Vir Biotechnology Provides Corporate Update and Reports Second Quarter 2023 Financial Results

August 3, 2023

– Phase 2 data readouts from ongoing chronic hepatitis B and chronic hepatitis delta programs on track for Q4 2023 –

– Increased focus on proprietary antibody platform and discontinuation of Vir's innate immunity small molecule platform –

– First participant to be dosed in Phase 1 trial of next-generation HIV vaccine, VIR-1388, anticipated in Q3 –

– $1.9 billion in cash, cash equivalents and investments as of June 30, 2023 –

– Conference call scheduled for 1:30 p.m. PT / 4:30 p.m. ET, Aug. 3, 2023 –

SAN FRANCISCO, Aug. 03, 2023 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today provided a corporate update and reported financial results for the second quarter ended June 30, 2023.

"Our strategy is to prioritize our monoclonal antibody platform, which has already yielded two impactful medicines for patients and, along with our artificial intelligence-enabled capabilities, plan to apply it more broadly in infectious diseases and beyond," said Marianne De Backer, M.Sc., Ph.D., MBA, Vir's Chief Executive Officer. "As we execute on this strategy, we look forward to our near-term catalysts, which include data readouts from our Phase 2 chronic hepatitis B and hepatitis delta programs in the fourth quarter. Our future prospects are rich with opportunity based on our deep pipeline and strong balance sheet."

Pipeline Programs

Chronic Hepatitis B (CHB)

- Multiple trials evaluating the potential for VIR-2218 and VIR-3434 to achieve a functional cure for CHB are on track with data expected in Q4 2023.
- In June, the Company presented new data from its CHB portfolio at the EASL™ (European Association for the Study of the Liver) Congress.
- In May, the Company announced the initiation of the Phase 2 PREVAIL platform trial and its THRIVE/STRIVE sub-protocols. The platform is evaluating combinations of VIR-2218, VIR-3434 and/or PEG-IFN-α in two CHB patient populations with the potential to evaluate other populations in the future. Initial data from this platform trial are expected in the first half of 2024.

Chronic Hepatitis Delta (CHD)

- The Phase 2 SOLSTICE trial evaluating VIR-2218 and VIR-3434 as monotherapy and in combination for the treatment of people living with CHD, the most aggressive form of viral hepatitis, remains on track with initial data expected in Q4 2023.
- In June, the Company presented preclinical *in vivo* and *in vitro* data demonstrating the antiviral properties of VIR-2218 and VIR-3434 against hepatitis delta virus at the EASL Congress. These data further support the clinical development of these investigational medicines as a treatment for the chronic suppression of hepatitis delta virus.

Influenza

- In July, Vir reported that the Phase 2 **P**rev**e**ntio**n** of **I**ll**n**es**s** D**u**e to Inf**l**uenza **A** (PENINSULA) trial evaluating VIR-2482 for the prevention of symptomatic influenza A illness did not meet primary or secondary efficacy endpoints.
- The Company continues to analyze the data and plans to share additional findings once available.

Human Immunodeficiency Virus (HIV)

- Vir expects the Phase 1 trial for VIR-1388, a novel T cell vaccine for the prevention of HIV, to begin dosing in Q3 2023. Vir's T cell platform utilizes human cytomegalovirus (HCMV) as a vector, which has the potential to induce high frequencies of antigen-specific, tissue-localizing effector memory T cells. The trial will be supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and the Bill & Melinda Gates Foundation, and will be conducted by the HIV Vaccine Trials Network. NIAID has provided funding throughout the product development lifecycle of VIR-1388.

COVID-19

- Sotrovimab currently has emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®) for early treatment of COVID-19. It has been supplied to more than 40 countries and remains in use outside of the US.

Preclinical Pipeline Candidates

- Vir is continuing to advance next-generation monoclonal antibodies (mAbs) based on its proprietary platform and enabled by AI and machine-learning capabilities to deliver high-quality solutions more efficiently. These include:
  - VIR-2981, an investigational neuraminidase-targeting mAb against both influenza A and B viruses.
  - VIR-8190, a mAb against respiratory syncytial virus (RSV) and human metapneumovirus (hMPV).
  - VIR-7229, a next-generation COVID-19 mAb that has been shown in laboratory studies to have high potency against a broad spectrum of historical and currently circulating variants.
- Additionally, the Company is advancing VIR-1949, a therapeutic T cell vaccine for control of precancerous lesions caused by human papillomavirus (HPV) based on Vir's HCMV vector platform.

