ORYZON Reports Financial Results and Provides Corporate Update for the Third Quarter Ended September 30, 2019

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, October 25th, 2019 – Oryzon Genomics, S.A. (ISIN Code: ES0167733015, ORY), a public clinical-stage biopharmaceutical company leveraging epigenetics to develop therapies in diseases with strong unmet medical need, today reported financial results for the third quarter of 2019 and provided an update on the Company's recent developments.

Third Quarter and Recent Highlights

- In JULY 2019 ORYZON presented blinded data from ETHERAL Phase IIa trial at the Alzheimer's Association International Conference in Los Angeles, USA, showing safety and changes in certain biomarkers.
- In JULY 2019 ORYZON raised its share capital by EUR 20 (approximately $22.2) million through a private placement
- In JULY 2019 ORYZON announced End of Patient Recruitment for its Phase IIa trials in aggression with vafidemstat: REIMAGINE and REIMAGINE-AD
- In SEPTEMBER 2019 ORYZON presented the first preliminary data from CLEPSIDRA, a Phase II trial investigating iadademstat in combination with standard-of-care in relapsing small cell lung cancer (SCLC) patients at the IASCL 20th World Conference on Lung Cancer (WCLC) and ESMO-2019 Congress in Barcelona, Spain.
- In SEPTEMBER 2019 ORYZON announced positive human efficacy data of vafidemstat in the autism spectrum disorder (ASD) cohort from the REIMAGINE Phase IIa clinical trial at the 32nd European College of Neuropsychopharmacology (ECNP) Congress.
- In OCTOBER 2019 ORYZON presented additional positive REIMAGINE efficacy data of vafidemstat in the treatment of aggression at the 2019 International College of Neuropsychopharmacology (CINP) meeting in Athens, Greece.

Corporate Update

R&D investments of $8.9 million for the 9 months ended September 30, 2019 have permitted Oryzon to significantly advance its clinical portfolio.

Iadademstat in oncology: In the third quarter, Oryzon continued to enroll patients in the ongoing clinical studies with iadademstat (ORY-1001) in leukemia and small cell lung cancer (SCLC).

CLEPSIDRA is a single arm Phase II trial evaluating the safety and clinical efficacy of iadademstat in combination with platinum/etoposide in second-line SCLC patients. Patients are screened on entry for proprietary tumor biomarkers identified by the company. In September, the company presented initial preliminary data from this study at the WCLC and ESMO conferences in Barcelona. The results presented at ESMO were from the first 8 patients in the study evaluable for efficacy. The combination of iadademstat plus carboplatin/etoposide showed promising results of clinical efficacy: Responses were observed in 6 out of 8 patients (75% response rate), with 4 partial remissions and 2 long-term disease

stabilizations. One of the PRs was a long-lasting response, with the patient currently at cycle 13 and still in response. This patient initially showed 78.7% tumor reduction, as determined by RECIST. After combination treatment and upon iadademstat monotherapy tolerability greatly improved and reduction of main and secondary lesions continued, with 86.3% of tumor reduction by RECIST criteria at the end of cycle 12. At that timepoint, all minor lesions were still progressively being reduced or disappearing. The most prevalent toxicity of the iadademstat plus carboplatin/etoposide combination reported was hematological alterations; the combination did not result in any neurological, hepatic or renal toxicity. Iadademstat alone did not cause haematological or other toxicity in the patients studied so far and was able to produce tumour reduction. The clinical trial continues to recruit patients and investigate dosing regimens to minimize hematological toxicity.

ALICE is a single arm Phase II study evaluating the safety and clinical efficacy of iadademstat in combination with the hypomethylating agent azacitidine in 1L-AML elderly patients who are not eligible for conventional therapy. The company presented preliminary data from this study at the European Hematology Association Conference (EHA-2109) in Amsterdam in June, showing that the combination was well tolerated, produced rapid responses (median TTR 1.5 months) and encouraging clinical activity signs. There were objective responses in 4 out of 5 evaluable patients (80% OR): 75% CRi and 25% PR, and 1 patient in CRi with decreasing need of transfusions.

