Viracta | Investor Relations

Viracta Therapeutics Reports First Quarter 2022 Financial Results and Recent Updates

Continued global expansion of NAVAL-1, the pivotal trial of Nana-val for the treatment of Epstein-Barr virus-positive (EBV$^+$) lymphoma; update on the initial cohort(s) that have advanced into Stage 2 anticipated in the second half of 2022

Preliminary safety and efficacy data for the Phase 1b/2 trial of Nana-val in advanced EBV$^+$ solid tumors anticipated in the second half of 2022

Cash balance of $92.2 million as of March 31, 2022; projected cash runway into mid-2024

SAN DIEGO, May 10, 2022 /PRNewswire/ -- Viracta Therapeutics, Inc. (Nasdaq: VIRX), a precision oncology company targeting virus-associated malignancies, today reported financial results for the first quarter of 2022 and provided an update on recent corporate progress.

"We have made encouraging progress in both clinical programs with our all-oral drug product candidate, Nana-val, which are advancing towards potential key catalysts in the second half of the year," said Ivor Royston, M.D., President and Chief Executive Officer of Viracta. "Since the first patient was dosed in January, our Phase 1b/2 trial of Nana-val in patients with advanced EBV-positive solid tumors has proceeded nicely and we anticipate reporting preliminary safety and efficacy data later this year. In addition, we are pleased to have expanded the clinical reach of NAVAL-1 beyond North America into Europe as well as Asia, and anticipate having an update on cohorts advancing into Stage 2 of the trial later this year."

First Quarter 2022 and Recent Highlights

Clinical

- **Continued global expansion and enrollment into NAVAL-1, the pivotal trial of Nana-val (nanatinostat and valganciclovir) for the treatment of patients with relapsed/refractory EBV$^+$ lymphoma.** NAVAL-1 employs a Simon two-stage design where patients are initially enrolled into six cohorts based on lymphoma subtype in Stage 1. If a pre-specified activity threshold is reached, additional patients will be enrolled in Stage 2. Lymphoma subtypes demonstrating promising activity in Stage 2 may be further expanded. If successful, the Company believes NAVAL-1 could potentially support multiple new drug application filings across various EBV$^+$ lymphoma subtypes. Clinical sites are open across the globe, including in the U.S., Canada, Europe, and Asia. The Company anticipates providing an update on the initial cohort(s) that may advance into Stage 2 of the trial in the second half of the year.
- **Dosed first patient in the Phase 1b/2 trial of Nana-val in patients with EBV$^+$ recurrent or metastatic nasopharyngeal carcinoma (R/M NPC) and other EBV$^+$ solid tumors.** Enrollment continues in the Phase 1b dose escalation part of the study, which is designed to evaluate safety and determine the recommended Phase 2 dose (RP2D) of Nana-val in patients with EBV$^+$ R/M NPC. In Phase 2, up to 60 patients with EBV$^+$ R/M NPC will be randomized to receive Nana-val at the RP2D with or without pembrolizumab to evaluate safety and preliminary efficacy. Additionally, patients with other EBV$^+$ solid tumors will be enrolled to receive Nana-val at the RP2D in a Phase 1b dose expansion cohort. Viracta anticipates reporting preliminary Phase 1b safety and efficacy data from the trial in the second half of 2022.

Corporate

- **Hosted key opinion leader webinar on Nana-val for the treatment of advanced EBV$^+$ solid tumors.** The webinar featured presentations from key opinion leader Ezra Cohen, MD, FRCPSC, FASCO (University of California, San Diego) and members of the Viracta management team. Topics discussed included the current treatment landscape and unmet medical need in NPC, the design of the Phase 1b/2 trial of Nana-val in advanced EBV$^+$ solid tumors, and preclinical data supporting the trial. A replay of the webinar is available here.

