
**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): February 14, 2021

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
(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 1.01 Entry into a Material Definitive Agreement.

Preliminary Agreement for Expanded Collaboration

On February 14, 2021, Vir Biotechnology, Inc. (the “Company”) and Glaxo Wellcome UK Limited (“GSK”) entered into a binding preliminary collaboration agreement (the “Preliminary Collaboration Agreement”), pursuant to which the parties agreed to expand their 2020 collaboration relating to research and development of therapies for coronaviruses, to include collaboration on three separate programs: (1) a program to research, develop and commercialize monoclonal antibodies (mAbs) for the prevention, treatment or prophylaxis of the influenza virus (the “Influenza Program”); (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”). Under the Influenza Program, the parties will collaborate to research, develop and commercialize the Company’s next generation mAbs for the prevention, treatment or prophylaxis of influenza. In addition, after the Company completes and reports Phase 2 trial outcomes for VIR-2482, an intramuscularly administered investigational mAb designed as a universal prophylactic for influenza A that has completed a Phase 1 trial, GSK will have the exclusive option to obtain exclusive rights to co-develop and commercialize VIR-2482 (the “Option”).

For a period of three years following the effective date of the Preliminary Collaboration Agreement (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, the parties will exclusively collaborate with respect to (a) all of the Company’s mAbs that the parties agree to develop for the prevention, treatment or prophylaxis of the influenza virus, until such time there are no mAbs of the Company being developed under the 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. The Company 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, the Company has 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). The parties will mutually agree upon the allocation of responsibility for development and early-stage manufacturing of products under the Expanded Functional Genomics Program and the Additional Programs (subject to GSK’s final decision making authority if the parties cannot agree), and GSK will be primarily responsible for commercial manufacturing and commercialization activities for products under the Functional Genomics Program and Additional Programs.

In general, the parties will share 50% of all development costs in accordance with the budget for each of the collaboration programs (other than for 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 commercially reasonable rates to be agreed in the definitive collaboration agreement, determined by 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 such program unilaterally, or also cease the conduct and funding of such collaboration product. 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.

The parties will continue to negotiate a more detailed collaboration agreement (the “Definitive Collaboration Agreement”), including more detailed financial terms, as well as operational provisions and consequences of any ongoing collaboration program as a result of a change of control of the Company. If the parties cannot reach agreement and enter into the Definitive Collaboration Agreement within 90 days following the effective date of the Preliminary Collaboration Agreement, the terms of the Definitive Collaboration Agreement will be determined through mediation and binding arbitration. The Preliminary Collaboration Agreement may be terminated by either party if the conditions for the effectiveness of the Preliminary Collaboration Agreement

(customary closing conditions, including the expiration or termination of the applicable waiting period under the HSR Act, as defined below) are not met by June 30, 2021. The Preliminary Collaboration will terminate upon the execution of the Definitive Collaboration Agreement, which will supersede the Preliminary Collaboration Agreement. The Definitive Collaboration Agreement will remain in effect, on a collaboration program-by-collaboration program basis, until there is no product being developed or commercialized under such collaboration program, unless earlier terminated by either party. Either party has the right to terminate the Preliminary Collaboration Agreement or the Definitive Collaboration Agreement in the case of the insolvency of the other party, an uncured material breach of the other party, or such other events that both parties agree to be included in the Definitive Collaboration Agreement.

GSK will make an upfront payment to the Company of \$225 million, 50% of which will become payable at the effective date of the Preliminary Collaboration Agreement and 50% of which will become payable at the effective date of the Definitive Collaboration Agreement. If GSK exercises the Option, GSK will pay the Company an Option exercise fee of \$300 million unless certain agreed product criteria for VIR-2482 are not met, in which case the parties will negotiate an alternative Option exercise fee. If the parties are unable to agree on an alternative Option exercise fee, then subject to certain rights of GSK, the Company will have the right to continue the development and commercialization of VIR-2482 by itself or with a third party. Upon achievement of a pre-defined regulatory milestone for the first product arising from the Influenza Program, GSK will make a milestone payment to the Company of up to \$200 million.

Stock Purchase Agreement

Concurrently with the execution of the Preliminary Collaboration Agreement on February 14, 2021, the Company entered into a stock purchase agreement (the “Stock Purchase Agreement”) with Glaxo Group Limited (“GGL”), an affiliate of GSK, pursuant to which GGL will purchase shares of the Company’s common stock (the “Shares”) for an aggregate purchase price of approximately \$120.0 million. The price per Share will be equal to the average of (a) the volume weighted average price of a share of the Company’s common stock for a seven trading day period, starting with the opening of trading on the seventh trading day prior to the date of the Stock Purchase Agreement and ending with the close of trading on the trading day prior to the date of the Stock Purchase Agreement and (b) the volume weighted average price of a share of the Company’s common stock for a seven trading day period, starting with the opening of trading on the seventh trading day prior to the Data End Date and ending with the close of trading on the trading day prior the Data End Date, subject to certain price collar adjustments. The “Data End Date” means the tenth trading day immediately following the date that the Company makes a public announcement regarding initial Phase 3 results for the COMET-ICE (COVID-19 Monoclonal antibody Efficacy Trial—Intent to Care Early) trial for VIR-7831.

