Vir Biotechnology Provides Corporate Update and Reports Fourth Quarter and Full Year 2019 Financial Results

March 26, 2020

SAN FRANCISCO, March 26, 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 fourth quarter and full year ended December 31, 2019.

“2019 was a very successful year of growth and progress for Vir, as we expanded our clinical and preclinical pipeline, built a robust research engine around our multiple platforms for fighting infectious disease, and completed an initial public offering,” said George Scangos, Ph.D., Chief Executive Officer of Vir. “In 2020, the value of our multi-platform approach has become evident as we rapidly execute our scientific strategy in pursuit of therapies for the COVID-19 pandemic, while simultaneously maintaining sharp focus on our ongoing programs in hepatitis B, influenza A, and HIV.”

Corporate Updates

- Yesterday, the company announced that it has identified multiple human monoclonal antibody development candidates that neutralize SARS-CoV-2, the virus responsible for COVID-19. Its lead development candidate was transferred at-risk to WuXi Biologics (stock code: 2269.HK) and Biogen Inc. (Nasdaq: BIIB) for manufacturing several weeks ago, and is anticipated to start human trials within 3-5 months. The ability of this antibody to neutralize the SARS-CoV-2 live virus has been confirmed in two separate laboratories. 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. The company believes that the conservation of this epitope will make it more difficult for escape mutants to develop. Vir is advancing two versions of its lead development candidate into clinical testing. Both versions will be half-life engineered in order to potentially extend the time they remain in the body. One will also be modified to potentially immunize against the virus at the same time it treats or prevents infection. This property is known as a vaccinal effect, meaning the antibody may elicit continued immune protection against the virus even after it is no longer present in the body.

- In February, the company announced a development and manufacturing collaboration with WuXi Biologics to advance and produce human monoclonal antibodies for the potential treatment of COVID-19. Under the terms of the agreement, the companies will work together on the clinical development, manufacturing, and commercialization of Vir’s proprietary antibodies. WuXi Biologics will conduct cell-line development, process and formulation development, and initial manufacturing for clinical development. If the antibodies receive regulatory approvals, WuXi Biologics has the right to commercialize therapies in Greater China and Vir has the right to commercialize therapies in all other markets worldwide.

- In March, the company announced that it signed a letter of intent with Biogen for the development and clinical manufacturing of human monoclonal antibodies for the potential treatment of COVID-19. Because of the urgency of the situation, the companies have begun work while a Clinical Development and Manufacturing Agreement is being negotiated. Subject to the completion of a definitive agreement, Biogen would continue cell line development, process development, and clinical manufacturing activities in order to advance the development of Vir’s proprietary antibodies.

- In March, the company and Alnylam Pharmaceuticals (Nasdaq: ALNY) announced an expansion of their existing collaboration to include the development and commercialization of RNA interference therapeutics targeting SARS-CoV-2. Under the agreement, the companies will bring forward one or more siRNAs to treat SARS-CoV-2 and potentially other coronaviruses. The collaboration will focus on development of siRNAs that Alnylam recently identified that target highly conserved regions of coronavirus RNAs. Alnylam has designed and synthesized over 350 siRNAs targeting all available SARS-CoV and SARS-CoV-2 genomes. Potent siRNA lead candidates will be further evaluated by scientists at Vir for in vitro and in vivo anti-viral activity, leading to the selection of a development candidate (DC). Vir will lead all development and commercialization of any selected DCs. At clinical proof of concept, Alnylam will have an option to share equally in the profits and losses associated with the development and commercialization of the coronavirus program. Alternatively, Alnylam may elect to earn development and commercialization milestones and royalties on net sales of products resulting from the collaboration in amounts agreed upon for the coronavirus program. This new program expands the companies’ existing licensing agreement announced in 2017 to now develop up to six novel siRNAs to treat infectious diseases.

- In March, the company announced 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. The joint project will augment ongoing efforts by both parties to identify antibodies that can be used to prevent or treat infection with existing and emerging viruses and help inform the development of vaccines. Under the terms of the agreement, Vir and NIAID will work together to identify and optimize combinations of antibodies against coronaviruses, including SARS-CoV-2, SARS and MERS, as well as antibodies that may be effective across additional types of coronaviruses. The two parties will exchange antibodies and other materials for testing in combination and individually and, by mutual agreement, will perform in vivo animal studies to analyze immune responses.

