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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)
May 21, 2021

Vir Biotechnology, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39083**	**81-2730369**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

499 Illinois Street, Suite 500
San Francisco, California 94158
(Address of principal executive offices, including zip code)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 per share	**VIR**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Item 8.01 Other Events.

On May 21, 2021, Vir Biotechnology, Inc. (the "Company") and GlaxoSmithKline plc ("GSK") issued a corrected press release announcing that the European Medicines Agency's Committee for Human Medicinal Products ("CHMP") has issued a positive opinion following the referral of sotrovimab to the CHMP under Article 5(3) of Regulation 726/2004. A copy of the corrected press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corrected Press Release of the Company, dated May 21, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VIR BIOTECHNOLOGY, INC.

Date: May 21, 2021

By: /s/ Howard Horn
Howard Horn
Chief Financial Officer

CORRECTION — EMA Issues Positive Scientific Opinion on GSK and Vir Biotechnology's Sotrovimab For the Early Treatment of COVID-19

– Opinion based on the EMA's Committee for Human Medicinal Products (CHMP) review of available data on sotrovimab (previously VIR-7831) for the early treatment of COVID-19 –

– EU member states can use the CHMP positive scientific opinion when making national decisions about the early use of sotrovimab prior to EMA marketing authorization –

– Discussions with global regulators regarding authorizations in additional countries continue to advance –

LONDON and SAN FRANCISCO, May 21, 2021 (GLOBE NEWSWIRE) — In a release issued under the same headline earlier today by Vir Biotechnology, Inc. please note that the third sub headline of the release has been updated. The corrected release follows:

GlaxoSmithKline plc and Vir Biotechnology, Inc. today announced that the European Medicines Agency's (EMA) Committee for Human Medicinal Products (CHMP) has issued a positive scientific opinion following the referral of sotrovimab to the CHMP under Article 5(3) of Regulation 726/2004. The opinion relates to the use of sotrovimab for the treatment of adults and adolescents (aged 12 years and over and weighing at least 40 kg) with COVID-19 who do not require oxygen supplementation and who are at risk of progressing to severe COVID-19.

The CHMP opinion under Article 5(3) can now be considered by the national authorities in EU member states when taking evidence-based decisions on the early use of the medicine prior to marketing authorization.

Christopher Corsico, senior vice president, development, GSK, said: "As the COVID-19 pandemic continues and the virus generates new variants of concern, including those that recently emerged in India, the need for therapies that can slow the progression of disease in patients who are at high risk for developing severe complications remains a top priority. Monoclonal antibody treatments are a critical part of a comprehensive solution to COVID-19, especially as less than 40% of adults across EU member states have received at least one dose of a vaccine to date[1]. We are encouraged by this positive scientific opinion from the EMA, as it hopefully brings us closer to making sotrovimab available for patients across Europe."

George Scangos, Ph.D., chief executive officer of Vir, said: "Today's opinion is great news for patients across Europe, as EU member states are now more easily able to move forward with their own temporary authorizations for sotrovimab. Based on our most recent in vitro data, sotrovimab continues to combat COVID-19 as it evolves and has retained activity against all circulating variants of concern. We look forward to continuing to work with regulators around the world to make sotrovimab available to more patients in need and help bring an end to the pandemic."

The CHMP reached its opinion following a review of data including an interim analysis of efficacy and safety data from the Phase 3 COMET-ICE (COVID-19 Monoclonal antibody Efficacy Trial—Intent to Care Early) trial, which evaluated sotrovimab as monotherapy for the early treatment of COVID-19 in adults at high risk of hospitalization. Efficacy results of the interim analysis, based on data from 583 randomized patients, demonstrated an 85% (p=0.002) reduction in hospitalization or death in those receiving sotrovimab compared to placebo, the primary endpoint of the trial. As a result, the Independent Data Monitoring Committee recommended that the trial be stopped for enrollment due to evidence of profound efficacy. The CHMP also considered data on the medicine's quality and safety.