Corporate Update

- In July, Vir made the decision to increase focus on its proprietary antibody platform and discontinue its innate immunity small molecule platform.
- In June, Sasha Damouni Ellis joined Vir as Executive Vice President and Chief Corporate Affairs Officer. Previously, she was Senior Vice President, Corporate Affairs and Investor Relations of Marinus Pharmaceuticals.
- In May, Jeff Calcagno, M.D., joined Vir as Executive Vice President and Chief Business Officer. He joined Vir from Johnson & Johnson (J&J), where he spent more than 12 years holding leadership roles of increasing responsibility within all three divisions of J&J Innovation (JJI), including as Global Transactions Lead for Infectious Diseases & Vaccines and as Head of JLABS Bay Area.

Second Quarter 2023 Financial Results

Cash, Cash Equivalents and Investments: As of June 30, 2023, the Company had approximately $1.9 billion in cash, cash equivalents and investments. In the second quarter of 2023, a payment of $273.6 million was made to GSK primarily for excess sotrovimab supply and manufacturing capacity that was reserved in 2022; a balance of $69.7 million remains, of which the Company anticipates making a payment of approximately $41.8 million to GSK in the third quarter of 2023.

Revenues: Total revenues for the quarter ended June 30, 2023, were $3.8 million compared to $(40.6) million for the same period in 2022.

Revenues were comprised of the following components:

(in millions)	Three months ended June 30		
	2023	**2022**	**% Change**
Collaboration revenue	$(13.8)	$(54.9)	(74.9%)
Contract revenue	1.1	12.3	(91.1%)
Grant revenue	16.5	2.1	>100 %
Total revenues	**$3.8**	**$(40.6)**	**>100 %**

Note: Numbers may not add due to rounding.

- **Collaboration revenue:** The year-over-year change in collaboration revenue was primarily driven by a $397.4 million charge for a profit-share constraint recorded in the second quarter of 2022 which more than offset the $342.5 million profit-sharing amount recorded in the same quarter. The constraint represents an estimate for excess sotrovimab supply and manufacturing capacity and reduces the profit-sharing amount. In the second quarter of 2023, collaboration revenue was $(13.8) million primarily due to sotrovimab sales that were more than offset by manufacturing costs and expenses to support activities where sotrovimab has marketing authorization. These activities are led by the Company's collaboration partner GSK.
- **Contract revenue:** The decrease in contract revenue was primarily driven by a $7.0 million upfront payment related to a license granted to GSK in the second quarter of 2022.
- **Grant revenue:** The increase in grant revenue was primarily driven by $11.8 million related to the Company's grant with Biomedical Advanced Research and Development Authority (BARDA) supporting the Company's Phase 2 PENINSULA trial evaluating VIR-2482 for the prevention of symptomatic influenza A illness in the second quarter of 2023.

Cost of Revenue: Cost of revenue for the second quarter of 2023 was not material compared to $27.9 million for the same period in 2022. The decrease was due to lower third-party royalties owed based on the sales of sotrovimab.

Research and Development Expenses (R&D): R&D expenses for the second quarter of 2023 were $171.9 million, which included $17.1 million of non-cash stock-based compensation expense, compared to $115.1 million for the same period in 2022, which included $14.1 million of non-cash

stock-based compensation expense. The increase was primarily driven by higher investments to support the advancement of our clinical programs and, in particular, VIR-2482.

Selling, General and Administrative Expenses (SG&A): SG&A expenses for the second quarter of 2023 were $47.1 million, which included $13.5 million of non-cash stock-based compensation expense, compared to $41.6 million for the same period in 2022, which included $13.0 million of non-cash stock-based compensation expense. The increase was primarily due to higher personnel-related costs to support the growth of the Company.

Other Income (Expense): Other income for the second quarter of 2023 was $17.6 million compared to other expense of $(8.5) million for the same period in 2022. The increase was primarily due to higher interest income related to higher interest rates along with an overall higher investment balance.

Benefit from Income Taxes: Benefit from income taxes for the second quarter of 2023 was $2.8 million compared to $157.2 million benefit from income taxes for the same period in 2022. The decrease was primarily due to the Company's inability to realize tax benefit associated with the net loss for the three months ended June 30, 2023.

Net Loss: Net loss attributable to Vir for the second quarter of 2023 was $194.8 million, or $1.45 per share, basic and diluted, compared to a net loss of $76.5 million, or $0.58 per share, basic and diluted, for the same period in 2022.

