NEWS RELEASE

Vir Biotechnology Reports Third Quarter 2024 Financial Results and Provides Corporate Update

10/31/2024

– Successful closing of exclusive worldwide licensing agreement with Sanofi for three potential best-in-class clinical-stage dual-masked T-cell engagers with initial clinical data anticipated in Q1 2025 –

– Key Phase 2 SOLSTICE data in chronic hepatitis delta to be presented at AASLD 2024 –

– The Company will host a Hepatitis Investor Event following AASLD on November 19, 2024 –

– Jason O'Byrne appointed as Chief Financial Officer –

– Conference call scheduled for October 31, 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 third quarter ended September 30, 2024.

"This quarter was transformational for Vir. We have bolstered our clinical pipeline with three potential best-in-class dual-masked T-cell engagers in oncology, and have sharpened our focus within infectious diseases to the areas where we believe we can make the most significant impact for patients. We are also thrilled to welcome Jason O'Byrne as our new CFO. Jason brings a wealth of financial leadership experience, further strengthening our ability to bring these potentially transformative therapies to patients as quickly as possible," said Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer, Vir Biotechnology. "Looking ahead, this is an exciting time for the Company. We eagerly anticipate critical data in our hepatitis programs in the fourth quarter and look forward to sharing initial clinical data from our dual-masked T-cell engagers in the first quarter of 2025."

Pipeline Programs

Chronic Hepatitis Delta (CHD)

- Preliminary data from the Phase 2 chronic hepatitis delta SOLSTICE study was presented at the European Study of the Liver (EASL) Meeting in June 2024. This data demonstrated the potential for transformative treatment for people living with chronic hepatitis delta, with both tobevibart as a monotherapy, and in combination with elebsiran, achieving high rates of virologic response and ALT normalization after 12 and 24 weeks of treatment. No treatment-related serious adverse events were observed.
- The combination of tobevibart and elebsiran has been granted Fast Track Designation by the U.S. FDA. Given the robust rates of virologic suppression observed with the combination, the Company is diligently working to advance this regimen into a pivotal development program as quickly as possible to address the urgent needs of these patients.
- At the upcoming American Association for the Study of Liver Diseases (AASLD) "The Liver Meeting" in November 2024, the Company will present additional data from the Phase 2 chronic hepatitis delta SOLSTICE trial, including: 24-week clinical data for both study cohorts in approximately 60 patients and further data for those patients who were on study beyond 24 weeks at the time of data cut-off.
    - One cohort assesses the combination of tobevibart and elebsiran administered every four weeks, while a second cohort evaluates tobevibart monotherapy administered every two weeks.
- The SOLSTICE trial is evaluating the safety, tolerability and efficacy of tobevibart and elebsiran for the treatment of chronic hepatitis delta.

Chronic Hepatitis B (CHB)

- The Company plans to share end-of-treatment data from the Phase 2 MARCH Part B trial as a Late Breaking presentation at the AASLD meeting in November 2024.
    - The MARCH-B trial is evaluating the safety, tolerability and antiviral activity of the triplet combination of tobevibart and elebsiran plus peginterferon alfa-2a in approximately 30 participants, and approximately 50 participants treated with the doublet combination of tobevibart and elebsiran.
    - The Company plans to share further data assessing a potential functional cure in the second quarter of 2025.

Solid Tumors

- VIR-5818 is a dual-masked HER2-targeted T-cell engager in clinical development designed to minimize off-tumor toxicity, potentially allowing for higher doses and increased efficacy to address the significant unmet needs of patients with HER2 expressing cancers.
    - A Phase 1 basket study of VIR-5818 as a monotherapy, and in combination with pembrolizumab, is on-going in multiple tumor types, including metastatic breast cancer and metastatic colorectal cancer.
    - The Company plans to share initial clinical data for VIR-5818 in the first quarter of 2025.

- VIR-5500 is a dual-masked PSMA directed T-cell engager in clinical development designed to minimize off-tumor toxicity and potentially improve efficacy relative to the existing approved PSMA-targeted therapies.
    - A Phase 1 dose escalation study of VIR-5500 is ongoing to assess its safety profile and optimal dose levels for future development in metastatic-castration resistant prostate cancer.
    - The Company plans to share initial clinical data for VIR-5500 in the first quarter of 2025.
- VIR-5525 is a dual-masked EGFR targeted T-cell engager with a cleared Investigational New Drug Application (IND) from the U.S. FDA.
    - The Company plans to initiate a Phase 1 basket study of VIR-5525 in the first quarter of 2025 in patients across a number of solid tumor indications of high unmet need, which may include metastatic head and neck squamous cell carcinoma, metastatic adenocarcinoma, squamous non-small cell lung cancer, and metastatic colorectal cancer.

Preclinical Pipeline Candidates

- The Company continues to advance pre-clinical assets in respiratory syncytial virus in partnership with GSK and pursue HIV cure in collaboration with the Bill & Melinda Gates Foundation.

