

Vir Biotechnology Provides Corporate Update and Reports First Quarter 2025 Financial Results

2025-05-07

- Initiated Phase 3 registrational ECLIPSE program in chronic hepatitis delta with first patient enrolled in Q1 2025; Program received U.S. FDA Breakthrough and Fast Track designations and EMA PRIME and Orphan Drug designations
- Dose escalation continues for PRO-XTEN™ dual-masked T-cell engagers VIR-5818 (HER2) and VIR-5500 (PSMA)
- On track to initiate a Phase 1 study of VIR-5525, the PRO-XTEN™ dual-masked EGFR-targeting T-cell engager, in the second quarter of 2025
- 24-week post-treatment data from Phase 2 MARCH study in chronic hepatitis B to be presented at EASL on May 9; Further development requires partner
- Strong financial position with approximately \$1.0 billion in cash and investments providing runway into mid-2027
- Conference call scheduled for May 7, 2025 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 first quarter ended March 31, 2025.

"The first quarter of 2025 marked significant progress in our mission of powering the immune system to transform lives," said Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer, Vir Biotechnology. "We successfully dosed the first patient in our ECLIPSE Phase 3 registrational program for hepatitis delta, a devastating disease with no FDA-approved treatment in the U.S. In our oncology portfolio, we are continuing dose escalation in our VIR-5818 HER2-targeting and VIR-5500 PSMA-targeting T-cell engager programs and preparing to initiate a Phase 1 study of our EGFR-targeting T-cell engager, VIR-5525, this quarter. We remain confident in our ability to deliver potentially transformative medicines for patients with significant unmet needs."

Pipeline Programs

Chronic Hepatitis Delta (CHD)

- ECLIPSE 1, the first Phase 3 trial of the Company's registrational program in CHD, enrolled its first patient in March 2025 and is progressing as planned. The clinical trial will assess the efficacy and safety of tobevibart and elebsiran compared to deferred treatment in regions such as the U.S. where bulevirtide is not available or other regions where its access is limited.
- The Company is advancing plans for the initiation of ECLIPSE 2, a Phase 3 trial that will evaluate the efficacy and safety of switching to tobevibart and elebsiran in people with CHD who have not achieved viral suppression with bulevirtide therapy.
- The Company plans to share Phase 2 SOLSTICE subgroup analysis data in CHD in a poster presentation at the European Association for the Study of the Liver (EASL) Congress 2025. The poster was selected by EASL to be highlighted during the poster tour on May 8, 2025.
- Tobevibart and elebsiran combination therapy is supported by multiple U.S. and EU regulatory designations, including U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation, U.S. FDA Fast Track designation, European Priority Medicines (PRIME) designation and European Orphan Drug designation, signifying the significant unmet need in CHD.

Solid Tumors

- VIR-5818, the only dual-masked HER2-targeting T-cell engager (TCE) in clinical trials, continues to advance through dose escalation as a monotherapy, and in combination with pembrolizumab, in multiple tumor types, including metastatic breast cancer and metastatic colorectal cancer.
 - In early Phase 1 data reported in January 2025, VIR-5818 showed tumor shrinkage across various tumor types in 50% (10/20) of participants receiving doses ≥ 400 $\mu\text{g/kg}$, with confirmed partial responses in 33% (2/6) of participants with HER2-positive colorectal cancer (CRC).
- VIR-5500, the only dual-masked PSMA-targeting TCE in clinical trials, continues to advance through dose escalation aiming to further optimize dosing and efficacy.
 - In early Phase 1 data reported in January 2025, VIR-5500 showed PSA reductions in 100% (12/12) of metastatic castration resistant prostate cancer (mCRPC) patients after an initial dose ≥ 120 $\mu\text{g/kg}$. PSA₅₀ response was confirmed in 58% (7/12) of participants.
- Early Phase 1 data for VIR-5818 and VIR-5500 reported in January 2025 showed promising safety profiles for both clinical candidates, with maximum tolerated dose (MTD) not yet reached, no dose-limiting cytokine release syndrome (CRS) observed and no CRS greater than grade 2 reported.

