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ORYZON reports third quarter 2026 financial results and provides corporate update

- **Updated clinical data from three iadademstat studies to be presented at ASH 2026, including encouraging results from ALICE-2 in first-line AML (95% ORR, 84% CRc and 74% CR) and FRIDA in relapsed/refractory FLT3-mutated AML (67% CRc rate at the recommended Phase II dose)**
- **New VIVALDI study evaluating iadademstat in first-line AML authorized in Spain, complementing preparations for the planned ALICE-3 Phase III program**
- **Vafidemstat EVOLUTION Phase IIb trial in schizophrenia continues enrolling patients across several European countries**
- **Vafidemstat Phase III PORTICO-2 trial in aggression in borderline personality disorder (BPD): Preparatory activities progress, with a planned FDA Type C meeting**
- **Vafidemstat Phase II HOPE-2 trial in Phelan-McDermid syndrome (PMS) receives authorization to initiate in Spain**
- **Cash position as of September 30, 2026, was $21.7 million (€19.1 million)**

MADRID, SPAIN and CAMBRIDGE, MA, UNITED STATES, November 10, 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 September 30, 2026, and provided a corporate update on recent developments.

“Since our last results update, Oryzon has continued to build the clinical evidence needed to advance our key development programs,” said Dr. Carlos Buesa, Oryzon’s Chief Executive Officer. “The three iadademstat abstracts accepted for ASH 2026 add to the growing body of clinical evidence supporting the activity of iadademstat across hematological malignancies. We are particularly encouraged by the high remission rates and promising survival results observed with iadademstat in combination with azacitidine and venetoclax in the Phase Ib ALICE-2 study in newly diagnosed AML. We look forward to presenting updated data at ASH in December.”

“Building on the ALICE-2 findings, we are preparing to engage with the FDA on the design of ALICE-3, our planned potentially registrational Phase III trial in first-line AML,” Dr. Buesa continued. “Our objective remains to initiate the study in 2027, subject to regulatory agreement and financing. Alongside our AML

program, preliminary positive findings in accelerated/blast-phase myeloproliferative neoplasms and ongoing clinical evaluation in myelodysplastic syndromes are helping us explore the broader potential of iadademstat."

"In CNS, we continue to advance the clinical development of vafidemstat across several indications," Dr. Buesa added. "The Phase IIb trial in schizophrenia, EVOLUTION, continues to enroll patients across several European countries, and we expect to complete enrollment in spring 2027, with topline data anticipated by the end of 2027. This readout could represent an important inflection point for the company's CNS program. The recent authorization of the HOPE-2 Phase II study in Phelan-McDermid syndrome marks another step forward for the program. In parallel, we are progressing with preparations for the PORTICO-2 Phase III trial in BPD and plan to request a Type C meeting with the FDA. Across our portfolio, we remain focused on disciplined execution, responsible allocation of resources and the continued strengthening of our intellectual property as we prepare for the next stages of clinical development."

Third Quarter and Recent Highlights

Iadademstat:

- Updated positive clinical data for iadademstat in hematological malignancies will be presented at the American Society of Hematology (ASH) 68th Annual Meeting, taking place December 12-15, 2026. Three abstracts, accepted for poster presentation, were published on November 4. A summary of the clinical data contained in the abstracts is provided below.

- One of the ASH abstracts relates to the ongoing ALICE-2 (NCT06357182) Phase Ib clinical trial of iadademstat in combination with azacitidine and venetoclax in patients with newly diagnosed AML, sponsored by the Oregon Health & Science University (OHSU) Knight Cancer Institute. As reported in the abstract, the iadademstat-azacitidine-venetoclax triplet combination continued to show high remission rates, rapid responses and encouraging early survival with a manageable safety profile. As of the July 2026 data for ASH abstract submission, among evaluable patients (n=19), overall response rate (ORR) was 95%, including an 84% composite complete remission (CRc) rate and a 74% pure complete response (CR) rate. After median follow-up of 8 months, 12-month overall survival (OS) was 76%, with median OS not yet reached. In patients with ELN2022 intermediate- or adverse-risk disease, 12-month OS rates were 100% and 74%, respectively, with median OS not reached. Updated data with additional patients and more mature responses will be presented at the meeting.

