ORYZON Reports Financial Results and Corporate Update for the 1st Quarter, 2019

-$0.04/share for the 3 months ended March 31st

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, May 13, 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 first quarter of 2019 and provided an update on the Company's recent developments.

R&D investments of $2.6 million for the 3 months ended March 31, 2019 have permitted Oryzon to significantly advance its clinical portfolio.

In this first quarter, the company has continued the enrollment of patients in the ongoing clinical studies in leukemia and small cell lung cancer (SCLC) with iadademstat (ORY-1001). ALICE is a single arm Phase II study of iadademstat in combination with the hypomethylating agent azacitidine in first line acute myeloid leukemia elderly patients who are not eligible for conventional therapy . The trial is studiyng the safety and clinical efficacy of the combination. CLEPSIDRA is a single arm Phase II trial of iadademstat in second-line SCLC patients in combination with platinum/etoposide. In CLEPSIDRA, the patients to be included are screened for proprietary tumor biomarkers identified by the scientists of the company. The trial is studying the safety and clinical efficacy of the combination.

The clinical development of vafidemstat (ORY-2001) has also continued timely with the ongoing Phase IIa clinical trials in Multiple Sclerosis (MS), SATEEN, and in mild and moderate Alzheimer's disease (AD), ETHERAL, the latter actively recruiting patients in Spain, France and the United Kingdom. During this first quarter the company received the approval from the US regulatory agency, FDA, to start ETHERAL in the US (IND approval).

There has also been progress in new preclinical experiments with vafidemstat and in the characterization of its Mechanism of Action that the company considers relevant and which will be communicated appropriately in scientific conferences. Additionally, the company has continued the exploration of other indications in Central Nervous System diseases that the company considers may be a relevant complementary option in the clinical development of the drug. Among them, the treatment of behavioral alterations present in patients with psychiatric diseases such as Borderline Personality Disorder (BPD), Autistic Spectrum Disorder, Attention Deficit and Hyperactivity Disorder, and others. These data, if positive, can significantly expand the potential clinical development of vafidemstat beyond the indications of AD and MS which the company is currently advancing clinically. In this line, the company is currently performing REIMAGINE, a Phase IIa “basket” clinical trial to evaluate the effect of vafidemstat to treat aggressiveness in patients in three psychiatric diseases and two neurodegenerative diseases. Gratifyingly, at the beginning of April, the company presented the first positive human efficacy data with vafidemstat, corresponding to the BPD cohort within the REIMAGINE clinical trial, at the 27th European Congress of Psychiatry (EPA 2019) in Warsaw, Poland. As for the primary endpoint,

vafidemstat was safe and well tolerated in the BPD patients and showed a trend on improving suicidal ideation. 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) Severity (CGI-S) and CGI-Improvement (CGI-I) scales and the NPI 4-item Agitation/Aggression subscale, and also several scales more generally assessing the global condition of the patient like the Global BPD checklist (BPDCL) scale and the Neuropsychiatric Inventory (NPI) total score.

The company's third LSD1 inhibitor, ORY-3001, in preclinical phase for non-oncological indications, has successfully completed the regulatory toxicology necessary to obtain the permits to start clinical studies.

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

In summary, the company has two "first-in-class" epigenetic experimental molecules in five Phase IIa clinical trials in humans and a third compound that has completed the regulatory preclinical phase.

First Quarter Highlights & relevant post-closing events

- In JANUARY 2019 ORYZON appoints Michael T. Ropacki, PhD as Vice President of Clinical Development for its CNS epigenetic program
- In FEBRUARY 2019 ORYZON announces publication by US scientists of a relevant paper for the therapeutic development of iadademstat (ORY-1001) in SCLC. The publication describes how iadademstat activates the NOTCH pathway, resulting in the repression of SCLC tumorigenesis in vitro and in patient-derived xenograft (PDX) models.
- In MARCH 2019 ORYZON publishes a paper in the Journal of Biological Chemistry, describing the design and development of a system that allows to assess that the drugs against LSD1 are effectively hitting the pharmacological target and the quantification of this target engagement. This methodology can be used for the different LSD1 inhibitors like the anticancer iadademstat or the CNS epigenetic drug vafidemstat both in patient-derived samples and also in preclinical lab models.
- In MARCH 2019 ORYZON announces FDA Approval of its IND for ETHERAL, a Phase IIa trial of vafidemstat in patients with mild to moderate AD.
- In MARCH 2019 ORYZON presents latest advances of vafidemstat at Oppenheimer's 29th Annual Healthcare Conference, including first efficacy data from the REIMAGINE trial.
- In APRIL 2019 ORYZON presents first in human efficacy data with vafidemstat in BPD patients from the REIMAGINE trial at the 27th European Congress of Psychiatry in Warsaw, Poland.
- In APRIL 2019 ORYZON presents vafidemstat efficacy data in ADHD patients from the REIMAGINE trial at the 7th World Congress on ADHD in Lisbon, Portugal.

Financial Update: First Quarter 2019 Financial Results

Research and development (R&D) expenses were $2.6 for the last 3 months ended March 31, 2019 compared to $2.3 for the last 3 months ended March 31, 2018. The $0.3 million increase was driven primarily to accelerate the operations related with the execution of clinical trials.

General and administrative expenses were $0.9 for the last 3 months ended March 31, 2019, compared to $0.9 for the last 3 months ended March 31, 2018

Net loss was $1.0 for the last 3 ended March 31, 2019 compared to a net loss of $0.8 for the last 3 ended March31, 2018.

Cash, cash equivalents and marketable securities totaled $32.7 million as of March 31, 2019, compared to $38.1 million as of March 31, 2018.

ORYZON GENOMICS SA

BALANCE SHEET DATA (UNAUDITED)[1]
(Amounts in thousands US $)

	March 31st, 2019	March 31st, 2018
Cash and cash equivalents	32.551	37.848
Marketable securities	159	224
Total Assets	73.158	72.720
Deferred revenue	0	0
Total Stockholders' equity	49.240	41.009

ORYZON GENOMICS SA

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

	Three Months Ended March 31st	
	2019	2018
Collaboration Revenue	0	0
Operating expenses:		
Research and Development	2.610	2.334
General and administrative	876	887
Total operating expenses	3.486	3.221
Loss from Operations	-3.486	-3.221
Other income, net	2.497	2.458
Net Loss	-989	-763
Net Financial & Tax	-368	-499
Net Result	-1.356	-1.262

Loss / profit per share allocable to common stockholders:		
Basic	-0,04	-0,04
Diluted	-0,04	-0,04

Weighted average Shares outstanding		
Basic	38.454.637	33.492.804
Diluted	38.454.637	33.492.804

[1] Spanish GAAP

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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