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1 European Centre for Disease Prevention and Control. COVID-19 Vaccine Tracker: European Centre for Disease Prevention and Control. www.vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab. 18 May 2021.

The CHMP also reviewed data from several in vitro studies which demonstrated that sotrovimab maintains activity against multiple circulating variants of concern, including the variants from Brazil (P.1), California (B.1.427/B.1.429), South Africa (B.1.351) and the UK (B.1.1.7), based on in vitro data from live virus and pseudotyped virus assays. Additional in vitro data demonstrating activity against variants from New York (B.1.526) and India (B.1.617) were also recently published by bioRxiv. The clinical impact of these variants is not yet known. Sotrovimab targets a conserved epitope of the spike protein which is less likely to mutate over time. Data collection and analysis is still ongoing.

The CHMP's review took place in parallel to the EMA's ongoing rolling review process, which is used to speed up the formal marketing application assessment of a promising medicine during a public health emergency. The rolling review will continue until enough evidence is available to support a formal Marketing Authorization Application.

An Emergency Use Authorization (EUA) application for sotrovimab has been submitted to the U.S. Food and Drug Administration (FDA) and it is also under review by other global regulators including Health Canada under the expedited Interim Order application pathway for COVID-19 drugs.

Sotrovimab is an investigational compound and has not been granted a marketing authorization anywhere in the world.

About the COMET-ICE Study Design

The multi-center, double-blind, placebo-controlled, Phase 3 COMET-ICE trial investigated intravenous (IV) infusion of sotrovimab in adults with mild or moderate COVID-19 at high risk of progression to severe disease.

This ongoing trial evaluated the safety and efficacy of a single IV infusion of sotrovimab (500 mg) or placebo in non-hospitalized participants globally. The safety of sotrovimab is primarily based on an interim analysis from 868 patients (430 patients in the treatment arm and 438 in the placebo arm) through Day 29. Among those studied, 63% were Hispanic or Latino and 7% were Black or African American. According to the U.S. Centers for Disease Control and Prevention, these populations are approximately three times more likely to be hospitalized and approximately two times more likely to die[2] of COVID-19. The primary efficacy endpoint was the proportion of patients who have progression of COVID-19 as defined by the need for hospitalization for at least 24 hours or death within 29 days of randomization.

The only event to occur with a frequency of greater than 1% in the sotrovimab arm was diarrhea (less than 1% in placebo group). All other adverse events with a frequency of greater than 1% occurred in the placebo arm. No other treatment-emergent adverse events were reported at a higher rate with sotrovimab compared to placebo. Sotrovimab's safety and efficacy is continuing to be studied in ongoing clinical trials with analysis of safety and efficacy data at Day 29 for the full population from COMET-ICE expected as early as the first half of 2021.

About the Sotrovimab Clinical Development Program

In addition to the COMET-ICE trial, the full COMET clinical development program for sotrovimab includes:

- **COMET-PEAK**: An ongoing Phase 2 trial with two parts: to compare the safety and viral kinetics of 500 mg intramuscularly (IM) administered sotrovimab to 500 mg intravenously administered sotrovimab among low-risk adults with mild to moderate COVID-19 and to evaluate the similarity in pharmacokinetics between sotrovimab manufactured by different processes

2 Data source: U.S. Centers for Disease Control and Prevention: Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity (https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html)

- **COMET-TAIL:** A Phase 3 trial expected to begin in the second quarter of 2021 as an early treatment for COVID-19 in high-risk adults to assess whether IM-administered sotrovimab can reduce hospitalization or death due to COVID-19
- **COMET-STAR:** A Phase 3 trial expected to begin in the third quarter of 2021 in uninfected adults at high risk to determine whether IM-administered sotrovimab can prevent symptomatic infection.

