Vivoryon Therapeutics N.V. Reports Full Year 2023 Financial Results and Provides Varoglutamstat and Strategic Updates

- *In-depth analysis of VIVIAD Phase 2b results is ongoing, including pre-specified and exploratory endpoints; findings to date are consistent with previously announced topline data observing no statistically significant or clinically meaningful effect of varoglutamstat on cognition and function in early AD up to 600mg twice a day (BID) dose*
- *Statistically significant improvement in kidney function observed with varoglutamstat 600mg BID in VIVIAD over two years based on pre-specified analysis of the estimated glomerular filtration rate*
- *Company plans to explore potential of varoglutamstat in kidney disease in a shift of strategic focus towards inflammatory and fibrotic disorders*
- *VIVA-MIND Phase 2 study to be discontinued early, in H2 2024, which will enable accelerated data analysis and inform varoglutamstat development strategy*
- *Company is taking steps to reduce cash utilization and will prioritize resources on exploring varoglutamstat in kidney disease, VIVIAD and VIVA-MIND data analysis, select pipeline programs, and continuing business development*
- *Based on current financial and business plans, including the discontinuation of VIVA-MIND, Company's cash runway is now expected to extend into Q2 2025 without additional financing*
- *Management to host conference call today at 3:00pm CEST (9:00am EDT)*

Halle (Saale) / Munich, Germany, April 24, 2024 – 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 twelve-month period ended December 31, 2023, and provided varoglutamstat and strategic updates including its pipeline development priorities and financial guidance.

"2023 was a year of clinical progress as we prepared for the readout from our VIVIAD Phase 2b study and advanced our U.S. study, VIVA-MIND, in early Alzheimer's disease. We were very disappointed to report negative results from VIVIAD in March of this year, given the significant unmet need for new disease-modifying therapies. Our ongoing analysis of the topline data confirms that there was no consistent effect of varoglutamstat on cognition and function at the 600mg dose and we are continuing our in-depth analysis to uncover key learnings and inform our long-term strategy in AD. Varoglutamstat's safety profile continues to look encouraging and we are excited to report today that we have observed a statistically significant improvement in kidney function based on pre-specified analysis of the estimated glomerular filtration rate measured in VIVIAD. This is in line with our prior hypothesis and results of

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pharmacological research on the role of the QPCT/L pathway beyond AD and is a very promising development. We are now prioritizing our resources and research and development activities to maximize value from varoglutamstat and our pipeline, with a focus on exploring its potential role in inflammatory and fibrotic diseases, including kidney disease, and determining additionally whether a path forward is viable in AD," said Frank Weber, M.D., CEO of Vivoryon.

He continued, "Based on the VIVIAD analysis, and an assessment of funding needs, we have taken the decision, jointly with our principal investigator, to discontinue the VIVA-MIND study in early AD in the second half of 2024. This will enable us to accelerate analysis of patients treated in the study and explore varoglutamstat's effect on certain endpoints including EEG theta power and kidney function and look for any trends in cognition. We hope the data from VIVA-MIND will increase our understanding of the role of QPCT/L inhibition in AD and evolve the science behind this devastating disease."

In light of recent developments, the Company is today announcing prioritization of its resources into research and development activities it believes have the greatest potential to provide a meaningful impact for patients and for value creation. Key priorities reflect the strategic shift towards a focus on inflammatory and fibrotic diseases and include:

- Exploring varoglutamstat's potential in inflammatory and fibrotic disorders, including of the kidney,
- Concluding VIVIAD Phase 2b clinical study program for varoglutamstat in Europe, including an in-depth analysis of the results presented on March 4, 2024, and further ongoing biomarker analysis,
- Discontinuing VIVA-MIND clinical Phase 2 study with varoglutamstat in the U.S. in the second half of 2024, earlier than planned, enabling accelerated analysis of the results which will contribute to the overall dataset informing varoglutamstat's development strategy moving forward,
- Assessing the potential of varoglutamstat in doses higher than 600mg BID orally in early Alzheimer's disease,
- Continuing to actively pursue potential business development and financing opportunities.

2023 and Post-Period Updates

Varoglutamstat Clinical Program:

VIVIAD study in early AD

VIVIAD (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 259 subjects with mild cognitive impairment (MCI) and mild Alzheimer's disease (AD).

