



Vivoryon Therapeutics N.V. Reports Third Quarter 2022 Financial Results and Highlights Operational Progress

HALLE (SAALE) / MUNICH, GERMANY, November 22, 2022 – Vivoryon Therapeutics N.V. (Euronext Amsterdam: VVY; NL00150002Q7) (**Vivoryon**), a clinical stage company focused on the discovery and development of small molecule medicines to modulate the activity and stability of pathologically altered proteins, today reported financial results for the third quarter of 2022, ending September 30, 2022, and provided an update on clinical and corporate progress.

“In the third quarter of 2022, we were very pleased to have strengthened our financial position with a successful private placement of up to EUR 30 million. Vivoryon is happy to welcome our new investor, KKR affiliate Memory Investments, while receiving continued support from our existing and longstanding investors. Our extended financial runway allows us to continue our focus on clinical development of varoglutamstat in Alzheimer’s disease as we see progress in both our VIVIAD and VIVA-MIND trials in Europe and the U.S., respectively,” said Ulrich Dauer, CEO of Vivoryon. “We are happy to report that we have completed enrollment for VIVIAD as planned. Given the recent challenges observed within the broader Alzheimer’s disease space, we believe it is a critical time for Vivoryon to evaluate how we are optimizing our clinical development programs for varoglutamstat as we work to provide meaningful benefit to our patients and their families. We are incredibly pleased with the safety profile of varoglutamstat observed to-date and are happy to share new updates to the program development today. We have carefully crafted a well-defined clinical development strategy and are pursuing a differentiated regulatory path to a potential approval for varoglutamstat with options for surrogate markers, reflecting patient benefit beyond the simple endpoint of plaque-removing potential. By utilizing both VIVIAD and VIVA-MIND to inform each respective trial, we expect to reach an exceptionally high level of clinical information for varoglutamstat.”

Portfolio Highlights (Q3 2022 and post-period)

VIVIAD

- VIVIAD ([NCT04498650](https://clinicaltrials.gov/ct2/show/study/NCT04498650)) is a state-of-the-art Phase 2b study conducted in Europe and designed to evaluate the safety, tolerability and efficacy of varoglutamstat in 250 subjects with mild cognitive impairment (MCI) and mild Alzheimer’s disease (AD).
- VIVIAD has completed enrollment as planned. Overall, 259 patients at 22 study centers in five European countries have been randomized into the study. The Company will continue to evaluate primary and secondary outcome measures, which include multiple cognitive, safety and biomarker endpoints. As previously guided, Vivoryon anticipates final follow-up visits in the second half of 2023. Given the flexibility built into the study protocol, the Company has decided to enable additional follow-up visits through year-end 2023, allowing for additional data collection and longer average treatment duration of participants. Consequently, Vivoryon anticipates the average treatment duration to be approximately 82 weeks, making it one of the longest treatment durations for a large



patient set within the AD clinical trial field. These changes are expected to provide Vivoryon with a larger and more meaningful set of data at the conclusion of the trial.

- Vivoryon now expects to report full data, including additional follow-up data, in the first quarter of 2024.

VIVA-MIND

- VIVA-MIND ([NCT03919162](https://clinicaltrials.gov/ct2/show/study/NCT03919162)) is a combined Phase 2a/b study for varoglutamstat conducted in the U.S. which seeks to enroll 180 patients with early AD into the Phase 2a adaptive dose finding part. About two thirds of the first cohort (600mg BID) have been treated to date with no adverse events of special interest (AESI) observed. Based on these encouraging findings, which corroborate VIVIAD study safety data, Vivoryon now plans to treat all 180 patients for at least 72 weeks, allowing for the opportunity to progress more seamlessly to a potential Phase 3 study. Using VIVA-MIND as an informed trial allows for more optionality with further advancement in clinical development while taking learnings from VIVIAD and other developments in the field into account.
- The primary endpoint for this study is the CDR-SB (clinical dementia rating scale – sum of boxes) score, an established approvable endpoint measuring a combination of cognitive abilities and activities of daily living. The study is coordinated by the Alzheimer’s Disease Cooperative Study (ADCS) and supported by a USD 15 million grant from the National Institute on Aging (NIA award number R01AG061146).
- All 180 patients included in the Phase 2a portion of VIVA-MIND will now continue to be treated for 72 weeks to increase quality and robustness of data and potentially allowing for a seamless transfer into a confirmatory Phase 3 study, if required. This prudent adaptation is designed to increase the probability of success of the VIVA-MIND study towards potential approval. Consequently, Vivoryon is no longer guiding towards an interim futility analysis as basis for a stage-gate decision. The Company intends to provide a status update on the study in the first quarter of 2023.