Pursuant to the terms of the Stock Purchase Agreement, GGL has agreed not to, without the Company’s prior written consent and subject to certain conditions and exceptions, among other things, directly or indirectly acquire additional shares of the Company’s outstanding common stock, seek or propose a tender or exchange offer, merger or other business combination involving the Company, solicit proxies or consents with respect to any matter, or undertake other specified actions related to the potential acquisition of additional equity interests in the Company (collectively, the “Standstill Restrictions”). The Standstill Restrictions will expire on the one-year anniversary of the Equity Closing Date (as defined below).

The Stock Purchase Agreement also provides that until the first anniversary of the Equity Closing Date, GGL will hold and not sell any of the Shares, subject to certain exceptions. The Company has 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 (the “Securities Act”), is not available for such resale without any volume or manner of sale restrictions.

The consummation of the transactions under each of the Preliminary Collaboration Agreement and the Stock Purchase Agreement are 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 (the “HSR Act”); provided, however, that in no event will the closing of the transactions under the Stock Purchase Agreement occur prior to the Data End Date (such closing, the “Equity Closing Date”).

The foregoing is only a brief description of the material terms of the Preliminary Collaboration Agreement and the Stock Purchase Agreement, does not purport to be a complete statement of the rights and obligations of the parties under these agreements and the transactions contemplated thereby, and is qualified in its entirety by the full text of such agreements, copies of which will be filed as exhibits to a subsequent filing with the Securities and Exchange Commission.

On February 17, 2021, the Company and GSK issued a joint press release announcing the transactions described above. A copy of the press release is attached to this report as Exhibit 99.1.

Item 3.02. Unregistered Sales of Equity Securities

See the description set forth under Item 1.01 above with respect to the Stock Purchase Agreement, which is incorporated into this Item 3.02 by reference. The Shares are being offered and sold to GGL pursuant to the exemption from the registration requirements provided in Section 4(a)(2) of the Securities Act for transactions by an issuer not involving any public offering. Accordingly, the Shares have not been registered under the Securities Act and may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act.

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 collaboration with GSK, the completion of the Definitive Collaboration Agreement, the total potential deal value of the collaboration, the ability to obtain clearance under the HSR Act and to satisfy the other closing conditions, the potential benefits of VIR-2482, and the Company’s ability to address influenza, respiratory diseases, coronaviruses, including the current COVID-19 pandemic, and future outbreaks of any such diseases. 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 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. 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

Exhibit No.	Description
99.1	<u>Joint Press Release of the Company and GSK, dated February 17, 2021.</u>

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: February 19, 2021

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



GSK and Vir Biotechnology Expand Coronavirus Collaboration to Advance New Therapeutics for Influenza and Other Respiratory Viruses

February 17, 2021

- Companies applying their combined expertise in immunology and infectious diseases to accelerate the development of promising monoclonal antibody candidates for influenza –
- Functional genomics collaboration expanded to include respiratory viruses, Vir’s unique technology, and access to GSK’s small molecule compounds –
- Additional exploration of up to three other antibodies for pathogens beyond influenza and coronaviruses –
- GSK is increasing its equity investment by \$120 million and making an upfront payment of \$225 million –

LONDON and SAN FRANCISCO, Feb. 17, 2021 (GLOBE NEWSWIRE) – GlaxoSmithKline plc (LSE/NYSE: GSK) and Vir Biotechnology, Inc. (Nasdaq: VIR) today announced they have signed a binding agreement to expand their existing collaboration to include the research and development of new therapies for influenza and other respiratory viruses.

The expanded collaboration, which builds on the agreement signed in 2020 to research and develop therapies for coronaviruses, provides GSK exclusive rights to collaborate with Vir on the development of potential best-in-class monoclonal antibodies (mAbs) for the prevention or treatment of influenza. These include VIR-2482, an intramuscularly administered investigational mAb designed as a universal prophylactic for influenza A that has completed a Phase 1 trial, as well as next-generation antibodies for the prevention or treatment of influenza during a three-year research period. GSK will have the exclusive option to co-develop VIR-2482 after Vir completes and reports Phase 2 trial outcomes, and will share development costs on the development of all other influenza mAbs.

Influenza causes up to 500,000 hospitalizations and 34,000 deaths each year in the United States alone,¹ approximately 75% of which are caused by influenza A.² The protection provided by current vaccines varies from season to season, based on the virus strains circulating. People over 65 years of age with at least one comorbidity, such as cardiovascular disease, diabetes or who are immunocompromised, are at significantly increased risk of flu and flu-related hospitalization and mortality. This is also a population where the currently available vaccines have historically had lower efficacy.