Corporate Update

- On August 1, 2024 the Company **announced** an exclusive worldwide license to three clinical-stage masked T-cell engagers (TCEs) with potential applications in a range of cancers, as well as the exclusive use of the proprietary PRO-XTEN™ masking platform for oncology and infectious disease. The Company **announced** closing of the agreement with Sanofi on September 9, 2024.
    - Key employees from Sanofi, possessing extensive scientific and development expertise in TCEs, and in-depth experience with the PRO-XTEN™ platform, joined the Company following the closing of the agreement.
- On August 1, 2024 the Company **announced** the phase-out of clinical programs in influenza, COVID-19, and its T-cell based viral vector platform. The Company is seeking partners to advance these clinical programs through further development. Additionally, the Company announced a workforce reduction of approximately 25%, or approximately 140 employees, and expects to end 2024 with approximately 435 employees – a decrease of approximately 200 from its peak headcount in the second quarter of 2023.
- On September 10, 2024, the Company **announced** the appointment of Jason O'Byrne as Executive Vice President and Chief Financial Officer, effective October 2, 2024. Mr. O'Byrne is an accomplished executive with more than 20 years of finance and operations experience, and brings leadership in capital allocation and formation, corporate strategy and operational excellence.
- The Company will host two virtual investor events instead of the previously scheduled R&D Day in the fourth

quarter of 2024. The first event, focusing on our hepatitis programs, will be held in November 2024, following the AASLD conference, and will provide detailed updates on our hepatitis delta and hepatitis B programs. In the first quarter of 2025, the Company will share initial clinical data for our masked T-cell engager programs during a second dedicated investor event.

Third Quarter 2024 Financial Results

Cash, Cash Equivalents and Investments: As of September 30, 2024, the Company had approximately $1.19 billion in cash, cash equivalents and investments, representing a decrease of approximately $245.1 million during the third quarter of 2024. The decrease includes a $103.7 million upfront payment made to Sanofi upon the closing of the agreement and a $75.0 million escrowed milestone payment reclassified to restricted cash. The escrowed milestone is subject to VIR-5525 achieving "first in human dosing" by 2026. Excluding the impact of the Sanofi agreement, the decrease in cash, cash equivalents and investments in the third quarter was approximately $66.4 million.

Revenues: Total revenues for the quarter ended September 30, 2024, were $2.4 million compared to $2.6 million for the same period in 2023.

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

Research and Development Expenses (R&D): R&D expenses for the third quarter of 2024 were $195.2 million, which included $8.9 million of non-cash stock-based compensation expense, compared to $145.0 million for the same period in 2023, which included $15.8 million of non-cash stock-based compensation expense. The increase was primarily driven by $102.8 million of the Sanofi upfront payment being recognized as in-process research and development expense, partially offset by lower clinical development costs and manufacturing costs associated with the discontinued flu asset, VIR-2482.

Selling, General and Administrative Expenses (SG&A): SG&A expenses for the third quarter of 2024 were $25.7 million, which included $7.8 million of non-cash stock-based compensation expense, compared to $40.9 million for the same period in 2023, which included $11.1 million of non-cash stock-based compensation expense. The decrease was largely 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 third quarter of 2024 were $12.7 million compared to $3.4 million for the same period in 2023. The increase was primarily driven by severance charges incurred related to our strategic restructuring announcement in August 2024 and to a lesser extent right-of-use asset impairment charges related to the closing of our Portland, Oregon facility, which was previously announced on December 13, 2023.

Other Income: Other income for the third quarter of 2024 was $17.8 million compared to $20.1 million for the same period in 2023. The decrease was primarily due to lower interest income.

(Provision for) Benefit from Income Taxes: Provision for income taxes for the third quarter of 2024 was $0.2 million compared to a benefit from income taxes of $3.2 million for the same period in 2023.

Net Loss: Net loss attributable to Vir for the third quarter of 2024 was $(213.7) million, or $(1.56) per share, basic and diluted, compared to a net loss of $(163.4) million, or $(1.22) per share, basic and diluted for the same period in 2023.

20 24 Financial Guidance

The Company has updated its operating expense guidance for the full-year 2024, which includes the upfront in-process research and development expense associated with the clinical-stage T-cell engagers licensed through its agreement with Sanofi:

(in $ millions)		
GAAP operating expense range:	$ 660 to $	680
The following expenses are included in the GAAP operating expense range:		
Upfront payment to Sanofi recognized as R&D expense in the third quarter of 2024	$103	
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 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 third 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 broadly neutralizing monoclonal antibody targeting the hepatitis B surface antigen. It is designed to inhibit the entry of hepatitis B and hepatitis delta viruses into hepatocytes, and to reduce the level of circulating viral 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. Tobevibart is administered subcutaneously, and it is currently in clinical development for treatment of patients with chronic hepatitis B and patients with chronic hepatitis delta.