Conference Call

Vir will host a conference call to discuss the Q2 results at 1:30 p.m. PT / 4:30 p.m. ET today. A live webcast will be available on https://investors.vir.bio/ and will be archived on www.vir.bio for 30 days.

About VIR-2218

VIR-2218 is an investigational subcutaneously administered hepatitis B virus-targeting small interfering ribonucleic acid (siRNA) that Vir believes has the potential to stimulate an effective immune response and have direct antiviral activity against hepatitis B virus and hepatitis delta virus. 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 could 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 antibody designed to block entry of hepatitis B and hepatitis delta viruses into hepatocytes and 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 hepatitis B virus and hepatitis delta virus, as well as to have an extended half-life. VIR-3434 was identified using Vir's proprietary mAb discovery platform.

About VIR-2482

VIR-2482 is an investigational hemagglutinin targeting, 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 flu pandemic. VIR-2482 is designed as a prophylactic for influenza A. 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. VIR-2482 was identified using Vir's proprietary mAb discovery platform. Under the collaboration agreement signed with GSK in 2021, GSK has an exclusive option to lead post-Phase 2 development and commercialization of VIR-2482.

The PENINSULA trial has been supported in whole or in part with federal funds from the Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction Number: 75A50122C00081.

About VIR-2981

VIR-2981 is an investigational neuraminidase-targeting monoclonal antibody against influenza viruses. It targets a region of the neuraminidase protein that is highly conserved across influenza A and B strains and is designed to inhibit the influenza neuraminidase, a key viral protein that facilitates release of new viruses in infected individuals. Preclinical data demonstrate the antibody's breadth and potency against all major strains of seasonal and pandemic influenza viruses and support the potential of this antibody in the prevention of influenza illness. Vir-2981 was identified using Vir's proprietary mAb discovery platform.

About VIR-1388

VIR-1388 is an investigational subcutaneously administered HIV T cell vaccine based on HCMV that has been designed to elicit abundant T cells that recognize HIV proteins in a way that differs from prior investigational HIV vaccines. VIR-1388 uses applied learnings from VIR-1111, Vir's initial investigational proof-of-concept HIV T cell vaccine, with the goal of creating a safe and effective HIV vaccine. VIR-1388 was identified using Vir's proprietary mAb discovery platform.

About Sotrovimab

Sotrovimab is an investigational SARS-CoV-2 neutralizing monoclonal antibody that was developed in collaboration with GSK. The antibody binds to an epitope on SARS-CoV-2 shared with SARS-CoV-1 (the virus that causes SARS). Sotrovimab, which incorporates Xencor, Inc.'s Xtend™ technology, has been designed to achieve high concentration in the lungs to achieve optimal penetration into airway tissues affected by SARS-CoV-2 and to have an extended half-life. Sotrovimab was identified using Vir's proprietary mAb discovery platform. Sotrovimab is currently not authorized in the US.

About VIR-7229

VIR-7229 is a preclinical monoclonal antibody that neutralizes all historical and currently circulating COVID-19 variants with high potency *in vitro*. Vir-7229 incorporates Xencor, Inc.'s Xtend™ technology. VIR-7229 was identified using Vir's proprietary mAb discovery platform.

About VIR-8190

VIR-8190 is a dual specificity monoclonal antibody that has the ability to potently neutralize both respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) strains. RSV and HMPV are recognized as significant causes of lower respiratory tract disease in high-risk populations, including infants and immunocompromised individuals. VIR-8190 was identified using Vir's proprietary mAb discovery platform.

About VIR-1949
VIR-1949 is a preclinical therapeutic vaccine designed to treat HPV-related high-grade squamous epithelial pre-cancer lesions (HSIL) and cancers. This vaccine uses HCMV as the vaccine vector. Based on preclinical data, HCMV vectors have the potential to induce high frequencies of antigen-specific, tissue-localizing effector memory T cells.

About Vir Biotechnology
Vir Biotechnology, Inc. is an immunology company focused on combining cutting-edge technologies to treat and prevent infectious diseases and other serious conditions. Vir has assembled two technology platforms that are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. Its current clinical development pipeline consists of product candidates targeting hepatitis B and hepatitis delta viruses, influenza A and B, human immunodeficiency virus and COVID-19. Vir has several preclinical candidates in its pipeline. Vir routinely posts information that may be important to investors on its website.