- Topline positive data from the Phase Ib FRIDA (NCT05546580) clinical trial of iadademstat in combination with gilteritinib in high-risk, heavily pre-treated patients with relapsed or refractory (R/R) FLT3-mutated AML were also published in a second ASH abstract. The iadademstat/gilteritinib combination demonstrated a manageable safety profile, similar to SoC treatment. The combination achieved a high composite complete remission rate of 67% (12/18) and a 31% 12-month survival rate at the recommended Phase 2 dose (RP2D).

- Interim results from a Phase II study evaluating ASTX727 with or without iadademstat in patients with accelerated/blast-phase myeloproliferative neoplasms (NCT06661915) were also reported at an ASH abstract. This study is sponsored by the U.S. National Cancer Institute (NCI) and is conducted under the Cooperative Research and Development Agreement (CRADA) between Oryzon and the

NCI. Based on data available as of the ASH 2026 abstract submission cut-off date, the combination of iadademstat and ASTX727 was well tolerated, with no dose-limiting toxicities (DLTs) observed. 50% of patients treated with the combination achieved acute leukemia response-partial (ALR-P) as best response. The trial continues in the dose escalation phase, and higher iadademstat dose level cohorts will be explored to inform the selection of a recommended Phase 2 dose of iadademstat for the randomized portion of the study.

- VIVALDI, a new Phase Ib pilot study sponsored by CETLAM (Grupo Cooperativo de Estudio y Tratamiento de las Leucemias Agudas y Mielodisplásicas), has been authorized in Spain. The study will evaluate iadademstat in combination with azacitidine and venetoclax in patients with newly diagnosed AML in subpopulations with poor responses to current standard-of-care treatment. CETLAM is a Spanish cooperative clinical research group that brings together specialists from leading hospitals in the research and treatment of acute myeloid leukemia and myelodysplastic syndromes. Oryzon is collaborating with CETLAM and supplying iadademstat for the study. This clinical study complements Oryzon's planned ALICE-3 Phase III program in the U.S., and will provide operational experience relevant to the program’s future European arm.

- Enrollment continued across ongoing iadademstat clinical studies in myelodysplastic syndromes (MDS, IIS-X005), essential thrombocythemia (IDEAL study), sickle cell disease (RESTORE study), and extensive-stage small cell lung cancer (ED-SCLC). These include studies conducted under the CRADA with the NCI, investigator-initiated studies (IIS), and Oryzon-sponsored trials. The company plans to share preliminary data from selected studies at future scientific meetings, subject to data availability and abstract acceptance.

- Oryzon has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a U.S. patent application covering combinations of iadademstat, or certain other LSD1 inhibitors, with gilteritinib and their use for the treatment of myeloid cancers, including AML. Once granted, the U.S. patent is expected to expire in 2042, excluding any potential patent term adjustment or patent term extension.

Vafidemstat:

- EVOLUTION Phase IIb trial of vafidemstat in schizophrenia continues to actively enroll patients. The study is primarily assessing its effects on negative symptoms, with cognitive impairment and positive symptoms included as secondary endpoints. Initially launched in Spain, EVOLUTION has been expanded to additional European countries (Bulgaria, Poland, Romania and Slovakia).

- Oryzon continues preparations for the Phase III PORTICO-2 trial of vafidemstat in aggression in borderline personality disorder (BPD). Following FDA feedback, the Company is refining the trial protocol and conducting additional work to support the proposed clinical outcome measures ahead of resubmission. The company plans to request a type C meeting with the FDA by the end of 2026 or in the first quarter of 2027.

- Oryzon has received approval to initiate the HOPE-2 Phase II study of vafidemstat for the treatment of Phelan-McDermid syndrome (PMS), a genetic disease associated with autism spectrum disorder. The study is a single-center, single-arm, open-label study and will be conducted in Spain. The

primary objective of the study is to evaluate the safety and tolerability of vafidemstat in adults with PMS. Secondary objectives include assessing the effect of vafidemstat on anger and aggression and overall disease. The HOPE-2 study forms part of the activities supported by the Med4Cure IPCEI EU initiative.

