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ORYZON reports financial results and corporate update for quarter ended March 31st, 2026

- **Updated positive data from iadademstat in 1L AML unfit patients to be presented at EHA, with 100% ORR, 93% CRc and 79% strict CR at abstract submission cut-off**
- **Positive updated data from iadademstat in relapsed/refractory FLT3-mut AML also accepted at EHA, showing 67% CRc**
- **Ongoing broad expansion of iadademstat clinical development across hematological malignancies, solid tumors and non-malignant hematology**
- **Active preparations underway for FDA protocol resubmission of the PORTICO-2 Phase III trial with vafidemstat in aggression in BPD**
- **Continued advancement of vafidemstat programs in schizophrenia and autism spectrum disorder**
- **Continued strengthening of IP protection for iadademstat and vafidemstat**
- **Strong cash position at the quarter ended March 2026: $25.4 million (€22.1 million)**

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, May 14, 2026 - Oryzon Genomics, S.A. (ISIN Code: ES0167733015, ORY), a clinical-stage biopharmaceutical company and a global leader in epigenetics, today reported financial results for the three months ended March 31, 2026, and provided a corporate update on recent developments.

"During the first months of 2026, Oryzon has continued to execute strongly across both its oncology/hematology and CNS franchises, while maintaining a solid financial position," said Dr. Carlos Buesa, Oryzon's Chief Executive Officer. "Most importantly, iadademstat continues to deliver highly encouraging clinical data in acute myeloid leukemia, further reinforcing our conviction in the compound's differentiated therapeutic potential and commercial opportunity."

"We are particularly excited about the upcoming presentations at EHA 2026, where updated safety and efficacy results from both the ALICE-2 and FRIDA studies will be presented," Dr. Buesa added. "In first-line AML, the triplet combination of iadademstat with azacitidine and venetoclax continues to demonstrate a highly competitive efficacy profile, which we believe compares very favorably with other emerging triplet regimens in the field. At EHA, we will present updated data from 18 patients, including encouraging activity in patients with adverse genetic backgrounds. Based on the progress achieved to date, we believe

iadademstat-based combinations may offer a differentiated and competitive opportunity for accelerated clinical development in first-line AML and could support advancement into a potentially pivotal Phase II/III program with the objective of pursuing accelerated regulatory approval."

"The iadademstat development platform continues to expand, reinforcing its potential as a high-value hematology and oncology asset," Dr. Buesa continued. "Enrollment is advancing across multiple investigator-sponsored studies at leading U.S. cancer centers and National Cancer Institute-sponsored trials in hematologic malignancies and solid tumors. At the same time, emerging opportunities in non-malignant hematology, including sickle cell disease and essential thrombocythemia, could materially enlarge the commercial and strategic scope of the franchise. Taken together, we believe iadademstat will deliver increasingly diversified clinical catalysts and generate sustained data, supporting a strong cadence of newsflow over the coming quarters."

"In CNS, we remain fully committed to advancing vafidemstat toward late-stage development," continued Dr. Buesa. "We continue to work closely on the activities required to support the Phase III PORTICO-2 protocol resubmission following FDA feedback, while also advancing the EVOLUTION schizophrenia study and preparations for the new HOPE-2 study in autism spectrum disorder. We believe vafidemstat continues to represent an important long-term value driver for Oryzon."

First Quarter and Recent Highlights

Iadademstat:

- Oryzon announced that updated positive data from the ongoing ALICE-2 Phase Ib clinical trial of iadademstat in combination with venetoclax and azacitidine in patients with newly diagnosed acute myeloid leukemia (AML) have been accepted for presentation at the European Hematology Association (EHA) 2026 Congress. As of the February 2026 data cutoff reported in the published abstract, the triplet combination continued to demonstrate favorable safety and high response rates. Among evaluable patients (n=14/15), the overall response rate (ORR) was 100% (14/14), with a complete response (CR) rate of 79% (11/14) and a composite complete remission rate (CRc: CR+CRh+CRi) of 93% (13/14). After a median follow-up of 6 months, the estimated 12-month overall survival rate was 74%. Updated data with additional patients and more mature responses will be presented at EHA in June 2026. This investigator-initiated study (IIS) is led by the Oregon Health & Science University (OHSU) Knight Cancer Institute and plans to enroll up to 24 patients to attain 21 evaluable patients. The trial continues to actively enroll patients.

