Vivoryon Therapeutics N.V. Reports Third Quarter 2023 Financial Results and Highlights Operational Progress

- *VIVIAD and VIVA-MIND studies both advancing as planned at 600mg twice daily following positive DSMB decisions; VIVIAD safety update with cut-off as of November 20, 2023, confirms low level of discontinuations*
- *On track to report VIVIAD final topline Phase 2b data during end of Q1/2024*
- *Commenced preparations for VIVALONG, an open-label extension study*
- *Unveiling focused growth strategy leveraging varoglutamstat and VIVIAD and investing in QPCT/L small molecule platform*
- *Chief Financial Officer transition with promotion of Anne Doering, CFA, effective March 1, 2024*
- *Management to host conference call today at 3:00 pm CET (9:00 am EST)*

Halle (Saale) / Munich, Germany, December 6, 2023 – 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 announced financial results for the third quarter of 2023, ended September 30, 2023, and provided an update on its corporate progress.

"In the third quarter of 2023, we continued to make significant progress with the clinical development of our core asset, varoglutamstat. From learnings across currently approved monoclonal antibodies, we see a clear unmet need among early Alzheimer's disease patients for a safe and effective oral therapy and we believe that varoglutamstat can address this gap," said Frank Weber, MD, CEO of Vivoryon. "We are preparing for the upcoming European Phase 2b VIVIAD study readout during the end of the first quarter of 2024 and potential discussions with the FDA thereafter. Separately, we have initiated the identification of novel oral QPTC/L inhibitors as second generation compounds in early AD from our oral small molecule platform. We are also integrating additional biomarkers of kidney function into the VIVIAD study to assess the potential of QPCT/L inhibitors in chronic kidney disease. We are committed to growing Vivoryon into a leading biotech company with our highly attractive programs that have prospects in multiple disease areas with high unmet need including AD, chronic kidney disease, NASH, oncology and orphan CNS."

Dr. Weber continued, "I would also like to express my gratitude to Florian Schmid, our CFO, who has decided not to renew his contract as a member of the Vivoryon executive leadership team and pursue other opportunities. Florian has played a significant role in increasing the

Vivoryon Therapeutics N.V.
www.vivoryon.com
Weinbergweg 22
06120 Halle (Saale)
Germany
contact@vivoryon.com

quality of our financial position and processes over the last several years. In light of this transition, I am excited to announce the promotion of Anne Doering as CFO whose extensive capital markets experience will be instrumental to Vivoryon's next phase of growth. To ensure a smooth transition we are pleased that Florian plans to continue with us as a strategic advisor after Anne assumes the CFO role."

Q3 2023 and Post-Period Portfolio Highlights

Varoglutamstat Clinical Program:

Varoglutamstat is a differentiated investigational small-molecule medicine in development to treat Alzheimer's disease (AD). It is currently being investigated in two large Phase 2 studies, VIVIAD (NCT04498650) in Europe and VIVA-MIND (NCT03919162) in the U.S., where it continues to show evidence of a favorable safety profile at the therapeutic dose of 600mg twice daily (BID), a dose demonstrated to result in a target occupancy of nearly 90%. In addition, VIVALONG, an open-label extension study, will allow for the potential confirmation of the long-term safety and health outcome benefits of varoglutamstat after patients have completed the double blinded studies VIVIAD and VIVA-MIND. The study will also generate relevant pharmacoeconomic data.

Varoglutamstat is designed to prevent N3pE-Abeta formation, rather than aiming to clear existing plaques, making it an intervention upstream of other approaches such as monoclonal antibodies (mAbs). Through a second mode of action, varoglutamstat also modulates neuroinflammation via the CCL2 pathway, which, in turn, has an impact on tau pathology.

VIVIAD

VIVIAD (NCT04498650) is a state-of-the-art Phase 2b study being conducted in Europe and is designed to evaluate the safety, tolerability, and efficacy of varoglutamstat in 259 subjects with mild cognitive impairment (MCI) and mild AD.

