



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

May 12, 2020

SAN FRANCISCO, May 12, 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 first quarter ended March 31, 2020.

"Since early January, we have moved rapidly to address what is likely the greatest global health challenge of our lifetime," said George Scangos, Ph.D., Chief Executive Officer of Vir. "Our immunologic approach to infectious disease, the technologies that we have assembled since our creation, and our exceptional people have put us in the privileged position to quickly formulate and begin executing a cohesive strategy to bring forward – together with our collaborators – multiple potential solutions to COVID-19. We are aggressively advancing these efforts, while maintaining sharp focus on our ongoing programs in hepatitis B, influenza A, and HIV."

Corporate Updates

SARS-CoV-2

- In March, the company announced that VIR-7831 and VIR-7832, monoclonal antibodies that have demonstrated the ability to neutralize SARS-CoV-2 live virus, are planned to proceed directly into a Phase 2 trial this summer pending regulatory review.
- During and following the quarter, the company entered into multiple manufacturing agreements for the production of clinical and commercial antibodies for its SARS-CoV-2 program, including:
 - A development and clinical manufacturing collaboration with WuXi Biologics (stock code: 2269.HK) in February;
 - A letter of intent for development and clinical manufacturing with Biogen, Inc. (Nasdaq: BIIB) in March; and
 - A binding agreement with Samsung Biologics Co., Ltd. (207940.KS) in April to perform large-scale manufacturing services, with a definitive agreement to be executed before July 31, 2020.
- In April, the company, GlaxoSmithKline Intellectual Property Development Limited and GlaxoSmithKline Biologicals SA (together, "GSK") signed a binding preliminary collaboration agreement to research, develop and commercialize solutions for coronaviruses, including SARS-CoV-2. The collaboration aims to accelerate the development of VIR-7831 and VIR-7832 and to identify new anti-viral antibodies that could be used as therapeutic or preventative options to help address the current COVID-19 pandemic and future outbreaks. The companies will also leverage their expertise in functional genomics and CRISPR screening to identify anti-coronavirus compounds that target cellular host genes. In addition, they will apply their combined expertise to research SARS-CoV-2 and other coronavirus vaccines. On April 22, the U.S. Federal Trade Commission granted early termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. On April 29, the company completed the sale of 6,626,027 shares of the company's common stock to Glaxo Group Limited at a price per share of \$37.73, for an aggregate purchase price of \$250.0 million. The company and GSK are continuing to negotiate the terms of a definitive collaboration agreement, which will supersede the preliminary collaboration agreement once executed.
- In May, the company and Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY) announced the selection of an RNA interference (RNAi) development candidate targeting the SARS-CoV-2 genome, VIR-2703. The companies plan to file an Investigational New Drug (IND) or IND equivalent application at or around year-end 2020 and plan to advance VIR-2703 as an inhalational formulation for the potential treatment and/or prevention of COVID-19. Previously, in March and April, the parties expanded their existing 2017 collaboration to include the development and commercialization of up to four additional RNAi therapeutics for infectious diseases, including one targeting SARS-CoV-2 and potentially other coronaviruses, and three targeting host factors for SARS-CoV-2 and potentially other coronaviruses, bringing the total number of infectious disease targets in the collaboration to nine.
- In March, the company entered into a research collaboration agreement with the National Institutes of Health (NIH) and the National Institute of Allergy and Infectious Diseases (NIAID), Vaccine Research Center (VRC) to advance characterization and development of antibodies against coronaviruses, including SARS-CoV-2.
- In March, the company and Generation Bio Co. entered into a collaborative research agreement to explore the potential for Generation Bio's non-viral gene therapy platform to extend the impact and reach of Vir's current or future human

monoclonal antibodies against SARS-CoV-2.

Hepatitis B virus (HBV)

- In April, the company announced that VIR-2218, a HBV-targeting small interfering ribonucleic acid (siRNA), demonstrated in a Phase 2 trial substantial, dose dependent reductions in hepatitis B surface antigen (HBsAg) in patients at doses ranging from 20 mg to 200 mg, which are durable at the higher doses for at least 6 months. Similar HBsAg reductions were observed in both HBeAg- and HBeAg+ patients. In addition, VIR-2218 was generally well tolerated, with the majority of treatment emergent adverse events (AEs) reported as mild in severity, and no clinically significant alanine transaminase (ALT) elevations observed. Based on these data, and as previously announced, the company anticipates starting a Phase 2 combination trial of VIR-2218 and pegylated interferon-alpha, or PEG-IFN-a, in the second half of 2020.
- As previously announced, the company anticipates VIR-3434, an HBV-neutralizing monoclonal antibody with the potential to also be a therapeutic vaccine, to start a Phase 1 clinical trial in the second half of 2020.

Influenza A and human immunodeficiency virus (HIV)

- As previously announced, the company anticipates:
 - VIR-2482, a monoclonal antibody being developed as universal prophylaxis for influenza A, to start a Phase 2 clinical trial in the northern hemisphere in the fourth quarter of 2020. Data from the first flu season (northern hemisphere) of the Phase 1/2 clinical trial are anticipated to be available in the first half of 2021, and from the second flu season (southern hemisphere) are anticipated to be available in the second half of 2021.
 - VIR-1111, an HIV T cell vaccine based on human cytomegalovirus (HCMV), to start a Phase 1 clinical trial in the second half of 2020.