- Updated positive data from the ongoing, fully enrolled Phase Ib FRIDA clinical trial of iadademstat in combination with gilteritinib in patients with relapsed or refractory (R/R) FLT3-mutated AML have also been accepted for presentation at EHA 2026. Updated data from the expansion cohort showed a favorable safety profile and a CRc rate of 67% (12/18 patients evaluable for response harboring canonical FLT3 mutations) in a heavily pre-treated patient population. These results compare favorably with gilteritinib monotherapy responses in contemporary real-world cohorts enriched for heavily pre-treated patients, which are reported to be 28% CR+CRi. Additional data from the study will be presented during the congress.

- A new Phase Ib trial of iadademstat in combination with an immune checkpoint inhibitor and radiotherapy in extensive-stage small cell lung cancer (ES-SCLC), sponsored by Yale University, has initiated patient enrollment. The study evaluates iadademstat in combination with atezolizumab and stereotactic body radiation therapy (SBRT), followed by maintenance therapy with atezolizumab and iadademstat, in patients with residual, progressive or recurrent ES-SCLC who previously received platinum-based chemotherapy with or without immune checkpoint inhibitor therapy.

- Enrollment has continued across additional ongoing iadademstat clinical studies, conducted under the Cooperative Research and Development Agreement (CRADA) with the U.S. National Cancer Institute (NCI) in first line AML, myeloproliferative neoplasms and small cell lung cancer, as well as an investigator-initiated study in myelodysplastic syndrome.

- Oryzon continues to advance the RESTORE Phase Ib trial of iadademstat in adult patients with sickle cell disease (SCD). The study will evaluate the safety and tolerability of iadademstat, establish the Recommended Phase II dose (RP2D), and investigate iadademstat's effect on inducing fetal hemoglobin (HbF) expression, a clinically meaningful endpoint in SCD. The trial is actively enrolling patients, and the Company expects initial clinical updates by year-end.

- Oryzon has received regulatory authorization from the European Medicines Agency (EMA) to initiate the IDEAL Phase II trial to evaluate iadademstat in adult patients with essential thrombocythemia (ET) who are resistant/intolerant to hydroxyurea. Site activation activities and study start-up preparations are ongoing.

- Oryzon has continued to strengthen the intellectual property position of iadademstat. The United States Patent and Trademark Office (USPTO) recently granted a patent covering methods for treating neoplastic diseases using combinations comprising iadademstat and other therapeutic agents, notably venetoclax. The patent is expected to remain in force until January 2039, including 681 days of patent term adjustment (PTA), excluding any potential patent term extension related to regulatory review. Patents covering combinations of iadademstat with venetoclax have also been granted in Australia, Brazil, Canada, Europe, India, Israel, Japan, Korea, Malaysia, Mexico, New Zealand, and Russia. In addition, Oryzon recently received a "Decision to grant" communication from the Mexican Patent Office covering combinations of iadademstat with PD-1 or PD-L1 inhibitors for cancer therapy. Once formally granted, such patent is expected to provide protection until at least 2040, excluding potential patent term extensions. Corresponding patents have already been granted or allowed in Australia, Europe, Japan, and Russia.

Vafidemstat:

- Oryzon continues active regulatory and development activities to support the advancement of the Phase III PORTICO-2 trial with vafidemstat in aggression in borderline personality disorder (BPD). Following receipt of written FDA feedback regarding study endpoints and certain non-clinical considerations, the Company is actively working on the generation of additional supporting information and protocol refinements required for resubmission. These activities include

qualitative research and endpoint-validation work intended to further support the proposed clinical outcome measures.

- To further enhance its CNS clinical development capabilities, Oryzon appointed Rolando Gutierrez-Esteinou, M.D., as Chief Medical Officer for CNS programs. Dr. Gutierrez-Esteinou is a Harvard-trained psychiatrist and senior clinical development executive with extensive experience in late-stage neuroscience programs and regulatory interactions in psychiatry indications.

