

**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 22, 2020

VIR BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware
(state or other jurisdiction
of incorporation)

001-39083
(Commission
File Number)

81-2730369
(I.R.S. 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 (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	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	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 1.01 Entry into a Material Definitive Agreement

On May 22, 2020, Vir Biotechnology, Inc. (the “Company”) and Biogen Inc. (“Biogen”) entered into a clinical development and manufacturing agreement (the “Agreement”), pursuant to which Biogen will perform process development activities and specified manufacturing services under agreed statements of work for certain pre-commercial and clinical supply of SARS-CoV-2 antibodies. Under the terms of the Agreement, the Company agreed to pay fees for Biogen’s performance of services as provided in each applicable statement of work, including costs to third parties on a pass-through basis. The parties entered into three statements of work for the process development and certain clinical manufacturing services simultaneously with the execution of the Agreement, with the cost of activities under such agreed statements of work totaling approximately \$13.8 million. The Agreement includes the right for Vir to request a technology transfer of all manufacturing technology and processes developed under the Agreement to Vir or any third party designated by Vir to conduct manufacturing of SARS-CoV-2 antibody using such technology, including applicable licenses to Vir under Biogen’s relevant intellectual property rights. In connection with any such technology transfer, the Company also agreed to pay an “access fee” to Biogen for each successful batch of SARS-CoV-2 antibody drug substance manufactured using certain improvements relating to increases in batch yield developed under the Agreement, whether such manufacturing is performed by the Company, its affiliates, or third parties. If the Company successfully manufactures all batches of SARS-CoV-2 antibody drug substance for which it is currently committed under its letter agreement with Samsung BioLogics Co., Ltd. dated April 9, 2020, based on the Company’s current working assumptions of manufacturing yield per batch, the access fee payable to Biogen in connection with the Samsung manufacture will total approximately \$100 million. The Company has the right to terminate the Agreement without cause upon 180 days’ prior written notice. Either party may terminate the Agreement upon the other party’s bankruptcy or uncured material breach.

The parties may discuss the possibility of negotiating a commercial supply agreement for the SARS-CoV-2 antibody products, but are not obligated to do so.

The foregoing description of the material terms of the Agreement is qualified in its entirety by reference to the full text of the Agreement, a copy of which will be filed as an exhibit to a subsequent filing with the Securities and Exchange Commission.

On May 29, 2020, the Company issued a press release announcing the transactions described above. A copy of the press release is attached to this report as Exhibit 99.1.

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,” “expect,” “plan,” “anticipate,” “estimate,” “intend,” “potential” 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. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this Current Report include statements regarding the potential benefits of the Company’s collaboration with Biogen, the total access fee payable to Biogen in connection the Samsung manufacture, the timing and scale of manufacturing activities, the demand for antibody therapies, the timing of commencement of clinical trials for the Company’s antibody product candidates and the Company’s ability to address the current COVID-19 pandemic and future outbreaks of the disease. Many factors may cause differences between current expectations and actual results including unexpected results during clinical trials, difficulties in obtaining regulatory approval, clinical site activation rates or clinical trial enrollment rates that are lower than expected, changes in expected or existing competition, delays or disruptions in the Company’s business or clinical trials due to the COVID-19 pandemic, 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 Current Report are discussed in the Company’s filings with the 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**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company, dated May 29, 2020.

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.

By: /s/ Howard Horn

Howard Horn

Chief Financial Officer

Dated: May 29, 2020



Vir Biotechnology and Biogen Execute Agreement to Manufacture SARS-CoV-2 Antibodies for Potential COVID-19 Treatment

SAN FRANCISCO – May 29, 2020 – Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that it has finalized a process development and manufacturing agreement with Biogen Inc. (Nasdaq: BIIB) based on the letter of intent that the companies announced in March. Under the agreement Biogen will perform process development activities and specified manufacturing and process transfer services to enable commercial supply of Vir's SARS-CoV-2 monoclonal antibodies.

