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

August 11, 2020

SAN FRANCISCO, Aug. 11, 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 second quarter ended June 30, 2020.

“Our organization is uniquely positioned and working rapidly to address the urgent need for solutions to the global COVID-19 pandemic” said George Scangos, Ph.D., chief executive officer of Vir. “We plan to enter the clinic with VIR-7831 in August and have prepared for success by putting in place multiple manufacturing, development, and commercialization agreements to rapidly provide access if approved. In addition, we have continued to execute on our other pipeline priorities, starting two new hepatitis B trials and preparing to start new influenza A and HIV trials. We also further strengthened our balance sheet through a successful follow-on offering.”

Corporate Update

SARS-CoV-2

Anticipated Milestones

- In August, the Company expects to start a Phase 2/3 clinical trial program for VIR-7831, a SARS-CoV-2 neutralizing monoclonal antibody. The Company anticipates that initial clinical data will be available before the end of the year. In vitro, VIR-7831 has demonstrated the ability to neutralize SARS-CoV-2, has a high barrier to resistance, an ability to recruit immune cells to kill already infected cells, and has been designed to achieve high lung tissue concentrations. The Company believes that the combination of these characteristics is essential to achieving maximal clinical efficacy. The clinical program for VIR-7831 includes planned trials for early treatment, hospitalized treatment, and prophylaxis. Because VIR-7831 has been engineered to have extended half-life, it has the potential to provide protection for up to six months.
- Later this year, the Company expects to start a Phase 2 trial of its other investigational SARS-CoV-2 neutralizing antibody, VIR-7832, which shares the same potentially differentiating characteristics as VIR-7831 but may also function as a therapeutic and/or prophylactic T cell vaccine.
- By the end of the year, the Company expects to complete preclinical studies of VIR-2703, an inhaled SARS-CoV-2-targeting small interfering ribonucleic acid (siRNA).

Collaborations

- Since April, the Company has continued to build its manufacturing network to produce clinical and commercial quantities of its SARS-CoV-2 antibodies including signing binding drug substance letter agreements with WuXi Biologics (Hong Kong) Limited (stock code: 2269.HK) and Samsung Biologics Co., Ltd. (207940.KS), and subsequently assigning them to GlaxoSmithKline Trading Services Limited of GlaxoSmithKline plc who entered into Master Service Agreements that superseded both letter agreements. The Company also entered into a process development agreement with Biogen, Inc. (Nasdaq: BIIB). The Company anticipates a potential capacity of up to 10 million doses in 2021, depending on titer, yield, and dose amount.
- In June, the Company signed a definitive collaboration agreement with Glaxo Wellcome UK Limited and Beecham S.A. of GlaxoSmithKline plc (collectively referred to as GSK) to research, develop and commercialize products for the prevention, treatment and prophylaxis of diseases caused by SARS-CoV-2, and potentially other coronaviruses. This agreement superseded the binding preliminary collaboration agreement signed in April.

Publications

- During and following the second quarter, three articles were published related to the Company’s efforts directed toward SARS-CoV-2:
    - In April, *Nature Biotechnology* published “Developing therapeutic monoclonal antibodies at pandemic pace” (Kelley), discussing how the time from discovery to proof-of-concept trials can be reduced to 5–6 months from a traditional timeline of 10–12 months.
    - In May, *Nature* published “Cross-neutralization of SARS-CoV-2 by a human monoclonal SARS-CoV antibody” (Pinto, et al.), detailing the identification and characterization of S309, the parent molecule of VIR-7831 and VIR-7832.
    - In July, *Nature* published “A perspective on potential antibody dependent enhancement of SARS-CoV-2” (Arvin, et al*.)*, outlining the challenges of predicting antibody dependent enhancement or ADE from in vitro or animal studies,

and the belief that the overall risk of ADE posed by antibody therapeutics for COVID-19 is low.