- VIR-2218, a hepatitis B virus (HBV)-targeting small interfering ribonucleic acid (siRNA) being developed for the functional cure of HBV, has completed Phase 1/2 dosing of all patient cohorts receiving 50 – 200 mg. To date, VIR-2218 has been generally well-tolerated in healthy volunteers given as a single dose up to 900 mg and in patients given as two doses of 20 mg, 50 mg, 100 mg or 200 mg each dose. The data also demonstrate 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. The company anticipates announcing additional details on this trial in the second quarter of 2020. In addition, 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.

- VIR-2482, a monoclonal antibody being developed as universal prophylaxis for influenza A, is in an ongoing Phase 1/2 clinical trial. All four dose cohorts (60 mg, 300 mg, 1200 mg, and 1800 mg) in healthy volunteers have completed enrollment. Due to the COVID-19 pandemic, the company now anticipates starting the Phase 2 clinical trial in the northern hemisphere in the fourth quarter of 2020, rather than in the southern hemisphere in the second quarter of 2020, as previously planned. Data from the first flu season (now in the 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 (now in the southern hemisphere) are anticipated to be available in the second half of 2021.

- VIR-3434, an HBV-neutralizing monoclonal antibody with the potential to also be a therapeutic vaccine, was planned to start a Phase 1 clinical trial in the first half of 2020. Due to the COVID-19 pandemic, however, the company now anticipates this trial to start in the second half of 2020.

- VIR-1111, a human immunodeficiency virus (HIV) T cell vaccine based on human cytomegalovirus (HCMV), was planned to start a Phase 1 clinical trial in the first half of 2020. Due to the COVID-19 pandemic, however, the company now anticipates this trial to start in the second half of 2020.

Fourth Quarter & Full Year 2019 Financial Results

- **Revenues:** Total revenues for the quarter ended December 31, 2019 were $1.0 million, compared to $3.1 million for same period in 2018. Total revenues for the year ended December 31, 2019 were $8.1 million, compared to $10.7 million for the same period in 2018. The decreases for the quarter and full year were primarily due to a decline in grant revenue.

- **Research and Development Expenses:** Research and development expenses were $52.9 million for the quarter ended December 31, 2019, which includes $1.1 million of non-cash stock-based compensation expense, compared to $22.0 million for the same period in 2018, which includes $0.3 million of non-cash stock-based compensation expense. For the year ended December 31, 2019, research and development expenses were $148.5 million, which includes $3.0 million of non-cash stock-based compensation expense, compared to $100.2 million for the same period in 2018, which includes $1.1 million of non-cash stock-based compensation expense. The increases for the quarter and full year were primarily due to an increase in personnel, ongoing clinical expenses relating to VIR-2218 and VIR-2482, and collaboration expenses.

- **General and Administrative Expenses:** General and administrative expenses were $11.8 million for the quarter ended December 31, 2019, which includes $1.6 million of non-cash stock-based compensation expense, compared to $7.9 million for the same period in 2018, which includes $0.6 million of non-cash stock-based compensation expense. For the year ended December 31, 2019, general and administrative expenses were $37.6 million, which includes $5.7 million of non-cash stock-based compensation expense, compared to $29.1 million for the same period in 2018, which includes $4.0 million of non-cash stock-based compensation expense. The increases for the quarter and full year were primarily due to an increase in personnel-related expenses related to additional headcount, as well as an increase in professional fees.

- **Net Loss:** Net loss for the quarter ended December 31, 2019 was $63.8 million, or $0.69 per share, basic, and $0.71 per share, diluted, compared to a net loss of $26.4 million, or $3.05 per share, basic and diluted, for the same period in 2018. For the year ended December 31, 2019, net loss was $174.7 million, or $5.76 per share, basic and diluted, compared to a net loss of $115.9 million, or $15.12 per share, basic and diluted, for the same period in 2018.

- **Cash and Cash Equivalents:** As of December 31, 2019, excluding restricted cash, Vir had approximately $407.7 million in cash, cash equivalents, and investments. For the year ended December 31, 2019, net cash used in operating activities and property and equipment purchases was $138.6 million. Based on current assumptions, the company expects to be able to fund its operating plan through at least the end of 2021.

