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)

November 10, 2020

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 2.02 Results of Operations and Financial Condition.

On November 10, 2020, Vir Biotechnology, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2020. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02, including the attached Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company, dated November 10, 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.

Date: November 10, 2020

By: /s/ Howard Horn

Howard Horn
Chief Financial Officer

Vir Biotechnology Provides Corporate Update and Reports Third Quarter 2020 Financial Results

SAN FRANCISCO, November 10, 2020 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR), a clinical-stage immunology company focused on treating and preventing serious infectious diseases, today provided a corporate update and reported financial results for the third quarter ended September 30, 2020.

“I am proud of the Vir team’s effort and success in accelerating our lead SARS-CoV-2 product candidate, VIR-7831, into a global Phase 3 trial, particularly in light of the more than 141,000 new COVID-19 infections recently reported in a single day in the U.S.,” said George Scangos, Ph.D., chief executive officer of Vir. “We expect to share initial results from the trial as early as January and look forward to advancing VIR-7831 into new patient populations alongside the initiation of a Phase 1b/2a trial for our second investigational SARS-CoV-2 neutralizing antibody, VIR-7832. Simultaneously, we continue to advance our broader portfolio of product candidates for chronic hepatitis B, influenza A and HIV, as we seek to address some of the world’s most challenging infectious diseases.”

Corporate Update

SARS-CoV-2 Updates

- In August, the Company initiated COMET-ICE (COVID-19 Monoclonal antibody Efficacy Trial - Intent to Care Early), a Phase 2/3 clinical trial evaluating VIR-7831, a potent SARS-CoV-2 neutralizing monoclonal antibody, for the early treatment of COVID-19 in patients who are at high risk of hospitalization.
- In September, an Independent Data Monitoring Committee recommended the global expansion into Phase 3 of the COMET-ICE trial based on a positive evaluation of safety and tolerability data from the Phase 2 lead-in. Global Phase 3 enrollment is ongoing and interim data may be available as early as January 2021. Results for the primary endpoint are expected in the first quarter of 2021.
- In connection with the advancement of its SARS-CoV-2 programs, the Company has established a strategic manufacturing network, which will enable the supply of millions of doses to patients the first year following approval, depending on titer and yield.

- The Company plans to initiate two additional Phase 3 trials in the COMET clinical development program for VIR-7831:
    - A trial for the treatment of hospitalized adults with COVID-19 is planned as a sub-study of the National Institutes of Health-sponsored ACTIV-3 trial and is expected to begin as soon as regulatory and ethical approvals are in place.
    - A trial for prophylaxis or prevention of symptomatic infection is expected to begin in the first quarter of 2021.
- The Company is also preparing to advance its second investigational SARS-CoV-2 neutralizing antibody into a Phase 1b/2a trial in the first quarter of 2021. VIR-7832 shares the same characteristics as VIR-7831, plus enhanced effector function, which may confer additional efficacy in treatment or prophylaxis by stimulating a T cell response.
- Pre-clinical studies for VIR-2703, an inhaled SARS-CoV-2-targeting small interfering ribonucleic acid (siRNA), are being led by Alnylam Pharmaceuticals, Inc. Alnylam is working to obtain additional efficacy data prior to further program advancement.

Additional Pipeline Updates

- In July, the Company initiated a Phase 2 combination trial of VIR-2218, an HBV-targeting siRNA, with pegylated interferon-alpha (PEG-IFN-α), evaluating the potential for this cocktail to result in functional cure of HBV-infected patients. Initial clinical data are anticipated in 2021.
- The Company also plans to evaluate VIR-2218 in combination with VIR-3434, an HBV-neutralizing monoclonal antibody with the potential to be a therapeutic T cell vaccine. VIR-3434 is currently being evaluated in a Phase 1 trial, the results of which are expected to enable the Company to initiate a Phase 2 combination trial of VIR-3434 in combination with VIR-2218 in 2021.
- In October, the Company presented data from its influenza A research program virtually at the Infectious Disease Society of America IDWeek 2020. Company presentations included two poster presentations on VIR-2482, an influenza A-neutralizing monoclonal antibody, and one oral presentation highlighting the severe economic and clinical burden of influenza A on elderly patients with underlying conditions in the United States. Initiation of the Phase 2 trial for VIR-2482, which was delayed due to the impact of COVID-19, is now expected in the fourth quarter of 2021 with proof-of-concept results anticipated in the first half of 2022.
- The Company expects to initiate a Phase 1 clinical trial for VIR-1111, an HIV T cell vaccine based on human cytomegalovirus, in the fourth quarter of this year. This trial is designed to determine whether VIR-1111 elicits a specific type of T cell immune response to HIV, known as an HLA-E restricted immune response.

Publications
During and following the third quarter, five manuscripts were published related to the Company's efforts to address SARS-CoV-2 and other conditions that may benefit from treatment with monoclonal antibodies.