Hepatitis B Virus (HBV)

- In April, the Company announced Phase 2 trial results for VIR-2218, an HBV-targeting siRNA, demonstrating substantial, durable, and dose dependent reductions in hepatitis B surface antigen (HBsAg) in patients and that VIR-2218 was generally well-tolerated.
- In May, the Company initiated a Phase 1 clinical trial in both healthy volunteers and patients with chronic HBV of VIR-3434, an HBV-neutralizing monoclonal antibody with the potential to also be a therapeutic T cell vaccine. The Company anticipates that data from this trial will enable it to start a Phase 2 clinical trial of VIR-3434 in combination with VIR-2218 in 2021.
- In June, Brii Biosciences Limited and Brii Biosciences Offshore Limited (collectively referred to as Brii Biosciences) exercised its option to obtain exclusive rights to develop and commercialize compounds and products arising from VIR-2218 in greater China pursuant to its 2018 agreement with the Company.
- In July, the Company started a Phase 2 combination trial of VIR-2218 and pegylated interferon-alpha (PEG-IFN-α). The combination trial aims to demonstrate safety and evaluate the potential for this cocktail to result in functional cure of HBV-infected patients. Initial clinical data are anticipated in 2021.
- In August, the Company will present virtually at EASL – The Digital International Liver Congress 2020, which will be held August 27–29, 2020. The Company has had four abstracts accepted, including one oral presentation, focused on the safety, pharmacokinetics, and biological activity of VIR-2218.

Influenza A and Human Immunodeficiency Virus (HIV)

- In the fourth quarter of this year, the Company expects to start a Phase 2 clinical trial in the northern hemisphere for VIR-2482, a monoclonal antibody being developed as a universal prophylactic for influenza A, followed by a second northern hemisphere season if necessary. This trial is designed to demonstrate safety and efficacy, and if successful, VIR-2482 may provide protection against both seasonal and pandemic strains of influenza A. Interim data from the first northern hemisphere flu season are anticipated in the first half of 2021.
- In the second half of the year, the Company expects to start a Phase 1 clinical trial for VIR-1111, an HIV T cell vaccine based on human cytomegalovirus. 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.

Follow-on Offering and New Board Appointment

- In July, the Company raised approximately $345.0 million in gross proceeds from an underwritten public offering of 8,214,285 shares of its common stock at a public offering price of $42.00 per share. This included the exercise in full by the underwriters of their option to purchase up to 1,071,428 additional shares of common stock.
- In July, the Company's Board of Directors appointed Elliott Sigal, M.D., Ph.D. to serve on the Board and as a member of its Compensation Committee. Dr. Sigal formerly served as Executive Vice President, Chief Scientific Officer and President of Bristol-Myers Squibb Company (BMS) Research and Development (R&D), where he played an instrumental role in bringing 14 new medicines to patients in need.

Second Quarter 2020 Financial Results

- **Revenues:** Total revenues for the quarter ended June 30, 2020 were $67.0 million, compared to $2.0 million for same period in 2019. The increase for the quarter was primarily due to $43.3 million related to the license granted to GSK under the collaboration agreement and $22.7 million from Brii Biosciences exercising its option to obtain exclusive rights to develop and commercialize compounds and products arising from VIR-2218 in greater China.
- **Research and Development Expenses:** Research and development expenses were $79.7 million for the quarter ended June 30, 2020, which includes $2.7 million of non-cash stock-based compensation expense, compared to $29.8 million for the same period in 2019, which includes $0.6 million of non-cash stock-based compensation expense. The increase for the quarter was primarily due to license and collaboration expenses (including $10.0 million paid to Alnylam Pharmaceuticals, Inc. (Alnylam) resulting from the Brii Biosciences option exercise), contract manufacturing expenses for our SARS-CoV-2 programs, personnel-related expenses related to additional headcount, and clinical trial startup activities related to VIR-7831, VIR-3434 and VIR-1111.
- **General and Administrative Expenses:** General and administrative expenses were $16.4 million for the quarter ended June 30, 2020, which includes $3.1 million of non-cash stock-based compensation expense, compared to $8.0 million for the same period in 2019, which includes $0.8 million of non-cash stock-based compensation expense. The increase for the quarter was primarily due to personnel-related expenses related 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 June 30, 2020 was $31.2 million, or $0.27 per share, basic and diluted, compared to a net loss of $33.9 million, or $3.64 per share, basic and diluted, for the same period in 2019.