Anticipated 2022 Milestones

- Provide preliminary Phase 1b safety and efficacy data from the Phase 1b/2 trial in advanced EBV$^+$ solid tumors: 2H 2022
- Update on NAVAL-1 cohort(s) that may progress from Stage 1 to Stage 2: 2H 2022

First Quarter 2022 Financial Results

- **Cash Position –** Cash and cash equivalents totaled approximately $92.2 million as of March 31, 2022, which Viracta expects will be sufficient to fund its operations into mid-2024, excluding any borrowing under its previously announced $50.0 million credit facility from Silicon Valley Bank and Oxford Finance.
- **Research and development expenses** – Research and development expenses were approximately $6.1 million for the three months ended March 31, 2022, compared to $4.0 million for the same period in 2021. The increase in research and development expenses for the three months ended March 31, 2022, was primarily due to increases in costs incurred to support the initiation of the NAVAL-1 and solid tumor trials as well as an increase in headcount and non-cash share-based compensation.
- **Acquired in-process research and development** – For the three months ended March 31, 2021, the acquired in-process research and development included non-cash and non-recurring cost of $84.5 million associated with the estimated fair value of the in-process research and development projects acquired in the Sunesis asset acquisition with no alternative future use, which was charged to expense on the Sunesis merger date.
- **General and administrative expenses** – General and administrative expenses were approximately $4.3 million for the three months ended March 31, 2022, compared to $3.8 million for the same period in 2021. The increase was largely due to incremental costs associated with being a publicly traded company including directors and officers' insurance costs, and non-cash share-based compensation.
- **Gain on Royalty Purchase Agreement** – For the three months ended March 31, 2021, the gain was associated with upfront proceeds of $13.5 million recorded in connection with the multi-license milestone and royalty monetization transaction with XOMA (US) LLC.
- **Adjusted loss from operations** – There was not a comparative adjustment to loss from operations for the quarter ended March 31, 2022. Adjusted income from operations for the quarter ended March 31, 2021, excluding the non-recurring and non-cash operating expenses associated with the write-off of in-process research and development acquired in the merger (a non-GAAP measure) was $5.6 million, compared to an unadjusted loss from operations of $78.8 million.
- **Net loss** – Net loss was approximately $10.5 million, or $0.28 per share (basic and diluted) for the quarter ended March 31, 2022, compared to a net loss of $79.2 million or $5.22 per share for the same period in 2021.

About Nana-val (Nanatinostat and Valganciclovir)

Nanatinostat is an orally available histone deacetylase (HDAC) inhibitor being developed by Viracta. Nanatinostat is selective for specific isoforms of Class I HDACs, which is key to inducing viral genes that are epigenetically silenced in EBV-associated malignancies. Nanatinostat is currently being investigated in combination with the antiviral agent valganciclovir as an all-oral combination therapy, Nana-val, in various subtypes of EBV-associated malignancies. Ongoing trials include a pivotal, global, multicenter, open-label Phase 2 basket trial in multiple subtypes of relapsed/refractory EBV^+ lymphoma (NAVAL-1) as well as a multinational Phase 1b/2 trial in patients with EBV^+ recurrent or metastatic nasopharyngeal carcinoma and other EBV^+ solid tumors.

About EBV-Associated Cancers

Approximately 90% of the world's adult population is infected with Epstein-Barr virus (EBV). Infections are commonly asymptomatic or associated with mononucleosis. Following infection, the virus remains latent in a small subset of lymphatic cells for the duration of the patient's life. Cells containing latent virus are increasingly susceptible to malignant transformation. Patients who are immunocompromised are at an increased risk of developing EBV^+ lymphomas. EBV is estimated to be associated with approximately 2% of the global cancer burden and is also associated with a variety of solid tumors, including nasopharyngeal carcinoma and gastric cancer.

About Viracta Therapeutics, Inc.

Viracta is a precision oncology company targeting virus-associated malignancies. Viracta's lead product candidate is an all-oral combination therapy of its proprietary investigational drug, nanatinostat, and the antiviral agent valganciclovir (collectively referred to as Nana-val). Nana-val is currently being evaluated in multiple ongoing clinical trials, including a pivotal, global, multicenter, open-label Phase 2 basket trial for the treatment of multiple subtypes of relapsed/refractory EBV^+ lymphoma (NAVAL-1), as well as a multinational Phase 1b/2 trial for the treatment of EBV^+ recurrent or metastatic nasopharyngeal carcinoma and other EBV^+ solid tumors. Viracta is also pursuing the application of its inducible synthetic lethality approach in other virus-related cancers.