Vafidemstat in neurological disease: The clinical development of vafidemstat (ORY-2001) has also continued with the ongoing Phase IIa clinical trials: SATEEN, in multiple sclerosis (MS), ETHERAL, in mild and moderate Alzheimer's disease (AD), and REIMAGINE and REIMAGINE-AD, evaluating the effect of vafidemstat to treat aggressiveness in patients in three psychiatric diseases -- borderline personality disorder (BPD), adult attention deficit and hyperactivity disorder (ADHD) and autism spectrum disorder (ASD) - and in AD, respectively.

In September, Oryzon presented positive efficacy data from the ASD cohort of the REIMAGINE clinical trial at the 32nd ECNP congress in Copenhagen, Denmark, followed in October by an expanded dataset from the ADHD, BDP and ASD cohorts, as well as aggregated data for all three cohorts, at the CINP congress in Athens, Greece. The primary endpoint was safety. Vafidemstat was shown to be safe and well tolerated without significant adverse events in all three cohorts. In terms of efficacy, after 2 months of vafidemstat treatment statistically significant findings included improvements in several scales measuring aggression such as the Clinical Global Impression (CGI) of Severity (CGI-S) and Improvement (CGI-I) scales and the Neuropsychiatric Inventory (NPI) 4-item Agitation/Aggression subscale, both in the aggregated data for all subjects as well as in each of the three individual cohorts (ADHD, ASD and BPD). Benefits were also observed on several scales more generally assessing the global condition of the patients, such as the Neuropsychiatric Inventory (NPI) total score, the global BPD checklist (BPDCL) scale (for BPD patients) and the ADHD Rating Scale (ADHD-RS) (for ADHD patients). On the strength of these data, the company is currently preparing a Phase IIb trial in BPD (PORTICO trial) and evaluating additional Phase IIb studies in ADHD and/or ASD.

The company has completed the recruitment in REIMAGINE-AD, with a total of 12 moderate or severe aggressive AD patients. The company announced in September that, following the recommendation of the clinical investigators, the trial has been extended from 2 months to 6 months to allow a better evaluation not only of the potential effect of vafidemstat on aggressiveness but also on other core

features that are present in this advanced stage of the disease. The company now expects to report results of this study in the second quarter of 2020.

ETHERAL is a randomized, double-blind, 3-arm, parallel-group study with a 24-week placebo-controlled period followed by a 24-week extension in which placebo patients are randomized to vafidemstat therapy, to evaluate the safety, tolerability and preliminary efficacy of vafidemstat in patients with mild to moderate AD. Recruitment of ETHERAL in Europe has been closed, with 117 patients randomized, while it continues in the parallel US arm (ETHERAL-US). Positive safety data from the first 104 patients in ETHERAL were presented at the 2019 Alzheimer's Association International Conference (AAIC-2019) in Los Angeles in July, suggesting the drug is safe and well tolerated in AD patients.

SATEEN is a pilot Phase IIa clinical trial evaluating vafidemstat in multiple sclerosis, where patients are treated with vafidemstat or placebo for 9 months under double blind followed by an open label extension period of 6 months where all patients are treated with vafidemstat. In September the company announced that the extension phase in patients with the secondary progressive form of the disease has been extended up to a maximum of 18 months of vafidemstat treatment to allow to assess the effect of vafidemstat as a therapeutic treatment for the progressive form of the disease which requires longer clinical observation periods.

In addition, progress has been made in programs in earlier phases.

Financial Update: Third Quarter 2019 Financial Results

Research and development (R&D) expenses were $3.5 and $8.9 million, respectively, for the first 3 and 9 months ended September 30, 2019 compared to the $1.9 and $6.2 million for the first 3 and 9 months ended September 30, 2018. The $2.7 million increase was driven primarily by expenses associated with advancing the company's clinical trials.

General and administrative expenses were $0.7 and $2.6 million, respectively, for the first 3 and 9 months ended September 30, 2019 compared to $0.8 and $2.5 million for the first 3 and 9 months ended September 2018.

Net losses were $1.0 and $3.4 million, respectively, for the 3 and 9 first months ended September 30, 2019, compared to net losses of $1.0 and $2.7 million for the first 3 and 9 months ended September 2018.

Negative net result of $3.0 million (-$0.07 per share) for the 9 first months ended September 30, 2019 as a consequence of -$1.7 million non-recurrent R&D tax deductions, compared to a negative net result of $0.5 million for the first 9 months ended September, 2018.