- **Cash and Cash Equivalents:** As of June 30, 2020, excluding restricted cash, the Company had approximately $552.4 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 enhance bioavailability and 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 enhance bioavailability, 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.

About VIR-2218

VIR-2218 is a subcutaneously administered HBV-targeting siRNA that has the potential to stimulate an effective immune response and has 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.

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 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," "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 the company'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 company's efforts to identify additional antibodies, 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 potential benefits of the company's collaborations and partnerships with WuXi Biologics (Hong Kong) Limited, Biogen, Inc., Samsung Biologics Co., Ltd., GSK, Alnylam and Brii Biosciences, the company's 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 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, clinical site activation rates or clinical trial enrollment rates that are lower than expected, 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.

Vir Biotechnology, Inc.
Condensed Consolidated Statements of Operations
(unaudited; in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Grant revenue	$ 719	$ 1,961	$ 5,950	$ 5,605
License revenue from a related party	22,747	—	22,747	—
Contract revenue	43,522	86	44,009	103
Total revenue	66,988	2,047	72,706	5,708
Operating expenses:				
Research and development	79,653	29,805	144,632	55,677
General and administrative	16,386	8,011	29,035	16,570
Total operating expenses	96,039	37,816	173,667	72,247
Loss from operations	(29,051)	(35,769)	(100,961)	(66,539)
Other income (expense):				
Interest income	825	2,307	2,580	4,552
Other income (expense), net	(2,895)	(447)	(9,964)	(592)
Total other income (expense)	(2,070)	1,860	(7,384)	3,960
Loss before provision for income taxes	(31,121)	(33,909)	(108,345)	(62,579)
Provision for income taxes	(46)	(19)	(62)	(19)
Net loss	$ (31,167)	$ (33,928)	$ (108,407)	$ (62,598)
Net loss per share, basic and diluted	$ (0.27)	$ (3.64)	$ (0.97)	$ (6.83)
Weighted-average shares outstanding, basic and diluted	114,980,652	9,327,651	111,684,283	9,165,311

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

	June 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 371,781	$ 109,335
Short-term investments	180,599	274,101
Restricted cash and cash equivalents, current	11,024	6,181
Prepaid expenses and other current assets	15,357	13,378
Total current assets	578,761	402,995
Intangible assets, net	35,082	35,694
Goodwill	16,937	16,937
Property and equipment, net	16,311	16,308
Operating right-of-use assets	15,177	—
Restricted cash and cash equivalents, noncurrent	1,192	7,300
Long-term investments	—	24,290
Other assets	8,778	8,547
TOTAL ASSETS	$ 672,238	$ 512,071

LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 4,382	$ 5,881
Accrued and other liabilities	38,560	26,495
Deferred revenue, current portion	7,298	6,181
Contingent consideration, current portion	4,700	8,200
Derivative liability	—	12,449
Total current liabilities	54,940	59,206
Deferred revenue, noncurrent	3,815	12,670
Operating lease liabilities, noncurrent	12,762	—
Contingent consideration, noncurrent	30,670	9,380
Deferred tax liability	3,305	3,305
Other long-term liabilities	2,967	3,568
TOTAL LIABILITIES	108,459	88,129
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of June 30, 2020 and December 31, 2019; no shares issued and outstanding as of June 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 117,727,086 and 107,648,925 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	12	11
Additional paid-in capital	1,040,988	793,051
Accumulated other comprehensive income (loss)	(295)	(601)
Accumulated deficit	(476,926)	(368,519)
TOTAL STOCKHOLDERS' EQUITY	563,779	423,942
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 672,238	$ 512,071

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