Viracta Therapeutics Reports Second Quarter 2021 Financial Results and Provides Clinical and Corporate Updates

Initiated NAVAL-1, a global pivotal trial for the treatment of relapsed/refractory EBV-positive lymphoma
Received FDA clearance of IND application for a Phase 1b/2 trial in EBV-positive solid tumors
Strengthened management team with the appointment of Ayman Elguindy, Ph.D., as Chief Scientific Officer
Cash and cash equivalents of approximately $122.7 million as of June 30, 2021

SAN DIEGO, Aug. 12, 2021 /PRNewswire/ -- Viracta Therapeutics, Inc. (Nasdaq: VIRX), a precision oncology company targeting virus-associated malignancies, today announced financial results for the second quarter of 2021 and provided clinical and corporate updates.

"We entered the second half of the year with strong momentum thanks to the completion of key milestones across our pipeline," said Ivor Royston, M.D., President and Chief Executive Officer of Viracta. "We believe Viracta is strongly-positioned to advance our novel therapy for the treatment of EBV-positive cancers forward, with our pivotal NAVAL-1 trial now open for enrollment and the recent clearance of our IND for EBV-positive solid tumors paving the way for a multicenter Phase 1b/2 trial. These two trials are targeting patient populations with a significant unmet medical need, and our expansion into solid tumors could meaningfully broaden our addressable patient market."

Second Quarter 2021 and Recent Highlights

Clinical

- **NAVAL-1, a global pivotal trial in Epstein-Barr virus (EBV)-positive (EBV $^{+}$) relapsed/refractory (R/R) lymphoma, now open for enrollment.** NAVAL-1 (**Na**natinostat in Combination with **Val**ganciclovir) is a global, multicenter, open-label Phase 2 basket trial. The trial, which will include multiple subtypes of R/R EBV-positive (EBV^{+}) lymphoma patients, is designed to evaluate the anti-tumor activity of the combination treatment of nanatinostat with valganciclovir and is anticipated to enroll up to approximately 140 patients. The primary endpoint of the trial is objective tumor response rate as assessed by an independent review committee. If successful, Viracta believes this trial could support multiple new drug application (NDA) filings across various EBV^{+} lymphoma subtypes.
- **Announced FDA clearance of IND application for a Phase 1b/2 trial in EBV^{+} solid tumors.** The multicenter Phase 1b/2 trial is designed to evaluate the safety and preliminary efficacy of Viracta's all-oral combination regimen in patients with advanced EBV^{+} solid tumors, and in combination with the PD-1 inhibitor pembrolizumab in recurrent or metastatic nasopharyngeal carcinoma. Initiation of the trial is expected in the second half of 2021.

Corporate

- **Strengthened company leadership with the appointment of Ayman Elguindy, Ph.D., as Chief Scientific Officer, and additional key additions to management team.** Dr. Elguindy has over 23 years of experience studying the role of viruses in cancer and spent the last decade as a faculty member at the Yale University School of Medicine, most recently as an Associate Professor in the Department of Pediatrics, Section of Infectious Disease, and Department of Pathology. Viracta also recently appointed Patric Nelson, MBA, as Senior Vice President, Business Development and Corporate Strategy and Biljana Nadjsombati, Pharm.D., as Vice President, Pharmaceutical Development.
- **Added as a member of the Russell 2000® Index and other FTSE Russell indexes.** In June 2021, Viracta was included as a member of the small-cap Russell 2000® Index, the all-cap Russell 3000® Index, and the Russell Microcap® Index.
- **Hosted key opinion leader webinar.** The webinar featured presentations by key opinion leaders (KOLs) Pierluigi Porcu, M.D. (Thomas Jefferson University) and Kristen Cunanan, Ph.D. (Stanford Medicine Quantitative Sciences Unit) who discussed the current treatment landscape and unmet medical need in R/R EBV^{+} lymphoma, and the design of NAVAL-1. For a replay of the webinar, click here.

Anticipated 2021 Milestones

- Initiation of a global Phase 1b/2 clinical trial in EBV^{+} solid tumors: H2 2021
- Updated data from Phase 1b/2 trial in R/R EBV^{+} lymphoma (VT3996-201): H2 2021

Second Quarter 2021 Financial Results

- **Cash position** – Cash and cash equivalents totaled approximately $122.7 million as of June 30, 2021. Viracta expects to end 2021 with greater than $100 million in cash and cash equivalents, which it expects will be sufficient to fund its operations into 2024.
- **Research and development expenses** – Research and development expenses were $5.4 million and $9.5 million for the three and six-months ending June 30, 2021, respectively, compared to $3.4 million and $6.8 million for the same periods in 2020. This increase was primarily due to incremental costs associated with the initiation of the NAVAL-1 trial.

