

Viracta Therapeutics Reports Second Quarter 2022 Financial Results and Recent Updates

Continued progress 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) expanding into Stage 2 is anticipated in the fourth quarter of 2022

Advanced the Phase 1b/2 trial of Nana-val in EBV⁺ solid tumors into the second dose escalation cohort; preliminary safety and efficacy data are anticipated in the fourth quarter of 2022

Cash, cash equivalents and investments of \$83.1 million as of June 30, 2022, provides projected runway into mid-2024

SAN DIEGO, Aug. 9, 2022 /PRNewswire/ -- [Viracta](#) Therapeutics, Inc. (Nasdaq: VIRX), a precision oncology company targeting virus-associated malignancies, today reported financial results for the second quarter of 2022 and provided an update on recent corporate developments.

"We are pleased with our corporate progress in the first half of 2022, having advanced both of our Nana-val clinical trials towards important milestones anticipated later this year, while maintaining a strong cash position that provides a projected runway into the middle of 2024," said Ivor Royston, M.D., President and Chief Executive Officer of Viracta. "The Phase 1b/2 trial in EBV-positive solid tumors is now enrolling patients in the second dose escalation cohort, and we are on track to report preliminary data in the fourth quarter. For the pivotal NAVAL-1 trial in EBV-positive lymphoma, we incorporated an important amendment into our clinical trial protocol, which allows for the evaluation of Nana-val as a second-line therapy in patients with EBV-positive peripheral T-cell lymphoma. Now, both T-cell lymphoma subtypes in NAVAL-1, extranodal NK/T-cell and peripheral T-cell, are enrolling second-line patients. We believe this is an acknowledgment of the high unmet medical need in T-cell lymphoma and the strength of our data to date."

Second Quarter 2022 and Recent Highlights

Clinical

- **Amended the protocol for NAVAL-1, the pivotal trial of Nana-val in relapsed/refractory EBV⁺ lymphoma to enable enrollment of second-line peripheral T-cell lymphoma patients.** The recently enacted protocol amendment is designed to enable the evaluation of Nana-val as an earlier therapeutic option, as the protocol previously required patients in this cohort be third-line or later. NAVAL-1 employs a Simon two-stage design with Stage 1 enrolling patients into six cohorts based on lymphoma subtype. 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, Viracta believes NAVAL-1 could potentially support multiple new drug application filings across various EBV⁺ lymphoma subtypes. The trial has sites open globally, including in the U.S., Canada, Europe, and Asia. An update on the initial cohort(s) that may advance into Stage 2 of the trial is anticipated in the fourth quarter of 2022.
- **Advanced to the second dose escalation cohort within the Phase 1b part of the Phase 1b/2 trial of Nana-val in patients with EBV⁺ recurrent/metastatic nasopharyngeal carcinoma (R/M NPC) and other EBV⁺ solid tumors.** Initiation of the second dose escalation cohort followed a favorable review of safety data from the first dose escalation cohort by the trial's independent Safety Monitoring Committee, which noted no dose-limiting toxicities in the trial to date. Enrollment is ongoing in the second dose cohort of the trial's Phase 1b portion, 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 of the trial, 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. The trial also includes a Phase 1b dose expansion cohort designed to evaluate Nana-val at the RP2D in patients with other EBV⁺ solid tumors. Preliminary safety and efficacy data from the Phase 1b dose escalation portion of the trial are anticipated in the fourth quarter of 2022.

Corporate and Thought Leadership

- **Dr. Royston honored with the Science History Institute's Biotechnology Heritage Award.** First bestowed in 1999, the Award honors extraordinary individuals whose work in biotechnology is helping to heal, fuel, and feed the world through discovery, innovation, commercialization, or public understanding. It was presented to Dr. Royston by the [Science History Institute](#) alongside the [Biotechnology Innovation Organization](#) (BIO), which represents more than 1,200 biotech companies, academic institutions, state

biotechnology centers, and related organizations across the United States and in more than 30 other nations.

- **Hosted key opinion leader (KOL) webinar on Nana-val for the treatment of advanced EBV⁺ solid tumors.** During the webinar, KOL Ezra Cohen, M.D., FRCPSC, FASCO (University of California, San Diego) and members of the Viracta management team discussed 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](#).

