Vivoryon Therapeutics N.V. Reports H1 2023 Financial Results and Highlights Operational Progress

- *Both VIVIAD and VIVA-MIND studies on track; final data from VIVIAD expected in Q1/2024, and a study update on VIVA-MIND expected in Q4/2023*
- *Varoglutamstat demonstrates very encouraging safety data with no drug-related ARIAs at therapeutic dose of 600 mg twice daily, a dose demonstrated to result in nearly 90% target occupancy*
- *DSMB meeting results support current protocol for VIVIAD and VIVA-MIND studies*
- *Frank Weber, MD, assumed Chief Executive Officer (CEO) and Anne Doering, CFA, assumed Chief Strategy & Investor Relations Officer (CS&IRO) position*
- *Appointed Kugan Sathiyanandarajah and Prof. Morten Asser Karsdal, MSc, PhD, mMBA as Non-Executive Board members*
- *Bolstered financial position with successful private placement of EUR 25 million to support ongoing clinical development, extending cash runway into 2H/2024*
- *Management to host conference call today at 3:00 pm CEST (9:00 am EDT)*

Halle (Saale) / Munich, Germany, September 7, 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 six-month period ended June 30, 2023, and provided an update on its corporate progress. The report is available on the Company's website https://www.vivoryon.com/investors-news/financial-information/

"We enter into the second half of 2023 with key milestones achieved and a strong cash position bringing us beyond the VIVIAD Phase 2b study read-out, an exceptionally talented, passionate team, encouraging safety results at 600 mg twice daily in the VIVIAD study of varoglutamstat and a precision recruitment strategy applied to successfully identify the right patients for VIVIAD," said Frank Weber, MD, CEO of Vivoryon. "Our achievements from the first half of this year include a successful fundraise significantly extending our cash runway and supportive independent Data Safety Monitoring Board decisions for VIVIAD and VIVA-MIND. We are laser focused on delivering VIVIAD study results in the first quarter of 2024 and monitor study progress as well as blinded safety and efficacy outcome parameters continuously. With varoglutamstat's favorable safety profile, ease of administration, and strong signs of efficacy and synaptic improvement, we believe we are uniquely positioned to bring a highly differentiated, potentially first-in-class therapeutic option to patients with Alzheimer's disease."

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H1 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 600 mg twice daily (BID), a dose demonstrated to result in a target occupancy of nearly 90%.

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 designed to evaluate the safety, tolerability, and efficacy of varoglutamstat in 259 (final number of randomized participants) subjects with mild cognitive impairment (MCI) and mild AD.

- In March 2023, Vivoryon announced an update on the clinical development of varoglutamstat, including the VIVIAD trial, at the International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders (AD/PD) in Gothenburg, Sweden. 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, to date, no on-target toxicity and no clinical signs of brain swelling or hemorrhages (ARIA), which are a limiting class side effect of Abeta antibodies. The discontinuation rate due to adverse events in VIVIAD was considerably lower than* in the completed Phase 2a SAPHIR study at comparable timepoints, while retaining a similar level of target inhibition (around 90%) at the dosing in both studies.
- In July 2023, Vivoryon presented a poster titled, "VIVIAD, a Phase 2b Study Investigating Varoglutamstat in Patients with MCI or Mild AD: Analysis of Baseline Cognition Data" at the Alzheimer's Association International Conference (AAIC), in Amsterdam, the Netherlands. These data demonstrated that Vivoryon's strategy of precisely recruiting individuals with evidence of at least minimal baseline deficits on the WAIS-IV Coding test, a well-known measure of cognitive function, successfully identifies patients with MCI, enabling a reliable assessment of potential cognitive improvement after treatment.
- In July 2023, Vivoryon announced a safety update based on data from all 259 randomized patients which showed no clinical signs of varoglutamstat associated ARIA`s at the cutoff date of June 14, 2023. After carefully reviewing the updated safety data, the independent Data Safety Monitoring Board (DSMB) decided in its recent

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meeting on June 22, 2023, that the study should continue as planned and that no additional DSMB meeting will be required until study completion.

- In July 2023, Vivoryon announced that it commenced preparations for an open-label extension (OLE) study to provide a long-term treatment option to patients after completion of treatment under the VIVIAD or VIVA-MIND protocol. The launch of the OLE study is contingent on the outcome of VIVIAD.
- Vivoryon remains on track to report the final data readout from the VIVIAD study in the first quarter of 2024.

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.