Preclinical Programs

- In October 2022, Nature Communications issued a joint publication of Vivoryon and Fraunhofer IZI and Monash University, Melbourne, Australia, “Helical ultrastructure of the metalloprotease meprin α in complex with a small molecule inhibitor.” This article outlines the protein’s involvement in tissue homeostasis by influencing inflammation, immunity, and extracellular matrix remodeling. Dysregulation of this protein family leads to many severe diseases that we aim to treat within our pipeline, including acute kidney injury, inflammatory disease, and some cancers. Deepening our understanding of meprin α ’s structure will strongly support our research and development program for selective and highly potent small molecule meprin inhibitors.

Corporate Development Highlights (Q3 2022 and post-period)

- On September 30, 2022, the Company entered into a private placement of 2,054,796 registered shares at an offering price of EUR 7.30 per share. The new shares from the capital increase represent 9.3% of Vivoryon’s existing share capital and have been issued from the Company’s authorized capital under exclusion of the existing



shareholders' pre-emptive rights. Consequently, the Company's issued share capital has increased to EUR 24,105,278.00 on completion of the private placement. In addition, the investors will have the option to purchase, in aggregate, up to another 2,054,796 registered shares at a price of EUR 7.30 during a period ending twelve months after the date of the approval of an EU Recovery Prospectus or three months after the achievement date of a defined clinical milestone, whichever is later. The gross proceeds of the private placement amount to EUR 15.0 million, and up to an additional EUR 15.0 million will be raised if the option to purchase the additional shares is exercised in full. Vivoryon intends to use the net proceeds from the offering to support the ongoing clinical development of its lead candidate varoglutamstat, currently in Phase 2 in Europe and the United States for the treatment of patients with Alzheimer's disease, as well as for general corporate purposes. The private placement was supported by Vivoryon's longstanding investor Claus Christiansen and KKR Dawn Aggregator L.P., a platform controlled by affiliates of Kohlberg Kravis Roberts & Co. L.P., a leading global investment firm, as new investor to the Company. On October 5, 2022, KKR Dawn Aggregator L.P. notified the Company that it had transferred and novated all of its rights and obligations under the investment agreement to its affiliate Memory Investments S.à r.l.

Financial Results for the Third Quarter of 2022

The Company generated no license revenues or other revenues in the nine months ended September 30, 2022. In the nine months ended September 30, 2021, the Company generated license revenues of EUR 10.8 million from a strategic regional licensing partnership in China.

Research and development expenses increased by EUR 2.5 million to EUR 16.1 million in the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021. This increase is primarily attributable to EUR 1.9 million higher expenses related to our clinical trial VIVIAD, which has advanced significantly compared to the nine months ended September 30, 2021.

General and administrative expenses for the nine months ended September 30, 2022 have increased by EUR 1.0 million to EUR 4.2 million, compared to the nine months ended September 30, 2021. The main reason for that development were higher expenses for share based payments with EUR 1.0 million following new share option grants in 2022.

