



Vivoryon Therapeutics N.V. Q1 2025 Financial Results and Operational Progress

- Continued progress in advancing varoglutamstat in kidney disease based on encouraging data and expansion of IP portfolio
- Varoglutamstat's pre-clinical dataset showing synergistic effect in combination with an SGLT-2 inhibitor in different treatment regimens
- Novel composition of matter patent for varoglutamstat granted after accelerated review in the U.S.; patent term to provide exclusivity through 2044 with subsequent opportunity for patent term extension
- Varoglutamstat meta-analysis data presented in oral presentation at ERA 2025
- Preparations ongoing for Phase 2b of varoglutamstat in diabetic kidney disease (DKD)
- Management to host a conference call today at 3:00 pm CEST (9:00 am EDT)

Halle (Saale) / Munich, Germany, June 17, 2025 – Vivoryon Therapeutics N.V. (Euronext Amsterdam: VVY; NL00150002Q7) (**Vivoryon**), a clinical stage company developing small molecule medicines for inflammatory and fibrotic disorders, with a primary focus on kidney diseases, today announced financial results for the three-month period ended March 31, 2025, and provided an update on its corporate progress.

"We have started the year 2025 focused on rounding out the evidence to support the success of varoglutamstat in kidney disease," said Frank Weber, MD, CEO of Vivoryon. "Building on solid Phase 2 clinical evidence of varoglutamstat's beneficial impact on eGFR, we have developed a viable clinical development strategy, with a planned Phase 2b study in diabetic kidney disease as a first step. Beyond varoglutamstat as single agent, our clinical program also includes investigation of varoglutamstat in combination with SGLT-2 inhibitors for which we have generated very promising preclinical data. On the IP side, we have been able to significantly extend protection of our key asset varoglutamstat with a new composition of matter patent in the U.S. With the groundbreaking clinical data demonstrating varoglutamstat's unique impact on kidney function, a deeper understanding of its MOA in inflammation and fibrosis, and a strengthened IP portfolio, we believe we are well on track to deliver a novel therapy that addresses a significant unmet medical need for patients suffering from kidney disease. In particular, we strive to change the likely trajectory toward kidney failure for patients with advanced DKD, who currently have little to no treatment options to halt progression of kidney failure or improve kidney function."



Q1 2025 and Post-Period Updates

Varoglutamstat Clinical Program

Meta-analysis of VIVIAD and VIVA-MIND study data

- On January 14, 2025, the Company disclosed a meta-analysis of VIVIAD and VIVA-MIND data which confirmed that treatment with varoglutamstat at 600mg twice daily significantly improved eGFR kidney function in the overall study population. Statistically significant differences between varoglutamstat and placebo were first observed at week 24 and were sustained until week 96.
- The meta-analysis also confirmed a substantially larger effect size in study participants with diabetes compared to those without diabetes.
- Data for varoglutamstat were presented at the 62nd ERA Congress of the European Renal Association in Vienna, Austria, June 6, 2025, showing consistent improvement in both trials independently, replicated in the meta-analysis and pooled analysis, thus providing converging evidence for the findings.

Synergistic effect of combination treatment with varoglutamstat and SGLT-2 inhibitors in pre-clinical animal model

- On April 29, 2025, Vivoryon disclosed preclinical data from a series of experiments in a chronic kidney disease animal model, analyzing different treatment regimens of varoglutamstat in combination with standard of care for kidney disease, the SGLT-2 inhibitor dapagliflozin.
- Data analysis revealed a synergistic *in vivo* effect for the combination treatment of dapagliflozin and varoglutamstat over a broad panel of markers, nearly normalizing pathology vs. control across the three key areas of inflammation, fibrosis and kidney function.
- Substantially de-risking the Company's DKD/CKD clinical development program, the strong synergistic effects observed on multiple outcome parameters suggest that QPCT/L inhibitors could be an ideal combination partner for patients treated with SGLT-2 inhibitors.
- Vivoryon is currently investigating additional animal models, including a DKD model, to provide further proof points.

Proposed clinical development plan in DKD

Vivoryon's key strategic priority for 2025 is to advance varoglutamstat in kidney disease and confirm the previously reported compelling data from two independent Phase 2 studies, VIVIAD and VIVA-MIND, by conducting a Phase 2b clinical study in patients with advanced diabetic kidney disease (DKD) stage 3b/4. Initiation of the Phase 2b and all future studies is subject to additional funding and/or partnership, which Vivoryon continues to actively explore.



Expanding intellectual property portfolio in kidney disease treatment

Vivoryon announced on May 27, 2025, that the United States Patent and Trademark Office (USPTO) has granted an additional patent covering the active polymorph of varoglutamstat. The new U.S. patent (US 12,312,335) was granted after an accelerated examination process and is expected to provide exclusivity through 2044 with subsequent opportunity for patent term extension of up to five years to 2049 under the Hatch-Waxman Act. Additional patents for medical use and dosing regimens under examination for varoglutamstat and related structures in kidney disease as monotherapy and in combination with SGLT-2 inhibitors.