- In July 2023, Vivoryon announced that the first cohort was fully randomized into the study as planned and the study is now recruiting participants into the second cohort, with 19 sites open across the U.S. In June 2023, the study's independent DSMB recommended to continue the study without modification, supporting the rationale for accelerated uptitration to 600 mg BID dosing.
- The Company intends to provide a study update in the fourth quarter of 2023.

Corporate Development Highlights

- In May 2023, Vivoryon announced the successful raise of EUR 25 million in an accelerated bookbuild offering through a private placement of 1,785,715 ordinary shares, with a nominal value of EUR 1.00 each, in the issued share capital of the Company at an issue price of EUR 14.00 per share (such shares the "New Shares"). The New Shares from the capital increase represented approximately 7.4% of Vivoryon's existing issued share capital and were issued from the Company's authorized capital under exclusion of the existing shareholders' pre-emptive rights. Consequently, the Company's issued share capital increased to EUR 25,890,993.00.
- In June 2023, Vivoryon announced the appointment of Kugan Sathiyanandarajah and Professor Dr. Morten Asser Karsdal as Non-Executive members to its Board of Directors, strengthening the Board with their extensive scientific knowledge and business acumen. Both appointments were approved during Vivoryon's Annual General Meeting which took place on June 21, 2023. All voting items were passed with a majority.
- In August 2023, Vivoryon announced that the Board identified long-standing member of Vivoryon's management team and Chief Medical Officer (CMO), Frank Weber, MD, as the optimal candidate to assume the responsibilities of CEO, effective

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August 14, 2023. Additionally, the Board proposed a newly created position, Chief Strategy & Investor Relations Officer (CS&IRO), which was assumed by Head of Investor Relations, Anne Doering, CFA. Vivoryon will hold an Extraordinary General Meeting (EGM) on Friday, September 15, 2023, related to their appointments as new members of Vivoryon's Board of Directors. The appointments follow the decision of Chief Executive Officer (CEO), Ulrich Dauer, PhD, to step down from his position following his notification to the Board to not renew his contract, previously announced on June 15, 2023. Dr. Dauer will support the Company through the transition period in an advisory role through the end of 2023.

- In August 2023, Vivoryon and Scenic Biotech B.V. ("Scenic") reached an agreement regarding the settlement of their patent dispute. In 2019, Vivoryon had initiated proceedings on the merits with the District Court of The Hague against Scenic, Stichting Het Nederlands Kanker Instituut-Antoni van Leeuwenhoek Ziekenhuis and Academisch Ziekenhuis Leiden h.o.d.n LUMC, 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.

Financial Results for the First Half Year 2023

No **revenues** were generated in the first half year of 2023 or the first half year of 2022.

Research and development expenses of EUR 6.3 million in the six months ended June 30, 2023, decreased by EUR 4.8 million compared to the six months ended June 30, 2022. This decrease is primarily attributable to EUR 2.5 million lower expenses related to our clinical trial VIVIAD and EUR 2.2 lower manufacturing cost for study drug production.

General and administrative expenses of EUR 4.4 million for the six months ended June 30, 2023, increased by EUR 2.1 million from EUR 2.3 million in the six months ended June 30, 2022. EUR 1.3 million of the increase is attributable to higher costs for the Non-Executive Board members, including share-based payments and compensation of EUR 0.9 million and one-time severance payments of EUR 0.4 million. Furthermore, an increase of EUR 0.8 million was largely due to higher consulting and personnel costs.

Net loss of EUR 10.7 million for the six months ended June 30, 2023, compares to EUR 12.6 million for the six months ended June 30, 2022.

The Company held EUR 29.6 million in **cash and cash equivalents** as of June 30, 2023, compared to EUR 26.6 million as of December 31, 2022. Additionally, in the six months ended

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June 30, 2023, the Company entered into Euro term deposits of EUR 9.0 million resulting in a reclassification of these funds in the balance sheet into financial assets.

Cash flows used in operating activities were EUR 20.3 million for the six months ended June 30, 2023, compared to EUR 10.2 million in the six months ended June 30, 2022. The change in operating cash flow by EUR (10.0) million mainly results from the reclassification of new term deposits with a term of more than three months of EUR (9.0) million that are disclosed in the Company`s financial assets and not in cash equivalents as well as other changes in working capital.

Cash flows provided from financing activities were EUR 23.4 million for the six months ended June 30, 2023, compared to EUR 19.6 million in the six months ended June 30, 2022. The cash flows from financing mainly result from a private placement on May 26, 2023, placing 1,785,715 registered shares at an offering price of EUR 14.00 per share with gross proceeds of EUR 25 million. The Company's issued share capital has increased to EUR 25,961,892, including the exercise of share options.