First Quarter 2020 Financial Results

- **Revenues:** Total revenues for the quarter ended March 31, 2020 were \$5.7 million, compared to \$3.7 million for same period in 2019. The increase for the quarter was primarily due to an increase in grant revenue.
- **Research and Development Expenses:** Research and development expenses were \$65.0 million for the quarter ended March 31, 2020, which includes \$1.5 million of non-cash stock-based compensation expense, compared to \$25.9 million for the same period in 2019, which includes \$0.4 million of non-cash stock-based compensation expense. The increase for the quarter was primarily due to an increase in collaboration expenses, personnel, and ongoing clinical expenses relating to VIR-2482 and VIR-3434.
- **General and Administrative Expenses:** General and administrative expenses were \$12.6 million for the quarter ended March 31, 2020, which includes \$1.5 million of non-cash stock-based compensation expense, compared to \$8.6 million for the same period in 2019, which includes \$2.0 million of non-cash stock-based compensation expense. The increase for the quarter was primarily due to increases in personnel-related expenses related to additional headcount, other facility expenses due to additional office space, and other expenses due to costs associated with operating as a public company.
- **Net Loss:** Net loss for the quarter ended March 31, 2020 was \$77.2 million, or \$0.71 per share, basic and diluted, compared to a net loss of \$28.7 million, or \$3.19 per share, basic and diluted, for the same period in 2019.
- **Cash and Cash Equivalents:** As of March 31, 2020, excluding restricted cash, Vir had approximately \$361.8 million in cash, cash equivalents, and investments.

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-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

and is the first development candidate selected in the company's expanded collaboration with Alnylam for up to four RNAi therapeutics for SARS-CoV-2 and potentially other coronaviruses.

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 prophylaxis 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 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," "expect," "plan," "anticipate," "estimate," "intend," "potential," "to be" 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, program updates and data disclosures for the company's clinical trials, the ability of VIR-7831, VIR-7832, and VIR-2703 to treat and/or prevent the SARS-CoV-2 virus and/or COVID-19, the company's efforts to identify additional antibodies, the timing and capacity to manufacture a product candidate to treat COVID-19, the potential benefits of the company's collaborations and partnerships with Wuxi Biologics, Biogen, Samsung Biologics, GSK, Alnylam Pharmaceuticals, NIH and NIAID, VRC and Generation Bio, the company's ability to enter into an agreement with Biogen, a definitive collaboration agreement with GSK, and a definitive agreement with Samsung Biologics, as well as the company's ability to address the COVID-19 pandemic. 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 neutralizing SARS-CoV-2, difficulty in collaborating with other companies or government agencies, challenges in accessing manufacturing capacity, clinical site activation rates or clinical trial enrollment rates that are lower than expected, changes in expected or existing competition, delays or disruptions on our 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 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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Condensed Consolidated Statements of Operations
(unaudited; in thousands, except share and per share data)

	Three Months Ended	
	March 31,	
	2020	2019
Revenues:		
Grant revenue	\$ 5,231	\$ 3,644
Contract revenue	487	17
Total revenue	5,718	3,661
Operating expenses:		
Research and development	64,979	25,872
General and administrative	12,649	8,559
Total operating expenses	77,628	34,431
Loss from operations	(71,910)	(30,770)
Other income (expense):		
Interest income	1,755	2,245
Other income (expense), net	(7,069)	(145)
Total other income (expense)	(5,314)	2,100
Loss before provision for income taxes	(77,224)	(28,670)
Provision for income taxes	(16)	—
Net loss	\$ (77,240)	\$ (28,670)
Net loss per share, basic and diluted	\$ (0.71)	\$ (3.19)
Weighted-average shares outstanding, basic and diluted	108,387,913	9,001,158

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

	March 31,	December 31,
	2020	2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 168,418	\$ 109,335
Short-term investments	187,193	274,101
Restricted cash and cash equivalents, current	9,101	6,181
Prepaid expenses and other current assets	12,829	13,378
Total current assets	377,541	402,995
Intangible assets, net	35,388	35,694
Goodwill	16,937	16,937
Property and equipment, net	16,238	16,308
Operating right-of-use assets	16,007	—
Restricted cash and cash equivalents, noncurrent	1,192	7,300
Long-term investments	6,139	24,290
Other assets	7,672	8,547
TOTAL ASSETS	\$ 477,114	\$ 512,071
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 18,768	\$ 5,881
Accrued and other liabilities	21,918	26,495
Deferred revenue, current portion	5,010	6,181

Contingent consideration, current portion	10,700	8,200
Derivative liability	—	12,449
Total current liabilities	<u>56,396</u>	<u>59,206</u>
Deferred revenue, noncurrent	6,562	12,670
Operating lease liabilities, noncurrent	13,531	—
Contingent consideration, noncurrent	14,045	9,380
Deferred tax liability	3,305	3,305
Other long-term liabilities	2,942	3,568
TOTAL LIABILITIES	<u>96,781</u>	<u>88,129</u>
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized as of March 31, 2020 and December 31, 2019; no shares issued and outstanding as of March 31, 2020 and December 31, 2019	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized as of March 31, 2020 and December 31, 2019; 108,350,368 and 107,648,925 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	11	11
Additional paid-in capital	825,833	793,051
Accumulated other comprehensive income (loss)	248	(601)
Accumulated deficit	(445,759)	(368,519)
TOTAL STOCKHOLDERS' EQUITY	<u>380,333</u>	<u>423,942</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 477,114</u>	<u>\$ 512,071</u>



Source: Vir Biotechnology, Inc.