- Initial clinical data demonstrate the PRO-XTEN™ masking technology's potential to minimize systemic toxicity while enabling selective killing of cancer cells in the tumor microenvironment, minimizing CRS and expanding the therapeutic index compared to traditional therapeutic approaches.
- The Company plans to initiate a Phase 1 study of VIR-5525, its PRO-XTEN™ dual-masked EGFR-targeting TCE, in the second quarter of 2025, to evaluate its potential across a number of solid tumor indications.

Chronic Hepatitis B (CHB)

- The Company will present functional cure data from the 24-week follow-up of the MARCH Part B Phase 2 clinical study evaluating combinations of tobevibart and elebsiran, alone, or in combination with pegylated interferon alfa (PEG-IFNα) at the EASL Congress 2025 on May 9, 2025.
- Future advancement in CHB by the Company will be contingent on securing a worldwide development and commercialization partner¹.

¹ Outside China Territory (People's Republic of China, Hong Kong, Taiwan, and Macau)

Preclinical Pipeline Candidates

- The Company continues to progress multiple undisclosed PRO-XTEN™ dual-masked TCEs against clinically validated targets with potential applications across a number of solid tumors. These preclinical candidates integrate the PRO-XTEN™ masking technology with novel TCEs discovered and engineered using Vir Biotechnology's antibody discovery platform and the Company's proprietary dAIsY™ (dataAI structure and antibody) AI engine.
- The Company has advanced a broadly neutralizing antibody to development candidate status in its HIV cure program in collaboration with the Gates Foundation.

Corporate Update

- In January 2025, the Company announced positive initial Phase 1 dose escalation data for two of its PRO-XTEN™ dual-masked TCEs.
- During the quarter, Vir Biotechnology and Alnylam Pharmaceuticals (Alnylam) amended and restated their collaboration agreement, with Alnylam electing not to opt-in to its profit-sharing option for elebsiran in CHB and CHD indications. The amended agreement provides the Company with the flexibility to pursue commercialization partners in markets outside the U.S.

First Quarter 2025 Financial Results

Cash, Cash Equivalents and Investments: As of March 31, 2025, the Company had approximately \$1.02 billion in cash, cash equivalents and investments, representing a decrease of approximately \$75.6 million during

the first quarter of 2025.

Revenues: Total revenues for the first quarter of 2025 were \$3.0 million compared to \$56.4 million for the same period in 2024. The decrease was primarily due to \$51.7 million of deferred revenue recognized during the first quarter of 2024 when GSK's rights to select up to two additional non-influenza target pathogens under the 2021 GSK Agreement expired on March 25, 2024.

Cost of Revenue: The change in cost of revenue for the first quarter of 2025 compared to the same period in 2024 was nominal.

Research and Development Expenses (R&D): R&D expenses for the first quarter of 2025 were \$118.6 million, which included \$7.0 million of non-cash stock-based compensation expense, compared to \$100.1 million for the same period in 2024, which included \$13.6 million of non-cash stock-based compensation expense. The increase was primarily driven by a \$30.0 million expense to Alnylam and initiation of the ECLIPSE Phase 3 registrational program, partially offset by lower headcount, deprioritized programs and the closing of the Company's St. Louis, Missouri and Portland, Oregon sites.

The Company is solely responsible for the development, manufacturing and commercialization activities associated with elebsiran after the amendment and restatement of the Company's agreement with Alnylam.

Selling, General and Administrative Expenses (SG&A): SG&A expenses for the first quarter of 2025 were \$23.9 million, which included \$7.1 million of non-cash stock-based compensation expense, compared to \$36.3 million for the same period in 2024, which included \$10.2 million of non-cash stock-based compensation expense. The decrease was largely due to ongoing cost saving realized through headcount reductions and other initiatives.