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 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).

Upcoming Investor and Analyst Events

- Vivoryon will hold an Extraordinary General Meeting (EGM) Friday, September 15, 2023, at 1:00 p.m. (CEST) related to the appointments of Frank Weber, MD, and Anne Doering, CFA, as new members of Vivoryon's Board of Directors. The full agenda and all relevant documents for the upcoming EGM are available on the Company's website (https://www.vivoryon.com/2023-extraordinary-general-meeting/)
- Vivoryon will host a virtual R&D Day with Key Opinion Leaders (KOLs) in Q4/2023 focused on, the Company's scientific approach, varoglutamstat and study design.

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Conference Call and Webcast
Vivoryon will host a conference call and webcast today, September 7, 2023, at 3:00 pm CEST (9:00 am EDT). A Q&A session will follow the presentation of the first half 2023 financial 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/BI37d47846ffb6452eaad13f500e1acec2

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/

*Please note a previous version was without “than”

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Vivoryon Therapeutics N.V. Financial Statements
Statement of Operations and Comprehensive Loss for the Six Months Ended June 30, 2023 and 2022

in kEUR, except for share data	For the six months ended June 30, 2023 (unaudited)	2022 (unaudited)
Research and development expenses	(6,259)	(11,067)
General and administrative expenses	(4,433)	(2,311)
Operating loss	**(10,692)**	**(13,378)**
Finance income	258	989
Finance expenses	(327)	(105)
Finance result	**(69)**	**884**
Result before income taxes	**(10,761)**	**(12,494)**
Income taxes	45	(89)
Net loss for the period	**(10,716)**	**(12,583)**
Items not to be reclassified subsequently to profit or loss		
Remeasurement of the net defined benefit pension liability	(9)	261
Total other comprehensive profit / (loss)	**(9)**	**261**
Comprehensive loss	**(10,725)**	**(12,322)**
Loss per share in EUR (basic and diluted)	(0.44)	(0.60)

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, 2023 and December 31, 2022 (audited)

in kEUR	June 30, 2023 (unaudited)	December 31, 2022 (audited)
ASSETS		
Non-current assets		
Property, plant and equipment	45	49
Intangible assets	473	494
Right-of-use assets	81	127
Financial assets	14	14
Total non-current assets	**613**	**684**
Current assets		
Financial assets	12,700	3,716
Other current assets and prepayments	2,459	423
Cash and cash equivalents	29,582	26,555
Total current assets	**44,742**	**30,694**
TOTAL ASSETS	**45,355**	**31,378**
Equity		
Share capital	25,962	24,105
Share premium	134,973	113,382
Other capital reserves	11,961	9,656
Accumulated other comprehensive loss	(189)	(180)
Accumulated deficit	(131,173)	(120,457)
Total equity	**41,534**	**26,506**
Non-current liabilities		
Pension liability	1,310	1,323
Provisions long-term	12	12
Lease liabilities	10	38
Deferred tax liabilities	189	234
Total non-current liabilities	**1,521**	**1,607**
Current liabilities		
Trade payables	1,291	2,543
Lease liabilities	75	94
Other liabilities	934	628
Total current liabilities	**2,300**	**3,265**
Total Liabilities	**3,821**	**4,872**
TOTAL EQUITY AND LIABILITIES	**45,355**	**31,378**

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Vivoryon Therapeutics N.V.
Unaudited Condensed Statements of Changes in Shareholders' Equity for the six months ended June 30, 2023 and 2022

in kEUR	Share capital	Share premium	Other capital reserves	Accumulated other compre-hensive loss	Accumulated deficit	Total equity
January 1, 2023	**24,105**	**113,382**	**9,656**	**(180)**	**(120,457)**	**26,506**
Net loss for the period	–	–	–	–	(10,716)	(10,716)
Remeasurement of the net defined benefit pension liability	–	–	–	(9)	–	(9)
Comprehensive loss	**–**	**–**	**–**	(9)	**(10,716)**	**(10,725)**
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	–	–	2,305	–	–	2,305
Exercise of share options	71	472	–	–	–	542
June 30, 2023	**25,962**	**134,973**	**11,961**	**(189)**	**(131,173)**	**41,534**
January 1, 2022	**20,050**	**83,211**	**6,168**	**(572)**	**(92,300)**	**16,557**
Net loss for the period	–	–	–	–	(12,583)	(12,583)
Remeasurement of the net defined benefit pension liability	–	–	–	261	–	261
Comprehensive loss	**–**	**–**	**–**	**261**	**(12,583)**	**(12,322)**
Proceeds from the issuance of common shares	2,000	19,000	–	–	–	21,000
Transactions costs of equity transactions	–	(1,030)	–	–	–	(1,030)
Share-based payments	–	–	1,032	–	–	1,032
June 30, 2022	**22,050**	**101,181**	**7,200**	**(311)**	**(104,883)**	**25,237**

