Vivoryon Therapeutics N.V. Reports H1 2025 Financial Results and Business Updates

- *Compelling kidney function data and meta-analysis from two Phase 2 studies, VIVIAD and VIVA-MIND, presented in oral presentation at ERA 2025*
- *Expanded IP portfolio including 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*
- *Pre-clinical data showing strong additive and synergistic effect of combination treatment with varoglutamstat and an SGLT-2 inhibitor; new VIVIAD analyses and pre-clinical data continue to support varoglutamstat's mechanism of action and potential in kidney disease*
- *Preparations ongoing for Phase 2b of varoglutamstat in diabetic kidney disease (DKD)*
- *Management to host conference call today at 3:00 pm CEST (9:00 am EDT)*

Halle (Saale) / Munich, Germany, September 4, 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 six-month period ended June 30, 2025, and provided a corporate update. The report is available on the Company's website https://www.vivoryon.com/financial-information/.

"In the first half of 2025, we have continued making substantial progress in advancing varoglutamstat in kidney disease, including significantly extending protection of our key asset varoglutamstat with a new composition of matter patent in the U.S.," said Frank Weber, MD, CEO of Vivoryon. "We were especially pleased to share our outstanding clinical study results with the medical community at ERA in June, further solidifying our view of varoglutamstat potentially becoming a novel therapeutic option for patients affected by kidney disease. Our data underscore varoglutamstat's unique ability to stabilize and even improve kidney function, as measured by eGFR values. Moreover, we are excited to have compiled evidence of a potential synergistic effect of varoglutamstat in combination with SGLT-2 inhibitors for which we have generated very promising pre-clinical data. We are continuing to elucidate varoglutamstat's mechanism of action in kidney disease. As more and more datapoints complete the picture, we strongly believe that varoglutamstat can effectively address the significant unmet need for new therapies that tackle the underlying inflammatory and fibrotic changes which are key drivers of disease progression in patients with CKD and DKD."

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H1 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 600 mg 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 were presented at the 62nd ERA Congress of the European Renal Association in Vienna, Austria, June 6, 2025, showing consistent improvement of kidney function in both studies independently, replicated in the meta-analysis and pooled analysis, thus providing consistent 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 pre-clinical 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.

New VIVIAD analyses and pre-clinical data continue to support varoglutamstat's mechanism of action and potential in kidney disease

Vivoryon has recently completed a series of supporting clinical data analyses and pre-clinical experiments which provide further evidence for varoglutamstat's potential to beneficially impact kidney function based on its proposed mechanism of action.

- Vivoryon has investigated the effects of varoglutamstat on inflammation, fibrosis and kidney function in an established advanced mouse model of DKD with type 2 diabetes and hypertension (ReninAAV UNx db/db). QPCT/L inhibition with varoglutamstat led to a statistically significant reduction in inflammation (CD11c), fibrosis (glomerulosclerosis) and plasma creatinine, supporting an improvement in kidney

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function. These data corroborate the effect of varoglutamstat on key kidney disease biomarkers previously reported in the ADI/CKD model and add to the overall body of evidence supporting varoglutamstat's potential in kidney disease including DKD.

- Vivoryon has established a novel, highly specific liquid chromatography-mass spectrometry (LC/MS)-based assay for analysis of biomarker samples in humans. This assay eliminates the need for anti-pE-specific antibodies that are often difficult to generate, thus posing technical limitations. An analysis of the inflammatory biomarker pE-CCL2 of VIVIAD study samples with this specific assay showed a statistically significant, dose-dependent reduction of pE-CCL2 in study participants treated with varoglutamstat versus placebo, confirming the previous analyses.
- Results from Vivoryon's VIVIAD Phase 2b study previously showed that reduction of pE-CCL2 was associated with an improvement of kidney function as measured by eGFR in study participants with and without diabetes at a dose group level. A novel analysis of VIVIAD evaluating the correlation pE-CCL2 levels and eGFR slope on an individual participant level revealed a statistically significant correlation between the change from baseline in pE-CCL2 serum levels at week 48 and the eGFR slope over time. Specifically, a decrease in pE-CCL2 was significantly correlated with a positive (improved) eGFR slope.

