, or First Option Exercise, and $7.0 million related to the additional license granted to GSK in mainland China, Hong Kong, Macau and Taiwan upon execution of the Amendment No. 1 to the 2020 GSK Agreement in the second quarter of 2022.

The increase in license revenue from a related party for the year ended December 31, 2022 compared to the same period in 2021 was due to $22.3 million related to Brii Bio's exercise of its option to obtain exclusive rights to develop and commercialize compounds and products arising from VIR-3434 in China, Taiwan, Hong Kong and Macau. No comparable amount was incurred for the same period in 2021.

The increase in grant revenue for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to the grant revenue recognized in connection with the BARDA agreement and the timing of research activities under the grant agreements with the Bill & Melinda Gates Foundation.

Cost of Revenue

The increase in cost of revenue for the year ended December 31, 2022 compared to the same period in 2021 was due to third-party royalties owed based on the sales of sotrovimab under the 2020 GSK Agreement.

Research and Development Expenses

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

	Year Ended December 31,		
	2022	2021	Change
		(in thousands)	
Personnel	$ 157,167	$ 121,779	$ 35,388
Clinical costs	118,849	97,505	21,344
Licenses, collaborations and contingent consideration	54,087	132,355	(78,268)
Contract manufacturing	47,960	31,613	16,347
Other	96,585	64,754	31,831
Total research and development expenses	$ 474,648	$ 448,006	$ 26,642

The increase in research and development expenses for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to the following factors:

- personnel-related expenses increased by $35.4 million, which was primarily attributable to an increase in our headcount;
- clinical costs increased by $21.3 million, which was primarily attributable to activities related to VIR-2482, VIR-2218 and VIR-3434, partially offset by activities related to the clinical trials for sotrovimab in the same period of 2021;
- contract manufacturing increased by $16.3 million, which was primarily related to an increase in manufacturing activities for our product candidates; and
- other research and development expenses increased by $31.8 million, which was primarily attributable to the allocation of facilities and other costs due to an increase in our headcount, and higher outsource research and lab-related expenses;

partially offset by

- licenses, collaborations and contingent consideration expenses decreased by $78.3 million, which was primarily attributable to a decrease of $50.6 million in costs under our collaboration agreements with GSK, and $37.2 million related to the change in fair value of the contingent consideration from our acquisition of Humabs BioMed SA, or Humabs, partially offset by $7.0 million recognized in connection with the termination of our development and manufacturing collaboration agreement with WuXi Biologics (Hong Kong) Limited, or WuXi Biologics.

Selling, General and Administrative Expenses

The increase in selling, general and administrative expenses for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to higher personnel-related expenses related to additional headcount, external consulting services, business tax expenses related to increased profit-sharing amount and allocated facilities costs due to higher lease expenses. This was partially offset by $39.4 million in fair value of the contingent consideration related to sales-based milestones from our acquisition of Humabs that were achieved in 2021.

Change in Fair Value of Equity Investments

In July 2021, Brii Bio Parent became a publicly traded company on the Stock Exchange of Hong Kong Limited. In connection with the initial public offering, our investment in shares of Brii Bio Parent became a marketable equity investment and subsequently remeasured to fair value at each reporting period. For the year ended December 31, 2022, we recognized an unrealized loss of $111.1 million due to the change in fair value of the equity investment, compared to an unrealized gain of $138.0 million for the same period in 2021.

Interest Income

The increase in interest income was primarily due to higher interest rates as well as higher balances of short-term and long-term investments, partially offset by higher amortization of premium on investment balances, for the year ended December 31, 2022 compared to the same period in 2021.

Other Income (Expense), Net

The increase in other income (expense), net for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to the change in fair value of the contingent consideration related to our acquisition of TomegaVax.

Provision for Income Taxes

The increase in provision for income taxes for the year ended December 31, 2022 compared to the same period in 2021 was primarily due to taxable income for 2022 attributable to collaboration revenue under the 2020 GSK agreement and the requirement under the Tax Cuts and Jobs Act of 2017 for taxpayers to capitalize and amortize research and development expenditures over five or fifteen years pursuant to Section 174 of the Internal Revenue Code of 1986, as amended.

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, 2022, we had $2.4 billion in cash, cash equivalents, and investments. As of December 31, 2022, we had retained earnings of $377.2 million. We entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, in 2020 pursuant to which we may from time to time offer and sell shares of our common stock for an aggregate offering price of up to $300.0 million, through or to Cowen, acting as sales agent or principal. We will pay Cowen a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide Cowen with customary indemnification and contribution rights. As of December 31, 2022, no shares have been issued under the Sales Agreement.

Our primary use of our capital resources is to fund our operating expenses, which consist primarily of expenditures related to identifying, acquiring, developing, manufacturing and in-licensing our technology platforms and product candidates, and conducting preclinical studies and clinical trials, and to a lesser extent, selling, general and administrative expenditures.

Future Funding Requirements

Based upon our current operating plan, we believe that our existing cash, cash equivalents and investments as of December 31, 2022 as noted above 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. Moreover, it is particularly difficult to estimate with certainty our future revenue and expenses given the dynamic and rapidly evolving nature of our business and the COVID-19 pandemic environment generally. For example, in March and April 2022, the FDA amended the EUA fact sheet to exclude sotrovimab use in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information, including variant susceptibility to these drugs and regional variant frequency. With these EUA revisions, sotrovimab is not currently authorized for use in any U.S. region. In light of these developments, we cannot predict whether (if at all) or to what extent sotrovimab may be reauthorized for use by the FDA in any U.S. region in the future. In addition, due to the evolving COVID-19 landscape and based on discussions with the FDA, we and GSK do not plan to file a BLA for sotrovimab at this time. It is possible that the FDA and other regulatory authorities may not grant sotrovimab full marketing approval for the treatment of COVID-19, or that any such marketing approvals, if granted, may have similar or other significant limitations on its use.

We may also need to raise additional capital to complete the development and commercialization of our product candidates and fund certain of our existing manufacturing and other commitments. 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. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to

relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. There can be no assurance that sufficient funds will be available to us on attractive terms or at all. If we are unable to obtain additional funding from these or other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. General economic conditions , both inside and outside the U.S., including heightened inflation, capital market volatility, interest rate and currency rate fluctuations, and economic slowdown or recession as well as the COVID-19 pandemic and geopolitical events, including civil or political unrest (such as the ongoing war between Ukraine and Russia) have resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital. and geopolitical events, including civil or political unrest (such as the ongoing war between Ukraine and Russia) have resulted in a significant disruption of global financial markets, market volatility, high levels of inflation, and interest rate fluctuations may increase our cost of financing or restrict our access to potential sources of future liquidity.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of biotechnology products, we are unable to estimate the exact amount of our operating capital requirements. See the section titled “Risk Factors—Risks Related to Our Financial Position and Capital Needs” for a description of certain risks that will affect our future capital requirements.

We have various operating lease arrangements for office and laboratory spaces located in California, Oregon, Missouri and Switzerland with contractual lease periods expiring between 2022 and 2033. As of December 31, 2022, we expect to make total lease payments of $175.0 million through 2033.

To date, we have entered into collaboration, license and acquisition agreements where the payment obligations are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones, and we are required to make royalty payments in connection with the sale of products developed under those agreements. For additional information regarding these agreements, including our payment obligations thereunder, see the sections titled “Business—Our Collaboration, License and Grant Agreements” and “Business—Our Acquisition Agreements,” as well as Note 4—Acquisitions and Note 7—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—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 periods indicated:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ 1,663,253	$ (47,589)
Investing activities	(1,193,461)	(140,814)
Financing activities	34,761	100,331
Net (decrease) increase in cash and cash equivalents and restricted cash and cash equivalents	$ 504,553	$ (88,072)

Operating Activities

During the year ended December 31, 2022, net cash provided by operating activities was $1.7 billion. This consisted primarily of net income of $515.8 million, non-cash charges of $575.9 million, and an increase in our net operating assets of $665.4 million, partially offset by $93.8 million for payment for contingent consideration in excess of acquisition date fair value. The change in our net operating assets of $665.4 million was primarily due to a decrease in collaboration receivable by $770.0 million resulting from our profit-share from the sale of sotrovimab, partially offset by a $33.3 million decrease in deferred revenue primarily driven by GSK's First Option Exercise and Brii Bio's exercise for VIR-3434 netted with the grants received from Bill & Melinda Gates Foundation, an increase in prepaid expenses and other current assets by $39.4 million and an increase in other assets by $11.8 million, which are due to timing of payments. The non-cash charges of $575.9 million primarily consisted of $369.5 million for change in estimated

constraint on profit-sharing amount, an unrealized loss of $111.1 million on our equity investment, $102.1 million for stock-based compensation expense and $8.7 million for noncash lease expense, partially offset by $15.2 million for deferred income tax.

During the year ended December 31, 2021, net cash used in operating activities was $47.6 million. This consisted primarily of net income of $528.6 million and non-cash charges of $203.3 million, offset by an unrealized gain of $138.0 million on our equity investment, payment of contingent consideration of $8.1 million for the achievement of a milestone related to our TomegaVax acquisition, a gain of $4.8 million from a sublease termination, and an increase in our net operating assets of $628.4 million. The change in our net operating assets of $628.4 million was primarily due to an increase in receivable from collaboration by $773.1 million resulting from our profit share from the sale of sotrovimab, and an increase in prepaid expenses and other current assets of $3.7 million, partially offset by an increase in deferred revenue of $92.0 million driven by the upfront fee received under the 2021 GSK Agreement, and an increase in accrued liabilities and other long-term liabilities of $58.5 million due to timing of payments. The non-cash charges of $203.3 million primarily consisted of $91.8 million for revaluation of contingent consideration, $83.8 million for stock-based compensation expense, $15.2 million for deferred income tax expense, $6.2 million for noncash lease expense, and $5.3 million for depreciation and amortization.

Investing Activities

During the year ended December 31, 2022, net cash used in investing activities was $1.2 billion. This consisted primarily of purchases of investments of $1.5 billion and property and equipment of $68.0 million, partially offset by $351.5 million in proceeds received from investments that matured during the period.

During the year ended December 31, 2021, net cash used in investing activities was $140.8 million. This consisted primarily of purchases of investments of $420.2 million and property and equipment of $21.8 million, partially offset by $301.2 million in proceeds received from investments that matured during the period.

Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was $34.8 million. This consisted primarily of proceeds from the issuance of our common stock to the Bill & Melinda Gates Foundation of $28.5 million under the stock purchase agreement, from exercises of stock options of $4.5 million, and from issuance of common stock under our employee stock purchase plan of $3.2 million, partially offset by $1.2 million for payment of contingent consideration.

During the year ended December 31, 2021, net cash provided by financing activities was $100.3 million. This consisted primarily of proceeds received from the issuance of our common stock to Glaxo Group Limited (an affiliate of GSK) of $85.2 million in March 2021, from exercises of stock options of $13.1 million, and from issuance of common stock under our employee stock purchase plan of $2.3 million.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States. The preparation of our consolidated financial statements requires us to make assumptions and estimates about future events and apply judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the related disclosures. We base our estimates on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates. The critical accounting policies, estimates and judgments that we believe to have the most significant impacts on our consolidated financial statements are described below. For more detail on our critical accounting policies, refer to Note 2—Summary of Significant Accounting Policies to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Revenue Recognition

Collaboration, License and Contract Revenue

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

For collaborative arrangements that fall within the scope of ASC 808, Collaborative Arrangements, or ASC 808, we first determine which elements of the collaboration are deemed to be performance obligations with a customer within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808 and are not subject to the guidance in ASC 606, we apply the revenue recognition model under ASC 606, including the royalty exception guidance and variable consideration guidance under ASC 606 as described below, or other guidance, as deemed appropriate. When we are considered an agent in elements of collaboration arrangements within the scope of ASC 808, we record our share of collaboration revenue in the period in which such sales occur. We are considered an agent when the collaboration partner controls the product before transfer to the customers and has the ability to direct the use of and obtain substantially all of the remaining benefits from the product. In these instances, collaboration revenue is based upon the net sales reported by our collaboration partners, net of cost of goods sold and allowable expenses (e.g., manufacturing, distribution, medical affairs, selling, and marketing expenses) in the period. In order to record collaboration revenue, we utilize certain information from our collaboration partner, including actual net product sales, and costs incurred for sales activities, and make key judgments based on business updates related to commercial and clinical activities such as expected commercial demand, commercial supply plan, manufacturing commitments, risks related to expired or obsolete inventories, and risks related to potential product returns or contract terminations. We use these estimates to determine whether payments due to us under our collaboration arrangements, such as profit-share payments, should be recognized as revenues 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 would not result in a material reversal of revenues in future reporting periods. For the periods covered in the financial statements presented, there have been no material changes to prior period estimates of revenues and expenses, except the profit-share amount constrained in the year ended December 31, 2022, as discussed in Note 7—Collaboration and License Agreements to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

We have entered into a number of license and collaboration agreements that fall within the scope of ASC 606. We evaluate the promised goods or services in these agreements to determine which ones represent distinct performance obligations. These agreements may include the following types of promised goods or services: (i) grants of licenses, (ii) performance of research and development services, and (iii) participation on joint research and/or development committees. They also may include options to obtain licenses to our intellectual property.

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

If there are multiple distinct performance obligations, we allocate the transaction price to each distinct performance obligation based on their estimated standalone selling prices, or SSP. We estimate the SSP for each distinct performance obligation by considering information such as market conditions, entity-specific factors, and information about our customer that is reasonably available to us. We consider estimation approaches that allow us to maximize the use of observable inputs. These estimation approaches may include the adjusted market assessment approach, the expected cost plus a margin approach or the residual approach. We also consider whether to use a different estimation approach or a combination of approaches to estimate the SSP for each distinct performance obligation. Developing certain assumptions (e.g., treatable patient population, expected market share, probability of success and product profitability, and discount rate based on weighted-average cost of capital) to estimate the SSP of a distinct performance obligation requires significant judgment. Accordingly, these assumptions are subject to uncertainty, and changing the methodology and/or assumptions could materially impact the estimated SSP for distinct performance obligations, and as a result, the amount and/or timing of revenue recognition.

For performance obligations satisfied over time, we estimate the efforts needed to complete the performance obligation and recognize 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, we recognize 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.

Management may be required to exercise considerable judgment in estimating revenue to be recognized. Judgment is required in identifying performance obligations, estimating the transaction price, estimating the SSP of identified performance obligations, and estimating the progress towards satisfaction of performance obligations.

Contingent Consideration and Embedded Derivatives

Contingent consideration related to business combinations and obligations required to be accounted for as embedded derivative financial instruments under Topic ASC 815, Derivatives and Hedging, are considered to be Level 3 instruments that are initially measured at their estimated fair values on the transaction date and subsequently remeasured with changes recorded in the consolidated statement of operations each subsequent reporting period.

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

The estimated fair value of the contingent consideration related to our acquisition of TomegaVax was determined based on a Monte Carlo simulation model that includes significant estimates and assumptions pertaining to probability and timing to achieve the required share price of our common stock, expected volatility and discount rate. Although the TomegaVax acquisition was accounted for as an asset acquisition, such contingent consideration met the definition of an embedded derivative financial instrument.

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 $868.0 million as of December 31, 2022, which primarily consisted of money market funds. We also had short-term and long-term investments of $1.5 billion as of December 31, 2022. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration and our holdings in U.S. government treasury bonds mature prior to our expected need for liquidity, we believe that our exposure to interest rate risk is not significant, and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We had no debt outstanding as of December 31, 2022.

Foreign Currency

The functional currency of our foreign subsidiaries is the U.S. dollar. Monetary assets and liabilities of our foreign subsidiaries are translated into U.S. dollars at period-end exchange rates and non-monetary assets and liabilities are translated to U.S. dollars using historical exchange rates. Revenue and expenses are translated at average rates throughout the respective periods. As of the date of this Annual Report on Form 10-K, we are exposed to foreign currency risk primarily related to the operations of our Swiss and Australian subsidiaries and our collaboration with GSK and consequently the Swiss Franc, Australian dollar and British pound. Transaction gains and losses are included in other income (expenses), net on the condensed consolidated statements of operations and were not material for the years ended December 31, 2022, 2021 and 2020.

Equity Investment Risk

We hold ordinary shares of Brii Bio Parent, which we acquired in connection with our collaboration, option and license agreement. These equity securities are measured at fair value with any changes in fair value recognized in our consolidated statements of operations. The fair value of these equity securities was approximately $31.9 million as of December 31, 2022. 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, 2022 by approximately $3.2 million.