Net loss for the nine months ended September 30, 2022 was EUR 18.9 million, compared to EUR 7.3 million for the nine months ended September 30, 2021. The difference is mainly due to the strategic regional licensing partnership in 2021, which resulted in a gross profit of EUR 9.2 million (nil in 2022). The Company held EUR 19.8 million in cash and cash equivalents as of September 30, 2022, compared to EUR 14.7 million as of December 31, 2021.

Cash flows provided from financing activities were EUR 19.1 million for the nine months ended September 30, 2022 compared to cash used in financing activities of EUR 0.1 million in the nine months ended September 30, 2021. The change mainly relates to a private placement on April 1, 2022 by way of accelerated book building, placing 2,000,000 registered shares at an offering price of EUR 10.50 per share. The Company's issued share capital has increased to EUR 22,050,482. The gross proceeds of the offering amounted to EUR 21.0 million. The



proceeds of the private placement entered into on September 30, 2022 are not included in cash flows provided from financing activities for the nine months ended September 30, 2022.

Financial Guidance

According to current planning and estimates, Vivoryon expects that its existing cash and cash equivalents will be sufficient to fund its research and development expenses as well as the general and administrative expenses and cash flows from investing and financing activities at least through December 2023. This does not include the exercise of the option to acquire up to an additional 2.054.796 shares for a period ending the later of twelve months after the date of the approval of an EU Recovery Prospectus or the achievement date of a defined clinical milestone.

Conference Call and Webcast

Vivoryon will host a conference call and webcast today, November 22, 2022, at 3:00 pm CET (9:00 am ET). A Q&A session will follow the presentation of the third quarter results and operational progress.

Please dial one of the following access numbers:

From Germany: +49 6917415712

From UK: +44 1 212818004

From the U.S.: +1 718 7058796

HD Webphone: [https://hdeu.choruscall.com/?\\$Y2FsbHR5cGU9Mg==](https://hdeu.choruscall.com/?$Y2FsbHR5cGU9Mg==)

Please dial in ten minutes prior to commencement.

A live webcast and slides will be made available at: www.vivoryon.com/investors-news/news-and-events/presentations-webcasts/

Approximately one day after the call, a slide-synchronized audio replay of the conference will be available on: www.vivoryon.com/investors-news/news-and-events/presentations-webcasts/

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About Vivoryon Therapeutics N.V.

Vivoryon is a clinical stage biotechnology company focused on developing innovative small molecule-based medicines. Driven by our passion for ground-breaking science and innovation, we strive to change the lives of patients in need suffering from severe diseases. We leverage our in-depth expertise in understanding post-translational modifications to develop medicines that modulate the activity and stability of proteins which are altered in disease settings. Beyond our lead program, varoglutamstat, which is in Phase 2 clinical development to treat Alzheimer's disease, we have established a solid pipeline of orally available small molecule inhibitors for various indications including cancer, inflammatory diseases, and fibrosis. www.vivoryon.com



Vivoryon Forward Looking Statements

This press release includes forward-looking statements, including, without limitation, those regarding the business strategy, management plans and objectives for future operations of the Vivoryon Therapeutics N.V. (the "Company"), estimates and projections with respect to the market for the Company's products and forecasts and statements as to when the Company's products may be available. Words such as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "project," "predict," "should" and "will" and similar expressions as they relate to the Company are intended to identify such forward-looking statements. These forward-looking statements are not guarantees of future performance; rather they are based on the Management's current expectations and assumptions about future events and trends, the economy and other future conditions. The forward-looking statements involve a number of known and unknown risks and uncertainties. These risks and uncertainties and other factors could materially adversely affect the outcome and financial effects of the plans and events described herein. Actual results, performance or events may differ materially from those expressed or implied in such forward-looking statements and from expectations. As a result, no undue reliance should be placed on such forward-looking statements. This press release does not contain risk factors. Certain risk factors that may affect the Company's future financial results are discussed in the published annual financial statements of the Company. This press release, including any forward-looking statements, speaks only as of the date of this press release. The Company does not assume any obligation to update any information or forward-looking statements contained herein, save for any information required to be disclosed by law.

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