“Biogen’s world-class cell line and process development expertise is a tremendous asset as we work with great urgency to develop our antibody candidates, including employing technology that is designed to maximize the yield of each manufacturing batch produced,” said Michael Kamarck, Ph.D., Chief Technology Officer of Vir. “The willingness of both Vir and Biogen to begin work before the definitive agreement was in place exemplifies our shared commitment to working in unconventional ways in the interest of the public good, and mutual recognition that bringing these therapies to people at the speed and scale that is needed requires the combined resources of multiple collaboration partners and significant manufacturing capacity.”

Vir’s SARS-CoV-2 antibody development candidates, VIR-7831 and VIR-7832, have demonstrated high affinity for the SARS-CoV-2 spike protein and the ability to neutralize SARS-CoV-2 in live-virus cellular assays. The execution of this definitive agreement allows Vir to advance the development of its antibody candidates and complements its existing manufacturing agreements with WuXi Biologics (stock code: 2269.HK) and Samsung Biologics Co., Ltd. (207940.KS).

Under the terms of the agreement, Biogen and Vir will collaborate to develop highly productive clonal cell lines and clinical and commercial manufacturing processes for Vir’s SARS-CoV-2 antibody candidates. These processes are designed to be transferrable to global biomanufacturing facilities designed for advanced biologics production. As part of the agreement, Vir has contracted with Biogen to conduct cGMP clinical manufacturing in the U.S. and provide technical support to facilitate rapid process transfer to Samsung Biologics, and potentially other large-scale biomanufacturing facilities in the U.S. and all other regions of the globe in order to provide reliable supply of a potential commercial product.

About VIR-7831

VIR-7831 is a monoclonal antibody that has demonstrated the ability to neutralize SARS-CoV-2 live virus in vitro. The antibody binds to an epitope on SARS-CoV-2 that is shared with SARS-CoV-1 (also known as SARS), indicating that the epitope is highly conserved, which may make it more difficult for escape mutants to develop. VIR-7831 has been engineered to have an extended half-life.

About VIR-7832

VIR-7832 is a monoclonal antibody that has demonstrated the ability to neutralize SARS-CoV-2 live virus in vitro. The antibody binds to an epitope on SARS-CoV-2 that is shared with SARS-CoV-1 (also known as SARS), indicating that the epitope is highly conserved, which may make it more difficult for escape mutants to develop. VIR-7832 has been engineered to have an extended half-life and to potentially function as a T cell vaccine.

About Vir's Antibody Platform

Vir has a robust method for capitalizing on unusually successful immune responses naturally occurring in people who are protected from, or have recovered from, infectious diseases. The platform is used to 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. Vir engineers the fully human antibodies that it discovers to enhance their therapeutic potential. This platform has been used to identify and develop antibodies for pathogens including Ebola (mAb114, currently in use in the Democratic Republic of Congo), hepatitis B virus, influenza A, malaria and others.

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 hepatitis B virus, influenza A, SARS-CoV-2, human immunodeficiency virus and tuberculosis. For more information, please visit www.vir.bio.

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,” “could,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “goal,” “intend,” “potential,” “candidate,” “continuing,” “developing” 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. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements regarding the potential benefits of Vir's collaboration with Biogen, the timing and scale of manufacturing activities, the demand for antibody therapies, the timing of commencement of clinical trials for VIR-7831 and VIR-7832, Vir's ability to address the current COVID-19 pandemic and future outbreaks of the disease, the ability of VIR-7831 and VIR-7832 to neutralize the SARS-CoV-2 virus, Vir's efforts to identify additional antibodies, as well as statements about the highly conserved nature of VIR-7831 and VIR-7832 making it more difficult for escape mutants to develop. Many factors may cause differences between current expectations and actual results including unexpected results during clinical trials, difficulties in obtaining regulatory approval, clinical site activation rates or clinical trial enrollment rates that are lower than expected, changes in expected or existing competition, delays or disruptions in the Vir's business or clinical trials due to the COVID-19 pandemic, unexpected litigation or other disputes, challenges in neutralizing SARS-CoV-2, difficulty in collaborating with other companies or government agencies, and challenges in accessing manufacturing capacity. 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.

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