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm

To the Shareholders 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, 2022 and 2021, the related consolidated statements of operations, consolidated statements of comprehensive income (loss), consolidated statements of stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 28, 2023 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 accounts or disclosures to which it relates.

Collaboration revenue constraint

Description of the Matter	The Company constrained collaboration revenue by $369.7 million for the year ended December 31, 2022 under its June 9, 2020 Definitive Collaboration Agreement with Glaxo Wellcome UK Limited and GlaxoSmithKline Biologicals S.A (individually and collectively referred to as "GSK") (collectively referred to as the "2020 GSK Collaboration"). As discussed in Note 7 to the consolidated financial statements, the Company recognized collaboration revenue under the 2020 GSK Collaboration in connection with its contractual share of sotrovimab profit-sharing amounts, net of amounts constrained in relation to anticipated future adjustments to manufacturing costs not yet charged by GSK. Auditing the Company's determination of collaboration revenue constrained was especially challenging because the calculation required a number of judgmental inputs, such as projected sales of sotrovimab, estimates made for future costs related to excess binding supply manufacturing commitments of sotrovimab and certain binding manufacturing capacity potentially not expected to be utilized, which have not yet been charged by GSK to the Company as allowable manufacturing expenses for the cumulative profit-sharing amounts earned to date.

How We Addressed the Matter in Our Audit	To test the collaboration revenue constraint, our audit procedures included, among others, testing the completeness and accuracy of the underlying data by obtaining direct confirmation from GSK regarding the terms and conditions of the collaboration, the amount of excess supply manufacturing commitments of sotrovimab and binding manufacturing capacity not expected to be utilized. To assess the reasonableness of the estimates made, we inquired of personnel outside of the accounting and finance function to verify the appropriateness of assumptions based on their understanding of the agreements in place between GSK and its counterparties. We inspected Joint Steering Committee minutes between GSK and the Company and the collaboration agreement between GSK and the Company. We also evaluated the Company's accounting analysis, which documents the judgments made to determine the amount of collaboration revenue to recognize during the year.

/s/ Ernst & Young LLP

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

San Mateo, California
February 28, 2023

VIR BIOTECHNOLOGY, INC.

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

	December 31,	
	2022	**2021**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 848,631	$ 347,815
Short-term investments	1,521,517	217,182
Restricted cash and cash equivalents, current	12,681	8,594
Receivable from collaboration	—	773,079
Equity investments	31,892	143,148
Prepaid expenses and other current assets	104,356	73,003
Total current assets	2,519,077	1,562,821
Intangible assets, net	32,755	33,287
Goodwill	16,937	16,937
Property and equipment, net	105,609	42,834
Operating right-of-use assets	82,557	87,220
Restricted cash and cash equivalents, noncurrent	6,656	7,006
Long-term investments	23,927	201,388
Other assets	14,570	2,775
TOTAL ASSETS	$ 2,802,088	$ 1,954,268
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 6,422	$ 6,521
Accrued and other liabilities	489,090	236,512
Deferred revenue, current portion	15,517	98,209
Total current liabilities	511,029	341,242
Deferred revenue, noncurrent	53,207	3,815
Operating lease liabilities, noncurrent	123,837	133,561
Contingent consideration, noncurrent	24,937	22,822
Deferred tax liability	3,253	18,439
Other long-term liabilities	7,862	2,540
TOTAL LIABILITIES	724,125	522,419
Commitments and contingencies (Note 9)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of December 31, 2022 and 2021, respectively; no shares issued and outstanding as of December 31, 2022 and 2021	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of December 31, 2022 and 2021, respectively; 133,236,687 and 131,161,404 shares issued and outstanding as of December 31, 2022 and 2021, respectively	13	13
Additional paid-in capital	1,709,835	1,571,535
Accumulated other comprehensive loss	(9,122)	(1,099)
Retained earnings (Accumulated deficit)	377,237	(138,600)
TOTAL STOCKHOLDERS' EQUITY	2,077,963	1,431,849
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 2,802,088	$ 1,954,268

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)

	Year Ended December 31,		
	2022	**2021**	**2020**
Revenues:			
Collaboration revenue	$ 1,505,469	$ 917,194	$ —
Contract revenue	52,714	169,874	44,498
License revenue from a related party	22,289	—	22,747
Grant revenue	35,325	8,347	9,123
Total revenues	1,615,797	1,095,415	76,368
Operating expenses:			
Cost of revenue	146,319	65,865	—
Research and development	474,648	448,006	302,411
Selling, general and administrative	161,762	160,793	70,937
Total operating expenses	782,729	674,664	373,348
Income (loss) from operations	833,068	420,751	(296,980)
Other income (expense):			
Change in fair value of equity investments	(111,140)	138,049	—
Interest income	28,092	439	2,836
Other income (expense), net	4,260	(9,437)	(4,467)
Total other income (expense)	(78,788)	129,051	(1,631)
Income (loss) before provision for income taxes	754,280	549,802	(298,611)
Provision for income taxes	(238,443)	(21,218)	(54)
Net income (loss)	$ 515,837	$ 528,584	$ (298,665)
Net income (loss) per share, basic	$ 3.89	$ 4.07	$ (2.51)
Net income (loss) per share, diluted	$ 3.83	$ 3.96	$ (2.51)
Weighted-average shares outstanding, basic	132,606,767	129,884,967	119,159,424
Weighted-average shares outstanding, diluted	134,810,908	133,437,126	119,159,424

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

VIR BIOTECHNOLOGY, INC.

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

	Year Ended December 31,		
	2022	**2021**	**2020**
Net income (loss)	$ 515,837	$ 528,584	$ (298,665)
Other comprehensive income (loss):			
Unrealized losses on investments	(7,524)	(957)	(50)
Amortization of actuarial loss	(499)	55	23
Adjustment to projected benefit obligations, net of tax	—	1,081	(650)
Other comprehensive income (loss)	(8,023)	179	(677)
Comprehensive income (loss)	$ 507,814	$ 528,763	$ (299,342)

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)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2019	107,648,925	$ 11	$ 793,051	$ (601)	$ (368,519)	$ 423,942
Reclassification of derivative liability to addition paid-in-capital	—	—	29,245	—	—	29,245
Issuance of common stock in connection with the achievement of a milestone	1,111,111	—	—	—	—	—
Issuance of common stock in connection with a collaboration agreement	6,626,027	1	206,698	—	—	206,699
Issuance of common stock for cashless exercise of warrants	211,774	—	—	—	—	—
Issuance of common stock in connection with a follow-on offering, net of issuance costs of $21,786	8,214,285	1	323,213	—	—	323,214
Vesting of restricted common stock	1,986,250	—	1,435	—	—	1,435
Exercise of stock options	1,618,368	—	4,059	—	—	4,059
Stock-based compensation	—	—	27,600	—	—	27,600
Other comprehensive loss	—	—	—	(677)	—	(677)
Net loss	—	—	—	—	(298,665)	(298,665)
Balance at December 31, 2020	127,416,740	13	1,385,301	(1,278)	(667,184)	716,852
Issuance of common stock in connection with a collaboration agreement	1,924,927	—	85,213	—	—	85,213
Issuance of common stock to settle a contingent consideration	42,737	—	1,860	—	—	1,860
Vesting of restricted common stock	89,261	—	—	—	—	—
Exercise of stock options	1,622,718	—	13,077	—	—	13,077
Issuance of common stock under employee stock purchase plan	65,021	—	2,300	—	—	2,300
Stock-based compensation	—	—	83,784	—	—	83,784
Other comprehensive income	—	—	—	179	—	179
Net income	—	—	—	—	528,584	528,584
Balance at December 31, 2021	131,161,404	13	1,571,535	(1,099)	(138,600)	1,431,849
Issuance of common stock in connection with a grant agreement	881,365	—	28,462	—	—	28,462
Vesting of restricted common stock	349,496	—	—	—	—	—
Exercise of stock options	696,963	—	4,534	—	—	4,534
Issuance of common stock under employee stock purchase plan	147,459	—	3,222	—	—	3,222
Stock-based compensation	—	—	102,082	—	—	102,082
Other comprehensive loss	—	—	—	(8,023)	—	(8,023)
Net income	—	—	—	—	515,837	515,837
Balance at December 31, 2022	133,236,687	$ 13	$ 1,709,835	$ (9,122)	$ 377,237	$ 2,077,963

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

VIR BIOTECHNOLOGY, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2022	**2021**	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$ 515,837	$ 528,584	$ (298,665)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Changes in estimated constraint on profit-sharing amount	369,535	—	—
Depreciation and amortization	6,251	5,278	4,400
Amortization of intangible assets	532	533	1,042
Impairment of intangible assets	—	—	832
(Accretion of discounts) amortization of premiums on investments, net	(8,943)	(244)	1,548
Noncash lease expense	8,709	6,172	3,371
Change in fair value of equity investments	111,140	(138,049)	—
Change in estimated fair value of contingent consideration	2,115	91,848	38,394
Payment of contingent consideration in excess of acquisition date fair value	(93,803)	(8,140)	(15,752)
Change in estimated fair value of derivative liability	—	—	16,796
Stock-based compensation	102,082	83,784	27,600
Change in deferred income taxes	(15,186)	15,186	(52)
Gain from a sublease termination	—	(4,844)	—
Other	(383)	697	23
Changes in operating assets and liabilities:			
Receivable from collaboration	770,038	(773,079)	—
Prepaid expenses and other current assets	(39,358)	(3,665)	(4,475)
Other assets	(11,795)	(1,483)	(1,100)
Accounts payable	797	(171)	(790)
Accrued liabilities and other long-term liabilities	(15,513)	58,498	46,614
Operating lease liabilities	(5,502)	(535)	(3,684)
Deferred revenue	(33,300)	92,041	(7,043)
Net cash provided by (used in) operating activities	1,663,253	(47,589)	(190,941)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Proceeds from sale of equipment	22	—	—
Purchases of property and equipment	(68,028)	(21,817)	(6,549)
Purchases of investments	(1,476,965)	(420,240)	(403,841)
Maturities of investments	351,510	301,243	400,348
Proceeds from disposal of an asset held for sale	—	—	180
Net cash used in investing activities	(1,193,461)	(140,814)	(9,862)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock, net of issuance costs	—	—	323,214
Proceeds from issuance of common stock in connection with a collaboration agreement	—	85,213	206,699
Proceeds from issuance of common stock in connection with a grant agreement	28,462	—	—
Payment of contingent consideration	(1,197)	—	(4,248)
Payment of principal on financing lease obligations	(260)	(259)	(250)
Proceeds from exercise of stock options	4,534	13,077	4,059
Proceeds from issuance of common stock under the employee stock purchase plan	3,222	2,300	—
Net cash provided by financing activities	34,761	100,331	529,474
Net increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents	504,553	(88,072)	328,671
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	363,415	451,487	122,816
Cash, cash equivalents and restricted cash and cash equivalents at end of period	$ 867,968	$ 363,415	$ 451,487
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Property and equipment purchases included in accounts payable and accrued liabilities	$ 1,020	$ 8,731	$ 382
Common stock issued for payment of contingent consideration	$ —	$ 1,860	$ —
Operating lease liabilities obtained in exchange of right-of-use asset	$ 4,046	$ 77,187	$ 48,495
Reclassification of derivative liability to additional paid-in capital	$ —	$ —	$ 29,245
SUPPLEMENTAL DISCLOSURE OF CASHFLOW INFORMATION:			
Cash paid during the period for income tax	$ 252,030	$ —	$ —
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH TO THE CONSOLIDATED BALANCE SHEETS:			
Cash and cash equivalents	$ 848,631	$ 347,815	$ 436,575
Restricted cash and cash equivalents, current	12,681	8,594	7,993
Restricted cash and cash equivalents, noncurrent	6,656	7,006	6,919
Total cash, cash equivalents and restricted cash	$ 867,968	$ 363,415	$ 451,487

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

1. Organization

Vir Biotechnology, Inc. (“Vir” or the “Company”) is a commercial-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Its current pipeline consists of sotrovimab (previously VIR-7831; and where marketing authorization has been granted, marketed under the brand name Xevudy®) and other product candidates targeting hepatitis B virus (“HBV”), hepatitis D virus (“HDV”), influenza A virus, coronavirus disease 2019 (“COVID-19”), and human immunodeficiency virus (“HIV”). Vir has assembled four technology platforms that are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes.

In September 2022, the Company formed a new wholly-owned subsidiary in Switzerland, Vir Biotechnology International GmbH (“VBI”), a Swiss limited liability company. The primary purpose of VBI is to support Vir's research and development and international commercial activities outside of the United States.

Follow-On Offering

On July 10, 2020, the Company issued and sold 8,214,285 shares of the Company’s common stock pursuant to a registration statement on Form S-1 (File No. 333-239689) and a registration statement on Form S-1 filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended (the “Securities Act”) (File No. 333-239747) (collectively, the “Registration Statements”). The Registration Statements became effective on July 7, 2020. The price of the shares sold in the follow-on offering was $42.00 per share and the Company received total gross proceeds from the offering of approximately $345.0 million. After deducting underwriting discounts and commissions of approximately $20.7 million and offering expenses of approximately $1.1 million, the net proceeds were approximately $323.2 million.

Sales Agreement

In November 2020, the Company entered into a sales agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”), under which the Company may from time to time offer and sell shares of its common stock for an aggregate offering price of up to $300.0 million, through or to Cowen, acting as sales agent or principal. The shares will be offered and sold under the Company’s shelf registration statement on Form S-3 and a related prospectus filed with the Securities and Exchange Commission (the “SEC”) on November 10, 2020. The Company will pay Cowen a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide Cowen with customary indemnification and contribution rights. As of December 31, 2022, no shares have been issued under the Sales Agreement.

Need for Additional Capital

Although the Company recorded net income for the years ended December 31, 2022 and 2021, respectively, it has otherwise incurred net losses since inception. The Company expects its earnings to be volatile and may 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, 2022, the Company had retained earnings of $377.2 million. The Company had $2.4 billion in cash, cash equivalents, and investments as of December 31, 2022. Based on the Company’s current operating plan, management believes that the $2.4 billion as of December 31, 2022 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 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 rates throughout the respective periods. Transaction gains and losses are included in other income (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 revenue and expense during the reporting periods. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

Segments

The Company operates as one reportable segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for purposes of allocating resources.

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

Although the Company received Emergency Use Authorization ("EUA"), temporary authorization or marketing approval for sotrovimab (under the brand name Xevudy®), sotrovimab is currently de-authorized in the U.S. and has limitations in use outside of the U.S. In addition, the Company is still subject to a number of other challenges and risks similar to other biopharmaceutical companies in the early stage, including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, the need to obtain marketing approval for its other product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of sotrovimab and other product candidates and protection of proprietary technology. If the Company does not successfully obtain regulatory approval, commercialize or partner any of its product candidates, it will be unable to generate revenue from product sales or maintain profitability. In addition, to the extent the COVID-19 pandemic, including the emergence of new variants or subvariants, adversely affects the Company's business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties discussed above.

The Company has implemented a number of plans and policies designed to address and mitigate the impact of the COVID-19 pandemic on its business. The extent to which the changing COVID-19 landscape impacts the Company's business, clinical development and regulatory efforts, corporate development objectives and the value of and market for its common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time.

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and investments. Cash and cash equivalents are deposited in checking and sweep accounts at a financial institution. Such deposits may, at times, exceed federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company's investment policy limits investments to certain types of securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and investments, and issuers of the investments to the extent recorded on the consolidated balance sheets. As of December 31, 2022 and 2021, the Company has no off-balance sheet concentrations of credit risk.

The Company is exposed to credit losses primarily through receivables from customers and collaborators and through its available-for-sale debt securities. The Company's expected loss allowance methodology for the receivables is developed using historical collection experience, current and future economic market conditions, a review of the current aging status and financial condition of the entities. Specific allowance amounts are established to record the appropriate allowance for customers that have a higher probability of default. Balances are written off when determined to be uncollectible. The Company's expected loss allowance methodology for the debt securities is developed by reviewing the extent of the unrealized loss, the size, term, geographical location, and industry of the issuer, the issuers' credit ratings and any changes in those ratings, as well as reviewing current and future economic market conditions and the issuers' current status and financial condition. The Company considered the current and expected future economic and market conditions surrounding the COVID-19 pandemic and interest rate policies and determined that the estimate of credit losses was not significantly impacted. There was no allowance for losses on available-for-sale debt securities attributable to credit risk for the years ended December 31, 2022 and 2021.

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 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 estimated fair value.

Available-for-Sale Debt Securities

The Company's valuations of marketable securities are generally derived from independent pricing services based on quoted prices in active markets for similar securities at period end. Generally, investments with original maturities beyond three months at the date of purchase and 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 comprehensive income (loss). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the 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 income (expense), net on the consolidated statements of operations.

