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): March 26, 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	**VIR**	**Nasdaq Global Select Market**

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 March 26, 2021 Vir Biotechnology, Inc. (the "Company") and GlaxoSmithKline plc ("GSK") announced the submission of an application to the U.S. Food and Drug Administration ("FDA") requesting Emergency Use Authorization ("EUA") for VIR-7831, an investigational dual-action SARS-CoV-2 monoclonal antibody for the treatment of adults and adolescents (aged 12 years and older weighing at least 40 kg) with mild-to-moderate COVID-19 who are at risk for progression to hospitalization or death.

The FDA EUA submission was based on 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 VIR-7831 as monotherapy for the early treatment of COVID-19 in adults at high risk of hospitalization. Results of the interim analysis, based on data from 583 patients enrolled in the trial, demonstrated an 85% (p=0.002) reduction in hospitalization or death in those receiving VIR-7831 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. Data from the registrational COMET-ICE trial also will form the basis for a Biologics License Application ("BLA") submission to the FDA. As the trial remains ongoing and blinded with patients continuing to be followed for 24 weeks, additional results, including epidemiology and virology data, will be forthcoming once the trial is completed.

Preclinical data suggest VIR-7831 targets a highly conserved epitope of the spike protein, which may make it more difficult for resistance to develop. New in vitro data from pseudotyped virus assays published online in bioRxiv in March 2021 support this hypothesis as they demonstrate that VIR-7831 maintains activity against current circulating variants of concern including the UK, South African and Brazilian variants.

The Company and GSK will continue discussions with the European Medicines Agency ("EMA") and other global regulators to make VIR-7831 available to patients with COVID-19 as soon as possible.

On March 29, 2021, the Company, Eli Lilly and Company ("Lilly") and GSK announced topline data from Lilly's expanded Phase 2 BLAZE-4 trial, studying low-risk adult patients with mild to moderate COVID-19. Results showed that investigational bamlanivimab (LY-CoV555) 700 mg co-administered with VIR-7831 500 mg, demonstrated a 70% ($p<0.001$) relative reduction in persistently high viral load (> 5.27; cycle threshold value < 27.5) at day 7 compared to placebo, meeting the primary endpoint.

In addition, bamlanivimab administered with VIR-7831 demonstrated a statistically significant reduction compared to placebo in the key virological secondary endpoints of mean change from baseline to days 3, 5 and 7 in SARS-CoV-2 viral load. There were no events for the secondary endpoint of COVID-19 related hospitalization or death by day 29 in either study arm. One patient (in the treatment arm) visited the emergency room for COVID-19 related symptoms. No serious adverse events were seen with co-administration of bamlanivimab and VIR-7831.

Bamlanivimab and VIR-7831 bind to different regions of the spike protein of SARS-CoV-2. Preclinical data suggest the administration of these two investigational antibodies together may provide protection against current variants of SARS-CoV-2 that are resistant to bamlanivimab.

The Company, Lilly and GSK anticipate engaging with global regulators, including the FDA, regarding the possible co-administration of bamlanivimab and VIR-7831 for the treatment of COVID-19.

Forward-Looking Statements

This Current Report on Form 8-K 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 the Company's expectations and assumptions as of the date of this Current Report. Forward-looking statements contained in this Current Report include, but are not limited to, statements regarding the timing of availability of preclinical and clinical data, clinical development program updates, and data disclosures related to VIR-7831, the ability of VIR-7831 to treat and/or prevent COVID-19 (as monotherapy and in combination with bamlanivimab), the potential of VIR-7831 in the

hospitalized population, the ability of VIR-7831 to neutralize the SARS-CoV-2 live virus, the ability of VIR-7831 to maintain full activity against variant strains of the virus, the Company's collaboration with GSK, and statements related to regulatory authorizations and approvals, including plans to continue discussions with the FDA, the EMA and other global regulators. Many factors may cause differences between current expectations and actual results, including challenges in obtaining regulatory approval, 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 our competitors, changes in expected or existing competition, delays in or disruptions to our business or clinical trials due to the COVID-19 pandemic, geopolitical changes or other external factors, and unexpected litigation or other disputes.

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: March 30, 2021

By: /s/ Howard Horn

Howard Horn
Chief Financial Officer