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 has a scheduled runtime 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 are 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 currently in pre-clinical stage and further development is subject to additional funding and/or partnership, which Vivoryon continues to actively explore.

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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. As of today, Vivoryon has not initiated any tranches of the SEPA.
- On May 1, 2025, Julia Neugebauer, PhD, assumed the newly created role of Chief Operating Officer (COO) of Vivoryon, heading investor relations and communications activities, spearheading market analysis, and overseeing various corporate functions.
- Vivoryon held its 2025 Annual General Meeting (AGM) on June 24, 2025, in Amsterdam, the Netherlands. The shareholders approved all items on the agenda of the meeting. The full agenda and all relevant documents are available on the Company's website (https://www.vivoryon.com/2025-annual-general-meeting/).
- Vivoryon CFO Anne Doering will be taking a temporary partial leave of absence in the coming months to attend to a serious family health matter. During this period, Marcus Irsfeld will assume the role of acting CFO, ensuring continuity in financial operations and supporting the company's strategic objectives.
    - Marcus is an experienced healthcare finance executive who has been working with Vivoryon as a strategic consultant since December 2024. He brings deep life sciences expertise, including five years as CFO of iOmx Therapeutics AG. He has also founded and co-founded several small and medium-sized enterprises, particularly in healthcare. He has led companies across Europe, the U.S., and China through all stages of growth, from founding and early-stage financing to exits and M&A. He holds a Masters degree in Business Administration (Diplom-Kaufmann) from the University of Münster.

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Financial Results for the First Half of 2025

Revenues were zero in the six months ended June 30, 2025, as well as in the six months ended June 30, 2024.

Research and development expenses decreased by EUR 7.5 million to EUR 2.8 million in the six months ended June 30, 2025, compared to EUR 10.3 million in the six months ended June 30, 2024. This reduction was largely attributable to a decrease in clinical development costs of EUR 5.6 million from the VIVIAD and VIVA-MIND studies and a reduction in production costs of EUR 1.5 million. R&D expenses in the reporting period mainly occurred for kidney related research.

General and administrative expenses were EUR 2.8 million in the six months ended June 30, 2025, compared to EUR 3.5 million in the six months ended June 30, 2024. The decrease of EUR 0.7 million was largely attributable to lower personnel costs of EUR 0.4 million and a decrease in legal and consulting cost of EUR 0.2 million.

Net loss for the six months ended June 30, 2025, was EUR 5.5 million, compared to EUR 13.6 million for the six months ended June 30, 2024.

The Company held EUR 4.8 million in **cash and cash equivalents** as of June 30, 2025, compared to EUR 9.4 million as of December 31, 2024.

Outlook & Financial Guidance

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 any funds possibly raised under the SEPA as well as other potential additional financing transactions, if any. This guidance is in line with the cash runway update published on April 29, 2025, the issuance date of its annual Financing Statements 2024.

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

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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. As such the Company has concluded that a material uncertainty exists that may cast significant doubt about its ability to continue as a going concern.
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, September 4, 2025, at 3:00 pm CEST (9:00 am EDT). A Q&A session will follow the presentation of the first half 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/BI5a3854fa349d497f8979340542813a0f

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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Vivoryon Therapeutics N.V. Financial Statements
Unaudited Statement of Operations and Comprehensive Loss for the Six Months Ended June 30, 2025 and 2024

in kEUR, except for share data	For the six months ended June 30, 2025 (unaudited)	2024 (unaudited)
Research and development expenses	(2,768)	(10,308)
General and administrative expenses	(2,755)	(3,501)
Operating loss	**(5,523)**	**(13,809)**
Finance income	74	303
Finance expenses	(24)	(53)
Finance result	**50**	**250**
Result before income taxes	**(5,473)**	**(13,559)**
Income taxes	—	—
Net loss for the period	**(5,473)**	**(13,559)**
Items not to be reclassified subsequently to profit or loss		
Remeasurement of the net defined benefit pension liability	26	39
Total other comprehensive profit / (loss)	**26**	**39**
Comprehensive loss	**(5,447)**	**(13,520)**
Loss per share in EUR (basic and diluted)	(0.21)	(0.52)

The accompanying notes are an integral part of these condensed interim financial statements.

