ORYZON First Quarter 2020 Results and Corporate Update

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, May 11th, 2020 – 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 first quarter of 2020 and provided an update on recent developments.

Dr Carlos Buesa, Oryzon's Chief Executive Officer, said, "Oryzon continued to advance its clinical programs in the first quarter. We are encouraged by the exciting signals of clinical efficacy observed in both our iadademstat oncology and vafidemstat neurology programs, combined with good safety and tolerability profiles."

During the last weeks of Q1 and into Q2 2020, the Covid-19 pandemic has impacted activities of pharma and biotech companies globally. As the company reported in an ad-hoc note released on April 17th, Oryzon has not canceled or postponed recruitment in ongoing clinical trials, however clinical operations have been adapted to protect the health of patients, their families and healthcare professionals, and to preserve the integrity of the trial data as much as possible. Also as previously disclosed, Oryzon is postponing the initiation of its vafidemstat Phase IIb trial in agitation-aggression in patients with borderline personality disorder (PORTICO trial) until lock-down conditions are eased sufficiently. To contribute to the global fight against the pandemic, Oryzon launched a Phase II clinical trial, named ESCAPE, in severe Covid-19 patients to prevent acute respiratory distress syndrome (ARDS). The trial was approved by the Spanish Drug Agency via an accelerated procedure as reported in an ad-hoc note released on April 24th.

First Quarter and Recent Highlights

Iadademstat in oncology:

- After positive efficacy data from Phase II trial ALICE investigating iadademstat in acute myeloid leukemia (AML), presented last December at the 61st ASH Annual Meeting and Exposition in Orlando, United States, the company continues this trial while adhering to all regulations put in place as a result of the pandemic.
  - Oryzon anticipates that visits, evaluations and recruitment will progressively return to normal levels in the next weeks
  - The company expects to present new efficacy data at the EHA-2020 Conference in June
- Positive preliminary efficacy data from Part 1 in the CLEPSIDRA Phase II trial in second-line small cell lung cancer (SCLC) patients was presented at the ESMO 2019 conference in Barcelona:
  - After obtaining the necessary safety data regarding hematological toxicity, and finalizing recruitment, Oryzon expects to present new efficacy and safety data at the ESMO conference in H2 2020

Vafidemstat in neurological disease:

- Positive efficacy data of vafidemstat in the treatment of aggression in severe and moderate Alzheimer's disease (AD) patients from the Phase II REIMAGINE-AD trial were reported at the AAT-AD/PD Conference in early April. The company had previously reported positive Phase IIa REIMAGINE efficacy data of vafidemstat in the treatment of aggression in psychiatric patients.
- Preliminary data from the ongoing Phase-IIa trial in mild and moderate AD patients treated for 6 months in Europe (ETHERAL-EU) were also presented at the AAT-AD/PD Conference in early April. ETHERAL is a randomized, double-blind, 3-arm, parallel-group study with a 24-week placebo-controlled period.
    - 117 patients randomized in the EU cohort
    - Primary endpoint met: positive safety data after 6 months of vafidemstat treatment
    - First in human data support pharmacological activity in the brain: vafidemstat reduced the CSF levels of the inflammatory biomarker YKL40 in treated patients. Strong YKL40 reduction after vafidemstat treatment has been previously observed in brain and spinal cord in multiple sclerosis (MS) animal models
    - Signals of improvement in the levels of neurogranin (a synaptic damage biomarker) and NFL were also presented
- We continue the parallel arm of the ETHERAL trial in the USA (ETHERAL-US).
- The company also continues the execution of the extension phase of the SATEEN Phase IIa clinical trial evaluating vafidemstat in MS in patients with the secondary progressive form of the disease up to a maximum of 18 months of vafidemstat treatment.

Financial Update: First Quarter 2020 Financial Results

Research and development (R&D) expenses were $4.3 million for the last 3 months ended March 31, 2020 compared to $2.6 million for the last 3 months ended March 31, 2019. The $1.7 million increase was driven primarily by expenses associated with advancing the company's clinical trials.

General and administrative expenses were $0.9 million for the last 3 months ended March 31, 2020 and for 3 months ended March 2019.

Net loss was $1.1 million for the last 3 months ended March 31, 2020, compared to net loss of $1.0 million for the last 3 months ended March 2019.

Cash, cash equivalents and marketable securities totaled $32.3 million as of March 31, 2020, compared to $32.7 million as of March 31, 2019.

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

	March 31st, 2020	March 31st, 2019
Cash and cash equivalents	32,121	32,551
Marketable securities	155	159
Total Assets	84,301	73,158
Deferred revenue	0	0
Total Stockholders' equity	65,709	49,240

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

	Three Months Ended March 31st	
	2020	2019
Collaboration Revenue	0	0
Operating expenses:		
Research and Development	4,316	2,610
General and administrative	846	876
Total operating expenses	5,161	3,486
Loss from Operations	-5,161	-3,486
Other income, net	4,013	2,497
Net Loss	-1,148	-989
Net Financial & Tax	-116	-368
Net Result	-1,264	-1,356

Loss / profit per share allocable to common stockholders:		
Basic	-0.03	-0.04
Diluted	-0.03	-0.04

Weighted average Shares outstanding		
Basic	45,488,554	38,454,637
Diluted	45,488,554	38,454,637

[1] Spanish GAAP

* Exchange Euro/Dollar (1.096 for 2020 and 1.1235 in 2019)

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 neurological 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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