Sotrovimab was also evaluated in the outpatient setting in BLAZE-4, a Phase 2 trial sponsored by Eli Lilly and Company, designed to assess the safety and efficacy of bamlanivimab (LY-CoV555) alone and bamlanivimab with other neutralizing antibodies, including sotrovimab, versus placebo in low-risk adults with mild to moderate COVID-19. An interim analysis found that bamlanivimab (700 mg) co-administered with sotrovimab (500 mg) demonstrated a 70% relative reduction of patients with persistently high viral load at day 7 compared to placebo, meeting the primary endpoint.

Additionally, sotrovimab, along with VIR-7832 is being evaluated in the Phase 1b/2a National Health Service-supported AGILE trial in adults with mild to moderate COVID-19. VIR-7832 (GSK4182137) is the second monoclonal antibody from the Vir-GSK collaboration to be investigated as a potential COVID-19 treatment.

About Sotrovimab (previously VIR-7831)

Sotrovimab is an investigational SARS-CoV-2 monoclonal antibody. Preclinical data suggest it has the potential to both block viral entry into healthy cells and clear infected cells. The antibody binds to an epitope on SARS-CoV-2 that is shared with SARS-CoV-1 (the virus that causes SARS), indicating that the epitope is conserved, which may make it more difficult for resistance to develop. Sotrovimab, which incorporates Xencor's Xtend™ technology, also has been designed to achieve high concentration in the lungs to ensure optimal penetration into airway tissues affected by SARS-CoV-2 and to have an extended half-life.

About VIR-7832 / GSK4182137

VIR-7832 is an investigational dual-action SARS-CoV-2 monoclonal antibody. Preclinical data suggest it has the potential to both block viral entry into healthy cells and an enhanced ability to clear infected cells. The antibody binds to an epitope on SARS-CoV-2 that is shared with SARS-CoV-1 (the virus that causes SARS), indicating that the epitope is highly conserved, which may make it more difficult for resistance to develop. VIR-7832, which incorporates Xencor's Xtend and other Fc technologies, has been designed to achieve high concentration in the lungs to ensure optimal penetration into airway tissues affected by SARS-CoV-2 and to have an extended half-life. Importantly, VIR-7832 also has been engineered to potentially enhance virus-specific T cell function, which could help treat and/or prevent COVID-19 infection.

About the Vir and GSK Collaboration

In April 2020, Vir and GSK entered into a collaboration to research and develop solutions for coronaviruses, including SARS-CoV-2, the virus that causes COVID-19. The collaboration uses Vir's proprietary monoclonal antibody platform technology to accelerate existing and identify new anti-viral antibodies that could be used as therapeutic or preventive options to help address the current COVID-19 pandemic and future outbreaks. The companies will leverage GSK's expertise in functional genomics and combine their capabilities in CRISPR screening and artificial intelligence to identify anti-coronavirus compounds that target cellular host genes. They will also apply their combined expertise to research SARS-CoV-2 and other coronavirus vaccines.

GSK Commitment to Tackling COVID-19

GSK's response to COVID-19 has been one of the broadest in the industry, with three potential treatments in addition to our vaccine candidates in development with partner organizations.

GSK is collaborating with several organizations on COVID-19 vaccines by providing access to our adjuvant technology. In addition to our work with Medicago, we recently announced positive Phase 2 data from our collaboration with Sanofi to develop an adjuvanted, protein-based vaccine candidate and expect to begin a Phase 3 trial in Q2. An earlier stage collaboration with SK Bioscience is also ongoing. SK Bioscience receives funding from CEPI and the Bill and Melinda Gates Foundation to develop differentiated, affordable COVID-19 vaccines for supply globally through the COVAX facility. The use of an adjuvant can be of particular importance in a pandemic since it may reduce the amount of vaccine protein required per dose, allowing more vaccine doses to be produced and contributing to protecting more people. Based on experience with other adjuvanted vaccines, there is potential for increased cross protection against COVID-19 variants which will be further studied.

GSK is also working with mRNA specialist, CureVac, to jointly develop next generation, multi-valent mRNA vaccines for COVID-19 with the potential to address multiple emerging variants in one vaccine. GSK will also support manufacturing of up to 100m doses of CureVac's first generation COVID-19 vaccine. GSK is also providing manufacturing support for up to 60m doses of Novavax' COVID-19 vaccine in the UK.