- In July 2023, Vivoryon announced a safety update based on data from all 259 randomized patients which showed no clinical signs of varoglutamstat associated ARIAs at the cutoff date of June 14, 2023. The independent Data Safety Monitoring Board (DSMB) decided the study should continue as planned and that no additional DSMB meeting will be required until study completion.
- In October 2023, Vivoryon hosted a virtual R&D Event with Key Opinion Leaders (KOLs) focused on the clinical utility of primary and secondary endpoints of the VIVIAD study. The primary endpoint, which is a combination of three elements of the Cogstate neuropsychological test battery (NTB), called "Cogstate 3-item scale," includes Identification, Detection and One Back tests and evaluates attention and working memory domains over 48-96 weeks. Key secondary efficacy endpoints include in

Vivoryon Therapeutics N.V.
www.vivoryon.com
Weinbergweg 22
06120 Halle (Saale)
Germany
contact@vivoryon.com

hierarchical order: Cogstate Brief Battery (CBB, 4-item scale), the full Cogstate NTB (8-item scale), the Amsterdam Instrumental Activities of Daily Living Questionnaire (A-IADL-Q), and electroencephalogram (EEG).

- In the VIVIAD study, discontinuation rates to date remain favorable (cut-off date of November 20, 2023). The total number of discontinuations remains low in VIVIAD throughout the study at less than 13% based on blinded data. In addition, the number of discontinuations due to adverse events (AEs) has remained at less than 4%.
- The statistical power of VIVIAD to detect a potential treatment difference of Cohen's d of 0.35 between active and placebo is confirmed to be above 80% as assumed in the study protocol.
- Vivoryon remains on track to share final topline data during the end of the first quarter of 2024 and the full dataset at a subsequent medical meeting. Following the VIVIAD data readout, the Company expects to conduct an end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in the second half of 2024.
    - The end of the active treatment phase in VIVIAD is estimated to occur by year end 2023, which is then followed by a minimum period of four weeks of safety follow-up visits with rigorous data and statistical analysis thereafter.
    - Vivoryon expects the final VIVIAD dataset to include an evaluation of patients following the 12-week titration period, which is the same for every patient randomized to the active arm. The 600mg BID is applied in approximately 75% of the treatment weeks of all patients and the 300mg BID is applied in approximately 25% of the treatment weeks.

VIVA-MIND

VIVA-MIND (NCT03919162) is a complementary Phase 2 study for varoglutamstat being conducted in the U.S. which seeks to enroll 180 patients with early AD into the Phase 2a adaptive dose finding portion and to enroll a further 234 patients in the Phase 2b portion of the study. VIVA-MIND is running in parallel to VIVIAD to provide robust evidence on slowing AD progression and to support Vivoryon's regulatory strategy.

- In October 2023, Vivoryon announced that the study's independent DSMB unanimously recommend that VIVA-MIND should proceed with a dose of 600mg BID through the remainder of Phase 2a and 2b. This decision follows the September 2023 DSMB quarterly safety review of adverse events and labs, and the October 2023 analysis of treatment-emergent adverse events of special interest (AESI) pertaining to skin and subcutaneous tissue disorders and hepatobiliary disorders, as well as target occupancy and plasma pharmacokinetic (PK) data.
- With VIVA-MIND, the Company has confirmed the feasibility of an up-titration protocol to the final dose of 600mg BID which is accelerated compared to the ongoing VIVIAD Phase 2b study. VIVA-MIND is continuing to recruit participants into the second cohort, with 21 sites open across the U.S.

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- Vivoryon's regulatory strategy for VIVA-MIND follows an adaptive trial design which includes the option to expand the study to a confirmatory Phase 3 study contingent on VIVIAD results and regulatory feedback.

VIVALONG

- In July 2023, Vivoryon announced that it commenced preparations for an open-label extension (OLE) study, VIVALONG, to provide a long-term treatment option to patients after completion of treatment under the VIVIAD or VIVA-MIND protocol.
- The launch of VIVALONG is contingent on the outcome of VIVIAD.
- Pending VIVIAD results, Vivoryon plans to assess the long-term treatment of varoglutamstat including positron emission tomography (PET) imaging and other key safety and efficacy endpoints.

Early-Stage Pipeline and Kidney Disease Exploration:

- Vivoryon is unveiling additional opportunities in R&D activities stemming from its proprietary oral small molecule QPCT/L inhibitor platform. Following the VIVIAD readout, Vivoryon plans to leverage findings to further bolster its platform capabilities and potentially nominate new development projects in 2024.
- The Company has initiated the identification of novel oral QPCT/L inhibitors as second generation compounds in early AD.
- The VIVIAD study will now include additional biomarkers to investigate the effect of QPCT/L inhibition on kidney function.
- Activities to identify suitable new chemical entity (NCE) oral QPCT/L inhibitors as potential development projects in 2024 are underway in multiple disease areas including AD, chronic kidney disease, NASH, oncology and orphan CNS, such as Huntington's disease and Down syndrome.

