

Vir Biotechnology Reports Second Quarter 2024 Financial Results and Announces Strategic Restructuring to Prioritize Clinical-Stage Pipeline Opportunities

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– Positive preliminary Phase 2 chronic hepatitis delta study data presented at EASL™ Congress 2024, FDA IND clearance with Fast Track Designation received underscoring the potential of combination therapy –

– Exclusive license agreement with Sanofi bolsters clinical pipeline –

– Strategic workforce restructuring and phasing out of influenza, COVID-19, and the Company's T cell-based viral vector platform programs –

– \$1.43 billion in cash, cash equivalents and investments as of June 30, 2024 –

– The Company lowers full-year 2024 operating expense guidance –

– Conference call scheduled for August 1, 2024 at 1:30 p.m. PT / 4:30 p.m. ET –

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today provided a corporate update and reported financial results for the second quarter ended June 30, 2024.

"The positive preliminary SOLSTICE Phase 2 study together with the recent FDA IND clearance and Fast Track designation for tobevibart and elebsiran for the treatment of chronic hepatitis delta infection highlight the encouraging momentum we're building towards addressing the substantial unmet medical need for patients affected by this life-threatening disease," said Marianne De Backer, M.Sc., Ph.D., MBA, Vir's Chief Executive Officer. "In addition, we are taking decisive steps to strategically restructure our organization and prioritize our resources to focus on the highest value near-term opportunities. These key strategic decisions will enable us to drive sustainable

growth and accelerate patient impact as we advance in our mission of powering the immune system to transform lives.”

Pipeline Programs

Chronic Hepatitis Delta (CHD)

- The Company presented positive **preliminary Phase 2** chronic hepatitis delta SOLSTICE study data at the European Association for the Study of the Liver, EASL™ Congress 2024.
 - Tobevibart monotherapy and combination therapy with elebsiran achieved high virologic response and ALT normalization in people living with the hepatitis delta virus after 12 and 24 weeks of treatment.
 - Complete 24-week treatment data on the approximately 60 participants is on track to be reported in the fourth quarter of 2024.
- On June 26, the U.S. Food and Drug Administration (FDA) **cleared** the Company's investigational new drug (IND) application and granted Fast Track designation for the combination of tobevibart and elebsiran for the treatment of chronic hepatitis delta infection.

Chronic Hepatitis B (CHB)

- The Phase 2 MARCH Part B study is fully enrolled with 48-week end of treatment data expected in the fourth quarter of 2024. The study is evaluating the safety, tolerability and antiviral activity of the combination of tobevibart and elebsiran with and without peginterferon alpha.
- Initial data from the Phase 2 PREVAIL platform study and its THRIVE/STRIVE sub-protocols is expected in the first half of 2025. These studies are evaluating combinations of tobevibart, elebsiran and/or peginterferon alpha in two patient populations: immune-active but treatment-naïve and inactive carriers.

Corporate Update

- As **announced** today, the Company signed an exclusive worldwide license agreement with Sanofi for multiple potential best-in-class clinical-stage T-cell engagers and exclusive use of the protease-cleavable masking platform, acquired by Sanofi from Amunix Pharmaceuticals. This license agreement is subject to the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Act Antitrust Improvements Act of 1976, as amended (HSR).
- The Company initiated a strategic restructuring to advance the development of its hepatitis programs and focus on the highest near-term value opportunities. The organizational realignment and optimization include phasing out programs in influenza, COVID-19, and the Company's T cell-based viral vector platform, as well as a workforce reduction of approximately 25% or approximately 140 employees. The Company expects to end

2024 with approximately 435 employees, a decrease of approximately 200 from its peak headcount in the second quarter of 2023. This includes the Sanofi employees who are expected to join Vir following receipt of HSR clearance.