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- In March 2024, Vivoryon announced topline data for VIVIAD. The study, which evaluated varoglutamstat up to 600mg BID, did not meet its primary endpoint of a statistically significant difference in cognitive improvement over time, assessed by the combined Z-score of the three elements of the Cogstate 3-item scale, as well as key secondary endpoints measuring cognition and function including the Cogstate Brief Battery (CBB); complete Cogstate neuropsychological test battery (NTB); the Amsterdam Instrumental Activities of Daily Living Questionnaire (A-IADL-Q) and electroencephalogram (EEG) global theta power.
- Safety results from the study showed that varoglutamstat was generally well tolerated and showed rates similar to placebo of serious and severe treatment emergent adverse events (TEAEs), low discontinuation rates due to adverse events and no evidence of symptomatic ARIAs (amyloid-related imaging abnormalities) in the clinical setting.
- Vivoryon is conducting an in-depth analysis of the VIVIAD data. While these analyses remain ongoing, findings to date confirm the topline results. Additionally, no statistically significant or clinically meaningful effect of varoglutamstat up to 600mg BID was observed on pre-specified subgroups. The only significant difference observed in favor of varoglutamstat was a lower change from baseline in the WAIS IV coding test and the letter fluency test, both measuring cognitive dysfunction, at week 48. Pharmacokinetic and QPCT/L enzyme inhibition data in VIVIAD were consistent with previous results.

VIVIAD study – results from kidney function exploratory analyses

- The VIVIAD protocol prospectively specified measurement of certain kidney function biomarkers. This was in line with the Company's previously announced growth strategy to explore varoglutamstat's potential effects on kidney function.
- Varoglutamstat 600mg BID increased the estimated glomerular filtration rate (eGFR) over the treatment period up to 96 weeks, indicating a potential benefit of varoglutamstat on kidney function. Analysis is ongoing including a closer analysis of VIVIAD results in patients with different eGFR levels at baseline.
- Given these statistically significant and clinically meaningful data, Vivoryon is evaluating a development path including business development and financing opportunities to further explore the potential of varoglutamstat and QPCT/L inhibitors in kidney disease.

VIVA-MIND study in early AD

VIVA-MIND (NCT03919162) is a Phase 2 study conducted in the U.S. evaluating the safety, tolerability, and efficacy of varoglutamstat in patients with early AD.

- Vivoryon announced today that, based on the ongoing review of VIVIAD data published March 4, 2024, and an assessment of funding needs, the Company has decided jointly with its principal investigator, to voluntarily discontinue the Phase 2 VIVA-MIND study in early AD in the U.S. in the second half of 2024. This will enable accelerated analysis of the results and will contribute to the overall dataset informing varoglutamstat's

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development strategy moving forward. Initial data from the study is anticipated by the end of 2024.

- In October 2023, Vivoryon announced the study's independent data and safety monitoring board (DSMB) recommended to continue VIVA-MIND with a 600mg BID dose throughout Phase 2a and 2b, which is an accelerated up-titration protocol compared to the VIVIAD Phase 2b study. This decision followed safety reviews and analyses of treatment-emergent adverse events of special interest (AESI) occurring in skin and subcutaneous tissue disorders and hepatobiliary disorders, target occupancy and pharmacokinetic (PK) data.

VIVALONG study

VIVALONG is an open-label extension (OLE) study offering a long-term treatment option to patients after completing VIVIAD or VIVA-MIND protocols.

- In line with the Company's cost reduction measures and given the developments of VIVIAD and VIVA-MIND, Vivoryon has decided to stop VIVALONG OLE study preparation activities.

Early-Stage Pipeline

Vivoryon is revisiting the early-stage opportunities in its R&D activities in line with its strategic shift.

- Future pre-clinical activities will involve exploring QPCT/L inhibitors for use in inflammatory and fibrotic disorders as well as in other indications such as oncology and CNS.
- Opportunities with meprin inhibitors will continue to be explored, in particular for fibrotic disorders.
- The Company's antibody program, PBD-C06, will remain active as a candidate for further potential partnering opportunities.
- The Company will continue to explore identification of second generation QPCT/L inhibitors with good blood brain barrier penetration.