Restructuring, Long-Lived Assets Impairment and Related Charges, Net: The change in restructuring, long-lived assets impairment and related charges, net for the first quarter of 2025 compared to the same period in 2024 was nominal. Our restructuring plans implemented in prior years were substantially completed by the end of 2024.

Other Income: Other income for the first quarter of 2025 was \$18.6 million compared to \$15.1 million for the same period in 2024. The increase was primarily driven by an unrealized gain on our equity investments, partially offset by lower interest income.

Provision for Income Taxes: The change in provision for income taxes for the first quarter of 2025 compared to the same period in 2024 was nominal.

Net Loss: Net loss for the first quarter of 2025 was \$121.0 million, or \$(0.88) per share, basic and diluted, compared to a net loss of \$65.3 million, or \$(0.48) per share, basic and diluted for the same period in 2024.

2025 Financial Guidance

Based on current operating plans, the Company expects its cash, cash equivalents and investments to fund its operations into mid-2027.

Conference Call

Vir Biotechnology will host a conference call to discuss the first 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 for 30 days.

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

VIR-5818, VIR-5500 and 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 can 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 is designed to help drug candidates stay in the bloodstream longer in their inactive form, allowing them to better reach the site of action and potentially allowing less frequent dosing regimens for patients and clinicians.

About Tobevibart and Elebsiran

Tobevibart is an investigational broadly neutralizing monoclonal antibody targeting the hepatitis B surface antigen (HBsAg). 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 was identified using Vir Biotechnology's proprietary monoclonal antibody discovery platform. The Fc domain has been engineered to increase immune engagement and clearance of HBsAg immune complexes and incorporates Xencor's Xtend™ technology to extend half-life. Tobevibart is administered subcutaneously, and it is currently in clinical development for the treatment of patients with chronic hepatitis delta and patients with chronic hepatitis B.

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 the treatment of patients with chronic hepatitis delta and patients with chronic hepatitis B.

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. Its clinical-stage portfolio includes infectious disease programs for chronic hepatitis delta and chronic hepatitis B infections and multiple dual-masked T-cell engagers across validated targets in solid tumor indications. Vir Biotechnology also has a preclinical portfolio of programs across a range of infectious diseases and oncologic malignancies. Vir Biotechnology routinely posts information that may be important to investors on its website.

Vir Biotechnology has exclusive rights to the PRO-XTEN™ masking platform for oncology and infectious disease. PRO-XTEN™ is a trademark of Amunix Pharmaceuticals, Inc., a Sanofi company.

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. Forward-looking statements contained in this press release include, but are not limited to, statements regarding: Vir Biotechnology's cash balance and anticipated runway; Vir Biotechnology's future financial and operating results and its expectations related thereto, including Vir Biotechnology's financial guidance; the therapeutic potential of Vir Biotechnology's CHD and CHB programs, as well as Vir Biotechnology's strategy, plans and expectations related thereto; the therapeutic potential of Vir Biotechnology's oncology solid tumor portfolio, preclinical pipeline and PRO-XTEN™ masked TCE platform, as well as Vir Biotechnology's strategy, plans and expectations related thereto; the potential of and Vir Biotechnology's expectations for its other pipeline programs; Vir Biotechnology's clinical development plans and expectations for its oncology and hepatitis programs, including protocols for and enrollment into ongoing and planned clinical studies, potential partnering opportunities, and data readouts and presentations, as well as anticipated timelines; the potential benefits, safety and efficacy of Vir Biotechnology's investigational therapies; Vir Biotechnology's strategy and plans; and any assumptions underlying any of the foregoing. Many factors may cause differences between current expectations and actual results, including, without limitation: unexpected safety or efficacy data or results observed during clinical studies or in data readouts, including the