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Vivoryon Therapeutics N.V.
Unaudited Condensed Statements of Cash Flows for the six months ended June 30, 2023 and 2022

in kEUR	For the six months ended June 30, 2023 (unaudited)	2022 (unaudited)
Operating activities		
Net loss for the period	(10,716)	(12,583)
Adjustments for:		
Finance result	69	(884)
Depreciation and amortization	79	81
Share based payments	2,305	1,032
Foreign currency gain (loss) from other items than cash	(59)	458
Deferred income tax	(45)	89
Other non-cash adjustments	(33)	307
Changing in:		
Financial assets	(8,938)	2,721
Other current assets and prepayments	(2,036)	44
Pension liabilities	(13)	(318)
Trade payables	(1,252)	(679)
Other liabilities	306	(504)
Interest received	51	3
Interest paid	(1)	(3)
Cash flows used in operating activities	**(20,283)**	**(10,237)**
Investing activities		
Purchase of plant and equipment	(9)	(2)
Cash flows used in investing activities	**(9)**	**(2)**
Financing activities		
Proceeds from the issuance of common shares	25,000	21,000
Capital raising costs	(2,095)	(1,374)
Proceeds from exercise of share options	542	—
Payment of lease liabilities	(47)	(46)
Cash flows provided by financing activities	**23,400**	**19,581**
Net increase in cash and cash equivalents	**3,109**	**9,342**
Cash and cash equivalents at the beginning of period	26,555	14,661
Effect of exchange rate fluctuation on cash held	(82)	380
Cash and cash equivalents at end of period	**29,582**	**24,383**

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Half Year Financial Report 2023

The condensed interim financial statements of Vivoryon have been prepared in accordance with IAS 34 Interim Financial Reporting and International Financial Reporting Standards (IFRS) of the International Accounting Standards Board, as adopted by the European Union (EU-IFRS). The half-year financial statements were not audited or reviewed. The reports are available on the Company's website www.vivoryon.com.

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About VIVIAD

VIVIAD 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 AD compared to placebo over the course of 48 to 96 weeks of treatment. The highest dose investigated in the study (600 mg twice daily) was selected by an independent Data Safety Monitoring Board (DSMB) as final dose after the dose-escalation portion of the study. Enrollment was completed with a total of 259 participants and the study was adapted in 2022 to enable an average treatment duration of ~82 weeks. The primary endpoint is a composite of the Neuropsychological Test Battery (NTB) focusing on changes in working memory and attention with secondary endpoints including multiple cognitive, safety and biomarker assessments.

About VIVA-MIND

VIVA-MIND is a complementary Phase 2 study being conducted in the U.S., coordinated by the Alzheimer's Disease Cooperative Study (ADCS) at the University of California San Diego (UCSD) School of Medicine and supported by the National Institute on Aging (NIA), part of the National Institutes of Health (NIH) with a USD 15 million grant (NIA award number R01AG061146). The study seeks to enroll 180 patients into the Phase 2a adaptive dose-finding portion with the Phase 2b portion, enrolling an additional 234 patients treated at the selected dose for at least 72 weeks, with a total of 414 patients being treated on stable doses of varoglutamstat for 18 months. The VIVA-MIND design was adapted in 2022 to enable all 180 patients in the Phase 2a portion to be treated for at least 72 weeks, allowing for the opportunity to progress seamlessly to a potential Phase 3 study. The flexible study design is aimed at increasing the probability of success by broadening option space for adjustments in clinical development based on learnings from VIVIAD and other developments in the field. The primary endpoint for this study is clinical dementia rating scale - sum of boxes (CDR-SB), an established approvable endpoint measuring a combination of cognitive abilities and activities of daily living. Secondary efficacy endpoints include quantitative EEG theta power, ADAS-Cog 13 and others. Exploratory endpoints include Mini-Mental State Examination (MMSE), Montreal Cognitive Assessment (MoCA), quantitative EEG alpha power, relative QPCT activity in CSF and others.

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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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