Cash, cash equivalents and marketable securities totaled $42.6 million as of September 30, 2019, compared to $26.2 million as of September 30, 2018.

On July 26th, the company announced a Private Placement with International Investors and issued 6,666,667 new common shares, at a price of EUR 3.00 per share. This generated gross proceeds of EUR 20 million (approximately $22.2 million at the exchange rate on that day).

ORYZON GENOMICS SA
BALANCE SHEET DATA (AUDITED)
(Amounts in thousands US $)

	September 30th, 2019	September 30th, 2018
Cash and cash equivalents	41,942	26,048
Marketable securities	654	164
Total Assets	87,591	65,148
Deferred revenue	0	0
Total Stockholders' equity	67,595	39,314

ORYZON GENOMICS SA
STATEMENTS OF OPERATIONS (AUDITED)[1]
(US $, amounts in thousands except per share data)

	Three Months Ended September 30th		Nine Months Ended September 30th	
	2019	2018	2019	2018
Collaboration Revenue	0	0	0	0
Operating expenses:				
Research and Development	3,462	1,942	8,884	6,233
General and administrative	742	816	2,588	2,481
Total operating expenses	4,204	2,758	11,472	8,714
Loss from Operations	-4,204	-2,758	-11,472	-8,714
Other income, net	3,208	1,776	8,035	6,032
Net Loss	-997	-982	-3,436	-2,682
Net Financial & Tax	-73	-153	455	2,193
Net Result	-1,069	-1,135	-2,981	-489

Loss / profit per share allocable to common stockholders:				
Basic	-0.02	-0.03	-0.07	-0.01
Diluted	-0.02	-0.03	-0.07	-0.01
Weighted average Shares outstanding				
Basic	43,676,960	33,492,804	40,275,076	33,492,804
Diluted	43,676,960	33,492,804	40,275,076	33,492,804

[1] Spanish GAAP
* Exchange Euro/Dollar (1.0889 for 2019 and 1.1576 in 2018)

About Oryzon

Founded in 2000 in Barcelona, Spain, Oryzon (ISIN Code: ES0167733015) is a clinical stage biopharmaceutical company considered as the European champion in Epigenetics. Oryzon has one of the strongest portfolios in the field. Oryzon's LSD1 program has rendered two compounds, vafidemstat and iadademstat, in clinical trials. In addition, Oryzon has ongoing programs for developing inhibitors against other epigenetic targets. Oryzon has a strong technological platform for biomarker identification and performs biomarker and target validation for a variety of malignant and neurodegenerative diseases. Oryzon has offices in Spain and the United States. For more information, visit www.oryzon.com

FORWARD-LOOKING STATEMENTS

This communication contains, or may contain, forward-looking information and statements about Oryzon, including financial projections and estimates and their underlying assumptions, statements regarding plans, objectives and expectations with respect to future operations, capital expenditures, synergies, products and services, and statements regarding future performance. Forward-looking statements are statements that are not historical facts and are generally identified by the words "expects," "anticipates," "believes," "intends," "estimates" and similar expressions. Although Oryzon believes that the expectations reflected in such forward-looking statements are reasonable, investors and holders of Oryzon shares are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Oryzon that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include those discussed or identified in the documents sent by Oryzon to the Spanish Comisión Nacional del Mercado de Valores (CNMV), which are accessible to the public. Forward-looking statements are not guarantees of future performance and have not been reviewed by the auditors of Oryzon. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date they were made. All subsequent oral or written forward-looking statements attributable to Oryzon or any of its members, directors, officers, employees or any persons acting on its behalf are expressly qualified in their entirety by the cautionary statement above. All forward-looking statements included herein are based on information available to Oryzon on the date hereof. Except as required by applicable law, Oryzon does not undertake any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. This press release is not an offer of securities for sale in the United States or any other jurisdiction. Oryzon's securities may not be offered or sold in the United States absent registration or an exemption from registration. Any public offering of Oryzon's securities to be made in the United States will be made by means of a prospectus that may be obtained from Oryzon or the selling security holder, as applicable, that will contain detailed information about Oryzon and management, as well as financial statements.

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