“This decision was not taken lightly yet is essential to ensure that our resources are aligned with our evolving strategy and that Vir is positioned for sustainable growth and long-term success,” said Marianne De Backer, M.Sc., Ph.D., MBA, Vir’s Chief Executive Officer. “I am grateful for every Vir employee who has helped to progress our journey to bring life-saving therapies to patients and their families.”

As a result of this strategic restructuring and prioritization the Company anticipates:

- Approximately \$50 million of annual workforce cost savings starting in 2025. Combined with the strategic actions taken in December 2023, the Company lowered its cost structure by approximately \$90 million since its peak in 2023, part of which will be redeployed to the newly anticipated key personnel from Sanofi.
- Cost savings of \$50 million through the end of 2025 due to the phasing out of certain programs. These savings will substantially be reinvested in the newly licensed programs from Sanofi following closing of the transaction.
- Restructuring expenses estimated at \$11 million to \$13 million, primarily related to employee severance cash payouts. The Company expects to recognize most of these expenses in the second half of 2024.
- The Company will host a virtual R&D Day in late November 2024.
- On May 29, 2024, the Company **announced** the appointment of Mark D. Eisner, M.D., M.P.H. as Executive Vice President and Chief Medical Officer, effective June 3, 2024. Dr. Eisner brings extensive late-stage clinical development expertise and deep knowledge in the fields of immunology and infectious disease.
- On April 18, 2024, the Company **announced** that founding board members Phillip Sharp, Ph.D. and Robert Perez would not stand for reelection. Effective May 29, 2024, two new independent directors were elected in their place, including Norbert Bischofberger, Ph.D., who brings close to 40 years of biotech leadership experience and Ramy Farid, Ph.D., whose pioneering work applying advanced computational methods to drug discovery has enabled high-quality, novel molecules for drug development and materials applications.

Second Quarter 2024 Financial Results

Cash, Cash Equivalents and Investments: As of June 30, 2024, the Company had approximately \$1.43 billion in cash, cash equivalents and investments. Cash, cash equivalents and investments declined by approximately \$78 million during the second quarter of 2024.

Revenues: Total revenues for the quarter ended June 30, 2024, were \$3.1 million compared to \$3.8 million for the

same period in 2023.

Cost of Revenue: Cost of revenue was nominal for the second quarter of 2024 and 2023.

Research and Development Expenses (R&D): R&D expenses for the second quarter of 2024 were \$105.1 million, which included \$13.1 million of non-cash stock-based compensation expense, compared to \$168.1 million for the same period in 2023, which included \$17.1 million of non-cash stock-based compensation expense. The decrease was primarily driven by lower clinical development costs and manufacturing costs associated with VIR-2482, lower contract manufacturing costs associated with the Company's hepatitis programs, and lower personnel costs related to cost savings initiatives implemented during the second half of 2023.

Selling, General and Administrative Expenses (SG&A): SG&A expenses for the second quarter of 2024 were \$30.3 million, which included \$9.1 million of non-cash stock-based compensation expense, compared to \$45.5 million for the same period in 2023, which included \$13.5 million of non-cash stock-based compensation expense. The decrease was primarily related to cost savings initiatives implemented during the second half of 2023.

Restructuring, long-lived assets impairment and related charges: Restructuring, long-lived assets impairment and related charges for the second quarter of 2024 was \$26.3 million compared to \$5.4 million for the same period in 2023. The increase was primarily related to impairment charges related to closing our St. Louis, Missouri facility previously announced on December 13, 2023.

Other Income: Other income for the second quarter of 2024 was \$18.7 million compared to \$17.6 million for the same period in 2023.

Benefit from Income Taxes: Benefit from income taxes for the second quarter of 2024 was \$1.5 million compared to \$2.8 million for the same period in 2023.

Net Loss: Net loss attributable to Vir for the second quarter of 2024 was \$(138.4) million, or \$(1.02) per share, basic and diluted, compared to a net loss of \$(194.8) million, or \$(1.45) per share, basic and diluted for the same period in 2023.