occurrence of adverse safety events; risks of unexpected costs, delays or other unexpected hurdles; the timing and amount of Vir Biotechnology's actual operating expenses, as determined in accordance with U.S. Generally Accepted Accounting Principles; difficulties in collaborating with other companies, some of whom may be competitors of Vir Biotechnology or otherwise have divergent interests, and uncertainty as to whether the benefits of Vir Biotechnology's various collaborations can ultimately be achieved; challenges in accessing manufacturing capacity; clinical site activation rates or clinical enrollment rates that are lower than expected; the timing and outcome of Vir Biotechnology's planned interactions with regulatory authorities, as well as general difficulties in obtaining any necessary regulatory approvals; successful development and/or commercialization of alternative product candidates by Vir Biotechnology's competitors, as well as changes in expected or existing competition; Vir Biotechnology's use of artificial intelligence and machine learning in its efforts to engineer next-generation proteins and in other research and development efforts; geopolitical changes or other external factors; and unexpected litigation or other disputes. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. 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. The actual results may vary from the anticipated results, and the variations may be material. You are cautioned not to place undue reliance on any scientific data presented or these forward-looking statements, which are based on Vir Biotechnology's available information, expectations and assumptions as of the date of this press release. Other factors that may cause Vir Biotechnology's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Vir Biotechnology's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as required by law, Vir Biotechnology assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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

	March 31, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 273,571	\$ 222,947
Short-term investments	517,367	678,051
Restricted cash and cash equivalents, current	88,151	89,385
Equity investments	10,724	4,350
Prepaid expenses and other current assets	42,394	47,725
Total current assets	932,207	1,042,458
Intangible assets, net	8,072	8,120
Goodwill	16,937	16,937
Property and equipment, net	61,681	63,183
Operating lease right-of-use assets	58,559	59,680
Restricted cash and cash equivalents, noncurrent	6,273	6,363
Long-term investments	218,140	190,015

Other assets	5,858	12,057
TOTAL ASSETS	\$ 1,307,727	\$ 1,398,813
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 3,725	\$ 5,081
Accrued and other liabilities	104,126	85,873
Deferred revenue, current	11,935	12,648
Contingent consideration obligation, current	17,500	16,060
Total current liabilities	137,286	119,662
Operating lease liabilities, noncurrent	88,170	90,139
Contingent consideration obligation, noncurrent	23,640	24,050
Other long-term liabilities	14,812	14,577
TOTAL LIABILITIES	263,908	248,428
Commitments and contingencies (Note 7)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized as of March 31, 2025 and December 31, 2024; no shares issued and outstanding as of March 31, 2025 and December 31, 2024	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized as of March 31, 2025 and December 31, 2024; 138,063,698 and 136,959,446 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	14	14
Additional paid-in capital	1,926,529	1,911,872
Accumulated other comprehensive loss	(1,975)	(1,717)
Accumulated deficit	(880,749)	(759,784)
TOTAL STOCKHOLDERS' EQUITY	1,043,819	1,150,385
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 1,307,727	\$ 1,398,813

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

	Three Months Ended March 31,	
	2025	2024
Revenues:		
Collaboration revenue	\$ (70)	\$ (987)
Contract revenue	1,864	52,191
Grant revenue	1,238	5,172
Total revenues	3,032	56,376
Operating expenses:		
Cost of revenue	—	59
Research and development	118,645	100,125
Selling, general and administrative	23,944	36,321
Restructuring, long-lived assets impairment and related charges, net	(10)	(48)
Total operating expenses	142,579	136,457
Loss from operations	(139,547)	(80,081)
Other income:		
Change in fair value of equity investments	6,382	(5,915)
Interest income	12,288	21,283
Other expense, net	(72)	(287)
Total other income	18,598	15,081
Loss before provision for income taxes	(120,949)	(65,000)
Provision for income taxes	(16)	(276)
Net loss	\$ (120,965)	\$ (65,276)
Net loss per share, basic and diluted	\$ (0.88)	\$ (0.48)
Weighted-average shares outstanding, basic and diluted	137,468,900	135,280,648

Investors

Richard Lepke

Senior Director, Investor Relations

rlepke@vir.bio

Source: Vir Biotechnology, Inc.