Restricted Cash and Cash Equivalents

Restricted cash and cash equivalents represent money market funds to secure standby letters of credit and security deposits with financial institutions, both under office and laboratory space lease agreements. Additionally, funds received from certain grants are restricted as to their use and are therefore classified as restricted cash and cash equivalents.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation and amortization. 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 long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future net undiscounted cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. No material impairment losses have been incurred to date.

Acquired Intangible Assets

The Company's intangible assets were acquired via business combinations or asset acquisitions. Indefinite-lived intangible assets represent the estimated fair value assigned to in-process research and development ("IPR&D") acquired in a business combination. 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 adjusted fair value. As of December 31, 2022, there have been no such impairments. For IPR&D, if a product candidate derived from the indefinite-lived intangible asset is developed and 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. IPR&D assets acquired as part of an asset acquisition are recorded at cost and expensed immediately if they have no alternative future uses.

Finite-lived intangible assets acquired are initially recognized at their fair value at the acquisition date. 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 may not be recoverable.

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.

Revenue Recognition

Collaboration, License and Contract Revenue

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

For collaborative arrangements that fall within the scope of ASC 808, Collaborative Arrangements ("ASC 808"), the Company first determines which elements of the collaboration are deemed to be a performance obligation with a customer within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808 and are not subject to the guidance in ASC 606, the Company applies the revenue recognition model under ASC 606, including the royalty exception guidance and variable consideration guidance under ASC 606 as described below, or other guidance, as deemed appropriate. When the Company is considered an agent in elements of collaboration arrangements within the scope of ASC 808, it records its share of collaboration revenue in the period in which such sales occur. The Company is considered an agent when the collaboration partner controls the product before transfer to the customers and has the ability to direct the use of and obtain substantially all of the remaining benefits from the product. In these instances, collaboration revenue is based upon the net sales reported by the Company's collaboration partners, net of cost of goods sold and allowable expenses (e.g., manufacturing, distribution, medical affairs, selling, and marketing expenses) in the period. In order to record collaboration revenue, the Company utilizes certain information from its collaboration partner, including actual net product sales, and costs incurred for sales activities, and makes key judgments based on business updates related to commercial and clinical activities such as expected commercial demand, commercial supply plan, manufacturing commitments, risks related to expired or obsolete inventories, and risks related to potential product returns or contract terminations. The Company uses these estimates to determine whether payments due to us under our collaboration arrangements, such as profit-share payments, should be recognized as revenues 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 would not result in a material reversal of revenues in future reporting periods.

The Company has entered into a number of license and collaboration agreements that fall within the scope of ASC 606. The Company evaluates the promised goods or services in these agreements to determine which ones represent distinct performance obligations. These agreements may include the following types of promised goods or services: (i) grants of licenses, (ii) performance of research and development services, and (iii) participation on joint research and/or development committees. They also may include options to obtain licenses to the Company's intellectual property.

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

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

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

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

Grant Revenue

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

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

Acquisitions

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.

When the Company determines that an entity acquired does not meet the definition of a business, the transaction is accounted for as an acquisition of assets. Therefore, the consideration paid to acquire IPR&D is expensed, and no goodwill is recorded. Any contingent consideration is generally recognized only when it becomes payable or is paid.

Embedded Derivatives

The Company evaluates its acquisitions, collaborative arrangements and other business development transactions to determine if embedded components of these contracts meet the definition of a derivative under ASC 815, Derivatives and Hedging. In general, embedded derivatives are required to be bifurcated from the host instrument if (i) the embedded feature is not clearly and closely related to the host contract and (ii) the embedded feature, if considered a freestanding instrument, meets the definition of a derivative. Embedded derivatives are reported on the consolidated balance sheets at their estimated fair values. Contingent consideration related to asset acquisitions that meet the definition of an embedded derivative is classified as contingent consideration on the consolidated balance sheets. Any change in estimated fair values, as determined at each measurement period, are recorded in the consolidated statements of operations based on the nature of the related contingencies. Changes in fair values of embedded derivatives related to the achievement of various milestones for product candidates are recorded within research and development expenses or selling, general and administrative expenses based on the nature of the relevant underlying activities. Otherwise, changes in fair values are recorded within other income (expense), net.

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 right-of-use 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 when the Company is reasonably certain it will exercise such options. ROU assets and lease liabilities are remeasured upon certain modifications to leases 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.

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 differences between the financial statement reporting and tax bases of assets and liabilities and net operating losses and credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized.

The Company’s tax positions are subject to income tax audits. The Company recognizes the tax benefit of an uncertain tax position only if it is more likely than not that the position is sustainable upon examination by the taxing authority, based on the technical merits. The tax benefit recognized is measured as the largest amount of benefit which is more likely than not to be realized upon settlement with the taxing authority. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on several factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues. The provision for income taxes includes the effects of any accruals that the Company believes are appropriate, as well as any related net interest and penalties.

Net Income (Loss) Per Share

Basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net income per common share is computed by dividing the net income by the sum of the weighted average number of common shares outstanding during the period plus any potential dilutive effects of common stock equivalents outstanding during the period calculated in accordance with the treasury stock method.

New Accounting Pronouncement Recently Adopted

In November 2021, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update (“ASU”) No. 2021-10, Government Assistance (Topic 832) (“ASU 2021-10”), which adds certain disclosure requirements with respect to government assistance, including (1) the types of assistance, (2) an entity’s accounting for the assistance, and (3) the effect of the assistance on financial statements. ASU 2021-10 is effective for annual periods beginning after December 15, 2021. The Company's adoption of ASU 2021-10 on January 1, 2022 did not result in any material impact on its consolidated financial statements and related disclosures.

3. Fair Value Measurements

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

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

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

Cash Equivalents and Available-for-Sale Debt 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:

		December 31, 2022			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
		(in thousands)			
Assets:					
Money market funds[1]	Level 1	$ 909,342	$ —	$ —	$ 909,342
U.S. government treasuries	Level 2	1,493,841	—	(8,396)	1,485,445
Total financial assets		$ 2,403,183	$ —	$ (8,396)	$ 2,394,787

(1) Includes $19.3 million of restricted cash equivalents.

		December 31, 2021			
	Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
		(in thousands)			
Assets:					
Money market funds[1]	Level 1	$ 345,098	$ —	$ —	$ 345,098
U.S. government treasuries	Level 2	419,442	—	(872)	418,570
Total financial assets		$ 764,540	$ —	$ (872)	$ 763,668

(1) Includes $15.6 million of restricted cash equivalents.

Accrued interest receivable excluded from both the fair value and amortized cost basis of the available-for-sale debt securities are presented within prepaid expenses and other current assets, and other assets in the consolidated balance sheets. Accrued interest receivable amounted to $2.5 million and $1.1 million as of December 31, 2022 and 2021, respectively. The Company did not write off any accrued interest receivable during the years ended December 30, 2022 and 2021.

The Company recognized total net unrealized loss of $8.4 million and $0.9 million in accumulated other comprehensive income (loss) as of December 31, 2022 and 2021, respectively. The gross unrealized losses related to U.S. government treasuries as of December 31, 2022 and 2021 were due to changes in interest rates. As of December 31, 2022 and 2021, there were no investments that have been in a continuous unrealized loss position for longer than 12 months. The Company determined that the gross unrealized losses on our investments as of December 31, 2022 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, 2022, no securities have contractual maturities of longer than two years.

Equity Investments

As of December 31, 2022, the Company's equity investment consisted solely of ordinary shares of Brii Biosciences Limited (“Brii Bio Parent”). The Company acquired the securities as partial consideration for entering into the collaboration, option and license agreement (the “Brii Agreement”) with Brii Bio Parent and Brii Biosciences Offshore Limited (“Brii Bio”) in May 2018. The Company concluded it does not have a controlling interest or significant influence over Brii Bio based on its ownership percentage and other factors. See further discussion in Note 7—Collaboration and License Agreements. In July 2021, Brii Bio Parent completed its initial public offering (“Brii Bio Parent IPO”) on the Stock Exchange of Hong Kong Limited, prior to which the securities were accounted for as equity securities without a readily determinable fair value. Upon the completion of the Brii Bio Parent IPO, the securities were considered to be marketable equity securities and subsequently remeasured at fair value at each reporting date. As of December 31, 2022, the Company remeasured the equity investment at a fair value of $31.9 million. For the year ended December 31, 2022, the Company recognized an unrealized loss of $111.1 million as other income in the consolidated statement of operations, net of an unrealized loss of $0.1 million related to foreign currency translation for the period. The Company classifies its equity investment in Brii Bio Parent as a Level 1 asset within the fair value hierarchy, as the value is based on a quoted market price in an active market.

Contingent Consideration

Contingent consideration includes potential milestone payments in connection with the acquisitions of Humabs BioMed SA (“Humabs”) and TomegaVax, Inc. (“TomegaVax”). See further discussion in Note 4—Acquisitions. The Company classifies the contingent consideration as Level 3 financial liabilities within the fair value hierarchy as of December 31, 2022 and 2021.

The estimated fair value of the contingent consideration related to the Humabs acquisition was determined by calculating the probability-weighted clinical, regulatory and commercial milestone payments based on the assessment of the likelihood and estimated timing that certain milestones would be achieved. As of December 31, 2022, the Company calculated the estimated fair value of the remaining clinical and regulatory milestones related to VIR-3434 using the following significant unobservable inputs:

Unobservable input	Range (Weighted-Average)1
Discount rates	13.8% - 15.1% (14.5%)
Probability of achievement	14.4% - 60.0% (43.6%)

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

For the commercial milestones, the Company used a Monte Carlo simulation because of the availability of discrete revenue forecasts. As of December 31, 2022, 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 VIR-3434:

Unobservable input	Value
Volatility	80.0%
Discount rate	12.0%
Probability of achievement	25.9%

The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. As of December 31, 2022 and 2021, the estimated fair value of the contingent consideration related to the Humabs acquisition was $23.4 million and $17.1 million, respectively, with changes in the estimated fair value recorded in research and development expenses, and selling, general and administrative expenses in the consolidated statements of operations based on the nature of the relevant underlying activities.

The estimated fair value of the contingent consideration related to the TomegaVax acquisition was determined by using a Monte Carlo simulation model which included estimates of both the probability and timing to achieve the required per-share price of the Company’s common stock, and incorporates assumptions as to expected volatility and discount rate. The discount rate captures the credit risk associated with the payment of the contingent consideration when earned and due. Although the TomegaVax acquisition was accounted for as an asset acquisition, such contingent consideration met the definition of an embedded derivative financial instrument. In February 2021, the Company achieved one of the milestones related to a specified per-share price of its common stock

resulting in a $10.0 million payable to the former TomegaVax's stockholders which was paid in July 2021. As of December 31, 2022, the fair value of the remaining contingent consideration was estimated using the following significant unobservable inputs:

Unobservable input	Value
Volatility	90.0%
Discount rate	4.4%

As of December 31, 2022 and 2021, the estimated fair value of the contingent consideration related to the TomegaVax acquisition was $1.5 million and $5.7 million, respectively, with changes in the estimated fair value recorded in other income (expense), net in the consolidated statements of operations.

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

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

	Contingent Consideration
Balance at December 31, 2021	$ 22,822
Changes in fair value	2,115
Balance at December 31, 2022	$ 24,937

4. Acquisitions

Acquisition of TomegaVax

In September 2016, the Company entered into an agreement and plan of merger ("TomegaVax Merger Agreement") to acquire all of the equity interests of TomegaVax. The primary asset purchased in the acquisition was an in-process cytomegalovirus ("CMV") vector-based vaccine platform for use in HBV, HIV, and tuberculosis. The acquisition was accounted for as an asset purchase.

In connection with the entry into the TomegaVax Merger Agreement, the Company also entered into a letter agreement with TomegaVax (the "TomegaVax Letter Agreement"), which provides for certain payments to TomegaVax's former stockholders before September 2024, in each case so long as the Company is continuing to pursue the development of the TomegaVax technology. Under the terms of the TomegaVax Letter Agreement, the Company will be required to pay to the former stockholders of TomegaVax milestone payments of up to an aggregate of $30.0 million if the per-share price of the Company's publicly traded common stock, or implied price per share of the Company's Series A-1 convertible preferred stock (or common stock upon conversion) upon a certain asset sale, merger or stock sale, is at least $45 (as adjusted in the case of any stock dividend, stock split or other similar recapitalization), with the amount of such payments determined by the share price and/or the stage of the Company's clinical development at the time of the relevant event triggering the payment. The share price of the Company's publicly traded common stock will be determined using the average of the daily volume-weighted average trading price of the Company's common stock for each trading day during a consecutive 90-day period. The foregoing payments are payable (i) during any date after the completion of an initial public offering by the Company or any successor or affiliate controlling the TomegaVax technology, provided that no payment will be due before the first anniversary of the initial public offering, (ii) upon the sale of all assets related to the TomegaVax technology or (iii) upon a merger or stock sale of the Company or any successor or affiliate controlling the TomegaVax technology, in each case subject to certain conditions with respect to the timing of the payments. The payments under the TomegaVax Letter Agreement can be made in cash or shares of the Company's common stock, at the discretion of the Company's board of directors.

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

The Company determined that the future milestone payments contain net settlement provisions and, therefore, they were required to be accounted for as embedded derivatives under the relevant accounting guidance. As of December 31, 2022, the estimated fair value of the embedded derivative was $1.5 million and was included in the contingent consideration liability on the consolidated balance sheet.

Acquisition of Humabs

In August 2017, the Company acquired all of the outstanding equity of Humabs, a private Swiss company, which discovers and develops monoclonal antibodies ("mAbs") derived from individuals whose immune systems have successfully responded to major diseases. The Company acquired all of Humabs' rights, title and interest in and to substantially all of the assets of Humabs except for rights under certain license agreements with third parties. The Company is obligated to pass through to the former Humabs shareholders any amounts received by Humabs under such license agreements, net of any program expenses. The transaction was accounted for as an acquisition of a business. In addition to the cash payment and issuance of common stock to the former Humabs shareholders at the acquisition date, the Company also agreed to pay additional amounts in cash upon the achievement of specified milestone events: (i) up to $135.0 million upon the achievement of clinical, regulatory and commercial milestones for VIR-3434; and (ii) up to $105.0 million upon the achievement of clinical, regulatory and commercial milestones for another product, which the Company elected as sotrovimab, a severe acute respiratory syndrome coronavirus 2 ("SARS-CoV-2") product.

During the year ended December 31, 2020, the Company achieved two of the specified clinical milestones for the HBV product and sotrovimab totaling $20.0 million. During the year ended December 31, 2021, the Company achieved the specified regulatory milestone of $35.0 million and sales milestones totaling $60.0 million related to sotrovimab, which were paid in January and February 2022, respectively. The estimated fair value of the remaining contingent consideration was $23.4 million as of December 31, 2022.

The acquired developed technologies that have associated patents issued are classified as finite-lived intangible assets and are amortized on a straight-lined basis over their estimated remaining useful lives, generally between seven to 12 years. The Company also acquired indefinite-lived intangible assets consisting of IPR&D. These assets will not be amortized until regulatory approval is obtained in a major market. At that time, the Company will determine the useful life of the asset and begin amortization. If the associated research and development effort is abandoned or otherwise impaired, the related IPR&D assets will be written-off and an impairment charge will be recorded. As of December 31, 2022, there have been no such impairments related to the IPR&D assets. The estimated fair value of the intangible assets was determined using the replacement cost method. The excess of the purchase price over the estimated fair value of the net assets acquired was recorded as goodwill. None of the goodwill is expected to be deductible for income tax purposes.

5. 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. The Company tests goodwill for impairment on an annual basis or sooner, if deemed necessary. There was no impairment for the year ended December 31, 2022.

Intangible Assets

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

	December 31,		Weighted-Average Remaining Useful Life (Years)
	2022	2021	
Developed technology	$ 4,260	$ 7,000	5.5
Contract-based intangible asset	502	502	12.9
Finite-lived intangible assets, gross	4,762	7,502	
Less accumulated amortization	(2,738)	(4,114)	
Less impairment of intangible assets	—	(832)	
Finite-lived intangible assets, net	$ 2,024	$ 2,556	

Finite-lived intangible assets are carried at cost less accumulated amortization. The contract-based intangible asset resulted from the product approval of a sublicensed intellectual property right in December 2020. The intellectual property right was previously accounted for as IPR&D. Amortization expense related to finite-lived intangible assets, included in research and development expenses on the consolidated statements of operations, totaled $0.5 million, $0.5 million and $1.0 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Management reviews finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable, like that of property and equipment.