Corporate Development Updates:

- In September 2023, Vivoryon held an Extraordinary General Meeting (EGM) related to the appointment of Frank Weber, MD, as CEO and Anne Doering, CFA, as Chief Strategy & Investor Relations Officer (CS&IRO). The shareholders approved all items on the agenda of the meeting, including the appointment of Dr. Weber and Anne Doering to the Company's Board as executive directors.
- The Company announced the appointment of Anne Doering as Chief Financial Officer (CFO), leveraging Ms. Doering's deep capital markets experience and enabling a smooth management transition as she succeeds Florian Schmid on March 1, 2024.

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Financial Results for the Third Quarter of 2023

No **revenues** were generated in the nine months ended September 30, 2023, or the nine months ended September 30, 2022.

Research and development expenses of EUR 10.4 million in the nine months ended September 30, 2023, decreased by EUR 5.6 million compared to the nine months ended September 30, 2022. This decrease is primarily attributable to EUR 3.0 million lower expenses related to our clinical trial VIVIAD and EUR 2.6 million lower manufacturing cost for study drug production.

General and administrative expenses of EUR 6.8 million for the nine months ended September 30, 2023, increased by EUR 2.6 million from EUR 4.2 million in the nine months ended September 30, 2022. The main reasons for the increase were EUR 0.9 million higher personnel costs, EUR 0.9 million higher costs for the non-executive Board and EUR 0.8 million higher consulting costs. The reasons for the cost increases in personnel and the non-executive Board were predominantly caused by accelerated share-option expenses and severance payments as a result of the 2023 Board changes.

Net loss of EUR 17.1 million for the nine months ended September 30, 2023, compares to EUR 18.9 million for the nine months ended September 30, 2022.

The Company held EUR 17.0 million in **cash and cash equivalents** as of September 30, 2023, compared to EUR 26.6 million as of December 31, 2022. In the nine months ended September 30, 2023, the Company entered into Euro term deposits of EUR 16.0 million resulting in a disclosure of these funds in the balance sheet as financial assets. Combining the cash and cash equivalents with the term deposits, Vivoryon has EUR 33.0 million in liquid funds at its disposal.

Cash flows used in operating activities were EUR (33.3) million for the nine months ended September 30, 2023, compared to EUR (14.7) million in the nine months ended September 30, 2022. The change in operating cash flow by EUR (18.5) million mainly results from newly disclosed term deposits with a term of more than three months of EUR (16.0) million that are disclosed in the Company`s financial assets and not in cash equivalents as well as other changes in working capital. Excluding this shift in cash to term deposits, cash flows used in operating activities would have been EUR (17.3) million.

Cash flows used in investing activities were EUR (0.5) million for the nine months ended September 30, 2023, compared to EUR 2.0 thousand in the nine months ended September 30, 2022.

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Cash flows provided from financing activities were EUR 24.2 million for the nine months ended September 30, 2023, including EUR 1.3 million from the exercise of share options, compared to EUR 19.1 million in the nine months ended September 30, 2022.

Financial Guidance

Including the proceeds from the capital raise completed in May 2023, 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 into the second half of 2024. This guidance does not include potential milestone payments from development partnerships, potential payments from licensing agreements and/or additional financing measures, as exercise of the options granted in connection with the private placement announced September 30, 2022 (see note 8.11 of the Company's annual financial statements for the year ended December 31, 2022).

Conference Call and Webcast
Vivoryon will host a conference call and webcast today, December 6, 2023, at 3:00 pm CET (9:00 am EST). A Q&A session will follow the presentation of the third quarter results.

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

To join the conference call via phone, participants may pre-register and will receive dedicated dial-in details to easily and quickly access the call via the following website: https://register.vevent.com/register/BI44eb013feef24cb5818e6711539120de

It is suggested participants dial into the conference call 15 minutes prior to the scheduled start time to avoid any delays in attendance.

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.

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www.vivoryon.com
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Germany
contact@vivoryon.com

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.

For more information, please contact:

Investor Contact
Stern IR
Janhavi Mohite
Tel: +1 212-362-1200
Email: janhavi.mohite@sternir.com

Media Contact
Trophic Communications
Valeria Fisher
Tel: +49 175 8041816
Email: vivoryon@trophic.eu