Vivoryon Therapeutics N.V. Reports Q3 2021 Financial Results and Highlights Operational Progress

HALLE (SAALE) / MUNICH, GERMANY, November 4, 2021 – Vivoryon Therapeutics N.V. (Euronext Amsterdam: VVY; NL00150002Q7) (**Vivoryon**), a clinical stage company focused on discovery and development of small molecule medicines to modulate the activity and stability of pathologically altered proteins, today announced financial results and the corporate update for the third quarter of 2021, ending September 30, 2021. The report is available on the Company's website at www.vivoryon.com/investors-news/financial-information.

"Throughout the third quarter, we made significant progress towards filling the gap of safe, widely available effective disease-modifying therapies in Alzheimer's disease. Both our newly initiated study VIVA-MIND in the U.S. and our ongoing European study VIVIAD are progressing steadily and we have implemented a number of measures to ensure that the Company is able to deliver on its objectives, including stringent clinical development beyond the currently ongoing studies," said Dr. Ulrich Dauer, CEO of Vivoryon.

Corporate Highlights and R&D Updates
Varoglutamstat

- In August 2021, details on the study background and design of Vivoryon's European Phase 2b study VIVIAD in patients with mild cognitive impairment and mild AD were published in the Journal "Alzheimer's Research & Therapy" (Vijverberg et al., https://doi.org/10.1186/s13195-021-00882-9). The study is enrolling patients as planned despite the ongoing global pandemic. To avoid delays in recruitment and as a reaction to COVID-19-related patient and staff protection policies implemented at German study sites, Vivoryon is in the process of increasing the overall number of study sites, aiming to more than double the originally planned number. VIVIAD remains on track for an interim safety readout in mid-22 and Vivoryon continues to anticipate final data in the second half of 2023.

- In September 2021, Vivoryon initiated its U.S. Phase 2a/b VIVA-MIND study for varoglutamstat in patients with early AD. VIVA-MIND is a combined Phase 2a/b study which seeks to enroll 180 patients into the Phase 2a adaptive dose finding part, with an interim futility analysis planned for H1/2023. If predefined criteria are fulfilled, the trial will pass a stage-gate into the Phase 2b part, 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 primary endpoint for this study is CDR-SB (clinical dementia rating scale – sum of boxes), an established approvable endpoint measuring a combination of cognitive abilities and activities of daily living. The VIVA-MIND study is sponsored by Vivoryon and the study director is Dr. Howard Feldman, Professor of Neurosciences and Director of the Alzheimer's Disease Cooperative Study (ADCS) at the University of California San Diego School of Medicine. The study is coordinated by the ADCS, and supported by the National Institute on Aging (NIA), part of the National Institutes of Health (NIH), with a US$15 million grant (NIA award number R01AG061146). The study is ongoing with two sites now approved to screen participants and a group of another seven sites having secured regulatory approval.

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Patent Portfolio

- In the third quarter of 2021, Vivoryon further expanded its patent portfolio. Year to date (as of October 31, 2021) a total of 16 additional patents have been granted for the Company's small molecule inhibitors and antibody-based medicines in development to treat AD and other diseases with exceptionally high medical need.

Post-period Events

- In October 2021, the Company announced that it has decided to expand its manufacturing capabilities for production of active pharmaceutical ingredient (API) by initiating a second line of manufacturing with an additional partner to ensure sustainable study drug supply with varoglutamstat for the VIVA-MIND U.S. study. This will increase the total number of manufacturing sites for varoglutamstat to three on two different continents, providing supply for VIVA-MIND beyond the ongoing Phase 2a adaptive dose finding part, as well as for potential future studies in other geographies, with the added benefit of increasing flexibility to react to global challenges such as the ongoing pandemic.