Based on the finite-lived intangible assets recorded as of December 31, 2022, the estimated future amortization expense for the next five years is as follows (in thousands):

Year Ending December 31:		
2023	$	532
2024		260
2025		213
2026		213
2027		213
Total	$	1,431

Indefinite-Lived Intangible Assets

As of December 31, 2022 and 2021, the Company had indefinite-lived intangible assets of $30.7 million, respectively, related to the purchased IPR&D from the Humabs acquisition. No impairment losses have been recorded for the years ended December 31, 2022 and 2021.

6. Grant Agreements

Bill & Melinda Gates Foundation Grants

The Company has entered into various grant agreements with the Bill & Melinda Gates Foundation, under which it was awarded grants totaling up to $55.7 million to support its HIV vaccine program, tuberculosis vaccine program, HIV vaccinal antibody program and malaria vaccinal antibody program. The term of the grant agreements will expire at various dates through December 2023, unless earlier terminated by the Bill & Melinda Gates Foundation for the Company’s breach, failure to progress the funded project, in the event of the Company’s change of control, change in the Company’s tax status, or significant changes in the Company’s leadership that the Bill & Melinda Gates Foundation reasonably believes may threaten the success of the project.

Concurrently with the execution of the grant agreement for the vaccinal antibody program, the Company entered into a stock purchase agreement with the Bill & Melinda Gates Foundation, under which the Bill & Melinda Gates Foundation purchased 881,365 shares of the Company’s common stock on January 13, 2022, at a price per share of $45.38, for an aggregate purchase price of approximately $40.0 million. The fair market value of the common stock issued to the Bill & Melinda 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 Bill & Melinda Gates Foundation based on its fair market value on the closing date and determined that the premium paid by the Bill & Melinda Gates Foundation should be included in the deferred revenue from the vaccinal antibody grant.

Payments received in advance that are related to future research activities along with the aforementioned premium received are deferred and recognized as revenue when the donor-imposed conditions are met, which is as the research and development activities are performed. The premium received by the Company is deferred and recognized over the same period as the grant proportionally. The Company recognized grant revenue of $8.6 million, $8.2 million and $8.6 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022 and 2021, the Company had deferred revenue of $15.5 million and $6.8 million, respectively. As of December 31, 2022 and 2021, the Company had $7.7 million and $1.8 million, respectively, within accrued and other liabilities, which may need to be refunded to the Bill & Melinda Gates Foundation.

Biomedical Advanced Research and Development Authority

In September 2022, the Company entered into an other transaction for advanced research agreement (the "BARDA Agreement") with the Biomedical Advanced Research and Development Authority ("BARDA"), part of the U.S. Department of Health and Human Services' Administration for Strategic Preparedness and Response. Under the BARDA Agreement, the Company may receive up to an estimated $1.0 billion to advance the development of a full portfolio of innovative solutions to address influenza and potentially other infectious disease threats. The Base Period (as defined below) for the BARDA Agreement includes government funding of approximately $55.0 million to reimburse a portion of expenses incurred by the Company to support the development of VIR-2482, an investigational prophylactic monoclonal antibody designed with the aim to protect against seasonal and pandemic influenza, including expenses related to the Phase 2 pre-exposure prophylaxis trial of VIR-2482. The BARDA Agreement also provides for additional BARDA funding after the exercise by BARDA of up to twelve options to further support the development of pre-exposure prophylactic antibodies including and beyond VIR-2482 for the prevention of influenza illness or possibly supporting medical countermeasures for other pathogens of pandemic potential. The BARDA Agreement has an initial term that commenced on September 30, 2022 and extends through January 2026 ("Base Period"), which may be extended by mutual written agreement of the Company and BARDA if certain conditions are met or if BARDA exercises any of its options, as described above, and is terminable by the Company and BARDA at any time under specified circumstances, including for convenience.

The Company recognized grant revenue under the BARDA Agreement of $26.4 million for the year ended December 31, 2022 and a corresponding other receivable in prepaid expenses and other current assets of $26.4 million as of December 31, 2022.

7. Collaboration and License Agreements

Collaboration Agreements with GSK

2020 GSK Agreement

On June 9, 2020, the Company, Glaxo Wellcome UK Limited and Beecham S.A. entered into a definitive collaboration agreement under the terms set forth in the preliminary collaboration agreement entered into by the Company and certain GSK entities in April 2020 (the "2020 Preliminary Agreement") (such definitive collaboration agreement, the "2020 GSK Agreement"). In December 2021, Beecham S.A. assigned and transferred all its rights, title, interest, and benefit in the 2020 GSK Agreement to GlaxoSmithKline Biologicals S.A. (Glaxo Wellcome UK Limited and GlaxoSmithKline Biologicals S.A., referred to, individually and together, as "GSK"), including all its rights to bring claims under such agreement. Concurrently with the execution of the 2020 Preliminary Agreement, the Company entered into a stock purchase agreement (the "2020 Stock Purchase Agreement") with Glaxo Group Limited ("GGL"), an affiliate of GSK, under which GGL purchased 6,626,027 shares of the Company's common stock on April 29, 2020, at a price per share of $37.73, for an aggregate purchase price of approximately $250.0 million. The 2020 Preliminary Agreement became effective as of April 29, 2020, which was also the closing date for the 2020 Stock Purchase Agreement ("Effective Date"). The 2020 GSK Agreement superseded and replaced the 2020 Preliminary Agreement between the parties. Under the terms of the 2020 GSK Agreement, the Company and GSK agreed to collaborate to research, develop and commercialize products for the prevention, treatment and prophylaxis of diseases caused by SARS-CoV-2, the virus that causes COVID-19, and potentially other coronaviruses. The collaboration initially focused on the development and commercialization of three types of collaboration products under three programs: (1) antibodies targeting SARS-CoV-2 and potentially other coronaviruses (the "Antibody Program"); (2) vaccines targeting SARS-CoV-2 and potentially other coronaviruses (the "Vaccine Program"), and (3) products based on genome-wide CRISPR screening of host targets expressed in connection with exposure to SARS-CoV-2 and potentially other coronaviruses (the "Functional Genomics Program").

For four years following the Effective Date, the parties agreed to conduct certain research and development activities under mutually agreed development plans and associated budgets for each of the three programs, and under the oversight of a joint steering committee ("JSC"). The Company is primarily responsible for the development and clinical manufacturing activities for the Antibody Program, and for conducting the initial development activities directed to a vaccine in the Vaccine Program. GSK is primarily responsible for the commercialization activities for the Antibody Program (including in mainland China, Hong Kong, Macau and Taiwan following the purchase of these rights in May 2022, as described below), the later-stage development, manufacturing and commercialization activities for the Vaccine Program and the development, manufacturing and commercialization activities for the Functional Genomics Program. Subject to an opt-out mechanism and Amendment No. 1 to the 2020 GSK Agreement (described below), the parties share all development costs, manufacturing costs and costs and expenses for the commercialization of the collaboration products, with the Company bearing 72.5% of such costs for the antibody products, 27.5% of such costs for the vaccine products, and equal sharing of such costs for the functional genomics products.

On a collaboration product-by-collaboration product basis, each party has the one-time right, at specified points in development, to opt-out of its co-funding obligations, and the other party may, at its election, either pursue such program unilaterally, or also cease research and development activities and funding of such collaboration product. If the opt-out provisions are not exercised by either party subject to the terms of the 2020 GSK Agreement, the parties share all profits and losses arising from any collaboration product in the same ratios in which the parties bore development costs for such collaboration program. For each collaboration product as to which a party exercises its opt-out right, the commercializing party pays to the opt-out party royalties on net sales of the applicable collaboration product at rates based on factors such as the stage of development of such collaboration product at the time the opt-out party exercises such right, and whether the opt-out party is the lead party, or a portion of the sublicense revenue if the commercializing party chooses to sublicense or otherwise divest rights to such collaboration product. On an antibody product-by-antibody product basis, the Company has a co-promotion right for such antibody product in the United States, under which the Company has the right to perform up to 20% of details in connection with such antibody product.

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

The Company considered the ASC 606 criteria for combining contracts and determined that the 2020 GSK Agreement and 2020 Stock Purchase Agreement should be combined into a single contract because they were negotiated and entered into in contemplation of one another. The fair market value of the common stock issued to GGL was $206.7 million, based on the closing stock price of $36.70 on the date of execution of the 2020 Preliminary Agreement and 2020 Stock Purchase Agreement and taking into account a discount for the lack of marketability due to the restrictions in place on the underlying shares, resulting in a $43.3 million premium received by the Company. The Company accounted for the common stock issued to GGL based on its fair market value on the transaction date and determined that the premium paid by GSK should be attributed to the transaction price of the 2020 GSK Agreement.

The Company concluded that the 2020 GSK Agreement contained four units of account: (i) the license granted to GSK under the Antibody Program (the “Antibody License”); (ii) the research and development activities (including clinical manufacturing) under the Antibody Program; (iii) the research and development activities under the Vaccine Program; and (iv) the research and development activities under the Functional Genomics Program. The Company considered the guidance in ASC 606 to determine which of these elements of the 2020 GSK Agreement are performance obligations with a customer. The Company determined that the Antibody License is within the scope of ASC 606, and accordingly, accounted for the Antibody License as a distinct performance obligation under ASC 606. The Antibody License is a functional intellectual property and is distinct from the associated research and development activities to be performed under the program due to its significant standalone functionality. All other elements of the 2020 GSK Agreement, including the research and development activities and participation in the JSC and subcommittees for each collaboration program, were not determined to be distinct performance obligations with a customer.

The transaction price for the Antibody License at inception was determined to be $43.3 million, representing the premium on the sale of common stock to GSK. The Company determined that GSK can benefit from the Antibody License at the time of grant and, therefore, the related performance obligation is satisfied at a point in time. As such, the Company recognized the $43.3 million as contract revenue during the second quarter of 2020.

The remaining units of account of the 2020 GSK Agreement were determined to be within the scope of ASC 808 as the Company and GSK are both active participants in the development, manufacturing and commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the activities of the arrangement. Furthermore, the Company and GSK participate in the commercial profit and loss sharing arrangement for each program commensurate with each party’s cost-sharing responsibilities during research and development. Because ASC 808 does not provide recognition and measurement guidance, the Company determined that the guidance in ASC 730, Research and Development, was appropriate to analogize to, based on the nature of the cost-sharing provisions of the 2020 GSK Agreement. The Company has concluded that payments to or reimbursements from GSK related to these services will be accounted for as an increase to or reduction of research and development expenses, respectively. Additionally, the Company is entitled to consideration from GSK related to profit and loss sharing arrangements (including royalties) contingent upon future sales of collaboration products. The Company concluded that any payments from GSK related to the profit and loss sharing arrangement (including royalties) contingent upon the commercialization of the products will be analogized to ASC 606 and, therefore, will be recognized when the related sales occur.

In May 2021, the U.S. Food and Drug Administration ("FDA") granted an EUA in the United States for sotrovimab, the first collaboration product under the Antibody Program. In April 2022, the FDA excluded the use of sotrovimab in all U.S. regions due to the continued proportion of COVID-19 cases caused by certain Omicron subvariants. As the lead party for all manufacturing and commercialization activities, GSK incurs all of the manufacturing, sales and marketing expenses and is the principal on sales transactions with third parties. As described in Note 2—Summary of Significant Accounting Policies, the Company's accounting policy related to the profit-share is to consider the agreed-upon share of the profit-sharing amounts each quarter and evaluate whether those amounts are subject to potential future adjustments based on the latest available facts and circumstances, subject to the terms of the 2020 GSK Agreement. As the Company is the agent, the Company recognizes its contractual share of the profit-sharing amounts or royalties (in case of an opt-out) as revenue, based on sales net of various estimated deductions such as rebates, discounts, chargebacks, credits and returns, less cost of sales and allowable expenses (including manufacturing, distribution, medical affairs, selling, and marketing expenses) in the period the sale occurs. Manufacturing costs include inventory revaluation adjustments, lower of cost or market inventory adjustments, inventory write-downs and write-offs, and binding purchase commitments with a third-party manufacturer among other manufacturing costs. 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.

As of December 31, 2022, GSK held certain potentially excess binding supply manufacturing commitments of sotrovimab and reserved certain binding manufacturing capacity potentially not expected to be utilized, which have not yet been reported to us as allowable manufacturing expenses for the cumulative profit-sharing amounts to date. We expect GSK to adjust allowable manufacturing expenses for our share of the potential charge for excess supply write-offs and unused binding manufacturing capacity and report to us as cost-sharing amounts in future periods. We evaluated the latest available facts and circumstances to update our evaluation of whether any portion of profit-sharing amounts should be constrained. In doing so, as of December 31, 2022, based on the current state of the COVID-19 pandemic, including the continued proportion of cases caused by certain Omicron subvariants, discussions with the FDA and other regulatory authorities, and the Company's expectations for future sales in light of these factors, the Company revised its estimate and determined that $369.7 million should be constrained from profit-sharing revenues earned during the year ended December 31, 2022 in relation to the Company's anticipated contractual share of potential future adjustments to manufacturing expenses and recorded such amount as adjustments to profit-sharing amounts. The Company re-assesses these estimates each reporting period. Actual results could materially differ from this estimate.

During the years ended December 31, 2022 and 2021, the Company recorded profit-sharing amounts and profit-sharing amounts constrained as components of collaboration revenue in the consolidated statements of operations, as follows:

	December 31,	
	2022	2021
	(in thousands)	
Collaboration revenue, net		
Profit-sharing amount	$ 1,875,147	$ 917,194
Profit-sharing amount constrained	(369,678)	—
Total collaboration revenue, net	$ 1,505,469	$ 917,194

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 $31.4 million, $77.3 million and $25.4 million during the years ended December 31, 2022, 2021 and 2020, respectively.

Amendment No. 1 to the 2020 GSK Agreement

On May 27, 2022, the Company and GSK entered into Amendment No. 1 to the 2020 GSK Agreement ("Amendment No. 1"). Pursuant to Amendment No. 1, the parties acknowledged that the antibody products that had been licensed to WuXi Biologics (Hong Kong) Limited ("WuXi Biologics") in mainland China, Hong Kong, Macau and Taiwan and had reverted to the Company pursuant to the Termination Agreement (described below) are now included in and governed by the 2020 GSK Agreement, subject to certain amendments relating to sotrovimab.

Under the terms of Amendment No. 1, GSK has the sole right to develop (including to seek, obtain or maintain regulatory approvals), manufacture and commercialize sotrovimab in and for mainland China, Hong Kong, Macau and Taiwan at GSK's sole cost

and expense (other than certain payments for which the Company remains responsible under certain of the Company's existing agreements with third parties). GSK paid the Company a one-time upfront payment of $7.0 million in consideration for the rights and licenses granted to GSK under Amendment No. 1. The Company recognized contract revenue of $7.0 million during the year ended December 31, 2022. In addition, GSK will be obligated to pay the Company tiered royalties on net sales of sotrovimab in mainland China, Hong Kong, Macau and Taiwan in percentages ranging from the high teens to the low thirties. Such royalties are payable to the Company during the term of the 2020 GSK Agreement applicable to the Antibody Program.

2021 Expanded GSK Collaboration

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

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

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

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

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

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

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

The Company considered the ASC 606 criteria for combining contracts and determined that the 2021 GSK Collaboration and 2021 Stock Purchase Agreement should be combined into a single contract because they were negotiated and entered into in contemplation of one another. The fair market value of the common stock issued to GGL was $85.2 million, based on the closing stock price of $52.70 on March 25, 2021, and taking into account a discount for the lack of marketability due to the restrictions in place on the underlying shares, resulting in a $34.8 million premium received by the Company. The Company accounted for the common stock issued to GGL based on its fair market value on the transaction date and determined that the premium paid by GSK should be attributed to the transaction price of the 2021 GSK Agreement.

The Company concluded that the 2021 GSK Agreement contained the following units of account: (i) the VIR-2482 Option; (ii) three distinct rights granted to GSK related to the Selected Pathogens (each, a “Selected Pathogen Right”); (iii) the license and know-how to the next-generation mAbs under the Influenza Program (the “Next Gen License”); (iv) the research and development activities for next-generation mAbs under the Influenza Program; and (v) the research and development activities, including license rights and know-how, under the Expanded Functional Genomics Program. The Company considered the guidance in ASC 606 to determine which of these elements of the 2021 GSK Agreement are performance obligations with a customer. The Company determined that the distinct performance obligations under ASC 606 consisted of (i) the Next Gen License and (ii) the three Selected Pathogen Rights, each representing a material right. All other elements of the 2021 GSK Agreement including the VIR-2482 Option, research and development activities, and participation in the JSC and subcommittees for each collaboration program were not determined to be distinct performance obligations with a customer. As of December 31, 2022, GSK had not exercised the VIR-2482 Option or the remaining two Selected Pathogen Rights (see below for GSK's selection of first pathogen).