2024 Financial Guidance

The Company is lowering its operating expense guidance for the full-year 2024, inclusive of its recently announced transaction with Sanofi and strategic restructuring. This reduction is primarily due to savings from workforce restructuring and phasing out of influenza, COVID-19, and the Company's T cell-based viral vector platform programs, as well as other ongoing cost saving efforts:

GAAP operating expense range:	\$	580	to	\$	610
The following expenses are included in the GAAP operating expense range:					
Stock-based compensation expense	\$	90	to	\$	80
Restructuring charges*	\$	40	to	\$	30

* Restructuring charges include employee severance cash payouts, as well as non-cash expense related to the closing of two R&D sites previously announced on December 13, 2023.

The revised guidance excludes the accounting impact of the upfront payment and an escrowed milestone payment in connection with the Sanofi agreement. The Company will incorporate any associated impact to its guidance in its third quarter 2024 earnings press release.

Approximately three percent of the GAAP operating expense will be funded by grants. These grants are recognized as revenue.

Except for the pending transaction with Sanofi, the GAAP operating expense guidance does not include the effect of GAAP adjustments caused by events that may occur subsequent to the publication of this guidance, including, but not limited to, business development activities, litigation, in-process R&D impairments, and changes in the fair value of contingent considerations.

Conference Call

Vir will host a conference call to discuss the second quarter 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 Tobevibart (VIR-3434)

Tobevibart is an investigational subcutaneously administered antibody designed to inhibit entry of hepatitis B and hepatitis delta viruses into hepatocytes, neutralize both hepatitis B virus and hepatitis delta virus virions and to reduce the level of virions and subviral particles in the blood. Tobevibart, which incorporates Xencor's Xtend™ and other Fc technologies, has been engineered to have an extended half-life and was identified using Vir's proprietary monoclonal antibody discovery platform.

About Elebsiran (VIR-2218)

Elebsiran is an investigational subcutaneously administered hepatitis B virus-targeting small interfering ribonucleic acid (siRNA) designed to degrade hepatitis B virus RNA transcripts and limit the production of hepatitis B surface

antigen. Vir believes it has the potential to 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. Elebsiran is the first asset in the Company's collaboration with Alnylam Pharmaceuticals, Inc. to enter clinical studies.

About Vir Biotechnology, Inc.

Vir Biotechnology, Inc. is a clinical-stage biopharmaceutical company focused on powering the immune system to transform lives by discovering and developing medicines for serious infectious diseases and cancer. Vir's clinical-stage portfolio includes infectious disease programs for chronic hepatitis delta and chronic hepatitis B infections. Vir also has a preclinical portfolio of programs across a range of other infectious diseases. 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 "should," "could," "may," "might," "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 anticipated expenditures and annual savings in connection with the restructuring; the anticipated timing of such cost impacts; Vir's cash balance; Vir's financial guidance; Vir's future financial and operating results and its expectations related thereto; Vir's ability to realize the anticipated benefits from the exclusive worldwide license agreement with Sanofi (the "Agreement"); difficulties or unanticipated expenses in connection with the Agreement, and the potential effects on Vir's earnings; the risk that Vir's investment in connection with the Agreement will lose value for any number of reasons; the ability of the parties to initiate, progress or complete clinical trials within currently anticipated timelines or at all, and the possibility of unfavorable results from studies, including those involving SAR446309 (AMX-818), SAR446329 (AMX-500) and SAR446368, and any additional programs that may become subject to the Agreement; the potential clinical effects, potential benefits, safety and efficacy of the investigational products that are the subject of these programs; data from ongoing studies evaluating such investigational products and programs; Vir's ability to file applications for regulatory approval or receive regulatory approvals in a timely manner or at all for such investigational products and programs, and the risk that any such approvals may be subject to significant limitations on use; the possibility that closing of the transaction might not occur, that the Agreement may be terminated for any number of reasons, or that development of the investigational products and programs subject to the Agreement may be discontinued, and therefore may never be successfully commercialized;

