Estimates Changed

Oryzon Genomics SA (ORY.SM)

MADRID

Rating	Buy
Price (11/10/26)	€2.43
12-Mo.Price Target	€12.00

Stock Data

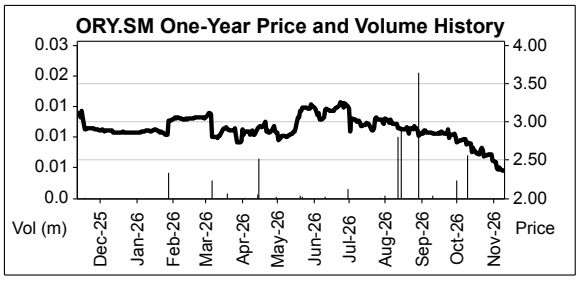
52-Week Range	€2.65- €3.76
Shares Out. (mil)	84.33
Mkt. Cap.(mil)	€219.20
3-Mo. Avg. Vol.	678
Cash (mil)	$21.7
Tot. Debt (mil)	$13.5

Rev ($M)

Yr Dec	Q1	Q2	Q3	Q4	FY
2025A	0.0A	0.0A	0.0A	0.0A	0.0A
2026E	0.0A	0.0A	0.0A	0.0E	0.0E
2027E					0.0E

EPS $

Yr Dec	Q1	Q2	Q3	Q4	FY	P/E
2025A	(0.03)A	0.00A	0.01A	(0.02)A	(0.04)A	NM
2026E	(0.02)A	0.00A	(0.02)A	(0.05)E	(0.09)E	NM
Prior			*(0.07)E*	*(0.08)E*	*(0.18)E*	NM
2027E					(0.29)E	NM
Prior					*(0.38)E*	NM



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ORY.SM 3Q26: Clinical Pipeline Progressing, Three ASH Presentations Coming

ORY ended 3Q26 with cash of $21.7M, enough funding into 2H27. In ALICE-2, first line AML patients taking iadademstat, azacitidine, and venetoclax had favorable safety and a 95% ORR, with a CRc rate of 84%, a 74% CR rate, and estimated 12-month OS of 76%. In heavily pre-treated rel/ref FLT3mut AML patients (FRIDA trial), iadademstat plus gilteritinib demonstrated favorable safety and a 67% CRc rate. ORY will present final ALICE-2 and updated FRIDA data at ASH and discuss with FDA the next, potentially registrational first-line AML trial design, which may start in 2027.

- **Updated ALICE-2 data in ASH abstract.** All 19 treated newly diagnosed AML patients were evaluable, showing a 95% (18/19) ORR and an 84% (16/19) CRc rate. The CRc rate consisted of a 74% (14/19) CR rate and an 11% (2/19) CRh rate. Both patients with TP53-mutated AML achieved CR. After a median follow up of eight months, median OS and event-free survival (EFS) were not reached. 12-month OS was 76% and median OS was not yet reached. Thus far, nine patients successfully transitioned to allogeneic transplant, and among them the estimated 12-month OS is 88%. Regarding safety, common adverse events of Grade ≥ 3 included thrombocytopenia and neutropenia. The triple regimen was found to be safe and enrollment continues at dose level 2, with a 20% toxicity rate threshold to identify the RP2D. Iadademstat doses used in ALICE-2 are 100ug and 150ug, with two de-escalation doses. The high efficacy of 74% true CR allows many patients to undergo allogeneic hematopoietic stem cell transplantation, which is about the best outcome achievable. We expect 21 total patients to eventually be enrolled.
- **Updated FRIDA data in ASH abstract.** A total of 18 heavily pre-treated FLT3mut FRIDA trial dose expansion cohort patients were efficacy evaluable, with CRc rate still at 67% (12/18), but with one more patient achieving MLFS. There was also a 31% predicted 12-month OS. Regarding Grade ≥ 3 adverse events among the 23 safety evaluable patients that happened to more than one patient, there was 35% (8/23) febrile neutropenic, 22% (5/23) pneumonia, and 9% (2/23) each of sepsis and failure to thrive. One death (pneumonia) was assessed as possibly related to iadademstat, and the other two fatal adverse events (pneumonia and disease progression) were deemed unrelated to treatment. In heavily pre-treated and refractory FLT3mut AML patients, 75ug iadademstat plus standard gilteritinib shows an impressive 67% CRc rate and thus the regimen is expected to be the RP2D for further evaluation.
- **Other ongoing iadademstat trials.** A Yale University-sponsored non-randomized Phase 1b trial evaluating iadademstat plus atezolizumab and stereotactic body radiation therapy in extensive-stage (i.e., residual, progressive or recurrent) small cell lung cancer (ES-SCLC) is enrolling patients. Patients will then take maintenance therapy with atezolizumab and iadademstat. Regarding the currently enrolling RESTORE trial in sickle cell disease (SCD), we expect to see initial data in the coming months and a final readout in 2027 followed by a registrational RESTORE-2 trial design outlined with Accelerated Approval based on HbF (an FDA approved endpoint) and full approval based on vaso-occlusive crises (VOCs). Enrollment continues in other iadademstat trials (conducted under a Cooperative Research and Development Agreement with the NCI), in first line AML, myeloproliferative neoplasms (subject of a third ASH 2026 presentation), small cell lung cancer, and as an investigator-initiated trial in myelodysplastic syndrome. ORY is also enrolling its Phase 2 trial evaluating iadademstat in essential thrombocythemia (ET) patients that are resistant/ intolerant to hydroxyurea. The primary endpoints *(continued on page 2)*