The transaction price for the 2021 GSK Agreement included fixed consideration consisting of the $225.0 million upfront fee paid by GSK and $34.8 million, representing the premium on the sale of common stock to GSK for a total of $259.8 million. All potential future milestones and other payments under the 2021 GSK Agreement are constrained since the Company could not conclude it was probable that a significant reversal in the amount recognized would not occur.

The respective estimated SSP for each of the performance obligations was determined to allocate the transaction price. The estimated SSP of each performance obligation was determined using methods that considered relevant market conditions, entity-specific factors and information about GSK, while maximizing the use of available observable inputs and using certain management assumptions (e.g., treatable patient population, expected market share, probability of success and product profitability, discount rate based on weighted-average cost of capital). For the Next Gen License, the Company determined that GSK can benefit from the license at the time the license is granted and, therefore, the related performance obligation is satisfied at a point in time. If any of the Selected Pathogen Rights are exercised, the Company will evaluate the related promises to identify the performance obligations to be transferred and the timing of revenue recognition. If any of the Selected Pathogen Rights expire prior to being exercised, the Company will recognize any deferred revenue allocated to that right as revenue at the time of expiration.

The research and development activities for the next-generation mAbs under the Influenza Program and the Expanded Functional Genomics Program were determined to be within the scope of ASC 808 as the Company and GSK are both active participants in the development, manufacturing and commercialization activities and are exposed to significant risks and rewards that are dependent on the commercial success of the activities of the arrangement. Furthermore, the Company and GSK participate in the commercial profit and loss sharing arrangement for each program commensurate with each party’s cost-sharing responsibilities during research and development. Because ASC 808 does not provide recognition and measurement guidance, the Company determined that

the guidance in ASC 730, Research and Development, was appropriate to analogize to based on the nature of the cost-sharing provisions of the agreement. The Company has concluded that payments to or reimbursements from GSK related to these services will be accounted for as an increase to or reduction of research and development expenses, respectively. The Company also concluded that any payments from GSK related to the profit and loss sharing arrangement (including royalties) contingent upon the commercialization of the related products will be analogized to ASC 606 and, therefore, will be recognized when the related sales occur.

Upon execution of the 2021 GSK Agreement, the Company granted the Next Gen License to GSK and therefore, recognized $168.3 million as contract revenue in the second quarter of 2021. As of December 31, 2022, the total unrecognized transaction price of $51.7 million is classified as noncurrent deferred revenue on the Company's consolidated balance sheet related to the remaining performance obligations, being the remaining two material rights resulting from the Selected Pathogen Rights. The Company reclassified the deferred revenue of $51.7 million from current to noncurrent as of December 31, 2022 based on the Company's revised expectations for future option exercises by GSK.

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.

Option Exercise by GSK

In September 2022, GSK exercised its first Selected Pathogen Right, selecting respiratory syncytial virus (“RSV”) as its first pathogen under the Additional Programs of the 2021 GSK Agreement (“First Option Exercise”). GSK agreed to retroactively share the research and development costs that the Company had incurred under its RSV program since April 2022 in accordance with the applicable provisions of the 2021 GSK Agreement.

The Company evaluated the First Option Exercise under ASC 606 and identified one performance obligation consisting of the license for a Selected Pathogen Right granted to GSK. The transaction price was determined to be $39.8 million which equals the deferred revenue allocated to the first Selected Pathogen Right at the inception of the 2021 GSK Agreement. The Company determined that the license is considered a functional intellectual property that is a distinct performance obligation. Specifically, the Company believes the license is capable of being distinct, as GSK has the capabilities to develop the license either on its own or by contracting with other third-parties. GSK can benefit from the license at the time of grant and, therefore, the related performance obligation is satisfied at a point in time. During the year ended December 31, 2022, the Company recognized the $39.8 million as contract revenue.

During the year ended December 31, 2022 and 2021, the Company recognized additional net research and development expenses of $2.3 million and $0.5 million, respectively, under the 2021 GSK Agreement.

Under both the 2020 GSK Agreement and the 2021 GSK Agreement, the Company has a receivable from collaboration of zero and $773.1 million as of December 31, 2022 and 2021, respectively.

Brii Biosciences

In May 2018, the Company entered into the Brii Agreement with Brii Bio Parent and Brii Bio, pursuant to which the Company granted to Brii Bio, with respect to up to four of the Company's programs, an exclusive option to obtain exclusive rights to develop and commercialize compounds and products arising from such programs in China, Taiwan, Hong Kong and Macau (collectively, the "China Territory") for the treatment, palliation, diagnosis, prevention or cure of acute and chronic diseases of infectious pathogen origin or hosted by pathogen infection (the "Field of Use"). The Company's HBV small interfering ribonucleic acid ("siRNA") program being developed under the Amended Alnylam Agreement (described below) is included within the Brii Agreement as a program for which Brii Bio may exercise one of its options. In partial consideration for the options granted by the Company to Brii Bio, Brii Bio Parent and Brii Bio granted the Company, with respect to up to four of Brii Bio Parent's or Brii Bio's programs, an exclusive option to be granted exclusive rights to develop and commercialize compounds and products arising from such Brii Bio programs in the United States for the Field of Use. The number of options that the Company may exercise for a Brii Bio program is limited to the corresponding number of options that Brii Bio exercises for a Vir program.

As partial consideration for the Company's entry into the Brii Agreement, upon closing of Brii Bio Parent's Series A preferred stock financing, the Company received ordinary shares equal to 9.9% of the outstanding shares in Brii Bio Parent. As a result of Brii Bio's right to exercise one of its options for the Company's HBV siRNA program, under the terms of the Amended Alnylam Agreement, the Company transferred to Alnylam Pharmaceuticals, Inc. ("Alnylam") a specified percentage of such equity consideration allocable to such program under a share transfer agreement in February 2020.

With respect to programs for which Brii Bio exercises its options, Brii Bio is required to pay the Company an option exercise fee for each such Vir program ranging from the mid-single-digit millions up to $20.0 million, determined based on the commercial potential of the licensed program. Brii Bio will also be required to pay regulatory milestone payments on a licensed product-by-licensed product basis ranging from the mid-single-digit millions up to $30.0 million, also determined based on the commercial potential of such program. Following commercialization, Brii Bio will be required to make sales milestone payments based on certain specified levels of aggregate annual net sales of products arising from each licensed program in the China Territory, up to an aggregate of $175.0 million per licensed program.

Upon exercise of each option for a Brii Bio program, the Company will be required to pay to Brii Bio an option exercise fee ranging from the low tens of millions to up to $50.0 million, determined based on the commercial potential of the licensed program. The Company will be required to make regulatory milestone payments to Brii Bio on a licensed product-by-licensed product basis ranging from the low tens of millions up to $100.0 million, also determined based on the commercial potential of such program. The Company will also be required to make sales milestone payments based on certain specified levels of aggregate annual net sales of products in the United States arising from each licensed program, up to an aggregate of $175.0 million per licensed program. As of December 31, 2022, the Company has not exercised any of its options.

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

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

From May 2018 until the closing of the Brii Bio Parent IPO in July 2021, Brii Bio Parent and its wholly-owned subsidiary Brii Bio were determined to be variable interest entities ("VIE") due to their reliance on future financing and having insufficient equity at risk. However, the Company did not have the power to direct activities that most significantly impact the economic success of these

entities and was not considered the primary beneficiary of these entities. Therefore, the Company did not consolidate Brii Bio Parent or Brii Bio. Subsequent to the Brii Bio Parent IPO, the Company determined that these entities are no longer VIEs. In addition, as Brii Bio Parent is a publicly-traded company, the Company's investment in its ordinary shares became a marketable equity investment with readily determinable fair value and is then subsequently remeasured to fair value at each reporting date (see Note 3—Fair Value Measurements). Prior to the Brii Bio Parent IPO, the Company accounted for its investment in Brii Bio Parent, which had a carrying value of $5.7 million, at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment from the same issuer.

Option Exercises by Brii Bio

In June 2020, Brii Bio exercised its option to obtain exclusive rights to develop and commercialize compounds and products arising from VIR-2218 in the China Territory. In consideration of the Company’s grant to Brii Bio of an exclusive license related to VIR-2218 in the China Territory, the Company received a $20.0 million option exercise fee in connection with the option exercise. Also, the Company is eligible to receive the following payments related to VIR-2218 in the China Territory: a $30.0 million regulatory milestone payment, up to $175.0 million in sales-based milestone payments, and royalties on net sales ranging from high-teens to high-twenties.

The Company evaluated the VIR-2218 transaction under ASC 606 and identified one performance obligation consisting of the license granted to Brii Bio. Under the Brii Agreement, Brii Bio is responsible for performing all research and development activities and the Company does not have any other performance obligations within the context of ASC 606 under the arrangement after the option exercise. The transaction price is determined to be $22.7 million which consists of the $20.0 million option exercise fee and $2.7 million of the deferred revenue allocated to the VIR-2218 option at the inception of the Brii Agreement. The Company determined that the license is considered a functional intellectual property that is a distinct performance obligation under ASC 606. Specifically, the Company believes the license is capable of being distinct, as Brii Bio has the capabilities to develop the license either on its own or by contracting other third parties. Brii Bio can benefit from the license at the time of grant and therefore, the related performance obligation is satisfied at a point in time. Additionally, all potential future milestones and other payments are constrained because the Company cannot conclude it is probable that a significant reversal in the amount recognized would not occur. The Company will re-evaluate the transaction price in each reporting period.

In July 2022, Brii Bio exercised its option to obtain exclusive rights to develop and commercialize compounds and products arising from VIR-3434 in the China Territory. In consideration of the Company’s grant to Brii Bio of an exclusive license related to VIR-3434 in the China Territory, the Company received a $20.0 million option exercise fee in connection with the option exercise. Also, the Company is eligible to receive the following payments related to VIR-3434 in the China Territory: a $30.0 million regulatory milestone payment, up to $175.0 million in sales-based milestone payments, and royalties on net sales ranging from mid-teens to mid-twenties.

The Company evaluated the VIR-3434 transaction under ASC 606 and identified one performance obligation consisting of the license granted to Brii Bio. Under the Brii Agreement, Brii Bio is responsible for performing all research and development activities and the Company does not have any other performance obligations within the context of ASC 606 under the arrangement after the option exercise. The transaction price was determined to be $22.3 million, which consists of the $20.0 million option exercise fee and $2.3 million of the deferred revenue allocated to the VIR-3434 option at the inception of the Brii Agreement. The Company determined that the license is considered a functional intellectual property that is a distinct performance obligation. Specifically, the Company believes the license is capable of being distinct, as Brii Bio has the capabilities to develop the license either on its own or by contracting with other third parties. Brii Bio can benefit from the license at the time of grant and, therefore, the related performance obligation is satisfied at a point in time. Additionally, all potential future milestones and other payments are constrained because the Company cannot conclude it is probable that a significant reversal in the amount recognized would not occur. The Company will re-evaluate the transaction price in each reporting period.

During the years ended December 31, 2022, 2021 and 2020, the Company recognized $22.3 million, zero and $22.7 million, respectively, as license revenue from a related party. During the year ended December 31, 2020, the Company separately paid $10.0 million, half of the option exercise proceeds, to Alnylam in connection with the Amended Alnylam Agreement (as defined below) that was recognized as research and development expense.

As of December 31, 2022, the Company also has a contract liability of $1.5 million within noncurrent deferred revenues, which represents deferred consideration for the remaining two options that the Company granted to Brii Bio. The deferred consideration will be recognized when Brii Bio exercises its remaining options or the remaining options expire.

Alnylam

In October 2017, the Company entered into the collaboration and license agreement with Alnylam, as amended in December 2019 and March, April and December 2020 (the "Amended Alnylam Agreement") for the development of siRNA products for the treatment of HBV, and following the exercise of certain program options, the development and commercialization of siRNA therapeutic products directed to up to four other infectious disease targets selected by the Company. The technology licensed under the Amended Alnylam Agreement forms the basis of the Company's siRNA technology platform.

Under the Amended Alnylam Agreement, the Company obtained a worldwide, exclusive license to develop, manufacture and commercialize the HBV siRNA product candidates, including VIR-2218, for all uses and purposes other than agricultural, horticultural, forestry, aquaculture and other residential applications (such excluded fields, the "Excluded Fields"). In addition, Alnylam granted the Company an exclusive option, for each of the infectious disease siRNA programs directed to the Company's selected targets, to obtain a worldwide, exclusive license to develop, manufacture and commercialize siRNA products directed to the target of each such program for all uses and purposes other than the Excluded Fields. On a product-by-product basis for each product arising from the HBV program and, following the Company's option exercise, the infectious disease program, Alnylam has an exclusive option, exercisable during a specified period prior to the initiation of a Phase 3 clinical trial for each such product, to negotiate and enter into a profit-sharing agreement for such product.

The Company and Alnylam were jointly responsible for funding the initial research and development activities for VIR-2218 through the completion of proof-of-concept trials. Prior to the exercise of the Company's option for each siRNA program directed to one of the Company's selected infectious disease targets, Alnylam is responsible for conducting all development activities, at the Company's expense, in accordance with an agreed-upon development plan. Following the Company's exercise of an option for a program and payment of the program option exercise fee and any outstanding program costs due to Alnylam, the Company is solely responsible, at the Company's expense (subject to Alnylam's exercise of a profit-sharing option), for conducting all development, manufacture and commercialization activities for products arising from each such program. If Alnylam exercises a profit-sharing option for a product, the Company will negotiate the terms of such profit-sharing agreement, which will include sharing equally with Alnylam all subsequent costs associated with the development of such product, as well as the profits and losses in connection with such product, subject to reimbursement by Alnylam of a portion of specified development costs in certain circumstances.

Upon the achievement of a certain development milestone, as further discussed below, the Company was obligated to issue shares of the Company's common stock equal to the lesser of (i) 1,111,111 shares or (ii) a certain number of shares based on the Company's stock price at the time such milestone is achieved (the "Milestone Shares"). The Company will be required to pay Alnylam up to $190.0 million in the aggregate for the achievement of specified development and regulatory milestones by the first siRNA product directed to HBV, and up to $115.0 million for the achievement of specified development and regulatory milestones by the first product directed to the target of each infectious disease siRNA program for which the Company exercised its option. Following commercialization, the Company will be required to pay to Alnylam up to $250.0 million in the aggregate for the achievement of specified levels of net sales by siRNA products directed to HBV and up to $100.0 million for the achievement of specified levels of net sales by products directed to the target of each infectious disease siRNA program for which the Company exercised its option. The Company may also be required to pay Alnylam tiered royalties at percentages ranging from the low double-digits to mid-teens on annual net sales of HBV products, and tiered royalties at percentages ranging from the high single-digits to the sub-teen double-digits on annual net sales of licensed infectious disease products, in each case subject to specified reductions and offsets. The royalties are payable on a product-by-product and country-by-country basis until the later of the expiration of all valid claims of specified patents covering such product in such country and 10 years after the first commercial sale of such product in such country.

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

The term of the Amended Alnylam Agreement will continue, on a product-by-product and country-by-country basis, until the expiration of all royalty payment obligations under the Amended Alnylam Agreement. If the Company does not exercise its option for an infectious disease program directed to one of its selected targets, the Amended Alnylam Agreement will expire upon the expiration of the applicable option period with respect to such program. However, if Alnylam exercises its profit-sharing option for any product, the term of the Amended Alnylam Agreement will continue until the expiration of the profit-sharing arrangement for such product. The Company may terminate the Amended 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 Amended Alnylam Agreement on 30 days' notice.

The Company incurred expenses under the Amended Alnylam Agreement of $1.4 million and $11.2 million during the years ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2020, in addition to the Milestone Shares, $15.0 million milestone payment to Alnylam, and the $10.0 million payment resulting from Brii Bio's option exercise in the first half of 2020, the Company incurred expenses of $11.5 million under the Amended Alnylam Agreement.

WuXi Biologics

In February 2020, the Company entered into a development and manufacturing collaboration agreement with WuXi Biologics (the "WuXi Biologics Collaboration Agreement") for the clinical development, manufacturing, and commercialization of the Company's proprietary antibodies developed for SARS-CoV-2. Under the WuXi Biologics Collaboration Agreement, WuXi Biologics conducted cell-line development, process and formulation development, and initial manufacturing for clinical development and had the right to commercialize products incorporating such SARS-CoV-2 antibodies in mainland China, Hong Kong, Macau and Taiwan under an exclusive license granted for the selected SARS-CoV-2 antibodies that were developed.