For additional information please visit www.viracta.com.

Forward-Looking Statements

This communication contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding: the details, timeline and expected progress for Viracta's ongoing trials and updates regarding the same; the significance of the Nana-val trial results, NAVAL-1 as a potential registration-enabling trial, the utility Viracta's therapeutic approach, the strength of Viracta's clinical dataset, the ability of Viracta to obtain one or more accelerated approvals, the timeline for further clinical program updates in the second half of 2022; Viracta's plans to provide updates on NAVAL-1 in the second half of 2022; expectations regarding the Company's pipeline and potential products; Viracta's cash projections and the sufficiency its cash and cash equivalents to fund operations into 2024; the future availability of capital under Viracta's credit facility; the expected 2022 milestones and key upcoming events and their significance; and other statements that are not historical facts. Risks and uncertainties related to Viracta that may cause actual results to differ materially from those expressed or implied in any forward-looking statement include, but are not limited to: Viracta's ability to successfully enroll patients in and complete its ongoing and planned clinical trials; Viracta's plans to develop and commercialize its product candidates, including all oral combinations of nanatinostat and valganciclovir; the timing of initiation of Viracta's planned clinical trials; the timing of the availability of data from Viracta's clinical trials; previous preclinical and clinical results may not be predictive of future clinical results; the timing of any planned investigational new drug application or new drug application; Viracta's plans to research, develop and commercialize its current and future product candidates; the clinical utility, potential benefits and market acceptance of Viracta's product candidates; Viracta's ability to manufacture or supplying nanatinostat, valganciclovir and pembrolizumab for clinical testing; Viracta's ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to Viracta's competitors and its industry; the impact of government laws and regulations; Viracta's ability to protect its intellectual property position; and Viracta's estimates regarding future expenses, capital requirements and need for additional financing in the future.

These risks and uncertainties may be amplified by the COVID-19 pandemic, which has caused significant economic uncertainty. If any of these risks materialize or underlying assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption "Risk Factors" and elsewhere in Viracta's reports and other documents that Viracta has filed, or will file, with the SEC from time to time and available at www.sec.gov.

The forward-looking statements included in this communication are made only as of the date hereof. Viracta assumes no obligation and does not intend to update these forward-looking statements, except as required by law or applicable regulation.

Investor Relations Contact:
Ashleigh Barreto
Head of Investor Relations & Corporate Communications
Viracta Therapeutics, Inc.
abarreto@viracta.com

Financials Attached

Viracta Therapeutics, Inc.
Selected Balance Sheet Highlights
(in thousands)

	March 31, 2022	December 31, 2021
	(Unaudited)	
Cash and cash equivalents	$ 92,199	$ 103,554
Total assets	$ 98,387	$ 108,552
Total liabilities	$ 12,782	$ 14,181
Stockholders' equity	$ 85,605	$ 94,371

Viracta Therapeutics, Inc.
Condensed Consolidated Statement of Operations and Comprehensive Loss
(in thousands except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 6,096	$ 4,024
Acquired in-process research and development	—	84,478
General and administrative	4,336	3,840
Total operating expenses	10,432	92,342
Gain on Royalty Purchase Agreement	—	13,500
Loss from operations	(10,432)	(78,842)
Total other expense	(114)	(389)
Net loss and comprehensive loss	$ (10,546)	$ (79,231)
Net loss per share, basic and diluted	$ (0.28)	$ (5.22)
Weighted-average common shares outstanding, basic and diluted	37,535,874	15,166,737

Viracta Therapeutics, Inc.
Reconciliation of GAAP Loss from Operations to Adjusted (Loss) Income from Operations
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Loss from operations	$ (10,432)	$ (78,842)
Less: Acquired in-process research and development	-	84,478
Adjusted (loss) income from operations	$ (10,432)	$ 5,636

SOURCE Viracta Therapeutics, Inc.

---

https://viracta.investorroom.com/2022-05-10-Viracta-Therapeutics-Reports-First-Quarter-2022-Financial-Results-and-Recent-Updates