Vir's ability to successfully commercialize any approved drug products resulting from the Agreement; potential of, and expectations for, Vir's pipeline; Vir's clinical and preclinical development programs; clinical studies, including the enrollment of clinical studies, and the expected timing of data readouts and presentations; the potential benefits, safety, and efficacy of Vir's investigational therapies; Vir's strategy and plans; and risks and uncertainties associated with drug development and commercialization. Many factors may cause differences between current expectations and actual results, including whether or when the anticipated cost reductions will be achieved; unexpected safety or efficacy data or results observed during clinical studies or in data readouts; the occurrence of adverse safety events; risks of unexpected costs, delays or other unexpected hurdles; difficulties in collaborating with other companies; 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 studies due to geopolitical changes or other external factors; failure to achieve any necessary regulatory approvals; the timing and amount of actual expenses, including, without limitation, Vir's anticipated combined GAAP R&D and SG&A expenses; 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 studies may not be indicative of full results or results from later stage or larger scale clinical studies 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 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 Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	June 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 296,864	\$ 241,576
Short-term investments	849,833	1,270,980
Restricted cash and cash equivalents, current	13,946	13,268
Equity investments	4,368	9,853
Prepaid expenses and other current assets	40,729	52,549
Total current assets	1,205,740	1,588,226
Intangible assets, net	18,899	22,565
Goodwill	16,937	16,937
Property and equipment, net	66,063	96,018
Operating lease right-of-use assets	62,266	71,182
Restricted cash and cash equivalents, noncurrent	6,366	6,448
Long-term investments	279,992	105,275
Other assets	13,292	12,409
TOTAL ASSETS	\$ 1,669,555	\$ 1,919,060
LIABILITIES AND STOCKHOLDERS' EQUITY		

CURRENT LIABILITIES:		
Accounts payable	\$ 4,389	\$ 6,334
Accrued and other liabilities	75,321	104,220
Deferred revenue, current	16,702	64,853
Total current liabilities	96,412	175,407
Operating lease liabilities, noncurrent	95,018	111,673
Contingent consideration, noncurrent	30,600	25,960
Other long-term liabilities	13,855	15,784
TOTAL LIABILITIES	235,885	328,824
Commitments and contingencies (Note 8)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized as of June 30, 2024 and December 31, 2023; no shares issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 136,590,097 and 134,781,286 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	14	13
Additional paid-in capital	1,878,013	1,828,862
Accumulated other comprehensive loss	(2,879)	(815)
Accumulated deficit	(441,478)	(237,824)
TOTAL STOCKHOLDERS' EQUITY	1,433,670	1,590,236
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 1,669,555	\$ 1,919,060

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

	Three Months Ended June 30,	
	2024	2023
Revenues:		
Collaboration revenue	\$ 55	\$ (13,779)
Contract revenue	886	1,057
Grant revenue	2,134	16,519
Total revenues	3,075	3,797
Operating expenses:		
Cost of revenue	52	22
Research and development	105,113	168,083
Selling, general and administrative	30,265	45,512
Restructuring, long-lived assets impairment and related charges	26,275	5,366
Total operating expenses	161,705	218,983
Loss from operations	(158,630)	(215,186)
Other income:		
Change in fair value of equity investments	429	(5,086)
Interest income	18,846	23,016
Other expense, net	(535)	(367)
Total other income	18,740	17,563
Loss before benefit from income taxes	(139,890)	(197,623)
Benefit from income taxes	1,512	2,848
Net loss	(138,378)	(194,775)
Net loss attributable to noncontrolling interest	—	—
Net loss attributable to Vir	\$ (138,378)	\$ (194,775)
Net loss per share attributable to Vir, basic and diluted	\$ (1.02)	\$ (1.45)
Weighted-average shares outstanding, basic and diluted	136,233,725	134,059,079

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