About Elebsiran (VIR-2218)

Elebsiran is an investigational 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. Current data indicates that it has the potential to have direct antiviral activity against hepatitis B virus and hepatitis delta virus. Elebsiran is administered subcutaneously, and it is currently in clinical development for treatment of patients with chronic hepatitis B and patients with chronic hepatitis delta. It is the first asset in Vir's collaboration with Alnylam Pharmaceuticals, Inc. to enter clinical studies.

About VIR-5818, VIR-5500, VIR-5525

VIR-5818, VIR-5500, VIR-5525 are investigational, clinical candidates currently being evaluated for the treatment of solid tumors. These assets leverage the PRO-XTEN™ masking technology with three different T-cell engagers (TCEs) targeting HER2, PSMA, and EGFR, respectively.

TCEs are powerful anti-tumor agents that direct the immune system, specifically T-cells, to destroy cancer cells. The PRO-XTEN™ masking technology is designed to keep the TCEs inactive (or masked) until they reach the tumor microenvironment, where tumor-specific proteases cleave off the mask and activate the TCEs leading to killing of cancer cells. By driving the activity exclusively to the tumor microenvironment, we aim to circumvent the traditionally high toxicity associated with TCEs and increase their efficacy and tolerability. Additionally, the mask also helps drug candidates stay in the bloodstream longer in their inactive form, allowing them to better reach the site of action and potentially allowing more convenient dosing regimens for patients and clinicians.

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, in addition to programs across several clinically validated targets in solid tumor indications. Vir also has a preclinical portfolio of programs across a range of other infectious diseases and oncologic malignancies. 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; Vir’s cash balance; Vir’s future financial and operating results and its expectations related thereto including Vir’s financial guidance; Vir’s ability to realize the anticipated benefits from the exclusive worldwide license agreement with Sanofi; 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 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.

PRO-XTEN™ is a trademark of Amunix Pharmaceuticals, Inc., a Sanofi company.

VIR BIOTECHNOLOGY, INC.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

(unaudited)

	September 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 168,350	$ 241,576
Short-term investments	740,607	1,270,980
Restricted cash and cash equivalents, current	89,598	13,268
Equity investments	5,517	9,853
Prepaid expenses and other current assets	43,085	52,549
Total current assets	1,047,157	1,588,226
Intangible assets, net	19,258	22,565
Goodwill	16,938	16,937
Property and equipment, net	64,791	96,018
Operating lease right-of-use assets	60,779	71,182
Restricted cash and cash equivalents, noncurrent	6,382	6,448
Long-term investments	271,495	105,275
Other assets	11,556	12,409
TOTAL ASSETS	$ 1,498,356	$ 1,919,060
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 7,305	$ 6,334
Accrued and other liabilities	94,658	104,220
Deferred revenue, current	15,198	64,853
Total current liabilities	117,161	175,407
Operating lease liabilities, noncurrent	93,405	111,673
Contingent consideration, noncurrent	33,170	25,960
Other long-term liabilities	13,893	15,784
TOTAL LIABILITIES	257,629	328,824
Commitments and contingencies (Note 8)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2024 and December 31, 2023; no shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 136,706,350 and 134,781,286 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	14	13
Additional paid-in capital	1,894,781	1,828,862
Accumulated other comprehensive gain (loss)	1,127	(815)
Accumulated deficit	(655,195)	(237,824)
TOTAL STOCKHOLDERS' EQUITY	1,240,727	1,590,236
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,498,356	$ 1,919,060

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

	Three Months Ended September 30,	
	2024	2023
Revenues:		
Collaboration revenue	$ (1,102)	$ (4,387)
Contract revenue	1,391	289
Grant revenue	2,091	6,737
Total revenues	2,380	2,639
Operating expenses:		
Cost of revenue	50	38
Research and development	195,178	145,028
Selling, general and administrative	25,744	40,933
Restructuring, long-lived assets impairment and related charges	12,712	3,372
Total operating expenses	233,684	189,371
Loss from operations	(231,304)	(186,732)
Other income:		
Change in fair value of equity investments	1,130	(2,707)
Interest income	17,527	21,931

Other (expense) income, net	(893)	882
Total other income	17,764	20,106
Loss before (provision for) benefit from income taxes	(213,540)	(166,626)
(Provision for) benefit from income taxes	(177)	3,213
Net loss	(213,717)	(163,413)
Net loss attributable to noncontrolling interest	—	—
Net loss attributable to Vir	$ (213,717)	$ (163,413)
Net loss per share attributable to Vir, basic and diluted	$ (1.56)	$ (1.22)
Weighted-average shares outstanding, basic and diluted	136,653,753	134,289,620

Media

Arran Attridge

Senior Vice President, Corporate Communications

aattridge@vir.bio

Investors

Richard Lepke

Senior Director, Investor Relations

rlepke@vir.bio

Source: Vir Biotechnology, Inc.