Termination of the WuXi Biologics Collaboration Agreement

On May 16, 2022, the Company and WuXi Biologics entered into a Termination Agreement (the "Termination Agreement") pursuant to which the Company and WuXi Biologics terminated the WuXi Biologics Collaboration Agreement. Other existing agreements between the Company and WuXi Biologics remain in effect.

Under the terms of the Termination Agreement, all licenses granted under the WuXi Biologics Collaboration Agreement were terminated and all rights to the SARS-CoV-2 antibody products in mainland China, Hong Kong, Macau and Taiwan reverted to the Company. The Company made a one-time termination payment to WuXi Biologics of $7.0 million and accounted for the payment as an acquisition of an IPR&D asset and, therefore, recognized research and development expense of $7.0 million during the second quarter of 2022. Under the terms of the Termination Agreement, the Company will be obligated to pay WuXi Biologics tiered royalties on net sales of sotrovimab in mainland China, Hong Kong, Macau and Taiwan ranging from low single digits to low double digits. Royalties are payable to WuXi Biologics for a specified royalty term and are subject to reduction in certain circumstances.

Rockefeller University

In July 2018, the Company entered into an exclusive license agreement with The Rockefeller University ("Rockefeller"), which was amended in May 2019, in September 2020, and in March 2021 (as amended, the "Rockefeller Agreement"). Under the Rockefeller Agreement, Rockefeller granted the Company a worldwide exclusive license under certain patent rights, and a worldwide non-exclusive license under certain materials and know-how covering certain antibody variants relating to a specified mutation leading to enhanced antibody function and utility, to develop, manufacture and commercialize infectious disease products covered by the licensed patents, or that involve the use or incorporation of the licensed materials and know-how, in each case for all uses and purposes for infectious diseases. The Company uses technology licensed under the Rockefeller Agreement in the Company's antibody platform and in the Company's product candidate VIR-3434.

The Company is required to pay annual license maintenance fees of $1.0 million, which can be creditable against royalties following commercialization. In addition, upon achievement of specified development, regulatory and commercial success milestone events, the Company is required to pay up to $80.3 million, in the aggregate, for up to six infectious disease products. Any follow-on products beyond six products may result in additional milestone event payments. The Company will also be required to pay to Rockefeller a royalty at a low single-digit percentage rate on net sales of licensed products, subject to certain adjustments. The Company's obligation to pay royalties to Rockefeller will terminate, on a product-by-product and jurisdiction-by-jurisdiction basis,

upon the latest of the expiration of the last valid claim of a licensed patent in such jurisdiction, the expiration of all regulatory exclusivity in such jurisdiction or 12 years following the first commercial sale of the applicable licensed product in such jurisdiction.

Under the Rockefeller Agreement, the Company recognized a total of $1.3 million, $4.7 million, and $1.3 million during the years ended December 31, 2022, 2021 and 2020, respectively, as research and development expenses related to certain development milestone payments, annual license maintenance fees, and estimated sublicense fees.

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

MedImmune

In September 2018, the Company entered into a license agreement, which was amended in September 2020 (as amended, the "MedImmune Agreement"), with MedImmune, LLC ("MedImmune"), under which the Company obtained a worldwide, exclusive license to develop and commercialize half-life extended versions of two specified antibodies under development by MedImmune that target influenza A and influenza B, respectively, for all uses in humans and animals. The Company is developing VIR-2482 using technology licensed under the MedImmune Agreement.

The Company is obligated to make development, regulatory, and commercial milestone payments of up to $331.5 million in the aggregate relating to influenza A and influenza B products. MedImmune is also entitled to receive tiered royalties based on net sales of products containing half-life extended versions of antibodies directed to influenza A and/or influenza B at percentages ranging from the mid-single-digits to sub-teen double-digits.

The MedImmune Agreement will remain in force until the expiration on a country-by-country and product-by-product basis of all of the Company's obligations to pay royalties to MedImmune. The Company may terminate the MedImmune Agreement in its entirety or on a product-by-product basis, for convenience, upon 120 days' notice. Either party may terminate the MedImmune Agreement for cause for the other party's uncured material breach on 60 days' notice or immediately in the event of bankruptcy of the other party. Additionally, MedImmune may terminate the MedImmune Agreement for cause on 30 days' written notice if the Company challenges the validity or enforceability of the patents to which the Company has obtained a license under the MedImmune Agreement.

Xencor

August 2019 License Agreement

In August 2019, the Company entered into a patent license agreement, which was amended in February 2021 (as amended, the "2019 Xencor Agreement") with Xencor, Inc. ("Xencor"). Under the 2019 Xencor Agreement, the Company obtained a non-exclusive, sublicensable (only to its affiliates and subcontractors) license to incorporate Xencor's licensed technologies into, and to evaluate, antibodies that target influenza A and HBV, and a worldwide, non-exclusive, sublicensable license to develop and commercialize products containing such antibodies incorporating such technologies for all uses, including the treatment, palliation, diagnosis and prevention of human or animal diseases, disorders or conditions. The Company is obligated to use commercially reasonable efforts to develop and commercialize an antibody product that incorporates Xencor's licensed technologies, for each of the influenza A and HBV research programs. These technologies are used in the Company's product candidates VIR-2482, incorporating Xencor's Xtend technology, and VIR-3434, incorporating Xencor's Xtend and other Fc technologies.

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

Under the 2019 Xencor Agreement, the Company recognized an immaterial amount during each of the years ended December 31, 2022, 2021 and 2020, as research and development expenses related to certain development milestone payments.

March 2020 License Agreement

In March 2020, the Company entered into a patent license agreement, which was amended in February 2021 (as amended, the "2020 Xencor Agreement"), with Xencor under which the Company obtained a non-exclusive, sublicensable (only to its affiliates and subcontractors) license to incorporate Xencor's licensed technologies into, and to evaluate, antibodies that target any component of a coronavirus, including SARS-CoV-2, SARS-CoV and MERS-CoV, and a worldwide, non-exclusive, sublicensable license to develop and commercialize products containing such antibodies incorporating such technologies for all uses, including the treatment, palliation, diagnosis and prevention of human or animal diseases, disorders or conditions. The Company is obligated to use commercially reasonable efforts to develop and commercialize an antibody product that incorporates Xencor's licensed technologies, for each of the coronavirus research programs. These technologies are used in sotrovimab, incorporating Xencor's Xtend technology.

In consideration for the grant of the license, the Company is obligated to pay royalties based on net sales of licensed products at the mid-single-digits. The royalties are payable, on a product-by-product and country-by-country basis, until the later of the expiration of the last to expire valid claim in the licensed patents covering such product in such country or 12 years. During the years ended December 31, 2022 and 2021, the Company recognized $114.5 million and $52.7 million, respectively, as cost of revenue for royalties due to Xencor from the sale of sotrovimab.

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

8. Balance Sheet Components

Property and Equipment, net

Property and equipment, net consists of the following:

	December 31,	
	2022	2021
	(in thousands)	
Laboratory equipment	$ 36,533	$ 20,012
Computer equipment	2,545	1,112
Furniture and fixtures	2,852	1,443
Leasehold improvements	84,422	7,834
Construction in progress	—	26,925
Property and equipment, gross	126,352	57,326
Less accumulated depreciation and amortization	(20,743)	(14,492)
Total property and equipment, net	$ 105,609	$ 42,834

Depreciation and amortization expenses were $6.3 million, $5.3 million and $4.4 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Accrued and Other Liabilities

Accrued and other liabilities consist of the following:

	December 31,	
	2022	2021
	(in thousands)	
Milestone payable	$ —	$ 95,000
Net profit-sharing constrained	357,762	$ —
Accrued royalties	10,447	58,672
Research and development expenses	48,880	28,073
Payroll and related expenses	28,286	29,753
Accrued income taxes	15,228	6,217
Excess funds payable under grant agreements	7,652	1,825
Operating lease liabilities, current	4,137	3,927
Other professional and consulting expenses	3,987	2,791
Other accrued expenses	12,711	10,254
Total accrued and other liabilities	$ 489,090	$ 236,512

9. Commitments and Contingencies

Lease Agreements

The Company has various operating lease arrangements for office and laboratory spaces located in California, Oregon, Missouri, and Switzerland with contractual lease periods expiring at various dates through 2033. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain lease agreements also provide the Company with the option to renew for additional periods ranging from one to five years. These renewal options are not considered in the remaining lease term unless it is reasonably certain that the Company will exercise such options.

In October 2021, the Company entered into a new sublease agreement for office and laboratory spaces in Missouri that will expire in December 2028, with no option to renew. Under this sublease arrangement, the Company is entitled to tenant improvement allowance of up to $14.7 million related to the design and construction of certain Company improvements.

In December 2021, the Company entered into a lease agreement with the new owner of the building at 1800 Owens Street in San Francisco for the lease of approximately 133,896 rentable square feet of office and laboratory space of such building. The Company previously occupied the same premises under a sublease agreement with a sublessor, which sublease was terminated concurrently with the execution of the new lease agreement. Accordingly, the related ROU asset and lease liability under the sublease arrangement were extinguished and the Company recognized a gain of $4.8 million in the consolidated statement of operations for the year ended December 31, 2021. The new lease will expire in December 2033, with no option to renew. Under this lease arrangement, the Company is entitled to tenant improvement allowance of up to $37.5 million related to the design and construction of certain Company improvements.

Under two of the operating lease arrangements in California and Missouri discussed above, the Company expected to fully utilize the tenant improvement allowance and, therefore, such amount was treated as a lease incentive that is payable to the Company at the lease commencement date.

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 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):

	Year Ended December 31,		
	2022	2021	2020
Operating lease cost	$ 15,910	$ 11,921	$ 4,591
Short-term lease cost	239	261	459
Variable lease cost	9,937	4,256	2,299
Total lease cost	$ 26,086	$ 16,438	$ 7,349
Other Information			
Weighted average remaining lease term (in years)	10.0	10.4	10.6
Weighted average incremental borrowing rate	5.2%	5.2%	7.7%
Cash paid for amounts included in the measurement of operating lease liabilities	$ 12,716	$ 6,250	$ 5,081
ROU assets obtained in exchange for new operating lease liabilities	$ 4,046	$ 77,187	$ 48,495

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 maturity of the Company's operating lease liabilities as of December 31, 2022 was as follows (in thousands):

	Amounts
2023	$ 19,450
2024	18,610
2025	16,303
2026	16,747
2027	16,927
Thereafter	86,994
Total lease payments	175,031
Less: imputed interest	(38,379)
Less: net tenant improvement allowance yet to be received	(26,294)
Present value of operating lease liabilities	$ 110,358

The following amounts were recorded in the consolidated balance sheets as of December 31, 2022 and 2021 (in thousands):

	December 31,	
	2022	2021
Operating Leases		
Prepaid expenses and other current assets [(1)]	$ 17,616	$ 49,536
Operating ROU assets	82,557	87,220
Accrued and other liabilities	$ 4,137	$ 3,927
Operating lease liabilities, noncurrent	123,837	133,561
Total operating lease liabilities	$ 127,974	$ 137,488

(1) For certain operating leases, lease incentives expected to be received exceeds the minimum lease payments expected to be paid over the next 12 months, therefore the net amount is recorded in prepaid expenses and other current assets.

Manufacturing and Supply Letter Agreements

In April 2020, the Company and Samsung Biologics Co., Ltd. (“Samsung”) entered into a binding letter agreement (the “Samsung Letter Agreement”), under which Samsung performs development and manufacturing services for the Company’s SARS-CoV-2 antibody program. In August 2020, the Company, GlaxoSmithKline Trading Services Limited (“GSKTSL”) and Samsung entered into an Assignment and Novation Agreement effective as of July 31, 2020, under which the Company assigned and transferred to GSKTSL all of the Company’s right, title, and interest in, to and under the Samsung Letter Agreement, and GSKTSL became the Company’s successor in interest in and to all of the Company’s rights, duties, and obligations in, to and under the Samsung Letter Agreement.

In August 2020, GSKTSL entered into a Master Services Agreement with Samsung (the “Samsung MSA”) in connection with the performance of the obligations of the Company and GSK under the 2020 GSK Agreement. In accordance with the terms of the 2020 GSK Agreement, the Company continues to be responsible for 72.5% of the costs under the Samsung MSA, and GSK bears 27.5% of such costs under the Samsung MSA, subject to certain conditions and exceptions. The Company’s commitment has been substantially recognized on its consolidated balance sheet as part of the profit-sharing amount constrained as of December 31, 2022, which is part of accrued and other liabilities, as discussed in Note 7—Collaboration and License Agreements.

Indemnification

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

10. Related Party Transactions

As a result of the Brii Agreement, the Company holds a minority equity interest in Brii Bio through its parent company, Brii Bio Parent. At the time when the Company entered into the Brii Agreement, the Company's Chief Executive Officer (the “CEO”), and another member of the Company's board of directors served on Brii Bio Parent’s board of directors. The Company's CEO, who is also a member of the Company's board of directors, resigned from Brii Bio Parent’s board of directors in June 2021. As of December 31, 2022, one member of the Company’s board of directors serves on Brii Bio Parent’s board of directors.

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 shall not be less than 100% of the estimated fair value on the date of grant. Options granted typically vest over a four-year period but may be granted with different vesting terms. As of December 31, 2022, there are 12,911,263 shares available for the Company to grant under the 2019 Plan.

2016 Equity Incentive Plan

In September 2016, the Company adopted the 2016 Equity Incentive Plan (the “2016 Plan”) for the issuance of ISO, NSO, SARs, restricted stock and other stock awards, to employees, non-employee directors, and consultants under terms and provisions established by the Company’s board of directors and approved by the stockholders.

Awards granted under the 2016 Plan expire no later than 10 years from the date of grant. For ISO and NSO, the option price shall not be less than 100% of the estimated fair value on the date of grant. Options granted typically vest over a four-year period but may be granted with different vesting terms.

In conjunction with adopting the 2019 Plan, the Company discontinued the 2016 Plan with respect to the new equity awards.

2019 Employee Stock Purchase Plan

In September 2019, the Company's board of directors adopted, with the approval of its stockholders, the 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, 2022, 118,288 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 (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	10,308,928	$ 31.75	8.2	
Granted	2,051,535	$ 28.07		
Exercised	(696,963)	$ 6.51		
Forfeited	(1,059,133)	$ 41.67		
Outstanding at December 31, 2022	10,604,367	$ 31.70	7.6	$ 52,307
Vested and expected to vest at December 31, 2022	10,604,367	$ 31.70	7.6	$ 52,307
Vested and exercisable at December 31, 2022	6,069,564	$ 27.06	7.0	$ 48,178

The aggregate intrinsic value of options exercised during the years ended December 31, 2022, 2021 and 2020 was $12.1 million $65.1 million and $53.1 million, respectively.

During the years ended December 31, 2022, 2021, and 2020, the estimated weighted-average grant date fair value of the options granted was $22.69, $47.62, and $25.49 per share, respectively.

As of December 31, 2022, the Company expects to recognize the remaining unamortized stock-based compensation expense of $127.4 million related to stock options, over an estimated weighted average period of 2.2 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:

	Year Ended December 31,		
	2022	2021	2020
Expected term of options (in years)	5.3 – 6.1	5.3 – 6.1	5.0 – 6.1
Expected stock price volatility	101.4% – 111.2%	103.1% – 112.1%	88.8% – 108.6%
Risk-free interest rate	1.6% – 4.3%	0.6% – 1.3%	0.3% – 1.2%
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—Since inception the expected volatility was determined by examining the historical volatilities for industry peers and using an average of historical volatilities of the Company's industry peers. Beginning the first quarter of 2022, 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 based the risk-free interest rate over the expected term of the stock options based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of the grant.

Expected Dividend Rate—The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its profit interest units in the foreseeable future.

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:

	Year Ended December 31,	
	2022	2021
Expected term of ESPP (in years)	0.5	0.5
Expected stock price volatility	59.0% – 86.0%	76.1% – 144.1%
Risk-free interest rate	0.1% – 4.5%	0.04% – 0.1%
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, 2022 and 2021 was $9.09 and $19.85 per share, respectively.