In September:

- *Science* published "Ultrapotent human antibodies protect against SARS-CoV-2 challenge via multiple mechanisms" (Tortorici, et al.), discussing the neutralizing abilities of two ultrapotent SARS-CoV-2 antibodies (S2E12 and S2M11) in clinical models.
- *Cell* published "Mapping Neutralizing and immunodominant sites on the SARS-CoV-2 spike receptor-binding domain by structure-guided high-resolution serology" (Piccoli, et al.), characterizing differences in both the binding properties and kinetics of neutralizing antibody responses to SARS-CoV-2.
- *EMBO Molecular Medicine* published "A combination of two human monoclonal antibodies cures symptomatic rabies" (de Melo, et al.), outlining proof-of-concept data for an antibody-based therapeutic approach for the treatment of symptomatic rabies.

In October:

- *Nature* published "Fc-optimized antibodies elicit CD8 immunity to viral respiratory infection" (Bournazos, et al.), detailing results from research in an influenza clinical model highlighting a new mechanism for enhancing the efficacy of monoclonal antibodies to treat viral infection and induce a protective response.

In November:

- bioRxiv published "The circulating SARS-CoV-2 spike variant N439K maintains fitness while evading antibody-mediated immunity" (Thomson, et al.), characterizing variation in the SARS-CoV-2 spoke protein and virulence of a prevalent immune evasion variant, N439K.

New Board Appointment

- In September, the Company announced the appointment of Janet Napolitano to the Board of Directors. Ms. Napolitano formerly served as the Governor of Arizona, the U.S. Secretary of Homeland Security under President Barack Obama, and most recently as the President of the University of California for the past seven years. Her appointment follows the July addition of Elliott Sigal, M.D., Ph.D., to the Board.

Third Quarter 2020 Financial Results

- **Revenues:** Total revenues for the quarter ended September 30, 2020 were $1.9 million, compared to $1.4 million for the same period in 2019. The increase for the quarter was primarily due to the timing of research activities under the HIV and TB grants with the Bill & Melinda Gates Foundation.

- **Research and Development Expenses:** Research and development expenses were $70.7 million for the quarter ended September 30, 2020, which includes $4.2 million of non-cash stock-based compensation expense, compared to $39.9 million for the same period in 2019, which included $0.9 million of non-cash stock-based compensation expense. The increase for the quarter was primarily due to contract manufacturing expenses for our SARS-CoV-2 programs, higher fair value of our contingent consideration due to achievement of clinical development milestones, personnel-related expenses due to additional headcount, and clinical costs due to activities related to VIR-7831, VIR-3434 and VIR-1111.
- **General and Administrative Expenses:** General and administrative expenses were $18.9 million for the quarter ended September 30, 2020, which includes $4.4 million of non-cash stock-based compensation expense, compared to $9.2 million for the same period in 2019, which includes $1.3 million of non-cash stock-based compensation expense. The increase for the quarter was primarily due to personnel-related expenses attributable to additional headcount, legal fees, external consulting and other expenses due to costs associated with operating as a public company.
- **Net Loss:** Net loss for the quarter ended September 30, 2020 was $84.6 million, or $0.67 per share, basic and diluted, compared to a net loss of $48.3 million, or $4.60 per share, basic and diluted, for the same period in 2019.
- **Cash and Cash Equivalents:** As of September 30, 2020, excluding restricted cash, the Company had approximately $826.6 million in cash, cash equivalents and investments.

About VIR-7831
VIR-7831 is a monoclonal antibody that has shown the ability to neutralize SARS-CoV-2 live virus in vitro and in vivo. 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 resistance to develop. VIR-7831 has been engineered with the potential to enhance lung bioavailability and have an extended half-life.

About VIR-7832
VIR-7832 is a monoclonal antibody that has shown 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 with the potential to enhance lung bioavailability, have an extended half-life, and function as a therapeutic and/or prophylactic T cell vaccine.

About VIR-2703
VIR-2703 is an inhaled SARS-CoV-2-targeting siRNA that has demonstrated the ability to significantly reduce SARS-CoV-2 live virus replication in vitro. VIR-2703 is designed to degrade the viral genome, leading to inhibition of viral protein synthesis and blocking the production of infectious virus. It targets a nucleic acid sequence in the SARS-CoV-2 genome that is highly conserved amongst currently available viral sequences and is also conserved in SARS-CoV-1 (also known as SARS). VIR-2703 leverages Alnylam Pharmaceuticals, Inc.'s latest advances in lung delivery of siRNAs.

About VIR-2218
VIR-2218 is a subcutaneously administered HBV-targeting siRNA that has the potential to stimulate an effective immune response and have direct antiviral activity against HBV. It is the first siRNA in the clinic to include Enhanced Stabilization Chemistry Plus (ESC+) technology to enhance stability and minimize off-target activity, which potentially can result in an increased therapeutic index. VIR-2218 is the first asset in the company's collaboration with Alnylam Pharmaceuticals, Inc. to enter clinical trials.