Pipeline Updates: Early-stage Pipeline

The Company has enlarged its portfolio by nominating a novel, next generation QPCT/L inhibitor showing compelling pharmacological activity. This candidate, VY2149, is a potential fast follower in DKD or could also be explored for other inflammatory and fibrotic diseases including orphan diseases and chronic kidney disease (CKD). VY2149 is expected to enter formal, late-stage pre-clinical development within this year, subject to additional funding and/or partnership, which Vivoryon continues to actively explore.

Corporate Development Updates

In April 2025, Vivoryon entered into a Standby Equity Purchase Agreement (SEPA) with Yorkville Advisors Global, LP, allowing for the purchase of up to EUR 15 million in ordinary shares over the next 36 months. Under the terms of this agreement, Yorkville has committed to acquiring these shares, providing Vivoryon with the right, but not the obligation, to sell them in individual tranches while excluding existing shareholders' pre-emptive rights. This agreement is expected to enhance Vivoryon's financial flexibility as the company seeks optimal funding solutions for its planned Phase 2b study in diabetic kidney disease.

On April 29, 2025, the Company announced the appointment of Julia Neugebauer, PhD, as Chief Operating Officer (COO), effective May 1, 2025, heading investor relations and communications activities, spearheading market analysis, and overseeing various corporate functions.

On May 13, 2025, Vivoryon announced that it will hold its 2025 Annual General Meeting on June 24, 2025. The full agenda and all relevant documents are available on the Company's website (<https://www.vivoryon.com/2025-annual-general-meeting/>)



Financial Results for the First Quarter of 2025

Revenues were zero in the three months ended March 31, 2025, as well as in the three months ended March 31, 2024.

Research and development expenses decreased by EUR 6.2 million to EUR 1.2 million in the three months ended March 31, 2025, compared to EUR 7.4 million in the three months ended March 31, 2024. This decrease was largely attributable to EUR 6.1 million lower third-party expenses consisting mainly of lower manufacturing cost (EUR 1.5 million) and lower clinical costs (EUR 4.5 million), predominantly due to the ramp-down of the VIVIAD and VIVA-MIND Phase 2b clinical studies.

General and administrative expenses were EUR 1.3 million in the three months ended March 31, 2025, compared to EUR 2.1 million in the three months ended March 31, 2024. The decrease by EUR 0.8 million was largely attributable to lower expenses for personnel (EUR 0.3 million) as well as legal and consulting fees (EUR 0.2 million).

Net loss for the three months ended March 31, 2025, was EUR 2.5 million, compared to EUR 9.3 million for the three months ended March 31, 2024.

The Company held EUR 7.0 million in **cash and cash equivalents** as of March 31, 2025, compared to EUR 9.4 million, as of December 31, 2024.

Outlook & Financial Guidance

As published on April 29, 2025, the issuance date of its annual Financial Statements 2024, the Company expects, based on its most recent financial and business plan, that its existing cash and cash equivalents will be sufficient to fund its operating plans into January 2026, subject to the occurrence of unforeseen circumstances and without taking into account the SEPA as well as other potential additional financing transactions, if any. This cash runway guidance reflects an overall reduction in cash utilization including the conclusion of the VIVIAD and VIVA-MIND studies while prudently investing in preparing to execute on the Company's kidney disease strategy. The initiation of the Phase 2b DKD study is subject to further additional funding and/or partnership, which the Company continues to actively explore.

The viability of the Company's business beyond its current guidance is dependent on its ability to raise additional funds to finance its operations which also depends on the success of its research and development activities such as those focusing on exploring opportunities in kidney disease.

The Company expects to have continuing operating losses for the foreseeable future and the need to raise additional capital to finance its future operations. The Company has concluded that the ability to continue as a going concern in the financial year 2026, as stated in the Company's Annual Report 2024 published on April 29, 2025, depends on the ability to



generate additional funding. Please refer to the Company's Annual Report 2024 for further information.

Conference call and webcast

Vivoryon will host a conference call and webcast today, June 17, 2025, at 3:00 pm CEST (9:00 am EDT). A Q&A session will follow the presentation of the first quarter 2025 results.

A live webcast and slides will be made available at: <https://www.vivoryon.com/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-conf.media-server.com/register/B12bf13b52bb70430396e12c44801813ac>

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: <https://www.vivoryon.com/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 for the treatment of inflammatory and fibrotic disorders of the kidney. Driven by its passion for ground-breaking science and innovation, the Company strives to improve patient outcomes by changing the course of severe diseases through modulating the activity and stability of pathologically relevant proteins. Vivoryon's most advanced program, varoglutamstat, a proprietary, first-in-class orally available QPCT/L inhibitor, is being evaluated to treat diabetic kidney disease. 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 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. The Company's results of operations, cash needs, financial condition, liquidity, prospects, future transactions, strategies 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:

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