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Vivoryon Therapeutics N.V.
Unaudited Condensed Statements of Financial Position as of June 30, 2025 and December 31, 2024 (audited)

in kEUR	June 30, 2025 (unaudited)	December 31,2024 (audited)
ASSETS		
Non-current assets		
Property, plant and equipment	19	24
Intangible assets	831	865
Right-of-use assets	70	100
Other non-current assets	255	228
Total non-current assets	**1,175**	**1,217**
Current assets		
Financial assets	30	63
Other current assets and prepayments	377	639
Cash and cash equivalents	4,837	9,365
Total current assets	**5,244**	**10,067**
TOTAL ASSETS	**6,419**	**11,284**
Equity		
Share capital	262	261
Share premium	161,477	161,477
Other capital reserves	16,524	15,777
Accumulated other comprehensive loss	(242)	(268)
Accumulated deficit	(174,840)	(169,367)
Total equity	**3,181**	**7,880**
Non-current liabilities		
Pension liability	1,265	1,317
Provisions long-term	663	647
Lease liability	11	42
Total non-current liabilities	**1,939**	**2,006**
Current liabilities		
Trade payables	1,025	1,015
Lease liabilities	61	60
Other liabilities	213	324
Total current liabilities	**1,299**	**1,399**
Total Liabilities	**3,238**	**3,405**
TOTAL EQUITY AND LIABILITIES	**6,419**	**11,284**

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Vivoryon Therapeutics N.V.
Unaudited Condensed Statements of Changes in Shareholders' Equity for the six months ended June 30, 2025 and 2024

in kEUR	Share capital	Share premium	Other capital reserves	Accumulated other compre-hensive loss	Accumulated deficit	Total equity
January 1, 2025	**261**	**161,477**	**15,777**	**(268)**	**(169,367)**	**7,880**
Net loss for the period	—	—	—	—	(5,473)	(5,473)
Remeasurement of the net defined benefit pension liability	—	—	—	26	—	26
Comprehensive loss	**—**	**—**	**—**	26	**(5,473)**	**(5,447)**
Proceeds from the issuance of common shares	1	—	—	—	—	1
Share-based payments	—	—	747	—	—	747
June 30, 2025	**262**	**161,477**	**16,524**	**(242)**	**(174,840)**	**3,181**
January 1, 2024	**26,067**	**135,671**	**13,599**	**(256)**	**(148,799)**	**26,282**
Net loss for the period	—	—	—	—	(13,559)	(13,559)
Remeasurement of the net defined benefit pension liability	—	—	—	39	—	39
Comprehensive loss	**—**	**—**	**—**	**39**	**(13,559)**	**(13,520)**
Share-based payments	—	—	1,218	—	—	1,218
June 30, 2024	**26,067**	**135,671**	**14,817**	**(217)**	**(162,358)**	**13,980**

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Vivoryon Therapeutics N.V.
Unaudited Condensed Statements of Cash Flows for the six months ended June 30, 2025 and 2024

in kEUR	For the six months ended June 30, 2025 (unaudited)	2024 (unaudited)
Operating activities		
Net loss for the period	(5,473)	(13,559)
Adjustments for:		
Finance result	(50)	(250)
Depreciation and amortization	73	73
Share based payments	747	1,218
Foreign currency gain (loss) from other items than cash	3	(25)
Other non-cash adjustments	1	19
Changing in:		
Financial assets	—	(4)
Other current assets and prepayments	262	383
Other long-term assets	(27)	—
Pension liabilities	(47)	(66)
Trade payables	10	(1,429)
Other liabilities	(96)	(13)
Interest received	103	353
Interest paid	(2)	—
Cash flows used in operating activities	**(4,496)**	**(13,300)**
Investing activities		
Purchase of plant and equipment	(4)	—
Proceeds from sale of financial assets	—	10,000
Cash flows used in investing activities	**(4)**	**10,000**
Financing activities		
Payment of lease liabilities	(30)	(28)
Proceeds from the issuance of common shares	2	—
Cash flows provided by financing activities	**(28)**	**(28)**
Net increase in cash and cash equivalents	**(4,528)**	**(3,328)**
Cash and cash equivalents at the beginning of period	9,365	18,562
Effect of exchange rate fluctuation on cash held	—	38
Cash and cash equivalents at end of period	**4,837**	**15,272**

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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.

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