About VIR-3434
VIR-3434 is a subcutaneously administered HBV-neutralizing monoclonal antibody designed to block entry of all 10 genotypes of HBV into hepatocytes and also to reduce the level of virions and subviral particles in the blood. VIR-3434 has been engineered to have an extended half-life as well as to potentially function as a T cell vaccine against HBV in infected patients.

About VIR-2482
VIR-2482 is an 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, which is typically five to six months long.

About VIR-1111
VIR-1111 is a subcutaneously administered HIV T cell vaccine based on HCMV that has been designed to elicit T cells that recognize HIV epitopes that are different from those recognized by prior HIV vaccines and to stimulate a different and specific type of T cell immune response to HIV, known as an HLA-E restricted immune response.

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 SARS-CoV-2, hepatitis B virus, influenza A, 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,” “expect,” “plan,” “aim,” “anticipate,” “estimate,” “intend,” “potential,” “prepare” 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 timing of commencement of clinical trials and completion of preclinical studies, the timing of availability of clinical data, the evaluation criteria, designs, program updates and data disclosures related to Vir’s clinical trials, the ability of VIR-7831, VIR-7832, and VIR-2703 to treat and/or prevent COVID-19 and other diseases caused by the SARS-CoV-2 virus, the clinical efficacy of VIR-7831 and VIR-7832, the capacity to manufacture, develop and commercialize a product candidate to treat COVID-19, the timing of availability and expected number of therapeutic doses, the ability to address the current global COVID-19 pandemic and future outbreaks of diseases caused by coronaviruses, the potential for the combination of VIR-2218 and PEG-IFN-α to result in the functional cure of HBV, the ability of VIR-3434 to neutralize and treat HBV, the ability of VIR-2482 to provide broad strain coverage for the flu, and the ability of VIR-1111 to elicit a T cell immune response to HIV. Many factors may cause differences between current expectations and actual results, including delays or failures in planned patient enrollment or retention, clinical site activation rates or clinical trial enrollment rates that are lower than expected, unexpected safety or efficacy data observed during preclinical or clinical studies, challenges in neutralizing SARS-CoV-2, other coronaviruses and HBV, 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 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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Vir Biotechnology, Inc.
Condensed Consolidated Statements of Operations
(unaudited; in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Grant revenue	$ 1,740	$ 1,166	$ 7,690	$ 6,771
License revenue from a related party	—	—	22,747	—
Contract revenue	188	237	44,197	340
Total revenue	1,928	1,403	74,634	7,111
Operating expenses:				
Research and development	70,684	39,863	215,316	95,541
General and administrative	18,859	9,220	47,894	25,790
Total operating expenses	89,543	49,083	263,210	121,331
Loss from operations	(87,615)	(47,680)	(188,576)	(114,220)
Other income (expense):				
Interest income	412	2,012	2,548	6,564
Other income (expense), net	2,616	(2,659)	(6,904)	(3,251)
Total other income (expense)	3,028	(647)	(4,356)	3,313
Loss before benefit from (provision for) income taxes	(84,587)	(48,327)	(192,932)	(110,907)
Benefit from (provision for) income taxes	(22)	13	(84)	(5)
Net loss	$ (84,609)	$ (48,314)	$ (193,016)	$ (110,912)
Net loss per share, basic and diluted	$ (0.67)	$ (4.60)	$ (1.66)	$ (11.53)
Weighted-average shares outstanding, basic and diluted	125,810,907	10,500,848	116,427,529	9,615,379

Vir Biotechnology, Inc.
Condensed Consolidated Balance Sheets
(unaudited; in thousands, except share and per share data)

	September 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 462,521	$ 109,335
Short-term investments	364,074	274,101
Restricted cash and cash equivalents, current	9,363	6,181
Prepaid expenses and other current assets	13,614	13,378
Total current assets	849,572	402,995
Intangible assets, net	33,944	35,694
Goodwill	16,937	16,937
Property and equipment, net	16,948	16,308
Operating right-of-use assets	14,762	—
Restricted cash and cash equivalents, noncurrent	1,201	7,300
Long-term investments	—	24,290
Other assets	9,895	8,547
TOTAL ASSETS	$ 943,259	$ 512,071
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 6,796	$ 5,881
Accrued and other liabilities	44,339	26,495
Deferred revenue, current portion	5,563	6,181
Contingent consideration, current portion	20,300	8,200
Derivative liability	—	12,449
Total current liabilities	76,998	59,206
Deferred revenue, noncurrent	3,815	12,670
Operating lease liabilities, noncurrent	12,092	—
Contingent consideration, noncurrent	31,712	9,380
Deferred tax liability	3,305	3,305
Other long-term liabilities	2,982	3,568
TOTAL LIABILITIES	130,904	88,129
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2020 and December 31, 2019; no shares issued and outstanding as of September 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 126,991,631 and 107,648,925 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	13	11
Additional paid-in capital	1,374,362	793,051
Accumulated other comprehensive loss	(485)	(601)
Accumulated deficit	(561,535)	(368,519)
TOTAL STOCKHOLDERS' EQUITY	812,355	423,942
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 943,259	$ 512,071