- **General and administrative expenses** – General and administrative expenses were $3.9 million and $7.7 million for the three and six-months ending June 30, 2021, respectively, compared to $0.9 million and $1.9 million for the same periods in 2020. This increase was primarily due to expenses associated with operating as a public company and non-recurring, costs related to the merger with Sunesis Pharmaceuticals, as well as non-cash share-based compensation.
- **Acquired in-process research and development** – Non-recurring, non-cash operating expenses of $0 and $84.5 million associated with the write-off of in-process research and development acquired in the merger were recorded for the three and six-months ending June 30, 2021.
- **Gain on Royalty Purchase Agreement** – Gain on Royalty Purchase Agreement for the six-months ending June 30, 2021 was associated with upfront proceeds of $13.5 million received in connection with the multi-license milestone and royalty monetization transaction with XOMA Corporation in March 2021.
- **Adjusted loss from operations** – 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. There is not a comparative adjustment to loss from operations for the same period in 2020.
- **Net loss** – Net loss was $9.2 million, or $0.25 per share (basic and diluted) for the quarter ended June 30, 2021, compared to a net loss of $4.2 million, or $15.52 per share (basic and diluted), for the same period in 2020. Net loss was $88.4 million, or $3.37 per share (basic and diluted) for the six months ended June 30, 2021, compared to a net loss of $8.7 million, or $32.13 per share (basic and diluted), for the same period in 2020.

About Nanatinostat

Nanatinostat (VRx-3996) 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 latent viral genes which are epigenetically silenced in EBV-associated malignancies. The nanatinostat and valganciclovir combination is being investigated in various subtypes of relapsed/refractory EBV^+ lymphoma in multiple clinical trials, including a registration-enabling global, multicenter, open-label basket trial.

About Viracta Therapeutics, Inc.

Viracta is a precision oncology company targeting virus-associated malignancies. Viracta's proprietary investigational drug, nanatinostat, is currently being evaluated in combination with the antiviral agent valganciclovir as an oral combination therapy for EBV^+ lymphoma. Viracta is also pursuing application of its inducible synthetic lethality approach in other EBV-associated malignancies, such as nasopharyngeal carcinoma, gastric carcinoma, and 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 and timeline for the ongoing and planned trials; the ability of Viracta to support multiple NDA filings from the NAVAL-1 trial; Viracta's ability to expand the impact and broaden the reach of its therapeutic approach, the timing of the initiation of the solid tumor trial and the updated date from the ongoing Phase 1b/2 trial; Viracta's cash projections and the sufficiency its cash and cash equivalents to fund operations into 2024; 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 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.

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

	June 30, 2021	December 31, 2020
	(Unaudited)	
Cash and cash equivalents	$ 122,721	$ 47,089
Total assets	$ 128,679	$ 48,305
Total liabilities	$ 11,582	$ 11,203
Stockholders' equity	$ 117,097	$ (46,200)

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 5,446	$ 3,361	$ 9,470	$ 6,807
Acquired in-process research and development	-	-	84,478	-
General and administrative	3,871	879	7,711	1,890
Total operating expenses	9,317	4,240	101,659	8,697
Gain on Royalty Purchase Agreement	-	-	13,500	-
Loss from operations	(9,317)	(4,240)	(88,159)	(8,697)
Total other income (expense)	147	4	(242)	44
Net loss and comprehensive loss	$ (9,170)	$ (4,236)	$ (88,401)	$ (8,653)
Net loss per share, basic and diluted	$ (0.25)	$ (15.52)	$ (3.37)	$ (32.13)
Weighted-average common shares outstanding, basic and diluted	37,221,407	273,056	26,255,992	269,325

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Loss from operations	$ (9,317)	$ (4,240)	$ (88,159)	$ (8,697)
Less: Acquired in-process research and development	-	-	84,478	-
Adjusted loss from operations	$ (9,317)	$ (4,240)	$ (3,681)	$ (8,697)

SOURCE Viracta

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https://viracta.investorroom.com/2021-08-12-Viracta-Therapeutics-Reports-Second-Quarter-2021-Financial-Results-and-Provides-Clinical-and-Corporate-Updates