- Oryzon has continued to reinforce its IP portfolio for vafidemstat with new Decisions to Grant in South Korea and the Philippines for patent applications covering the use of vafidemstat for the treatment of non-aggressive symptoms of borderline personality disorder, in New Zealand for a patent application covering the use of vafidemstat for the treatment of aggression and social withdrawal, and in Mexico for a patent application covering the use of vafidemstat for the treatment of certain non-aggressive symptoms of autism spectrum disorder.

Earlier stage programs:

- ORY-4001, Oryzon's highly selective histone deacetylase 6 (HDAC6) inhibitor for neurological disorders, continues IND-enabling studies to enable future 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: Third quarter 2026 Financial Results

Research and development (R&D) expenses were $4.6 million and $16.0 million for the quarter and nine months ended September 30th, 2026, compared to $3.9 and $9.6 million for the quarter and nine months ended September 30th, 2025.

General and administrative expenses were $1.0 and $3.8 million for the quarter and nine months ended September 30th, 2026, compared to $1.2 and $3.9 million for the quarter and nine months ended September 30th, 2025.

Net losses were $1.6 and $5.2 million for the quarter and nine months ended September 30th, 2026, compared to $1.2 and $4.6 million for the quarter and nine months ended September 30th, 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 $3.0 million (–$0.04 per share) for the nine months ended September 30th, 2026, compared to a negative net result of $1.4 million (–$0.02 per share) for the nine months ended September 30th, 2025.

Cash, cash equivalents, and marketable securities totaled $21.7 million (€19.1 million) as of September 30, 2026.

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BALANCE SHEET DATA (UNAUDITED)[1]

(Amounts in thousands US $)

	September 30th, 2026	September 30th, 2025
Cash and cash equivalents	21,701	40,430
Marketable securities	0	0
Total Assets	169,496	172,341
Deferred revenue	0	0
Total Stockholders' equity	147,977	138,279

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STATEMENTS OF OPERATIONS (UNAUDITED)[1]

(US $, amounts in thousands except per share data)

	Three Months Ended September 30th		Nine Months Ended September 30th	
	2026	2025	2026	2025
Collaboration Revenue	0	0	0	0
Operating expenses:				
Research and Development	4,623	3,857	15,968	9,627
General and administrative	1,007	1,232	3,812	3,890
Total operating expenses	5,630	5,089	19,780	13,517
Loss from Operations	-5,630	-5,089	-19,780	-13,517
Other income, net	3,981	3,894	14,582	8,879
Net Loss	-1,649	-1,195	-5,198	-4,638
Net Financial & Tax	233	1,613	2,228	3,243
Net Result	-1,416	418	-2,970	-1,395
Loss per share allocable to common stockholders:				
Basic	-0.02	0.01	-0.04	-0.02
Weighted average Shares outstanding				
Basic	81,921,612	75,197,026	79,000,488	72,523,994

[1] Spanish GAAP

* Exchange Euro/Dollar (1.1355 for 2026 and 1.1741 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, which is being evaluated in several ongoing Phase I and II studies and has demonstrated strong preliminary clinical activity in acute myeloid leukemia, including a 95% 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 reported in both trials: 95% overall response rate (ORR) and 84% composite complete remission rate (CRc), with 74% strict CR in 1L AML, and 67% CRc in R/R Flt3-mut AML (as per ASH 2026 abstracts). Subject to positive final data in the ALICE-2 study, the company has announced plans to conduct a potentially registrational study in 1L 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 ongoing trials in sickle cell disease and essential thrombocythemia. 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 the potential to address psychiatric and neurodevelopmental 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 towards Phase III development for the treatment of aggression in BPD, with a Phase III trial currently in preparation. Vafidemstat is also being evaluated in the ongoing double-blind, randomized, placebo-controlled Phase IIb EVOLUTION trial in schizophrenia, targeting negative symptoms. In addition, Oryzon is deploying a CNS precision medicine approach with vafidemstat in genetically defined patient subpopulations of certain CNS disorders, as well as in neurodevelopmental syndromes, including the recently approved HOPE-2 clinical trial in 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 person 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

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