- Enrollment continues in the EVOLUTION Phase IIb clinical trial evaluating vafidemstat in schizophrenia, focused primarily on negative symptoms, with secondary endpoints assessing effects on cognitive impairment and positive symptoms. The study, initially conducted in Spain, continues its expansion into additional European countries (Bulgaria, Poland, Romania and Slovakia).

- Oryzon is completing preparations for the HOPE-2 Phase II trial to evaluate vafidemstat in aggression in autism spectrum disorder (ASD). The trial will focus on genetically-defined ASD subpopulations, in particular individuals with Phelan-McDermid syndrome (PMS). The study will initially be conducted in Spain as part of the activities supported under the Med4Cure IPCEI EU initiative.

- Oryzon has also continued to strengthen its IP portfolio for vafidemstat. The Company recently received a "Decision to grant" communication from the USPTO covering methods for treating non-aggressive symptoms of BPD with LSD1 inhibitors such as vafidemstat. Once granted, the U.S. patent is expected to remain in force until at least 2040, excluding any potential patent term adjustments or extensions. Corresponding patents in this family have already been granted or allowed in Australia, Europe, Japan, Mexico, Russia, Singapore, and South Africa. In addition, Oryzon received a further "Decision to grant" communication from the Japanese Patent Office covering the use of vafidemstat for the treatment of aggressiveness and social withdrawal. Corresponding patents in this family have already been granted or allowed in Australia, Canada, Europe, Hong Kong, Israel, South Korea, Malaysia, the Philippines, and Russia, and are expected to remain in force until at least 2038, excluding any potential patent term extensions.

Earlier stage programs:

- ORY-4001, Oryzon's highly selective histone deacetylase 6 (HDAC6) inhibitor for neurological disorders, continues to advance through IND-enabling studies to prepare the compound for clinical trials. The program remains focused on potential applications in Amyotrophic Lateral Sclerosis (ALS), Charcot-Marie-Tooth disease (CMT) and other neurological disorders.

Financial Update: First quarter 2026 Financial Results

Research and development (R&D) expenses totaled $5.2 million in the first quarter ended March 31, 2026, representing a significant increase from the $2.6 million reported in the first quarter ended March 31, 2025.

General and administrative expenses were $1.5 million for the first quarter ended March 31, 2026, compared to $1.2 million for the first quarter ended March 31, 2025.

Net losses were $2.0 million for the first quarter ended March 31, 2026, compared to net losses of $1.6 million for the first quarter ended March 31, 2025. The result is as expected, given the biotechnology business model where companies in the development phase typically have a long-term maturation period for products and do not have recurrent income.

Negative net result was $1.4 million (–$0.02 per share) for the first three months ended March 31, 2026, compared to a negative net result of $1.8 million (–$0.03 per share) for the first three months ended March 31, 2025.

Cash, cash equivalents, and marketable securities totaled $25.4 million as of March 31, 2026.

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

	March 31st, 2026	March 31st, 2025
Cash and cash equivalents	25,421	4,126
Marketable securities	0	0
Total Assets	162,930	116,070
Deferred revenue	0	0
Total Stockholders' equity	136,011	92,335

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

	Three Months Ended March 31st	
	2026	2025
Collaboration Revenue	0	0
Operating expenses:		
Research and Development	5,171	2,582
General and administrative	1,495	1,173
Total operating expenses	6,666	3,755
Loss from Operations	-6,666	-3,755
Other income, net	4,673	2,171
Net Loss	-1,993	-1,584
Net Financial & Tax	585	-252
Net Result	-1,408	-1,836
Loss per share allocable to common stockholders:		
Basic	-0.02	-0.03
Weighted average Shares outstanding		
Basic	77,513,372	64,747,081

[1] Spanish GAAP

* Exchange Euro/Dollar (1.1498 for 2026 and 1.0815 for 2025)