Scientific Presentations

- **Highlighted the design of the Phase 1b/2 trial of Nana-val in advanced EBV⁺ solid tumors in a poster at the American Society of Clinical Oncology (ASCO) Annual Meeting.** The poster was presented by A. Dimitrios Colevas, M.D. (Stanford Cancer Institute), during a session titled, "Head and Neck Cancer." A copy of the poster is available [here](#).
- **Presented an overview of the Company's novel "Kick and Kill" approach to targeting EBV-associated malignancies at the 20th International Symposium on EBV and Associated Diseases.** The presentation was delivered by Viracta's Chief Scientific Officer, Dr. Ayman Elguindy, and included previously announced data demonstrating Nana-val's mechanism of action and anti-cancer activity. The symposium was sponsored by the International Association for Research on Epstein-Barr Virus and Associated Diseases.

Anticipated 2022 Milestones

- Provide preliminary Phase 1b safety and efficacy data from the Phase 1b/2 trial in advanced EBV⁺ solid tumors: Q4 2022
- Update on NAVAL-1 cohort(s) that may progress from Stage 1 to Stage 2: Q4 2022

Second Quarter 2022 Financial Results

- **Cash position** - Cash, cash equivalents and short-term investments totaled approximately \$83.1 million as of June 30, 2022, which Viracta expects will be sufficient to fund its operations into mid-2024, excluding any incremental 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 \$6.3 million and \$12.4 million for the three and six months ended June 30, 2022, respectively, compared to approximately \$5.4 million and \$9.5 million for the same periods in 2021. The increase in research and development expenses was primarily due to increases in costs incurred to support the advancement and expansion of our clinical development programs, including incremental costs to support NAVAL-1, our pivotal trial in R/R EBV⁺ lymphoma, and the initiation of our Phase 1b/2 trial for the treatment of EBV⁺ solid tumors, as well as an increase in headcount and non-cash share-based compensation.
- **Acquired in-process research and development** - The acquired in-process research and development for the six months ended June 30, 2021 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 asset acquisition with no alternative future use, which was charged to expense upon the completion of the transaction in February 2021.
- **General and administrative expenses** - General and administrative expenses were approximately \$4.2 million and \$8.5 million for the three and six months ended June 30, 2022, respectively, compared to approximately \$3.9 million and \$7.7 million for the same periods in 2021. The change was primarily driven by an increase in non-cash share-based compensation.
- **Gain on royalty purchase agreement** - The gain on royalty purchase agreement for the six months ended June 30, 2021, 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 quarters ended June 30, 2022, and 2021. There was not a comparative adjustment to loss from operations for the six months ended June 30, 2022. Adjusted loss from operations for the six months ended June 30, 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 \$3.7 million, compared to an unadjusted loss from operations of \$88.2 million.
- **Net loss** - Net loss was approximately \$10.6 million, or \$0.28 per share (basic and diluted) for the quarter ended June 30, 2022, compared to a net loss of \$9.2 million or \$0.25 per share (basic and diluted) for the same period in 2021. Net loss was approximately \$21.1 million, or \$0.56 per share (basic and diluted) for the six months ended June 30, 2022, compared to a net loss of \$88.4 million or \$3.37 per share (basic and diluted) 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 Epstein-Barr virus (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 including lymphoma, 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 Epstein-Barr virus-positive (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 anticipated 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

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

	June 30, 2022 (Unaudited)	December 31, 2021
Cash and cash equivalents and short-term investments	\$ 83,145	\$ 103,554
Total assets	\$ 89,155	\$ 108,552
Total liabilities	\$ 12,152	\$ 14,181
Stockholders' equity	\$ 77,003	\$ 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 6,324	\$ 5,446	\$ 12,420	\$ 9,470
Acquired in-process research and development	—	—	—	84,478
General and administrative	4,181	3,871	8,517	7,711
Total operating expenses	10,505	9,317	20,937	101,659
Gain on Royalty Purchase Agreement	—	—	—	13,500
Loss from operations	(10,505)	(9,317)	(20,937)	(88,159)
Total other income (expense)	(77)	147	(191)	(242)
Net loss and comprehensive loss	\$ (10,582)	\$ (9,170)	\$ (21,128)	\$ (88,401)
Net loss per share, basic and diluted	\$ (0.28)	\$ (0.25)	\$ (0.56)	\$ (3.37)
Weighted-average common shares outstanding, basic and diluted	37,599,244	37,221,407	37,567,734	26,255,992

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Loss from operations	\$ (10,505)	\$ (9,317)	\$ (20,937)	\$ (88,159)
Less: Acquired in-process research and development	—	—	—	84,478
Adjusted loss from operations	\$ (10,505)	\$ (9,317)	\$ (20,937)	\$ (3,681)

SOURCE Viracta Therapeutics, Inc.

<https://viracta.investorroom.com/2022-08-09-Viracta-Therapeutics-Reports-Second-Quarter-2022-Financial->

