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): April 5, 2022

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** **(Address of principal executive offices)**	**94158** **(Zip Code)**

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

(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:

☐ 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 25, 2022, Vir Biotechnology, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") had amended the Emergency Use Authorization ("EUA") Fact Sheet for sotrovimab, an investigational monoclonal antibody. FDA determined that, based on the totality of available evidence, including new live virus data generated by the Company, it is unlikely that the sotrovimab 500 mg dose would be effective against the Omicron BA.2 variant, and FDA updated its website 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. The Company today announced that as of April 5, 2022, the FDA's exclusion has been extended to all U.S. regions due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 sub-variant. The Company and GlaxoSmithKline ("GSK") are preparing a package of data in support of a higher dose of sotrovimab for the Omicron BA.2 subvariant and are sharing these data with regulatory and health authorities around the world for discussion.

In connection with today's announcement, the Company is also reaffirming additional information it reported in a Current Report on Form 8-K filed by the Company with the U.S. Securities and Exchange Commission on March 25, 2022, including:

- The Company still expects to recognize approximately $1.1 billion of sotrovimab collaboration revenues when sotrovimab doses are delivered in the first half of 2022.
- The Company and GSK still expect to manufacture approximately 2 million doses in the first half of 2022 and additional doses in the second half of 2022.
- The Company and GSK still plan to submit a Biologics License Application for sotrovimab to the FDA in the second half of 2022.
- The Company and GSK still expect to commence two Phase 3 trials in the second quarter of 2022 to assess the use of sotrovimab in uninfected immunocompromised patients to determine whether sotrovimab can prevent symptomatic COVID-19 infection. One trial is a platform trial, and one trial is a company sponsored trial, COMET-STAR. The primary endpoint for both trials is incidence of symptomatic PCR-confirmed COVID-19. The analysis of the primary endpoint of COMET-STAR will be event driven and is still expected to be as early as the second half of 2022.
- The Company still expects initial data from the Randomized Evaluation of COVID-19 Therapy (RECOVERY) Trial, which is evaluating sotrovimab among patients hospitalized with COVID-19 in the United Kingdom, in the second half of 2022.
- The Company still expects additional data from the United Kingdom's National Health Service-supported AGILE initiative evaluating VIR-7832, an investigational dual-action SARS-CoV-2 monoclonal antibody, in a Phase 1b/2a trial of adults with mild-to-moderate COVID-19 in the first half of 2022.

Forward-Looking Statements

This Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "expect," "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 Form 8-K. Forward-looking statements contained in this Form 8-K include, but are not limited to, statements regarding the ability of sotrovimab to treat and/or prevent COVID-19, the terms and limitations of use of the EUA for sotrovimab, the Company's collaboration with GSK, near-term collaboration revenue related to agreements for doses of sotrovimab, the timing and expected number of therapeutic doses that the Company will be able to supply to patients, planned discussions with global regulatory agencies as well as planned submissions and filings and the timing thereof, the timing of availability of data, program updates, data disclosures and publications related to sotrovimab and VIR-7832, the ability of sotrovimab to maintain activity against the Omicron BA.2 subvariant, and the clinical development program for sotrovimab and VIR-7832. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, actual timing and content of submissions to and decisions made by the regulatory authorities regarding sotrovimab; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or

refuse to approve or may delay approval of sotrovimab; challenges in the treatment of hospitalized patients, difficulties in collaborating with other companies or government agencies, successful development and/or commercialization of alternative product candidates by the Company's competitors, changes in expected or existing competition, delays in or disruptions to the Company'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 Form 8-K are discussed in the Company's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as required by law, the Company assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
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 thereunto duly authorized.

VIR BIOTECHNOLOGY, INC.

Date: April 5, 2022

By: /s/ Howard Horn

Howard Horn
Chief Financial Officer and Secretary