

**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): September 28, 2022

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
(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 September 28, 2022, Vir Biotechnology, Inc. (the “Company”) entered into an Other Transaction Authority Agreement (the “BARDA Agreement”) with the Biomedical Advanced Research and Development Authority (“BARDA”), part of the U.S. Department of Health and Human Services’ Administration for Strategic Preparedness and Response, to help advance the Company’s development of a full portfolio of innovative solutions to address influenza and potentially other infectious disease threats. The BARDA Agreement provides for potential total investments by BARDA of up to \$1 billion. BARDA will invest approximately \$55 million initially over a base period, commencing in September 2022, and extending through January 2026, for the ongoing and rapid development of VIR-2482, an investigational prophylactic monoclonal antibody designed with the aim to protect against seasonal and pandemic influenza. The development of VIR-2482 under the BARDA Agreement will include a Phase 2 pre-exposure prophylaxis trial expected to begin in the second half of 2022 with initial data anticipated in mid-2023. The balance of the award is subject to BARDA exercising up to 12 options in further support of the development of pre-exposure prophylactic antibodies including and beyond VIR-2482 for the prevention of influenza illness or possibly supporting medical countermeasures for other pathogens of pandemic potential. The BARDA Agreement has an initial term that commences on September 30, 2022, and extends through January 31, 2026, which may be extended by mutual written agreement of the Company and BARDA if certain conditions are met or if BARDA exercises any of its options, as described above, and is terminable by BARDA at any time under specified circumstances, including for convenience. This program has been funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under OT number: 75A50122C00081.

On October 4, 2022, the Company issued a press release announcing that it had been awarded the BARDA Agreement. A copy of the press release is attached hereto as Exhibit 99.1.

Forward-Looking Statements

This Current Report on Form 8-K (this “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,” “expect,” “anticipate,” “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 Company’s strategy and plans, the potential benefits of VIR-2482 to protect against seasonal and pandemic influenza, the timing and design for VIR-2482’s Phase 2 clinical trial, including anticipated timing of data readouts, statements regarding the Company’s scientific and executional expertise and the Company’s expectations related to the potential success of its current and future clinical development programs for influenza as well as other infectious diseases with future pandemic potential. Many factors may cause differences between current expectations and actual results, including uncertainty as to whether the anticipated benefits of the BARDA collaboration can be achieved; unexpected safety or efficacy data or results observed during clinical trials or in data readouts; clinical site activation rates or clinical trial enrollment rates that are lower than expected; 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. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated October 4, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)



Vir Biotechnology Awarded U.S. Government Contract to Support Pandemic Preparedness for Influenza and Other Infectious Disease Threats

– First award from the agency’s solicitation for contracts for Pre-Exposure Prophylaxis for Influenza –

– Initial investment of approximately \$55 million from Biomedical Advanced Research and Development Authority to support development of VIR-2482, an investigational prophylactic monoclonal antibody for seasonal and pandemic influenza viruses –

– Multi-year contract also allows for potential total investment of up to \$1 billion in the development of influenza and other emerging infectious disease or medical countermeasure candidates –

SAN FRANCISCO, October 4, 2022 – Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services’ (HHS) Administration for Strategic Preparedness and Response (ASPR), has awarded Vir a multi-year contract with the potential for up to \$1 billion to advance the development of a full portfolio of innovative solutions to address influenza and potentially other infectious disease threats.

As part of BARDA’s ongoing effort to prepare and respond to public health emergencies, the agency will invest approximately \$55 million initially for the ongoing and rapid development of VIR-2482, an investigational prophylactic monoclonal antibody (mAb) designed to protect against seasonal and pandemic influenza. This includes a Phase 2 pre-exposure prophylaxis trial expected to begin in the second half of 2022 with initial data anticipated in mid-2023. The balance of the award is subject to BARDA exercising up to 12 options in further support of the development of pre-exposure prophylactic antibodies including and beyond VIR-2482 for the prevention of influenza illness or possibly supporting medical countermeasures for other pathogens of pandemic potential.

“COVID-19 reinforced the ever-present global threat of infectious diseases, and the critical need for readily available solutions in advance of the next pandemic,” said Rajesh Gupta, M.D., M.S., M.P.H., vice president, global health portfolio and public-private partnerships at Vir Biotechnology. “We are proud to have contributed to the fight against COVID-19 with the delivery of sotrovimab, and to have helped address Ebola with the co-discovery of ansuvimab-zykl. We now look forward to applying our scientific and executional expertise to this BARDA collaboration focused on advancing innovative solutions to influenza, as well as other infectious diseases with future pandemic potential.”

“Just as the COVID-19 pandemic required unprecedented cross-sector collaboration around the globe, tackling the outbreaks and pandemics of tomorrow will require an ‘all hands on deck’ approach that unites a broad array of public and private organizations,” said Bolyn Hubby, Ph.D., executive vice president and chief corporate affairs officer at Vir Biotechnology. “Today’s announcement represents the culmination of our ongoing dialogue with the U.S. government around our shared interest in protecting society from global infectious disease threats, and we are thrilled to embark on this broad, multi-year collaboration.”

The BARDA agreement also outlines potential support for Vir's clinical development of additional future pandemic influenza mAbs, as well as the potential development of up to 10 emerging infectious disease or Chemical, Biological, Radiological, and Nuclear medical countermeasure candidates.

The agreement between Vir and BARDA was made under Other Transaction Authority, which allows flexible, strategic collaboration between the government and industry to foster innovation and promote collaboration.

This program has been funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under OT number: 75A50122C00081.

About Seasonal and Pandemic Influenza

Seasonal influenza is a highly contagious respiratory disease that can cause severe illness and life-threatening complications. It varies from season to season, but in past years, seasonal influenza has led to approximately 4 million hospitalizations, and about 500,000 deaths a year worldwide with approximately 500,000 hospitalizations and 34,000 deaths in the U.S. alone. There remains a significant unmet need to address the shortcomings of current preventative and therapeutic options, which provide efficacy ranging from 10-60%.

Pandemic influenza is a contagious airborne respiratory disease, which is unpredictable in timing and severity and for which humans have little or no immunity. Four influenza pandemics have occurred over the past century, with the most severe being the 1918 "Spanish flu", which is estimated to have caused up to 50 million deaths worldwide.

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, which incorporates Xencor's Xtend™ Technology, also has been half-life engineered so a single dose has the potential to last the entire flu season. Under the collaboration agreement signed with GlaxoSmithKline (GSK) in 2021, GSK has an exclusive option to lead post-Phase 2 development and commercialization of VIR-2482.

About Vir Biotechnology

Vir Biotechnology is a commercial-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 and hepatitis D viruses, influenza A and human immunodeficiency virus. Vir routinely posts information that may be important to investors on its website.

Forward-Looking Statements

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