As part of the new collaboration agreement, the companies will also engage in two additional research programs. The first is an expansion of their current functional genomics collaboration to develop potential pan-coronavirus therapeutics to now include other respiratory virus targets. Under the second program, the companies will collaborate to develop up to three neutralizing monoclonal antibodies identified using Vir’s antibody technology platform to target non-influenza pathogens during a three-year research period.

Dr. Hal Barron, Chief Scientific Officer and President R&D, GSK, said: “We believe, now more than ever, that it is very important to develop new therapies to treat and ideally prevent infectious diseases. I am delighted that we are expanding our collaboration with Vir whose focus on novel antibodies, expertise in functional genomics, unique technology and talented scientists will further strengthen GSK’s position as a world leader in infectious diseases.”

George Scangos, Ph.D., CEO, Vir Biotechnology, said: “GSK has been a valuable strategic partner and scientific collaborator in the fight against COVID-19. As part of our functional genomics collaboration directed at COVID-19, we have turned up multiple targets that have the potential to treat influenza and other respiratory viruses, and it makes sense to extend the scope of our collaboration to include these new targets. This expanded collaboration supports the rapid advancement of multiple promising investigational compounds in our pipeline, increasing the likelihood that these potential life-saving treatments will reach patients sooner, and will advance our shared goal of developing single drugs that can address multiple ‘bugs.’”

Under the terms of the agreement, GSK will make an upfront payment of \$225 million and a further equity investment in Vir of \$120 million. Initially, Vir will continue to fund the development of VIR-2482 through completion of Phase 2 trials, after which time, if GSK exercises its option to co-develop VIR-2482, it will pay an option fee of \$300 million. Following option exercise for VIR-2482, and for each other program in the expanded collaboration, the companies will share the development costs and related profits associated with this agreement. GSK will also pay Vir up to \$200 million based on the successful delivery of pre-defined regulatory milestones. The equity investment and collaboration agreement are conditional upon customary conditions including regulatory review by the appropriate regulatory agencies under the Hart-Scott-Rodino Act.

GSK and Vir entered into an initial strategic collaboration in April 2020 to research and develop solutions for coronaviruses, including SARS-CoV-2, the virus that causes COVID-19. The focus of the collaboration to date has been the development of specific antibody candidates identified by Vir’s monoclonal antibody platform, VIR-7831 and VIR-7832, that have demonstrated the potential to both block viral entry into healthy cells and clear infected cells, and to provide a high barrier to resistance. VIR-7831 is currently in two global Phase 3 studies as monotherapy and one Phase 2 study as combination therapy, with initial results from the first of the Phase 3 studies expected in the first quarter of 2021. VIR-7832 has been accepted into the NHS-supported AGILE Phase 1b/2a study with a planned start in February 2021.

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 SARS-CoV-2, hepatitis B virus, influenza A, Ebola (mAb114, approved for use in the U.S. as Ebanga™ and marketed by Ridgeback Therapeutics LP), malaria and others.

About VIR-2482

VIR-2482 is an investigational intramuscularly administered influenza A-neutralizing monoclonal antibody. In vitro, it has been shown to cover all major strains of influenza A that have arisen since the 1918 Spanish flu pandemic. VIR-2482 is designed as a universal prophylactic for influenza A. It has the potential to overcome the limitations of current flu vaccines and lead to meaningfully higher levels of protection due to its broad strain coverage and because it does not rely on an individual to create their own protective antibody response. VIR-2482 has been half-life engineered so that a single dose has the potential to last the entire flu season.

About VIR-7831 / GSK4182137

VIR-7831 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 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-7831 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 / GSK4182136

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 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. Importantly, VIR-7832 has also 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 are leveraging 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 are also applying their combined expertise to research SARS-CoV-2 and other coronavirus vaccines.

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.

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.

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 statements regarding the potential benefits of the collaboration with GSK, the completion of a definitive collaboration agreement, the total potential deal value of the collaboration, the ability to obtain clearance under the HSR Act and to satisfy the other closing conditions, the potential benefits of VIR-2482, and Vir's ability to address influenza, respiratory diseases, coronaviruses, including the current COVID-19 pandemic, and future outbreaks of any such diseases. 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 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.

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 under Item 3.D "Risk Factors" in the company's Annual Report on Form 20-F for 2019 and as set out in GSK's "Principal risks and uncertainties" section of the Q4 Results and any impacts of the COVID-19 pandemic.

Registered in England & Wales:

No. 3888792

Registered Office:

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TW8 9GS

- 1 2018-2019 flu season data from the Centers for Disease Control and Prevention.
- 2 Zhou et al. *Clinical Infectious Diseases*. 2012;54:1427-1436.

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Source: Vir Biotechnology, Inc.