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-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-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-1111

VIR-1111 is a subcutaneously administered HIV T cell vaccine based on human cytomegalovirus (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" 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 the company's antibodies to neutralize the SARS-CoV-2 virus, the company's efforts to identify additional antibodies, the timing of manufacturing a product candidate to treat COVID-19, the potential benefits of the company's collaborations with Wuxi Biologics, Biogen and Alnylam, including whether or not any DCs will be identified and selected and whether or not any DCs will be successfully developed and commercialized under the Alnylam collaboration, the company's ability to enter into an agreement with Biogen, and 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, challenges in identifying and selecting DCs, 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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Vir Biotechnology, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenue:				
Grant revenue	$ 609	$ 3,119	$ 7,380	$ 9,800
Contract revenue	371	7	711	868
Total revenue	980	3,126	8,091	10,668
Operating expenses:				
Research and development	52,932	21,973	148,472	100,229
General and administrative	11,807	7,949	37,598	29,131
Total operating expenses	64,739	29,922	186,070	129,360
Loss from operations	(63,759)	(26,796)	(177,979)	(118,692)
Other income (expense):				
Interest income	1,947	621	8,511	2,540
Other income (expense), net	(1,810)	(198)	(5,061)	(212)
Total other income (expense)	137	423	3,450	2,328
Loss before benefit from (provision for) income taxes	(63,622)	(26,373)	(174,529)	(116,364)
Benefit from (provision for) income taxes	(149)	(20)	(154)	480
Net loss	$ (63,771)	$ (26,393)	$ (174,683)	$ (115,884)
Net loss per share, basic	$ (0.69)	$ (3.05)	$ (5.76)	$ (15.12)
Net loss per share, diluted	$ (0.71)	$ (3.05)	$ (5.76)	$ (15.12)
Weighted-average shares outstanding, basic	91,871,498	8,653,054	30,349,920	7,666,463
Weighted-average shares outstanding, diluted	91,901,590	8,653,054	30,349,920	7,666,463

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

	December 31,	
	2019	**2018**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 109,335	$ 47,598
Short-term investments	274,101	50,845
Restricted cash and cash equivalents, current	6,181	10,761
Prepaid expenses and other current assets	13,378	8,579
Total current assets	402,995	117,783
Intangible assets, net	35,694	36,917
Goodwill	16,937	16,937
Property and equipment, net	16,308	12,290
Restricted cash and cash equivalents, noncurrent	7,300	1,003
Long-term investments	24,290	—
Other assets	8,547	6,666
TOTAL ASSETS	$ 512,071	$ 191,596
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 5,881	$ 6,473
Accrued liabilities	26,495	14,534
Deferred revenue, current	6,181	8,761
Advanced proceeds from preferred stock financing	—	10,140
Contingent consideration, current	8,200	—
Derivative liability	12,449	—

Total current liabilities	59,206	39,908
Deferred revenue, noncurrent	12,670	6,561
Convertible preferred stock warrant liability	—	1,024
Contingent consideration, noncurrent	9,380	9,250
Deferred tax liability	3,305	3,305
Other long-term liabilities	3,568	1,588
TOTAL LIABILITIES	88,129	61,636
Commitments and contingencies		
Convertible preferred stock, $0.0001 par value; zero and 421,450,000 shares authorized as of December 31, 2019 and 2018, respectively; zero and 69,910,520 shares issued and outstanding as of December 31, 2019 and 2018, respectively; aggregate liquidation preference of zero and $333,058 as of December 31, 2019 and 2018, respectively	—	309,137
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock, $0.0001 par value; 10,000,000 and zero shares authorized as of December 31, 2019 and 2018; no shares issued or outstanding as of December 31, 2019 and 2018	—	—
Common stock, $0.0001 par value; 300,000,000 and 558,350,000 shares authorized as of December 31, 2019 and 2018, respectively; 107,648,925, and 8,858,799 shares issued and outstanding as of December 31, 2019 and 2018, respectively	11	1
Additional paid-in capital	793,051	14,672
Accumulated other comprehensive loss	(601)	(14)
Accumulated deficit	(368,519)	(193,836)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	423,942	(179,177)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 512,071	$ 191,596

Source: Vir Biotechnology, Inc.