- *(continued from page 1)* of the multicenter, single-arm ET trial are safety, tolerability, and efficacy (reduction of the percentage of patients with abnormal platelet counts), and patients will be treated for 24 weeks, with another 245 weeks for patients responding to therapy.
- **New iadademstat trials.** ORY will be starting the Phase 1b VIVALDI trial in Spain to evaluate iadademstat plus azacitidine and venetoclax in newly diagnosed AML in subpopulations with poor responses to current standard-of-care. ORY is collaborating with CETLAM and supplying iadademstat for the trial, which complements the planned ALICE-3 Phase 3 program in the U.S. ALICE-3 is currently in the planning stages, with ORY to engage the FDA in the coming months.
- **CNS still a value-driver.** ORY's biggest value driver in CNS is vafidemstat in BPD, and to that end ORY received positive FDA feedback from its End-of-Phase 2 meeting supporting a Phase 3 trial (PORTICO-2) using STAXI-2 Trait Anger as the primary endpoint. ORY then submitted a Phase 3 protocol that incorporated the FDA's suggestions (including adding OAS-M as a key secondary endpoint and conducting qualitative/psychometric work). ORY subsequently received FDA feedback that the PORTICO-2 protocol needs improvement, and will address the FDA's comments and resubmit the protocol and then request a Type C meeting in late 2026/early 2027. ORY's recently established U.S.-centric CNS Clinical Advisory Board and CNS-savvy Chief Medical Officer should be taken as a strong sign that the CNS program is still very much alive.
- **EVOLUTION trial.** The Phase 2b EVOLUTION trial evaluating vafidemstat in schizophrenia continues to enroll patients in Spain and the EU, and is looking to establish vafidemstat efficacy on negative symptoms (primary endpoint) and cognitive impairment and positive symptoms (secondary endpoints) in patients with schizophrenia. ORY expanded EVOLUTION trial enrollment to include additional European countries to accelerate recruitment. After ORY evaluated the effect sizes or vafidemstat in treating BPD, the company increased EVOLUTION's enrollment target to 84 patients. EVOLUTION is partially funded by the Spanish Ministry of Science. We expect enrollment completion in 2Q27 and results later in 2027.
- **HOPE-2 trial.** ORY is finalizing plans for a single-arm Phase 2 trial named HOPE-2 to evaluate vafidemstat in aggression in autism spectrum disorder (ASD). HOPE-2 will include, inter alia, genetically-defined ASD subpopulations, such as Phelan-McDermid syndrome (PMS), will initially be conducted in Spain (where it has received authorization to start), and be supported by ORY's Med4Cure IPCEI EU initiative.

Oryzon Genomics SA
Income Statement
Fiscal Year ends December
(in 000, except per share items)