About Oryzon

Founded in 2000 and headquartered in Barcelona, Spain, Oryzon (ISIN: ES0167733015) is a clinical-stage biopharmaceutical company and a European leader in epigenetics, with a strong focus on personalized medicine for central nervous system (CNS) disorders and oncology. Oryzon's team comprises highly experienced pharmaceutical professionals based in Barcelona, Boston, and New Jersey. The Company has an advanced clinical portfolio built around two LSD1 inhibitors: iadademstat, its oncology/hematology program, with several ongoing Phase I and II studies and which has demonstrated strong preliminary clinical activity in acute myeloid leukemia, including a 100% overall response rate (ORR) in first-line AML; and vafidemstat, its lead CNS program, which is Phase III–ready in Borderline Personality Disorder (BPD). In addition, Oryzon is advancing a broader epigenetics pipeline targeting other mechanisms, including HDAC6, for which the Company has nominated ORY-4001 as a clinical candidate for potential development in Charcot–Marie–Tooth disease (CMT), amyotrophic lateral sclerosis (ALS), and other neurological disorders. The Company also operates a robust platform for biomarker identification and target validation across malignant and neurological diseases. For more information, visit www.oryzon.com

About Iadademstat

Iadademstat (ORY-1001) is an oral, highly selective inhibitor of the epigenetic enzyme LSD1, with potent differentiating effect in hematologic cancers. Iadademstat has shown encouraging safety and strong clinical activity in combination with azacitidine in a Phase IIa trial in elder 1L acute myeloid leukemia (AML) patients (ALICE trial). Iadademstat is currently being evaluated in combination with azacitidine and venetoclax in 1L AML in the ALICE-2 trial, an investigator-initiated study (IIS) led by OHSU, and in combination with gilteritinib in the company-sponsored Phase Ib FRIDA trial in relapsed/refractory FLT3-mutant AML, with highly encouraging preliminary safety and efficacy data in both trials: 100% overall response rate (ORR) and 93% composite complete remission rate (CRc), with 79% strict CR in 1L AML, and 67% CRc in R/R Flt3-mut AML. Additional studies in hematologic malignancies include an IIS in myelodysplastic syndrome (MDS) and National Cancer Institute (NCI)-sponsored trials in myeloproliferative neoplasms and 1L AML conducted under the Cooperative Research and Development Agreement (CRADA) between Oryzon and the NCI. Beyond hematological cancers, iadademstat is being evaluated in extensive stage small cell lung cancer (ED-SCLC) in a Phase I/II randomized trial in 1L in combination with immune checkpoint inhibition (ICI) sponsored by NCI and led by the Memorial Sloan Kettering Cancer Center, and an IIS trial in combination with ICI and radiotherapy. Oryzon has also expanded iadademstat into non-oncological hematology indications, with trials in sickle cell disease (approved by EMA, enrolling) and essential thrombocythemia (approved by EMA). Iadademstat has orphan drug designation for AML in the US and EU and for SCLC in the US.

About Vafidemstat

Vafidemstat (ORY-2001) is an oral, CNS-optimized LSD1 inhibitor with potential to address neuropsychiatric disorders through epigenetic modulation. In preclinical studies, vafidemstat has demonstrated effects on cognition, neuroinflammation, aggression, and social behavior, as well as neuroprotective and anti-inflammatory activity across multiple CNS disease models. Oryzon has completed several Phase II clinical trials with vafidemstat, including the REIMAGINE and REIMAGINE-AD trials in aggression in patients with different psychiatric disorders and in aggressive/agitated patients with moderate or severe AD, respectively, with positive clinical results reported in both trials. Following completion of the global randomized double blind Phase IIb PORTICO trial in borderline personality disorder (BPD), vafidemstat is advancing as a Phase III-ready asset for agitation/aggression in BPD (PhIII in preparation). Vafidemstat is also being evaluated in the ongoing double-blind, randomized, placebo-controlled Phase IIb EVOLUTION trial in negative symptoms of schizophrenia. In addition, Oryzon is also deploying a CNS precision medicine approach with vafidemstat in genetically defined patient subpopulations of certain CNS disorders, as well as in neurodevelopmental syndromes, including preparations for a new clinical trial in aggression in autistic conditions such as Phelan-McDermid syndrome.

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

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