Restricted Stock Activity

The Company's RSAs and RSUs were summarized as follows:

	Shares	Weighted Average Grant Date Fair Value Per Share
	RSU	RSU
Unvested as of December 31, 2021	1,271,334	$ 59.93
Granted	2,097,128	$ 27.87
Vested	(349,496)	$ 58.26
Forfeited	(349,788)	$ 40.86
Unvested as of December 31, 2022	2,669,178	$ 37.46

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

As of December 31, 2022, there was $77.0 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 2.8 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:

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Research and development	$ 53,153	$ 42,554	$ 13,663
Selling, general and administrative	$ 48,929	$ 41,230	13,937
Total stock-based compensation	$ 102,082	$ 83,784	$ 27,600

12. Net Income (Loss) Per Share

Basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net income (loss) per common share is computed by dividing the net income (loss) by the sum of the weighted-average number of common shares outstanding during the period plus any potential dilutive effects of common stock equivalents outstanding during the period calculated in accordance with the treasury stock method. For periods that the Company was in a net loss position, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential common securities outstanding would have been anti-dilutive. The following is a calculation of the basic and diluted net income per share (in thousands, except share and per share data):

	Year ended December 31,		
	2022	2021	2020
Net income (loss), basic and diluted	$ 515,837	$ 528,584	$ (298,665)
Weighted-average shares outstanding, basic	132,606,767	129,884,967	119,159,424
Weighted-average effect of dilutive securities:			
Options to purchase common stock	2,130,212	3,513,438	—
Restricted shares subject to future vesting	73,851	35,488	—
Shares to purchase under Employee Stock Purchase Plan	78	—	—
Contingently issuable shares	—	3,233	—
Weighted-average shares outstanding, diluted	134,810,908	133,437,126	119,159,424
Net income (loss) per share, basic	$ 3.89	$ 4.07	$ (2.51)
Net income (loss) per share, diluted	$ 3.83	$ 3.96	$ (2.51)

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

	As of December 31,		
	2022	2021	2020
Options issued and outstanding	8,853,734	5,764,308	9,798,282
Restricted shares subject to future vesting	2,646,748	1,088,304	89,261
Warrants to purchase common stock	—	—	—
Total	11,500,482	6,852,612	9,887,543

13. Defined Contribution Plan

The Company sponsors a 401(k) retirement savings plan for the benefit of its employees. Eligible employees may contribute a percentage of their compensation to this plan, subject to statutory limitations. The Company made contributions to the plan for eligible participants, and recorded contribution expenses of $4.0 million, $2.7 million, and $1.8 million for the years ended December 31, 2022, 2021 and 2020, respectively.

14. Income Taxes

Income (loss) before provision for income taxes consists of the following (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Domestic	$ 692,445	$ 535,989	$ (309,697)
Foreign	61,835	13,813	11,086
Total income (loss) before provision for income taxes	$ 754,280	$ 549,802	$ (298,611)

The components of income tax expense consist of the following (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Current:			
Federal	$ 238,550	$ 3,526	$ —
State	2,432	105	—
Foreign	12,647	2,401	106
	253,629	6,032	106
Deferred:			
Federal	(15,186)	15,186	(21)
State	—	—	(31)
	(15,186)	15,186	(52)
Provision for income taxes	$ 238,443	$ 21,218	$ 54

A reconciliation between the expected income tax provision at the federal statutory rate and the reported income tax expense is as follows:

	Year Ended December 31,		
	2022	2021	2020
U.S. federal statutory income tax rate	21.0%	21.0%	21.0%
Foreign tax at less than federal statutory rate	(0.3)	(0.2)	0.9
Prior year tax rate adjustment	—	—	(1.9)
State taxes, net of federal benefit	0.1	0.7	2.7
Research and development tax credit	(2.0)	(1.6)	1.8
Permanent items	(7.4)	1.8	1.3
Changes in valuation allowance	21.1	(17.9)	(25.3)
Other	(0.9)	0.1	(0.5)
Effective income tax rate	31.6%	3.9%	0.0%

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, 2022 and 2021, are related to the following:

	December 31,	
	2022	2021
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 14,793	$ 15,030
Research and development tax credit carryforward	12,123	11,375
Equity compensations	24,250	15,065
Reserves and accruals	85,977	7,115
Capitalized research and development	75,680	—
Lease liabilities	18,553	28,612
Intangible assets	18,348	19,657
Deferred tax assets	249,724	96,854
Deferred tax liabilities:		
Unrealized gain on investments	(5,880)	(30,170)
ROU assets	(20,834)	(28,483)
Property and equipment	(13,151)	(2,422)
IPR&D	(8,511)	(8,511)
Deferred tax liabilities	(48,376)	(69,586)
Valuation allowance	(204,601)	(45,707)
Net deferred tax liabilities	$ (3,253)	$ (18,439)

Although the Company has taxable income for the year 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 net deferred tax assets will be fully realizable. Accordingly, the Company has provided a valuation allowance against its net deferred tax assets. For the year ended December 31, 2022, the Company recorded a valuation allowance increase of $158.9 million, primarily based on the estimated 2022 taxable income. The valuation allowance is decreased by $114.2 million for the year ended December 31, 2021 and increased by $74.1 million for the year ended December 31, 2020. As of December 31, 2022, the Company has net operating loss carryforwards of $20.9 million for federal purposes and $111.4 million for state tax purposes. If not utilized, these carryforwards will begin to expire in 2037 for federal and in 2031 for state tax purposes. As of December 31, 2022, the Company also has net operating loss carryforwards of $10.6 million for Australian tax purposes, which have an indefinite carryforward period, and no net operating loss carryforward for Swiss tax purposes.

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, 2022 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, 2022, the Company has research tax credit carryforwards of $0.4 million and $15.9 million for federal and state tax purposes, respectively. If not utilized, the federal carryforward will expire in various amounts beginning in 2036. The California credits can be carried forward indefinitely.

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

Uncertain Tax Positions

As of December 31, 2022 and 2021, the Company had an unrecognized tax benefit balance of $10.6 million and $7.4 million, respectively, related to transfer pricing and research and development tax credits. A portion of the unrecognized tax benefits as of December 31, 2022, if recognized, would reduce the Company's effective tax rate by 0.7%. Other unrecognized tax benefits as of

December 31, 2022, 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 reduce the Company's effective tax rate. There are no provisions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date. Because the statute of limitations does not expire until after the net operating loss and credit carryforwards are actually used, the statutes are still open on calendar years ending December 31, 2017 forward for federal and state purposes.

The Company did not recognize any expense for interest and penalties related to uncertain tax positions during 2022, 2021 and 2020, and the Company does not have any amounts related to interest and penalties accrued at December 31, 2022. 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, 2022, 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:

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Gross unrecognized tax benefits at January 1	$ 7,422	$ 4,877	$ 2,725
Addition for tax positions taken in the prior years	—	—	—
Reduction for tax positions taken in the prior years	(12)	(62)	(588)
Addition for tax positions taken in current year	3,228	2,607	2,740
Gross unrecognized tax benefits at December 31	$ 10,638	$ 7,422	$ 4,877

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, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Exchange Act as of the end of the period covered by this Annual Report on Form 10-K. 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 is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. 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.

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, we concluded that our internal control over financial reporting was effective as of December 31, 2022.

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, 2022.

Changes in Internal Control Over Financial Reporting

Remediation of Previously Reported Material Weakness

A material weakness, as defined in Rule 12b-2 under the Exchange Act, is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with our preparation of our financial statements as of and for the quarter ended June 30, 2022, we identified a material weakness in our internal control over financial reporting. With respect to the determination of the estimated profit-sharing amount to be constrained under the definitive collaboration agreement dated June 9, 2020, or the 2020 GSK Agreement, between the Company and Glaxo Wellcome UK Limited and GlaxoSmithKline Biologicals S.A. (individually and collectively referred to as GSK), our management review control procedures were not designed in a manner that would ensure relevant information and key judgments are obtained and analyzed at the appropriate level of precision, on a timely basis, between non-financial personnel and those

responsible for financial reporting as of June 30, 2022. Management concluded that the control deficiency represented a material weakness as of June 30, 2022.

Following the identification of the material weakness in our internal controls over financial reporting as of June 30, 2022, we prepared a remediation action plan and implemented that plan to improve the controls related to the determination of the estimated profit-sharing amount to be constrained under the 2020 GSK Agreement, which included the following actions:

- We enhanced communication procedures and the timeliness of those procedures between non-financial personnel and those responsible for financial reporting related to relevant business information.
- We designed specific procedures, at the appropriate level of precision, to review and ensure the completeness of the Company's analysis, including the analysis of material assumptions, resulting in comprehensive documentation supporting management's judgments and ensuring the completeness and the accuracy of the underlying information.

During the fourth quarter of 2022, we successfully completed the testing necessary to conclude that the material weakness has been remediated. The material weakness had no impact on any amounts reported in the financial statements for the fiscal year ended December 31, 2022 or for any previous period.

There have been no changes in our internal control over financial reporting that occurred during our fourth fiscal quarter ended December 31, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Shareholders 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, 2022, 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, 2022, 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, 2022 and 2021, the related consolidated statements of operations, consolidated statements of comprehensive income (loss), consolidated statements of stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes and our report dated February 28, 2023 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 28, 2023

Item 9B. Other Information.

None.

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 2023 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” (except for the section titled “Executive Compensation—Pay Versus Performance”) 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” 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 Selection 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

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-39083), filed with the SEC on October 16, 2019).
3.2	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-39083), filed with the SEC on October 16, 2019).
4.1	Form of Common Stock Certificate of the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 30, 2019).
4.2	Amended and Restated Investors' Rights Agreement, by and among the Company and certain of its stockholders, dated November 29, 2017 (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
4.3	Description of Capital Stock (incorporated herein by reference to Exhibit 4.4 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on March 26, 2020).
10.1+	Vir Biotechnology, Inc. 2019 Equity Incentive Plan, (incorporated herein by reference to Exhibit 4.8 to the Company's Form S-8 (File No. 333-234212), filed with the SEC on October 15, 2019).
10.2+	2019 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 4.11 to the Company's Form S-8 (File No. 33-234212), filed with the SEC on October 15, 2019).
10.3+	Form of Indemnity Agreement by and between the Company and its directors and executive officers (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.4+	Forms of Option Grant Notice and Option Agreement under Vir Biotechnology, Inc. 2019 Equity Incentive Plan, (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.5+	Form of Restricted Stock Unit Grant Notice and Unit Award Agreement under Vir Biotechnology, Inc. 2019 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.5 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on February 25, 2021).
10.6+	Vir Biotechnology, Inc. 2016 Equity Incentive Plan, as amended (incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).

10.7+	Forms of Incentive Stock Option Notice and Agreement, Non-Qualified Stock Option Notice and Agreement, Restricted Stock Agreement, Restricted Stock Agreement and Restricted Stock Purchase Agreement under the Vir Biotechnology, Inc. 2016 Equity Incentive Plan, as amended (incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.8+	Non-Employee Director Compensation Policy.
10.9+	Amended and Restated Employment Letter Agreement between the Company and George Scangos, dated August 27, 2019 (incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.10+	Amended and Restated Employment Letter Agreement between the Company and Howard Horn, dated August 27, 2019 (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.11+	Amended and Restated Employment Letter Agreement between the Company and Phil Pang, dated August 27, 2019 (incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.12+	Amended and Restated Employment Letter Agreement between the Company and Herbert Virgin, dated September 3, 2019 (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.13+	Employment Letter Agreement between the Company and Steven Rice, dated August 22, 2019 (incorporated herein by reference to Exhibit 10.3 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on November 10, 2020).
10.14+	Promotion Letter Agreement between the Company and Steven Rice, dated July 30, 2020 (incorporated herein by reference to Exhibit 10.4 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on November 10, 2020).
10.15+	Amended and Restated Employment Letter Agreement between the Company and Ann (Aine) M. Hanly, dated May 4, 2021 (incorporated herein by reference to Exhibit 10.6 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on May 6, 2021).
10.16+	Employment Agreement between Humabs BioMed SA (f/k/a Humabs Holding GmbH) and Johanna Friedl-Naderer, dated December 16, 2021 (incorporated herein by reference to Exhibit 10.1 to the Company's Form 10-Q (File No. 001-39803), filed with the SEC on May 5, 2022).
10.17+	Agreement on Transfer of Employment and Amendment of Employment Agreement between Humabs BioMed SA, Vir Biotechnology International GmbH and Johanna Friedl-Naderer, dated December 19, 2022.
10.18+	Vir Biotechnology, Inc. Change in Control and Severance Benefit Plan (incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.19†	Collaboration, Option, and License Agreement between the Company and Brii Biosciences Limited (previously named BiiG Therapeutics Limited), dated May 23, 2018 (incorporated herein by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.20†	Collaboration and License Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated October 16, 2017 (incorporated herein by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.21†	Amendment No.1 to the Collaboration and License Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated December 17, 2019 (incorporated herein by reference to Exhibit 10.19 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on March 26, 2020).
10.22†	Amendment No.2 to the Collaboration and License Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated March 3, 2020 (incorporated herein by reference to Exhibit 10.20 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on March 26, 2020).

10.23†	Amendment No.3 to the Collaboration and License Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated April 1, 2020 (incorporated herein by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 (File No. 333-239689), filed with the SEC on July 6, 2020).
10.24†	Letter Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated December 23, 2020 (incorporated herein by reference to Exhibit 10.24 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on February 25, 2021).
10.25†	Common Stock Issuance Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated October 16, 2017 (incorporated herein by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.26†	Amendment No. 1 to the Common Stock Issuance Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated December 17, 2019 (incorporated herein by reference to Exhibit 10.22 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on March, 26, 2020).
10.27†	Letter Agreement between the Company and Alnylam Pharmaceuticals, Inc., dated November 13, 2018 (incorporated herein by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.28†	License Agreement between the Company and MedImmune, LLC, dated September 7, 2018 (incorporated herein by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.29†	Amendment No. 1 to License Agreement between the Company and MedImmune, LLC, dated September 1, 2020 (incorporated herein by reference to Exhibit 10.29 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on February 25, 2021).
10.30†	Second Revised and Restated Master License Agreement between the Company and Oregon Health & Science University, dated August 27, 2019 (incorporated herein by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.31†	Letter Agreement between the Company and the stockholders of TomegaVax, Inc. set forth therein, dated September 12, 2016 (incorporated herein by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.32†	Agreement and Plan of Merger between the Company, Vir Merger Sub, Inc., Agenovir Corporation, and Dr. Stephen R. Quake, dated January 2, 2018 (incorporated herein by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.33†	Securities Purchase Agreement between the Company, Humabs BioMed SA, the shareholders of Humabs set forth therein, the option-holders of Humabs set forth therein and Fortis Advisors LLC and certain Securityholders, dated August 22, 2017 (incorporated herein by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.34†	Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated January 26, 2018 (incorporated herein by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.35†	Amendment No. 1 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated April 18, 2019 (incorporated herein by reference to Exhibit 10.31 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on March 26, 2020).
10.36†	Amendment No. 2 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated February 24, 2020 (incorporated herein by reference to Exhibit 10.32 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on March 26, 2020).
10.37†	Amendment No. 3 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated May 22, 2020 (incorporated herein by reference to Exhibit 10.38 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on February 25, 2021).

10.38†	Amendment No. 4 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated December 8, 2020 (incorporated herein by reference to Exhibit 10.39 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on February 25, 2021).
10.39†	Amendment No. 5 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated June 2, 2021 (incorporated herein by reference to Exhibit 10.3 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on August 5, 2021).
10.40†	Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated March 16, 2018 (incorporated herein by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.41†	Amendment No. 1 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated April 22, 2019 (incorporated herein by reference to Exhibit 10.34 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on March 26, 2020).
10.42†	Amendment No. 2 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated October 28, 2019 (incorporated herein by reference to Exhibit 10.35 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on March 26, 2020).
10.43†	Amendment No. 3 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated May 29, 2020 (incorporated herein by reference to Exhibit 10.12 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on August 11, 2020).
10.44†	Amendment No. 4 to the Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated June 16, 2021 (incorporated herein by reference to Exhibit 10.4 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on August 5, 2021).
10.45†	Amendment No. 5 to Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated December 8, 2021 (incorporated herein by reference to Exhibit 10.43 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on February 28, 2022).
10.46†	Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated November 5, 2021 (incorporated herein by reference to Exhibit 10.44 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on February 28, 2022).
10.47†	Amended and Restated Letter Agreement between the Company and the Bill & Melinda Gates Foundation, dated January 12, 2022 (incorporated by reference to Exhibit 10.45 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on February 28, 2022).
10.48	Stock Purchase Agreement between the Company and the Bill & Melinda Gates Foundation, dated January 12, 2022 (incorporated herein by reference to Exhibit 10.46 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on February 28, 2022).
10.49†	Grant Agreement between the Company and the Bill & Melinda Gates Foundation, dated January 12, 2022 (incorporated herein by reference to Exhibit 10.47 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on February 28, 2022).
10.50†	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 (incorporated herein by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.51†	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 (incorporated herein by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.52†	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 (incorporated herein by reference to Exhibit 10.30 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).

