

# Vivoryon Therapeutics N.V. Reports Q1 2023 Financial Results and Highlights Operational Progress

Halle (Saale) / Munich, Germany, May 16, 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 and corporate updates for the first quarter of 2023, ending March 31, 2023.

"In the first quarter of 2023, we continued to advance our lead program for Alzheimer's disease, varoglutamstat, through both the VIVIAD and VIVA-MIND studies and reported further data demonstrating both strong tolerability and improvements in pathological hallmarks, synaptic function and connectivity, cognition, memory and attention in AD patients," said Dr. Ulrich Dauer, CEO of Vivoryon. "Amidst steady clinical progress with varoglutamstat, we are also encouraged by the recent activity and developments in the broader AD treatment landscape, in particular the emerging clinical evidence validating our approach of targeting neurotoxic N3pE-Abeta. We believe we are well-positioned for varoglutamstat to provide an effective and much-needed therapeutic option that alleviates issues with administration for patients with this devastating disease. Vivoryon has an exciting year ahead and we look forward to reporting important safety updates later this year for our VIVA-MIND trial in the U.S. and final data from our VIVIAD study in the first quarter of next year."

#### Q1 2023 and Post-Period Portfolio Highlights

#### **Varoglutamstat Clinical Program:**

- VIVIAD (NCT04498650) is a state-of-the-art Phase 2b study being 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).
  - o In March 2023, Vivoryon provided an update on varoglutamstat clinical development for the treatment of AD at the International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders (AD/PD). As of the data cut-off date of January 5, 2023, over 100 of the 259 participants randomized into the VIVIAD study had been treated for at least 48 weeks. Varoglutamstat showed no on-target toxicity and no clinical signs of brain swelling or hemorrhages (ARIA), which are a limiting class side effect of Abeta antibodies and has been well-tolerated in the study to date. Both the total number of SAEs and the discontinuation rate were considerably lower than the respective numbers at the 800 mg BID varoglutamstat dose in Vivoryon's completed Phase 2a SAPHIR study, while retaining a similar level of target inhibition (around 90%) at the dosing in both studies.
  - Vivoryon remains on track to report the final data readout from the VIVIAD study in the first quarter of 2024.



- VIVA-MIND (NCT03919162) is a complementary Phase 2 study for varoglutamstat conducted in the U.S. which seeks to enroll 180 patients with early AD into the Phase 2a adaptive dose finding portion and enroll a further 234 patients in the Phase 2b portion of the study.
  - In March 2023, Vivoryon announced the study is ongoing and continuing to recruit patients at 18 sites across the U.S. The study's independent DSMB recently provided a unanimous recommendation to continue the study without modification. The Company anticipates a decision on final trial size following the data readout of the VIVIAD study.
  - Vivoryon expects the first cohort to be fully randomized into the study within the second quarter of this year and plans to provide the next update on the VIVA-MIND study in the second half of 2023.

#### **Corporate Development Highlights:**

- In May 2023, Vivoryon announced it will hold its 2023 Annual General Meeting on Wednesday, June 21, 2023, at 1:00 p.m. (CEST) in Amsterdam, the Netherlands. The full agenda and all relevant documents are available on the Company's website (<a href="https://www.vivoryon.com/annual-general-meeting-2023/">https://www.vivoryon.com/annual-general-meeting-2023/</a>).
- In May 2023, Vivoryon announced intended changes among the Non-Executive members of its Board of Directors at the 2023 Annual General Meeting. Reflecting Vivoryon's continued progress towards becoming a late-stage clinical development company and in line with its commitment to meeting international best-practice standards for corporate governance and diversity, the Company proposes the appointment of Kugan Sathiyanandarajah and Professor Morten Asser Karsdal as new members to Vivoryon's Non-Executive Board of Directors. The proposed appointments follow the decision of the two long-standing members Dinnies Johannes von der Osten, PhD, and Jörg Neermann, PhD, to step down at the upcoming Annual General Meeting.

### Financial Results for Q1 of 2023

No **revenues** were generated in the first quarter of 2023.

Research and development expenses decreased by EUR 2.7 million to EUR 3.1 million in the three months ended March 31, 2023, compared to EUR 5.8 million in the three months ended March 31, 2022. This decrease was largely attributable to a reduction of EUR 1.6 million from lower manufacturing cost due to the completion of study drug supply projects with the remaining reduction due to lower clinical costs from the further progress of the Phase 2b clinical trial VIVIAD.

**General and administrative expenses** were EUR 1.9 million in the three months ended March 31, 2023, compared to EUR 0.8 million in the three months ended March 31, 2022. The increase of EUR 1.1 million was largely attributable to EUR 0.8 million higher expenses for share-based payments.



**Net loss** for the three months ended March 31, 2023, was EUR 5.1 million, compared to EUR 6.4 million for the three months ended March 31, 2022.

The Company held EUR 17.1 million in **cash and cash equivalents** as of March 31, 2023, compared to EUR 26.6 million as of December 31, 2022. In the three months ended March 31, 2023, the Company entered into a Euro term deposit of EUR 3.0 million resulting in the reallocation of the funds to financial assets from cash and cash equivalents.

#### **Financial Guidance**

Following the capital raise settled in October 2022, 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 the general and administrative expenses and cash flows from investing and financing activities at least through end of December 2023. This guidance does not include exercise of share options issued in October 2022, potential milestone payments from development partnerships, potential payments from licensing agreements and/or additional financing measures, as far as such payments have not yet been recognized in revenues. The financial guidance takes into account all costs to ensure sustainable study drug supply with varoglutamstat for the VIVA-MIND U.S. study.

Additional information regarding other relevant information is included in the financial statements as of December 31, 2022, which were part the Company's Annual Report 2022.

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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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