Corporate Development Updates

- In March 2024, Kugan Sathiyanandarajah and Professor Dr. Morten Asser Karsdal stepped down from Vivoryon's Board of Directors. They had been previously appointed as Non-Executive Directors in June 2023.
- In March 2024, Anne Doering, CFA, assumed the role of Chief Financial Officer (CFO) of Vivoryon, following her previous position as Chief Strategy & Investor Relations Officer.
- In October 2023, Vivoryon hosted a virtual R&D Event with Key Opinion Leaders (KOLs), focusing on varoglutamstat.

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- In September 2023, Vivoryon held an Extraordinary General Meeting (EGM) related to the appointment of Frank Weber, MD, as CEO and Executive member of the Board of Directors. He followed Dr. Ulrich Dauer, former CEO of Vivoryon, after Dr. Dauer's announcement in June 2023 to not renew his contract with the Company.
- In August 2023, Vivoryon and Scenic Biotech B.V. ("Scenic") reached an agreement regarding the settlement of their patent dispute in connection with certain of Vivoryon´s patents related to varoglutamstat (PQ912) and certain other QPCT inhibitors. As part of the settlement, Scenic's affiliate, Scenic Immunology B.V., and Vivoryon have entered into a patent license agreement, under which Scenic Immunology B.V. granted to Vivoryon certain rights to certain patents controlled by Scenic Immunology B.V. in the field of oncology.
- In May 2023, Vivoryon successfully raised EUR 25 million through an accelerated bookbuild offering. The private placement totaled 1,785,715 ordinary shares, at an issue price of EUR 14.00 per share.

Financial Results for the Full Year 2023

Revenues for the year ended December 31, 2023, reflected a EUR 3.6 million reversal in license revenue, compared to no revenue in the year ended December 31, 2022. The reversal is related to license revenues recognized in 2021 from a strategic regional licensing partnership with Simcere Pharmaceutical Group Ltd. ("Simcere") to treat Alzheimer's disease (AD) in Greater China, which includes a variable compensation for the first milestone. This variable milestone payment of EUR 3.6 million is based on the initiation of the first human clinical trial of varoglutamstat in mainland China. After the end of the reporting period the anticipated first milestone revenues were re-assessed. Due to the VIVIAD Phase 2b study not meeting its primary and key secondary endpoints, it is expected that the first human clinical trial in mainland China will not start before further clarity from an in-depth analysis of the VIVIAD results as well as from additional analysis of the full data and its implications. Therefore, revenues for the variable compensation (first development milestone) are no longer highly probable. As a consequence, the milestone-receivable of EUR 3.6 million was impaired and the respected revenues were reversed, as of December 31, 2023.

Research and development expenses decreased by EUR 2.6 million to EUR 17.6 million in the year ended December 31, 2023, compared to EUR 20.2 million in the year ended December 31, 2022. The decrease is primarily attributable to EUR 2.7 million lower third-party expenses, mainly due to EUR 3.6 million lower manufacturing costs, partially offset by EUR 1.7 million higher clinical costs, mainly due to the progress of the Phase 2b VIVIAD clinical study.

General and administrative expenses were EUR 8.6 million in the year ended December 31, 2023, compared to EUR 8.9 million in the year ended December 31, 2022. The decrease of EUR 0.3 million is largely attributable to the release of EUR 2.6 million of previously capitalized capital raising costs in 2022, partially offset by EUR 2.2 million higher expenses for personnel,

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legal and consulting, as well as costs for Non-Executive Directors. The reasons for the cost increases in personnel and for the Non-Executive Directors of the Board were predominantly caused by accelerated share-option expenses (EUR 0.3 million) and severance payments (EUR 0.6 million) as a result of the 2023 Board changes.

Net loss in the year ended December 31, 2023, was EUR 28.3 million, compared to EUR 28.2 million in the year ended December 31, 2022.

The Company held EUR 18.6 million in **cash and cash equivalents** as of December 31, 2023, plus term deposits of EUR 10.0 million disclosed under current financial assets, compared to cash and cash equivalents of EUR 26.6 million as of December 31, 2022.