GSK is also exploring potential therapeutic or treatment options for COVID-19 patients. We are collaborating with Vir Biotechnology to develop existing and identify new anti-viral antibodies that could be used as therapeutic or preventive options for COVID-19. We recently reported that an Independent Data Monitoring Committee recommended that the Phase 3 COMET-ICE trial evaluating sotrovimab as monotherapy for the early treatment of COVID-19 in adults at high risk of hospitalization be stopped for enrollment due to evidence of profound efficacy, based on an interim analysis of data from the trial. We are also assessing whether an investigational monoclonal antibody, otilimab, can help severely ill COVID-19 patients aged over 70 who experience an overreaction of their immune system.

Vir's Commitment to COVID-19

Vir was founded with the mission of addressing the world's most serious infectious diseases. In 2020, Vir responded rapidly to the COVID-19 pandemic by leveraging our unique scientific insights and industry-leading antibody platform to explore multiple monoclonal antibodies as potential therapeutic or preventive options for COVID-19. Sotrovimab is the first SARS-CoV-2-targeting antibody Vir advanced into the clinic. It was carefully selected for its demonstrated promise in preclinical research, including an anticipated high barrier to resistance and potential ability to both block the virus from entering healthy cells and clear infected cells. Vir is continuing to pursue novel therapeutic and prophylactic solutions to combat SARS-CoV-2 and future coronavirus pandemics, both independently and in collaboration with its partners.

About GSK

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com/about-us.

About Vir Biotechnology

Vir Biotechnology is a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Vir has assembled four technology platforms that are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. Its current development pipeline consists of product candidates targeting COVID-19, hepatitis B virus, influenza A and human immunodeficiency virus. For more information, please visit www.vir.bio.

GSK Cautionary Statement Regarding Forward-Looking Statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2020 and any impacts of the COVID-19 pandemic.

Vir Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "plan," "potential," "aim," "promising" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Vir's expectations and assumptions as of the date of this press release. Forward-looking statements contained in this press release include, but are not limited to, statements regarding the timing and availability of sotrovimab to providers and patients, including arrangements with commercial payers, the timing of availability of clinical data, program updates and data disclosures related to sotrovimab, the ability of sotrovimab and VIR-7832 to treat and/or prevent COVID-19, the potential of sotrovimab in the hospitalized population, the ability of sotrovimab to neutralize the SARS-CoV-2 live virus, the ability of sotrovimab to maintain activity against variants of concern, including the Indian variant, and other potential pandemics,

and statements related to regulatory authorizations and approvals, including plans and discussions with global regulators in additional countries. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, challenges in the treatment of hospitalized patients, difficulties in collaborating with other companies or government agencies, challenges in accessing manufacturing capacity, successful development and/or commercialization of alternative product candidates by Vir's competitors, changes in expected or existing competition, delays in or disruptions to Vir's business or clinical trials due to the COVID-19 pandemic, geopolitical changes or other external factors, and unexpected litigation or other disputes. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Vir's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as required by law, Vir assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

Vir Biotechnology Contacts:
Neera Ravindran, MD
VP, Head of Investor Relations & Strategic Communications
nravindran@vir.bio
+1 415 506 5256

Cara Miller
VP, Corporate Communications
cmiller@vir.bio
+1 415 941 6746

GSK Contacts:

Media:	Simon Steel	+44 (0) 20 8047 5502	(London)
	Tim Foley	+44 (0) 20 8047 5502	(London)
	Kristen Neese	+1 804 217 8147	(Philadelphia)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Lyndsay Meyer	+1 202 302 4595	(Washington DC)
Analysts/Investors:	James Dodwell	+44 (0) 20 8047 2406	(London)
	Sonya Ghobrial	+44 (0) 7392 784784	(Consumer)
	Mick Readey	+44 (0) 7990 339653	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(Philadelphia)