- Also in October 2021, Vivoryon and its collaboration partners published data providing strong preclinical evidence of treatment with a combination of the Company's small molecule QPCT/L inhibitor varoglutamstat and its N3pE amyloid-specific antibody PBD-C06 having an additive effect on reducing brain Abeta pathology in transgenic mice. The data, published in the "International Journal of Molecular Sciences" (Hoffmann et al., https://doi.org/10.3390/ijms222111791), support the hypothesis of a potential benefit of a combination therapy designed to simultaneously target two different and independent molecular pathways, namely reducing N3pE amyloid production by QPCT/L inhibition and clearing existing Abeta deposits through anti-N3pE-immunotherapy. This provides a strong rationale for the evaluation of therapies combining varoglutamstat with monoclonal antibodies to treat AD.

Financial Results for Q3 of 2021

In Q3, the Company generated license revenues of EUR 10.8 million from a strategic regional licensing partnership signed with its partner Simcere on June 29, 2021 for Greater China. No revenues were generated in 2020, respectively.

Research and development expenses incurred for the nine months ended September 30, 2021 increased over the corresponding period in 2020 by EUR 3.6 million. This increase was mainly driven by EUR 2.9 million higher expenses for production and Vivoryon's clinical studies, as well as EUR 0.7 million higher expenses for share-based payments.

General and administrative expenses increased by EUR 1.2 million for the nine months ended September 30, 2021. This increase is largely attributable to EUR 0.3 million higher consulting costs and EUR 0.7 million higher expenses for share based payments. The increase in consulting costs resulted from preparations for a potential future listing on Nasdaq.

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Net loss for the nine months ended September 30, 2021 was EUR 7.3 million, compared to EUR 12.2 million for the nine months ended September 30, 2020. The Company held EUR 19.9 million in cash and cash equivalents as of September 30, 2021, compared to EUR 26.3 million as of December 31, 2020.

Financial Guidance

On October 18, 2021, Vivoryon updated its financial guidance to account for costs associated with the expansion of its manufacturing capabilities for production of active pharmaceutical ingredient (API) by initiating a second line of manufacturing with an additional partner to ensure sustainable study drug supply with varoglutamstat for the VIVA-MIND U.S. study. According to current planning and estimates, the Company now expects a cash reach until mid-2022. A detailed update on anticipated working capital requirements and associated potential financing activities as well as resulting timelines will be given in the context of Vivoryon's regular filings.

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Unaudited Condensed Interim Financial Statements

Vivoryon Therapeutics N.V.
Condensed Statements of Operations and Comprehensive Income and Loss

(in k EUR, except for share data)	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Revenue	10,764	—	10,764	—
Cost of Sales	(488)	—	(488)	—
Gross Profit	**10,276**	—	**10,276**	—
Research and development expenses	(4,128)	(3,653)	(13,584)	(10,032)
General and administrative expenses	(857)	(847)	(3,193)	(1,986)
Other operating income	—	—	6	—
Operating profit / (loss)	**5,292**	**(4,500)**	**(6,496)**	**(12,018)**
Finance income	398	119	617	156
Finance expenses	(199)	(251)	(301)	(344)
Finance result	**199**	**(133)**	**316**	**(186)**
Result before income taxes	**5,491**	**(4,633)**	**(6,180)**	**(12,206)**
Income taxes	(1,082)	—	(1,082)	—
Net profit / (loss) for the period	**4,410**	**(4,633)**	**(7,261)**	**(12,206)**
Items not to be reclassified subsequently to profit or loss				
Remeasurement of the net defined benefit pension liability	89	—	89	(20)
Total other comprehensive profit / (loss)	**89**	**—**	**89**	**(20)**
Comprehensive profit / (loss)	**4,499**	**(4,633)**	**(7,172)**	**(12,224)**
(Earnings)/ Loss per share in € (basic and diluted)	0.22/ 0.22	(0.23)	(0.36)	(0.61)

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Vivoryon Therapeutics N.V.
Condensed Statements of Financial Position