10.53	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 (incorporated herein by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.54†	Amendment Agreement between the Company (as successor in interest to Humabs BioMed SA) and the Institute for Research in Biomedicine, dated January 29, 2018 (incorporated herein by reference to Exhibit 10.32 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.55†	Exclusive License Agreement between the Company and The Rockefeller University, dated July 31, 2018 (incorporated herein by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.56†	Amendment to Exclusive License Agreement between the Company and The Rockefeller University, dated May 17, 2019 (incorporated herein by reference to Exhibit 10.34 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.57†	Second Amendment to Exclusive License Agreement between the Company and The Rockefeller University, dated September 28, 2020 (incorporated herein by reference to Exhibit 10.51 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on February 25, 2021).
10.58†	Third Amendment to Exclusive License Agreement between the Company and The Rockefeller University, dated March 1, 2021 (incorporated herein by reference to Exhibit 10.5 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on May 6, 2021).
10.59†	Sub-License and Collaboration Agreement between the Company (as successor in interest to Humabs BioMed SA) and MedImmune, LLC, dated March 20, 2012 (incorporated herein by reference to Exhibit 10.35 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.60†	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 (incorporated herein by reference to Exhibit 10.36 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.61†	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 (incorporated herein by reference to Exhibit 10.37 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.62†	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 (incorporated herein by reference to Exhibit 10.38 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.63†	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 (incorporated herein by reference to Exhibit 10.39 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.64†	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 (incorporated herein by reference to Exhibit 10.40 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.65†	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 (incorporated herein by reference to Exhibit 10.41 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.66	Lease Agreement between the Company and ARE-SAN FRANCISCO NO. 43, LLC, dated March 30, 2017 (incorporated herein by reference to Exhibit 10.42 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).

10.67	First Amendment to Lease Agreement between the Company and ARE-SAN FRANCISCO NO. 43, LLC, dated April 10, 2019 (incorporated herein by reference to Exhibit 10.43 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.68†	Lease Agreement between the Company and KRE Exchange Owner LLC, dated December 16, 2021 (incorporated herein by reference to Exhibit 10.66 to the Company's Form 10-K (File No. 001-39083), filed with the SEC on February 28, 2022).
10.69†	Patent License Agreement between the Company and Xencor, Inc., dated August 15, 2019 (incorporated herein by reference to Exhibit 10.44 to the Company's Registration Statement on Form S-1 (File No. 333-233604), filed with the SEC on September 3, 2019).
10.70†	Amendment 1 to Patent License Agreement between the Company and Xencor, Inc., dated February 23, 2021 (incorporated herein by reference to Exhibit 10.3 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on May 6, 2021).
10.71†	Patent License Agreement between the Company and Xencor, Inc., dated March 25, 2020 (incorporated herein by reference to Exhibit 99.1 to the Company's Form 8-K (File No. 001-39083), filed with the SEC on June 19, 2020).
10.72†	Amendment 1 to Patent License Agreement between the Company and Xencor, Inc., dated February 23, 2021 (incorporated herein by reference to Exhibit 10.4 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on May 6, 2021).
10.73†	Definitive Collaboration Agreement between the Company, Glaxo Wellcome UK Limited and Beecham S.A., dated June 9, 2020 (incorporated herein by reference to Exhibit 10.54 to the Company's Registration Statement on Form S-1 (File No. 333-239689), filed with the SEC on July 6, 2020).
10.74	Stock Purchase Agreement between the Company and Glaxo Group Limited, dated April 5, 2020 (incorporated herein by reference to Exhibit 10.55 to the Company's Registration Statement on Form S-1 (File No. 333-239689), filed with the SEC on July 6, 2020).
10.75†	Preliminary Collaboration Agreement between the Company and Glaxo Wellcome UK Limited, dated February 14, 2021 (incorporated herein by reference to Exhibit 10.1 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on May 6, 2021).
10.76†	Definitive Collaboration Agreement between the Company and Glaxo Wellcome UK Limited, dated May 18, 2021 (incorporated herein by reference to Exhibit 10.2 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on August 5, 2021).
10.77†	Amendment No. 1 to the Definitive Collaboration Agreement between the Company and Glaxo Wellcome UK Limited dated May 27, 2022 (incorporated herein by reference to Exhibit 10.2 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on August 9, 2022).
10.78†	Stock Purchase Agreement between the Company and Glaxo Group Limited, dated February 14, 2021 (incorporated herein by reference to Exhibit 10.2 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on May 6, 2021).
10.79†	Binding Letter Agreement between the Company and Samsung Biologics Co., Ltd., dated April 9, 2020 (incorporated herein by reference to Exhibit 10.57 to the Company's Registration Statement on Form S-1 (File No. 333-239689), filed with the SEC on July 6, 2020).
10.80	Assignment and Novation Agreement among the Company, GlaxoSmithKline Trading Services Limited and Samsung Biologics Co., Ltd., dated July 31, 2020 (incorporated herein by reference to Exhibit 99.2 to the Company's Form 8-K (File No. 001-39083), filed with the SEC on August 7, 2020).
10.81†	Letter of Intent between the Company and WuXi Biologics (Hong Kong) Limited, dated June 15, 2020 (incorporated herein by reference to Exhibit 10.59 to the Company's Registration Statement on Form S-1 (File No. 333-239689), filed with the SEC on July 6, 2020).
10.82†	Termination Agreement between the Company and WuXi Biologics (Hong Kong) Limited dated May 16, 2022 (incorporated herein by reference to Exhibit 10.1 to the Company's Form 10-Q (File No. 001-39083), filed with the SEC on August 9, 2022).

10.83	Sales Agreement, dated as of November 10, 2020, by and between the Company and Cowen and Company, LLC. (incorporated by reference to Exhibit 1.2 to the Company's registration statement on Form S-3 (Filed No. 333-250013), filed with the SEC on November 10, 2020).
21.1	List of subsidiaries of the Company.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page to this report).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

+ 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 28, 2023

By: /s/ **George Scangos**

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

Date: February 28, 2023

By: /s/ **Howard Horn**

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints George Scangos, Ph.D., Johanna Friedl-Naderer, Howard Horn and Vanina de Verneuil, 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/ George Scangos George Scangos, Ph.D.	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 28, 2023
/s/ Howard Horn Howard Horn	Chief Financial Officer and Secretary *(Principal Financial and Accounting Officer)*	February 28, 2023
/s/ Vicki Sato Vicki Sato, Ph.D.	Chairman of the Board of Directors	February 28, 2023
/s/ Jeffrey S. Hatfield Jeffrey S. Hatfield	Director	February 28, 2023
/s/ Robert More Robert More	Director	February 28, 2023
/s/ Janet Napolitano Janet Napolitano	Director	February 28, 2023
/s/ Robert Nelsen Robert Nelsen	Director	February 28, 2023
/s/ Robert Perez Robert Perez	Director	February 28, 2023
/s/ Saira Ramasastry Saira Ramasastry	Director	February 28, 2023
/s/ Phillip Sharp Phillip Sharp, Ph.D.	Director	February 28, 2023
/s/ Elliott Sigal Elliott Sigal, M.D., Ph.D.	Director	February 28, 2023

VIR BIOTECHNOLOGY, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

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

Annual Cash Compensation

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

1. Annual Board Service Retainer:
   a. All Eligible Directors: $50,000
   b. Non-executive chairperson of the Board: $75,000 (inclusive of Annual Board Service Retainer)

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

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

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

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2019 Equity Incentive Plan (the "***Plan***"). All stock options granted under this Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the

underlying common stock on the date of grant, and a term of 10 years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Grant: For each Eligible Director who is first elected or appointed to the Board following the effective date of this Policy, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted two equity awards (the "***Initial Grants***") with a value of $400,000 in the aggregate comprised of (i) a stock option to purchase shares of the Company's common stock (the "***Initial Option Grant***") and (ii) a restricted stock unit award covering shares of the Company's common stock (the "***Initial RSU Grant***"). The total number of shares subject to the Initial Option Grant will be initially calculated in accordance with the Black-Scholes valuation methodology and the total number of shares subject to the Initial RSU Grant will be initially calculated in accordance with the Fair Market Value as of the grant date, and such resulting number of shares shall be divided between the Initial Grants based on a fixed ratio of two shares subject to the Initial Option Grant for every one share subject to the Initial RSU Grant, with the number of shares subject to the Initial Option Grant rounded down to the nearest whole share and in no event exceeding 16,000 shares and the number of shares subject to the Initial RSU Grant rounded down to the nearest whole share and in no event exceeding 8,000 shares.

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

   In addition, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted the additional awards on the same terms as the Annual Grants (as defined below), except (i) the $400,000 aggregate value of the additional awards shall first be multiplied by a fraction, the numerator of which equals 12 minus the number of calendar months that have occurred since the last annual meeting of stockholders and the denominator of which equals 12, and (ii) such additional awards will vest in full upon the earlier of (i) the one-year anniversary of the date the Annual Grants to the Eligible Directors were last made and (ii) the next annual meeting of stockholders, subject to the Eligible Director's Continuous Service (as defined in the Plan) on the vesting date, and will vest in full upon a Change in Control (as defined in the Plan), subject to the Eligible Director's Continuous Service (as defined in the Plan) on such date.

2. Annual Grant: On the first market trading day after each annual stockholders meeting of the Company, each Eligible Director who continues to serve as a member of the Board following such stockholders meeting will be automatically, and without further action by

the Board or Compensation Committee of the Board, granted two equity awards (collectively, the "***Annual Grants***") with a value of $400,000 in the aggregate comprised of (i) a stock option to purchase shares of the Company's common stock (the "***Annual Option Grant***"); and (ii) a restricted stock unit award covering shares of the Company's common stock (the "***Annual RSU Grant***"). The shares subject to each Annual Grant will vest in full on the one-year anniversary of the grant date, subject to the Eligible Director's Continuous Service (as defined in the Plan) on the vesting date, and will vest in full upon a Change in Control (as defined in the Plan), subject to the Eligible Director's Continuous Service (as defined in the Plan) on such date. The total number of shares subject to the Annual Option Grant will be initially calculated in accordance with the Black-Scholes valuation methodology as of the grant date and the total number of shares subject to the Annual RSU Grant will be initially calculated in accordance with the Fair Market Value as of the grant date, and such resulting number of shares shall be divided between the Annual Grants based on a fixed ratio of two shares subject to the Annual Option Grant for every one share subject to the Annual RSU Grant, with the number of shares subject to the Annual Option Grant rounded down to the nearest whole share and in no event exceeding 16,000 shares and the number of shares subject to the Annual RSU Grant rounded down to the nearest whole share and in no event exceeding 8,000 shares.

Eligible Director Compensation Limit

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

Approved by the Board of Directors: December 14, 2022 Effective: January 1, 2023

Exhibit 10.17

AGREEMENT ON TRANSFER
OF EMPLOYMENT AND AMENDMENT OF EMPLOYMENT AGREEMENT
("Agreement")

Dated: December 19, 2022

Between

Humabs BioMed SA (“Humabs”)
Via dei Gaggini 3
6500 Bellinzona, Switzerland

A subsidiary of
Vir Biotechnology, Inc. (“**VIR**”)
499 Illinois Street, Suite 500
San Francisco, CA 94158
USA

And

Vir Biotechnology International GmbH (“VBI”)
Grafenauweg 8
6300 Zug, Switzerland

And

Johanna Friedl-Naderer (“Employee”)
[Address]
[Address]

(Humabs, VBI and the Employee together the "Parties", each a "Party")
(Humabs, VBI and their direct and indirect affiliates (i.e. any entity which, directly or indirectly, controls, or is controlled by, or is under common control with such entity) from time to time the "Group", each a "Group Company")

Recitals
Humabs BioMed SA and the Employee concluded an employment contract dated 16 December 2021 (the "Employment Agreement"). Humabs BioMed SA appreciates and values the Employee's commitment and engagement and wishes the Employee to assume the role of Group Chief Operations Officer (COO) retroactively as of March 2, 2022, and to amend the Employment Agreement accordingly;

In addition, the Employee shall receive a monthly housing allowance retroactively as of 1 September 2022;

As of January 1, 2023, the employment relationship shall be transferred and continued between VBI and the Employee; and,

Based on the above premises, which form an integral part hereof, the Parties agree as follows:

Amendment of Section 3
Section 3 of the Employment Agreement is amended as follows:
“As of March 2, 2022, the Employee shall hold the position of Group Chief Operations Officer (COO) of the Group.” The Employee’s duties and responsibilities shall encompass the usual and customary duties, responsibilities and authority of the Group COO and such other duties and responsibilities as are assigned to the Employee hereunder by the Board of her then-current direct Employer (whether Humabs or VBI), the Group’s CEO and/or the Group’s Board, from time to time. Furthermore, the Employee’s duties and responsibilities are additionally governed by the organizational regulations of her then-current Employer and/or the Group.
The Employee reports to the Group CEO as well as the Board of her then-current direct Employer and/or the Group’s Board.

Amendment of Section 7
The following addition is made to section 7 of the Employment Agreement:
"As of 1 September 2022, the Employee is entitled to a monthly housing allowance of USD 10'000 gross to be paid in CHF for a gross total of monthly CHF 9’861, minus applicable withholding and deductions if any."

Change of Employer
The Parties hereby agree to transfer the Employment Agreement with all rights and obligations as of January 1, 2023. As of said date, the Employee will have an employment relationship with VBI only, and her employment relationship will then become subject to the jurisdiction and any unique statutory requirements of the Canton of Zug, including without limitation, the public holidays recognized from time to time within Zug. For calculation of years of service, March 2, 2022 will be considered the start date of the employment. The Parties agree that the transfer does not trigger any severance payment obligation.

Miscellaneous
All other provisions of the Employment Agreement and of the Letter Agreement (dated February 18th, 2022) remain in force unchanged and related rights and obligations set forth therein extend to VBI on and after January 1, 2023.

Governing Law and Jurisdiction
This Agreement shall be governed by the substantive laws of Switzerland (excluding its rules on conflict of laws). Venue for any dispute arising from this Agreement shall be the courts according to article 34 of the Swiss Civil Procedural Code.

This Addendum is made on the date set forth on the cover page of this Agreement.

Humabs BioMed SA:

_____
Filippo Riva
Managing Director

Vir Biotechnology International GmbH:

_____
George Scangos
Group CEO and VBI Managing Director

The Employee:

_____
Johanna Friedl-Naderer

Exhibit 21.1

Subsidiaries of Vir Biotechnology, Inc.

Name of Subsidiary	State or Other Jurisdiction of Incorporation or Organization
Agenovir Corporation	Delaware
Encentrio Therapeutics, Inc.	Delaware
Encentrio Therapeutics International GmbH	Switzerland
Humabs BioMed SA	Switzerland
Statera Health, LLC	Delaware
TomegaVax, Inc.	Delaware
Vir AU Biotechnology Pty Ltd.	Australia
Vir Biotechnology International GmbH	Switzerland
Vir Predictive Medicine, Inc.	Delaware
VirAb, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Forms S-8 Nos. 333-234212, 333-237410, 333-253547 and 333-263088) pertaining to the 2016 Equity Incentive Plan, 2019 Equity Incentive Plan and 2019 Employee Stock Purchase Plan of Vir Biotechnology, Inc.; and

(2) Registration Statement (Form S-3 No. 333-250013) of Vir Biotechnology, Inc.;

of our reports dated February 28, 2023, with respect to the consolidated financial statements of Vir Biotechnology, Inc. and the effectiveness of internal control over financial reporting of Vir Biotechnology, Inc. included in this Annual Report (Form 10-K) of Vir Biotechnology, Inc. for the year ended December 31, 2022.

/s/ Ernst & Young LLP

San Mateo, California

February 28, 2023

Exhibit 31.1

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

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

1. I have reviewed this Annual Report on Form 10-K of Vir Biotechnology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: February 28, 2023

By: /s/ **George Scangos**

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

Exhibit 31.2

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

I, Howard Horn, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vir Biotechnology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: February 28, 2023

By: /s/ **Howard Horn**

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Vir Biotechnology, Inc. (the "Company") on Form 10-K for the period ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), George Scangos, Ph.D., President, Chief Executive Officer and Director of the Company and Howard Horn, Chief Financial Officer and Secretary of the Company, each hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 28th of February 2023.

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

"This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Vir Biotechnology, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing."