Vir Biotechnology Provides Corporate Update and Reports Fourth Quarter and Full Year 2020 Financial Results

February 25, 2021

SAN FRANCISCO, Feb. 25, 2021 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today provided a corporate update and reported financial results for the fourth quarter and full year ended December 31, 2020.

“Vir closed 2020 delivering strong progress across our entire development pipeline with six distinct molecules addressing four serious infectious diseases. Our momentum continues in 2021 with the signing of new collaborations designed to help speed the development of multiple promising candidates, as well as pending data from two Phase 3 studies evaluating our novel monoclonal antibody, VIR-7831, against COVID-19,” said George Scangos, Ph.D., chief executive officer of Vir Biotechnology. “Additionally, we are now evaluating an intramuscular formulation of VIR-7831, and expect the first trial evaluating VIR-7832, our second antibody aimed at COVID-19, to begin shortly. Vir’s strong execution is evident across our full portfolio, with the recent compelling initial data from our Phase 1 trial of VIR-3434 demonstrating a significant and rapid reduction in hepatitis B surface antigen, and the continued forward momentum of our influenza and HIV programs. We anticipate a transformational year ahead.”

Corporate Update

Expanded GSK Collaboration

- In February, the Company signed a binding agreement with Glaxo Wellcome UK Limited, a subsidiary of GlaxoSmithKline plc, 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 for the prevention or treatment of influenza. As part of the agreement, the companies will also engage in two additional research programs: 1) an expansion of the current functional genomics collaboration to include other respiratory virus targets; 2) the development of up to three neutralizing monoclonal antibodies identified using Vir's antibody technology platform to target non-influenza pathogens during a three-year research period. Under the terms of the agreement, GSK, through its subsidiaries, will make an upfront payment of $225 million and a further equity investment in Vir of $120 million. Vir will fund the development of VIR-2482 through completion of Phase 2 trials, after which time GSK may pay a fee of $300 million to exercise its option to co-develop VIR-2482. The companies will share the development costs and related profits associated with the development of all other programs in this expanded collaboration. GSK may also pay Vir up to $200 million based on the successful delivery of pre-defined regulatory milestones for the first product arising from the influenza program.

SARS-CoV-2 Updates

- In October, based on a positive evaluation of safety and tolerability data of VIR-7831 from the Phase 2 lead-in, the Company began enrolling patients in the global Phase 3 portion of COMET-ICE (COVID-19 Monoclonal antibody Efficacy Trial – Intent to Care Early). VIR-7831 is a dual-action SARS-CoV-2 monoclonal antibody that, among other attributes, 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 (the virus that causes COVID-19) 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. COMET-ICE is evaluating VIR-7831 for the early treatment of COVID-19 in adults at high risk of hospitalization or death. Primary endpoint results are expected in the first quarter of 2021. If positive, these data will be used to seek Emergency Use Authorization and, ultimately, approval through the submission of a Biologics License Application.
- In December, the Company announced the initiation of the National Institutes of Health (NIH)-sponsored ACTIV-3 Phase 3 trial evaluating VIR-7831 for the treatment of hospitalized adults with COVID-19. An evaluation of the benefit/risk profile of VIR-7831 in this challenging patient population is expected in the first quarter of 2021 and will determine whether VIR-7831 continues in the next part of the ACTIV-3 trial.
- In January, the Company announced an agreement with the National Health Service-supported AGILE initiative to evaluate VIR-7832 in a Phase 1b/2a trial of adults with mild to moderate COVID-19. VIR-7832 shares the same characteristics as VIR-7831 but has also been engineered to potentially be a therapeutic T cell vaccine to further help treat and/or prevent COVID-19. The AGILE trial, which is the first to test VIR-7832 in humans, is expected to begin in the first quarter of 2021.
- In January, the Company announced a collaboration with Eli Lilly and Company to evaluate whether the administration of VIR-7831 together with Eli Lilly’s bamlanivimab (LY-CoV555) can provide potential benefits beyond monotherapy in low-risk adults with mild to moderate COVID-19. Initial results for this arm of Eli Lilly’s Phase 2 BLAZE-4 trial are expected in the first half of 2021.

- In February, the Company initiated COMET-Patient SafEty, TolerAbility, PharmacoKinetics, or COMET-PEAK , a Phase 2 study with two parts. The first part will evaluate the similarity in pharmacokinetics between VIR-7831 manufactured by different processes. The second part will compare the safety and viral kinetics of intramuscularly (IM) administered VIR-7831 to intravenously (IV) administered VIR-7831 among low-risk adults with mild to moderate COVID-19. The low, 500 mg dose of VIR-7831 lends itself to administration via an IM route and could facilitate broader access to monoclonal antibody therapy in settings where IV administration is not feasible.
- In the second quarter of 2021, the Company plans to initiate two additional trials evaluating IM administration of VIR-7831:
  • COMET-TAIL (Treatment of Acute COVID-19 with Intramuscular monocLonal antibody) – a Phase 3 trial in high-risk adults to assess whether IM-administered VIR-7831 can reduce hospitalization or death due to COVID-19
  • COMET-STAR (Stop Transmission of Acute SARS-CoV-2) – a Phase 3 trial in uninfected adults at high risk to determine whether IM-administered VIR-7831 can prevent symptomatic infection
- In connection with the advancement of Vir's SARS-CoV-2 monoclonal antibody programs, the Company has established a strategic manufacturing network that will enable the manufacture of approximately two million doses to patients the first year following potential Emergency Use Authorization, and several fold that in the second year, depending on titer and yield.

Chronic Hepatitis B Virus (HBV) Updates

- In January, Vir entered into a clinical collaboration with Gilead Sciences, Inc. to evaluate the Company's HBV-targeting small interfering ribonucleic acid (siRNA), VIR-2218, in a Phase 2 combination therapy trial with selgantolimod (GS-9688), Gilead's investigational TLR-8 agonist, and nivolumab, an approved PD-1 inhibitor, in both treatment-experienced and treatment-naïve patients with HBV. The trial, which is aimed at developing a functional cure for chronic HBV, is expected to start in 2021.
- In late January, the Company announced initial topline data from an ongoing Phase 1 trial evaluating VIR-3434, an HBV-neutralizing monoclonal antibody with the potential to be a therapeutic T cell vaccine, for the treatment of patients with chronic HBV. The first blinded cohort consisted of eight patients with chronic HBV who were taking nucleoside reverse transcriptase inhibitors, two of whom received placebo, and six of whom received a single dose of 6 mg VIR-3434. Six of eight patients responded and achieved a mean 1.3 $\log_{10}$ IU/mL reduction in serum HBV surface antigen (HBsAg) by day eight, the day when nadir was achieved in most patients. Additional clinical data are anticipated in the second quarter of 2021. The Company also expects to initiate a Phase 2 trial of VIR-3434 in combination with VIR-2218 in the second half of 2021.
- In February, the Company presented encore data on VIR-2218 at the Asian Pacific Association for the Study of the Liver. Presentations included preliminary results from the Company's ongoing Phase 2 trial of VIR-2218 (oral) and data characterizing the urine and plasma pharmacokinetics of VIR-2218 (poster). One-year response durability data for VIR-2218 as a monotherapy for HBV are anticipated in the first half of 2021.
- During the quarter, the Company continued to progress a Phase 2 combination trial of VIR-2218 with pegylated interferon-alpha (PEG-IFN-α) to evaluate the potential for this combination to result in a functional cure for HBV. Initial clinical data are anticipated in the second quarter of 2021.
- The Company expects Brii Biosciences Offshore Limited (Brii Bio) to initiate a Phase 2 trial evaluating VIR-2218 in combination with BRII-179, an investigational T cell vaccine, in the first half of 2021.

Additional Pipeline Updates

- In October, the Company presented new clinical data on VIR-2482 and health economics research on the burden of influenza A on the elderly at the Infectious Disease Society of America IDWeek 2020. 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.
- In January, the Company initiated a Phase 1 clinical trial of VIR-1111, an investigational HIV T cell vaccine based on human cytomegalovirus (HCMV). This proof-of-concept vaccine is designed to test the hypothesis that this new approach can elicit potentially protective immune responses that differ from other HIV vaccines, which, if observed, could potentially have utility in additional types of infections and other challenging areas, including cancer. Initial clinical data are anticipated in the second half of 2021.

Publications
During and following the fourth quarter, seven manuscripts were published related to the Company's efforts to address SARS-CoV-2 and other viruses.

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 spike protein and virulence of a prevalent immune evasion variant, N439K.

In December:

- *The Lancet Regional Health – Europe* published “Risk assessment and seroprevalence of SARS-CoV-2 infection in healthcare workers of COVID-19 and non-COVID-19 hospitals in Southern Switzerland” (Piccoli, et al.), demonstrating that the use of protective measures was effective in reducing nosocomial viral transmission among hospital healthcare workers.

In January:

- *bioRxiv* published “N-terminal domain antigenic mapping reveals a site of vulnerability for SARS-CoV-2” (McCallum, et al.), characterizing the N-terminal domain (NTD) on the SARS-CoV-2 spike protein.
- *Cell* published “Circulating SARS-CoV-2 spike N439K variants maintain fitness while evading antibody-mediated immunity” (Thompson, et al), which was previously posted on *bioRxiv*. The paper characterized the virulence, fitness, clinical and epidemiologic impact, molecular features and immune response to N439K, a prevalent receptor binding motif (RBM) variant of the SARS-CoV-2 spike protein first identified in Scotland in March 2020, and how this mutation might evade immunity.

In February:

- *medRxiv* published “SARS-CoV-2 B.1.1.7 escape from mRNA vaccine-elicited neutralizing antibodies” (Collier, et al.), which highlights the importance of designing next- generation vaccines with mutated S sequences and using alternative viral antigens.
- *Research Square* published “SARS-CoV-2 variants show resistance to neutralization by many monoclonal and serum-derived polyclonal antibodies” (Diamond, et al.), which indicates that the cell line in which the virus is grown and the cell line in which the assays are performed significantly affected the *in vitro* potency of certain antibodies against SARS-CoV-2.

New Board Appointment

- In December, the Company appointed Jeffrey Hatfield to the Board of Directors. Mr. Hatfield is an accomplished industry executive with more than three decades of commercial and business experience. He currently serves as chief executive officer of Vividion Therapeutics, Inc.

Fourth Quarter and Full Year 2020 Financial Results

- **Revenues:** Total revenues for the quarter ended December 31, 2020, were, $1.7 million, compared to $1.0 million for the same period in 2019. Total revenues for the year ended December 31, 2020, were $76.4 million, compared to $8.1 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. The increase for the year was primarily due to $43.3 million of revenue related to the license granted to GSK under our collaboration agreement, and $22.7 million of revenue related to Brii Biosciences’ exercise of its option to obtain exclusive rights to develop and commercialize compounds arising from VIR-2218 in the China territory.
- **Research and Development Expenses:** Research and development expenses were $87.1 million for the quarter ended December 31, 2020, which includes $5.3 million of non-cash stock-based compensation expense, compared to $52.9 million for the same period in 2019, which included $1.1 million of non-cash stock-based compensation expense. For the year ended December 31, 2020, research and development expenses were $302.4 million, which includes $13.7 million of non-cash stock-based compensation expense, compared to $148.5 million for the same period in 2019, which includes $3.0 million of non-cash stock-based compensation expense. The increase for the quarter and the full year was primarily due to contract manufacturing expenses for our SARS-CoV-2 program, higher fair value of our contingent consideration due to achievement of clinical development milestones, costs incurred under our collaboration with GSK, personnel-related expenses due to additional headcount, and clinical costs due to activities related to VIR-7831, VIR-3434 and VIR-2218.
- **General and Administrative Expenses:** General and administrative expenses were $23.0 million for the quarter ended December 31, 2020, which includes $5.0 million of non-cash stock-based compensation expense, compared to $11.8 million for the same period in 2019, which includes $1.6 million of non-cash stock-based compensation expense. For the year ended December 31, 2020, general and administrative expenses were $70.9 million, which includes $13.9 million of non-cash stock-based compensation expense, compared to $37.6 million for the same period in 2019, which includes $5.7 million of non-cash stock-based compensation expense. The increase for the quarter and the full year 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, including additional compliance-related expenses as a result of no longer being an emerging growth company.

- **Net Loss:** Net loss for the quarter ended December 31, 2020, was $105.6 million, or $0.83 per share, basic and diluted, compared to a net loss of $63.8 million, or $0.69 per share, basic, and $0.71 per share, diluted, for the same period in 2019. For the year ended December 31, 2020, net loss was $298.7 million, or $2.51 per share, basic and diluted, compared to a net loss of $174.7 million, or $5.76 per share, basic and diluted, for the same period in 2019.
- **Cash and Cash Equivalents:** As of December 31, 2020, excluding restricted cash, the Company had approximately $736.9 million in cash, cash equivalents and investments. For the year ended December 31, 2020, net cash used in operating activities and property and equipment purchases was $197.5 million.

About VIR-7831
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, which incorporates Xencor's Xtend™ technology, 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.

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About VIR-2218
VIR-2218 is an investigational 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 an investigational 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, which incorporates Xencor's Xtend and other Fc technologies, has been engineered to potentially function as a T cell vaccine against HBV in infected patients, as well as to have an extended half-life.

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 that a single dose has the potential to last the entire flu season.

About VIR-1111
VIR-1111 is an investigational subcutaneously administered HIV T cell vaccine based on HCMV that has been designed to elicit abundant T cells that recognize HIV epitopes in a way that differs from prior HIV 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.

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, but are not limited to, statements regarding the timing of availability of clinical data, program updates and data disclosures related to Vir's clinical trials, the ability of VIR-7831 and VIR-7832 to treat and/or prevent COVID-19 and the timing and expected number of therapeutic doses that Vir will be able to supply to patients, the potential of Vir's combination therapy trials with VIR-2218 to result in a functional cure for HBV, initial topline data from the ongoing Phase 1 trial of VIR-3434 in the treatment of patients with HBV and VIR-3434's potential to be a therapeutic T cell vaccine, 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 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 Vir's competitors, changes in expected or existing competition, delays in or disruptions to Vir's business or clinical trials due to the COVID-19 pandemic, geopolitical changes or other external factors, and unexpected litigation or other disputes.

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,	
	2020	2019	2020	2019
Revenue:				
Grant revenue	$ 1,433	$ 609	$ 9,123	$ 7,380
License revenue from a related party	—	—	22,747	$ —
Contract revenue	301	371	44,498	711
Total revenue	1,734	980	76,368	8,091
Operating expenses:				
Research and development	87,095	52,932	302,411	148,472
General and administrative	23,043	11,807	70,937	37,598
Total operating expenses	110,138	64,739	373,348	186,070
Loss from operations	(108,404)	(63,759)	(296,980)	(177,979)
Other income (expense):				
Interest income	288	1,947	2,836	8,511
Other income (expense), net	2,437	(1,810)	(4,467)	(5,061)
Total other income (expense)	2,725	137	(1,631)	3,450
Loss before benefit from (provision for) income taxes	(105,679)	(63,622)	(298,611)	(174,529)
Benefit from (provision for) income taxes	30	(149)	(54)	(154)
Net loss	$ (105,649)	$ (63,771)	$ (298,665)	$ (174,683)
Net loss per share, basic	$ (0.83)	$ (0.69)	$ (2.51)	$ (5.76)
Net loss per share, diluted	$ (0.83)	$ (0.71)	$ (2.51)	$ (5.76)
Weighted-average shares outstanding, basic	127,295,719	91,871,498	119,159,424	30,349,920
Weighted-average shares outstanding, diluted	127,295,719	91,901,590	119,159,424	30,349,920

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

	December 31,	
	2020	2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 436,575	$ 109,335
Short-term investments	300,286	274,101
Restricted cash and cash equivalents, current	7,993	6,181
Prepaid expenses and other current assets	27,511	13,378
Total current assets	772,365	402,995
Intangible assets, net	33,820	35,694
Goodwill	16,937	16,937
Property and equipment, net	17,946	16,308
Operating right-of-use assets	61,947	—
Restricted cash and cash equivalents, noncurrent	6,919	7,300
Long-term investments	—	24,290
Other assets	8,827	8,547
TOTAL ASSETS	$ 918,761	$ 512,071
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,077	$ 5,881
Accrued and other liabilities	76,936	26,495
Deferred revenue, current portion	6,451	6,181
Contingent consideration, current portion	10,600	8,200
Derivative liability	—	12,449
Total current liabilities	99,064	59,206
Deferred revenue, noncurrent	3,815	12,670
Operating lease liabilities, noncurrent	66,556	—
Contingent consideration, noncurrent	25,374	9,380
Deferred tax liability	3,253	3,305
Other long-term liabilities	3,847	3,568
TOTAL LIABILITIES	201,909	88,129

Commitments and contingencies		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of December 31, 2020 and 2019; no shares issued or outstanding as of December 31, 2020 and 2019	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of December 31, 2020 and 2019, respectively; 127,416,740 and 107,648,925 shares issued and outstanding as of December 31, 2020 and 2019, respectively	13	11
Additional paid-in capital	1,385,301	793,051
Accumulated other comprehensive loss	(1,278)	(601)
Accumulated deficit	(667,184)	(368,519)
TOTAL STOCKHOLDERS' EQUITY	716,852	423,942
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 918,761	$ 512,071

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Source: Vir Biotechnology, Inc.