Cash flows used in operating activities were EUR 21.5 million in the year ended December 31, 2023, compared to EUR 21.8 million in the year ended December 31, 2022.

Cash flows used in investing activities were EUR 10.5 million in the year ended December 31, 2023, compared to EUR 13 thousand in the year ended December 31, 2022. This difference reflects the net purchase of term deposits in the amount of EUR 10.0 million during 2023.

Cash flows provided from financing activities were EUR 24.2 million in the year ended December 31, 2023, compared to EUR 33.4 million in the year ended December 31, 2022.

Outlook & Financial Guidance

The Company expects, on the basis of its most recent financial and business plan, that its existing cash and cash equivalents will be sufficient to fund its operating plans, excluding any additional financings, into the second quarter of 2025.

This cash runway guidance reflects an overall reduction in cash utilization including the ramp down of spending on VIVIAD as it approaches its conclusion, the discontinuation of VIVA-MIND, the discontinuation of VIVALONG preparation activities given the developments of VIVIAD and VIVA-MIND, as well as the streamlining of manufacturing costs and programs for API development. These activities also represent a change in focus of research and development resources towards inflammatory and fibrotic disorders, such as of the kidney, from an emphasis on Alzheimer's disease.

The viability of the Company beyond the second quarter of 2025 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.

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The financial statements have been prepared on the basis that the Company will continue as a going concern. The Company expects to have continuing operating losses for the foreseeable future and the need to raise additional capital to finance its future operations, and, as of April 24, 2024, the Company has concluded that the ability to continue as a going concern in the financial year 2025 depends on the ability to generate additional funding. Please refer to the Company's Annual Report 2023 for further information.

Conference Call and Webcast
Vivoryon will host a conference call and webcast today, April 24, 2024, at 3:00 pm CEST (9:00 am EDT). A Q&A session will follow the presentation of the full year 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/BI3fef74de02dc40daa7cbe0aac7731e74

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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Vivoryon Therapeutics N.V. Financial Statements
Statement of Operations and Comprehensive Loss for the Years Ended December 31, 2023 and 2022

in kEUR, except for share data	2023	2022
Revenue	(3,620)	—
Cost of Sales	525	—
Gross profit	**(3,095)**	**—**
Research and development expenses	(17,637)	(20,224)
General and administrative expenses	(8,600)	(8,908)
Other operating income	495	19
Other operating expense	—	—
Operating loss	**(28,837)**	**(29,113)**
Finance income	726	1,710
Finance expense	(465)	(952)
Finance result	**261**	**758**
Result before income taxes	**(28,576)**	**(28,355)**
Income taxes	234	199
Net loss for the period	**(28,342)**	**(28,156)**
Items not to be reclassified subsequently to profit or loss		
Remeasurement of the net defined benefit pension liability	(76)	392
Total other comprehensive (loss) / income	(76)	392
Comprehensive loss	**(28,418)**	**(27,764)**
Loss per share in EUR (basic and diluted)	(1.12)	(1.28)

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

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Vivoryon Therapeutics N.V.
Statements of Financial Position as December 31, 2023 and 2022

in kEUR	2023	2022
ASSETS		
Non-current assets		
Property, plant and equipment	40	49
Intangible assets	941	494
Right-of-use assets	36	127
Financial assets	–	14
Total non-current assets	**1,017**	**684**
Current assets		
Financial assets	10,165	3,716
Other current assets and prepayments	1,085	423
Cash and cash equivalents	18,562	26,555
Total current assets	**29,812**	**30,694**
TOTAL ASSETS	**30,829**	**31,378**
Equity		
Share capital	26,067	24,105
Share premium	135,671	113,382
Other capital reserves	13,599	9,656
Accumulated other comprehensive loss	(256)	(180)
Accumulated deficit	(148,799)	(120,457)
Total equity	**26,282**	**26,506**
Non-current liabilities		
Pension liability	1,353	1,323
Provisions long-term	12	12
Lease liabilities	–	38
Deferred tax liabilities	–	234
Total non-current liabilities	**1,365**	**1,607**
Current liabilities		
Trade payables	2,894	2,543
Lease liabilities	38	94
Other liabilities	250	628
Total current liabilities	**3,182**	**3,265**
Total Liabilities	**4,547**	**4,872**
TOTAL EQUITY AND LIABILITIES	**30,829**	**31,378**