(in k EUR)	September 30, 2021	December 31, 2020
ASSETS		
Non-current assets		
Intangible assets	544	565
Property, plant and equipment	74	80
Right-of-use assets	241	310
Financial assets	14	3
Total non-current assets	**873**	**958**
Current assets		
Other current assets and prepayments	2,265	2,466
Financial assets	6,387	21
Cash and cash equivalents	19,861	26,306
Total current assets	**28,513**	**28,793**
TOTAL ASSETS	**29,386**	**29,751**
Equity		
Share capital	20,020	19,975
Share premium	82,784	82,143
Other capital reserves	5,788	4,404
Accumulated other comprehensive loss	(566)	(655)
Accumulated deficit	(86,906)	(79,646)
Total equity	**21,120**	**26,221**
Non-current liabilities		
Pension liability	1,835	1,981
Provisions long-term	12	—
Lease liabilities	156	224
Total non-current liabilities	**2,003**	**2,205**
Current liabilities		
Provisions	35	47
Trade payables	5,284	911
Lease liabilities	92	90
Other liabilities	852	276
Total current liabilities	**6,263**	**1,325**
Total Liabilities	**8,266**	**3,530**
TOTAL EQUITY AND LIABILITIES	**29,386**	**29,751**

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Vivoryon Therapeutics N.V.
Statements of Changes in Shareholders' Equity for the nine months ended September 30, 2021 and 2020

(in k EUR)	Share capital	Share premium	Other capital reserves	Accumulated other comprehensive loss	Accumulated deficit	Total equity
January 1, 2021	**19.975**	**82.143**	**4.404**	**(655)**	**(79.646)**	**26.221**
Net loss for the period	—	—	—	—	(7,261)	(7,261)
Remeasurement of the net defined benefit pension liability	—	—	—	89	—	89
Comprehensive income / (loss)	**—**	**—**	**—**	**89**	**(7,261)**	**(7,172)**
Share-based payments	—	—	1,384	—	—	1,384
Proceeds from exercise of share options	45	641	—	—	—	686
September 30, 2021	**20,020**	**82,784**	**5,788**	**(566)**	**(86,906)**	**21,120**
January 1, 2020	**19,975**	**82,143**	**4,245**	**(562)**	**(63,136)**	**42,665**
Net loss for the period	—	—	—	—	(12,206)	(12,206)
Remeasurement of the net defined benefit pension liability	—	—	—	(20)	—	(20)
Comprehensive loss	**—**	**—**	**—**	**(20)**	**(12,206)**	**(12,226)**
Share-based payments	—	—	4	—	—	4
September 30, 2020	**19,975**	**82,143**	**4,249**	**(582)**	**(75,342)**	**30,443**

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Vivoryon Therapeutics N.V.
Condensed Statements of Cash Flows

(in k EUR)	For the nine months ended September 30, 2021	2020
Operating activities		
Net loss for the period	(7,261)	(12,206)
Adjustments for:		
Finance result	(316)	188
Depreciation and amortization	125	106
Share based payments	1,384	4
Other non-cash adjustments	524	(69)
Changing in:		
Other current assets and prepayments	201	772
Other financial assets	(6,377)	307
Pension liabilities	(146)	(32)
Provisions	—	(210)
Trade payables	4,372	386
Other liabilities	(577)	8
Interest received	19	27
Interest paid	(5)	(6)
Taxes paid	(433)	—
Cash flows used in operating activities	**(7,336)**	**(10,741)**
Investing activities		
Purchase of plant and equipment	(20)	(18)
Purchase of intangible assets	(8)	(557)
Cash flows used in investing activities	**(28)**	**(575)**
Financing activities		
Payment of lease liabilities	(67)	(68)
Proceeds from exercise of share options	686	—
Cash flows provided / (used in) by financing activities	**619**	**(68)**
Net decrease in cash and cash equivalents	**(6,745)**	**(11,384)**
Cash and cash equivalents at the beginning of period	26,306	41,524
Effect of exchange rate fluctuation on cash held	300	(160)
Cash and cash equivalents at end of period	**19,861**	**29,980**

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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

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. This press release does not constitute an offer to sell or the solicitation of an offer to buy any securities of the Company in any jurisdiction.