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," "expect," "anticipate," "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 Vir's strategy and plans; Vir's cash balance; Vir's future financial and operating results and its expectations related thereto; potential of, and expectations for, Vir's pipeline; Vir's clinical development programs, clinical trials, including the enrollment of Vir's clinical trials, and the expected timing of data readouts and presentations; the potential benefits, safety, and efficacy of Vir's investigational therapies; and risks and uncertainties associated with drug development and commercialization. Many important factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data or results observed during clinical trials or in data readouts; the timing and outcome of Vir's planned interactions with regulatory authorities; difficulties in obtaining regulatory approval; uncertainty as to whether the anticipated benefits of Vir's collaborations with other companies can be achieved; difficulties in collaborating with other companies; challenges in accessing manufacturing capacity; clinical site activation rates or clinical trial enrollment rates that are lower than expected; 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, geopolitical changes or other external factors; and unexpected litigation or other disputes. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later-stage or larger-scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented. 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 US 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 Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	June 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 666,949	$ 848,631
Short-term investments	1,166,953	1,521,517
Restricted cash and cash equivalents, current	13,163	12,681
Equity investments	13,531	31,892
Prepaid expenses and other current assets	85,736	104,356
Total current assets	1,946,332	2,519,077
Intangible assets, net	25,590	32,755
Goodwill	16,937	16,937
Property and equipment, net	104,126	105,609
Operating right-of-use assets	74,934	82,557
Restricted cash and cash equivalents, noncurrent	6,744	6,656
Long-term investments	52,358	23,927
Other assets	16,853	14,570
TOTAL ASSETS	$ 2,243,874	$ 2,802,088
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 12,362	$ 6,422
Accrued and other liabilities	197,580	489,090
Deferred revenue, current portion	15,681	15,517
Total current liabilities	225,623	511,029
Deferred revenue, noncurrent	53,207	53,207

Operating lease liabilities, noncurrent	117,815	123,837
Contingent consideration, noncurrent	24,927	24,937
Other long-term liabilities	12,094	11,115
TOTAL LIABILITIES	433,666	724,125
Commitments and contingencies (Note 7)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of June 30, 2023 and December 31, 2022; no shares issued and outstanding as of June 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 134,230,494 and 133,236,687 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	13	13
Additional paid-in capital	1,771,536	1,709,835
Accumulated other comprehensive loss	(2,903)	(9,122)
Retained earnings	41,562	377,237
TOTAL STOCKHOLDERS' EQUITY	1,810,208	2,077,963
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 2,243,874	$ 2,802,088

VIR BIOTECHNOLOGY, INC.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Collaboration revenue	$ (13,779)	$ (54,941)	$ 32,795	$ 1,174,715
Contract revenue	1,057	12,254	1,195	12,536
Grant revenue	16,519	2,058	32,764	4,579
Total revenues	3,797	(40,629)	66,754	1,191,830
Operating expenses:				
Cost of revenue	22	27,921	1,929	118,070
Research and development	171,860	115,082	329,503	205,309
Selling, general and administrative	47,101	41,590	93,879	79,845
Total operating expenses	218,983	184,593	425,311	403,224
(Loss) income from operations	(215,186)	(225,222)	(358,557)	788,606
Other income (expense):				
Change in fair value of equity investments	(5,086)	(11,390)	(18,189)	(106,429)
Interest income	23,016	2,200	44,323	2,588
Other (expense) income, net	(367)	691	(8,388)	3,421
Total other income (expense)	17,563	(8,499)	17,746	(100,420)
(Loss) income before benefit from (provision for) income taxes	(197,623)	(233,721)	(340,811)	688,186
Benefit from (provision for) income taxes	2,848	157,228	5,080	(246,058)
Net (loss) income	$ (194,775)	$ (76,493)	$ (335,731)	$ 442,128
Net loss attributable to noncontrolling interest	$ —	$ —	$ (56)	$ —
Net (loss) income attributable to Vir	$ (194,775)	$ (76,493)	$ (335,675)	$ 442,128
Net (loss) income per share attributable to Vir, basic	$ (1.45)	$ (0.58)	$ (2.51)	$ 3.34
Net (loss) income per share attributable to Vir, diluted	$ (1.45)	$ (0.58)	$ (2.51)	$ 3.28
Weighted-average shares outstanding, basic	134,059,079	132,450,018	133,807,357	132,326,244
Weighted-average shares outstanding, diluted	134,059,079	132,450,018	133,807,357	134,643,840

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