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Vivoryon Therapeutics N.V.
Statements of Changes in Shareholders' Equity for the Years Ended December 31, 2023 and 2022

in kEUR	Share capital	Share premium	Other capital reserves	Accumulated other comprehensive loss	Accumulated deficit	Total equity
January 1, 2022	**20,050**	**83,211**	**6,168**	**(572)**	**(92,300)**	**16,557**
Net loss for the period	—	—	—	—	(28,156)	(28,156)
Remeasurement of the net defined benefit pension liability	—	—	—	392	—	392
Comprehensive (loss) / income	**—**	**—**	**—**	**392**	**(28,156)**	**(27,764)**
Proceeds from the issuance of common shares	4,055	31,945	—	—	—	36,000
Transaction costs of equity transactions	—	(1,774)	—	—	—	(1,774)
Share-based payments	—	—	3,488	—	—	3,488
December 31, 2022	**24,105**	**113,382**	**9,656**	**(180)**	**(120,457)**	**26,506**
Net loss for the period	—	—	—	—	(28,342)	(28,342)
Remeasurement of the net defined benefit pension liability	—	—	—	(76)	—	(76)
Comprehensive (loss) / income	**—**	**—**	**—**	**(76)**	**(28,342)**	**(28,418)**
Proceeds from the issuance of common shares	1,786	23,214	—	—	—	25,000
Transaction costs of equity transactions	—	(2,095)	—	—	—	(2,095)
Share-based payments	—	—	3,943	—	—	3,943
Proceeds from exercise of share options	176	1,170	—	—	—	1,346
December 31, 2023	**26,067**	**135,671**	**13,599**	**(256)**	**(148,799)**	**26,282**

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Vivoryon Therapeutics N.V.
Statements of Cash Flows for the Years ended December 31, 2023 and 2022

in kEUR	2023	2022
Operating activities		
Net loss for the period	(28,342)	(28,156)
Adjustments for:		
Finance result	(261)	(758)
Depreciation and amortization	167	161
Share based payments	3,943	3,488
Capitalized capital raising costs that were expensed	—	2,633
Deferred income tax	(234)	(199)
Reversal of Revenue and Accounts Receivable	3,095	—
Changing in		
Financial assets	—	3,090
Other current assets and prepayments	(662)	294
Pension liabilities	(94)	(122)
Provisions	—	(35)
Trade payables	538	(1,724)
Other liabilities	(17)	(471)
Interest received	328	9
Interest paid	(2)	(4)
Cash flows used in operating activities	**(21,541)**	**(21,794)**
Investing activities		
Purchase of plant and equipment	(14)	(11)
Purchase of intangible assets	(500)	(2)
Purchase of financial assets	(19,000)	—
Proceeds from sale of financial assets	9,000	—
Cash flows used in investing activities	**(10,514)**	**(13)**
Financing activities		
Proceeds from the issuance of common shares	25,000	36,000
Transaction costs of equity transactions	(2,095)	(1,774)
Capital raising costs	—	(753)
Payment of lease liabilities	(94)	(92)
Proceeds from exercise of share options	1,346	—
Cash flows provided by / (used in) financing activities	**24,157**	**33,381**
Net decrease in cash and cash equivalents	**(7,898)**	**11,574**
Cash and cash equivalents at the beginning of period	26,555	14,661
Effect of exchange rate fluctuation on cash held	(95)	320
Cash and cash equivalents at the end of period	**18,562**	**26,555**

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Annual Financial Report 2023

The financial statements of Vivoryon have been prepared in accordance with International Financial Reporting Standards (IFRS) of the International Accounting Standards Board, as adopted by the European Union (EU-IFRS) and with Section 2:362(9) of the Netherlands Civil Code. The auditor KPMG has issued an unqualified auditor's report for both statements. The reports are available on the Company's website www.vivoryon.com.

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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 its passion for ground-breaking science and innovation, the Company strives to change the lives of patients in need suffering from severe diseases. The Company leverages its 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. The Company has established a pipeline of orally available small molecule inhibitors for various indications including Alzheimer's disease, inflammatory and fibrotic disorders, including of the kidney, and cancer. 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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