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	2020A	2021A	2022A	2023A	2024A	1Q25	2Q25	3Q25	4Q25	2025A	1Q26A	2Q26A	3Q26A	4Q26E	2026E	2027E	2028E	2029E	2030E
Global iadademstat sales										-					-	-	65,039	74,645	78,082
Global vafidemstat royalty										-					-	-	276,933	415,702	489,021
Total revenue										**-**					**-**	**-**	**341,972**	**490,346**	**567,103**
Cost of revenue										-					-	-	9,756	11,197	11,712
R&D	13,591	15,118	17,701	16,324	8,992	2,582	2,962	3,857	5,171	14,805	5,171	6,319	4,623	5,085	21,198	25,438	26,710	26,977	27,247
G&A	3,484	5,529	4,771	4,180	3,830	1,173	1,382	1,232	1,701	5,594	1,495	1,275	1,007	1,027	4,804	9,608	10,089	10,593	11,123
Total operating expenses	**17,075**	**20,647**	**22,472**	**20,504**	**12,822**	**3,755**	**4,344**	**5,089**	**6,872**	**20,399**	**6,666**	**7,594**	**5,630**	**6,112**	**26,002**	**35,046**	**46,554**	**48,767**	**50,082**
Operating income	**(17,075)**	**(20,647)**	**(22,472)**	**(20,504)**	**(12,822)**	**(3,755)**	**(4,344)**	**(5,089)**	**(6,872)**	**(20,399)**	**(6,666)**	**(7,594)**	**(5,630)**	**(6,112)**	**(26,002)**	**(35,046)**	**295,417**	**441,579**	**517,021**
Other income (net)	11,805	12,510	16,661	15,557	8,059	2,171	2,623	3,894	4,804	13,689	4,673	6,007	3,981	2,000	16,661	7,000	7,000	6,000	5,000
Net income (pretax)	**(5,269)**	**(8,137)**	**(5,811)**	**(4,947)**	**(4,763)**	**(1,584)**	**(1,721)**	**(1,195)**	**(2,068)**	**(6,710)**	**(1,993)**	**(1,587)**	**(1,649)**	**(4,112)**	**(9,341)**	**(28,046)**	**302,417**	**447,579**	**522,021**
Net financial & tax	(1,098)	(2,760)	(1,276)	(1,299)	(810)	252	(1,842)	(1,590)	(484)	(3,648)	(585)	(1,422)	(233)	(300)	(2,540)	(1,500)	75,604	111,895	130,505
Net income	**(4,171)**	**(5,377)**	**(4,535)**	**(3,648)**	**(3,953)**	**(1,836)**	**121**	**395**	**(1,584)**	**(3,062)**	**(1,408)**	**(165)**	**(1,416)**	**(3,812)**	**(6,801)**	**(26,546)**	**226,813**	**335,685**	**391,516**
EPS basic	**(0.08)**	**(0.10)**	**(0.08)**	**(0.06)**	**(0.06)**	**(0.03)**	**0.00**	**0.01**	**(0.02)**	**(0.04)**	**(0.02)**	**(0.00)**	**(0.02)**	**(0.05)**	**(0.09)**	**(0.29)**	**2.37**	**3.35**	**3.72**
EPS diluted	**(0.08)**	**(0.10)**	**(0.08)**	**(0.06)**	**(0.06)**	**(0.03)**	**0.00**	**0.01**	**(0.02)**	**(0.04)**	**(0.02)**	**(0.00)**	**(0.02)**	**(0.05)**	**(0.09)**	**(0.29)**	**2.37**	**3.35**	**3.72**
Basic shares outstanding	49,235	52,762	53,354	57,616	62,848	64,747	77,513	75,197	77,513	74,365	77,513	77,518	81,922	82,741	79,923	91,015	95,566	100,344	105,361
Diluted shares outstanding	49,235	52,762	53,354	57,616	62,848	64,747	77,513	75,197	77,513	74,365	77,513	77,518	81,922	82,741	79,923	91,015	95,566	100,344	105,361

Source: SEC filings, company press releases, and ROTH Capital Partners

Valuation: Oryzon Genomics SA (ORY.SM)

Our 12-month price target of €12, is based on a DCF analysis using a 35% discount rate that is applied to all cash flows and the terminal value, which is based on a 4x multiple of our projected 2030 operating income of $517 million. We arrive at this valuation by projecting future revenue from vafidemstat in borderline personality disorder, as well as from iadademstat in AML and SCLC.

Factors that could impede shares of ORY.SM from achieving our price target include vafidemstat and iadademstat failing to generate statistically significant clinical results. Also, regulatory agencies could fail to approve these drugs even if pivotal clinical trials are statistical successes, due to the agency viewing the results as not clinically meaningful. Loss of key management personnel could also impede achieving our price target, as could smaller than projected commercial opportunity due to changes in market size, competitive landscape, and drug pricing and reimbursement.

Risks: Oryzon Genomics SA (ORY.SM)

- **Clinical risk.** ORY.SM's clinical staged products could fail to deliver statistically significant results in late-stage clinical trials, substantially reducing the value of ORY.SM's product candidates and therefore our target price.
- **Regulatory risk.** Even if successful in the clinic, ORY.SM's products could fail to be approved by domestic and/or foreign regulatory bodies, which would reduce ORY.SM's value and therefore our target price.
- **Financing risk.** ORY.SM will need additional capital to fund its operations, and such financing may not occur, or it could be substantially dilutive to existing investors.
- **Competitive risk.** For any future approved ORY.SM products, they may not be well adopted in a competitive marketplace, which would adversely affect ORY.SM's value and therefore our target price.
- **High stock price volatility.** This issue is common among small-cap biotechnology companies with relatively low trading volumes.

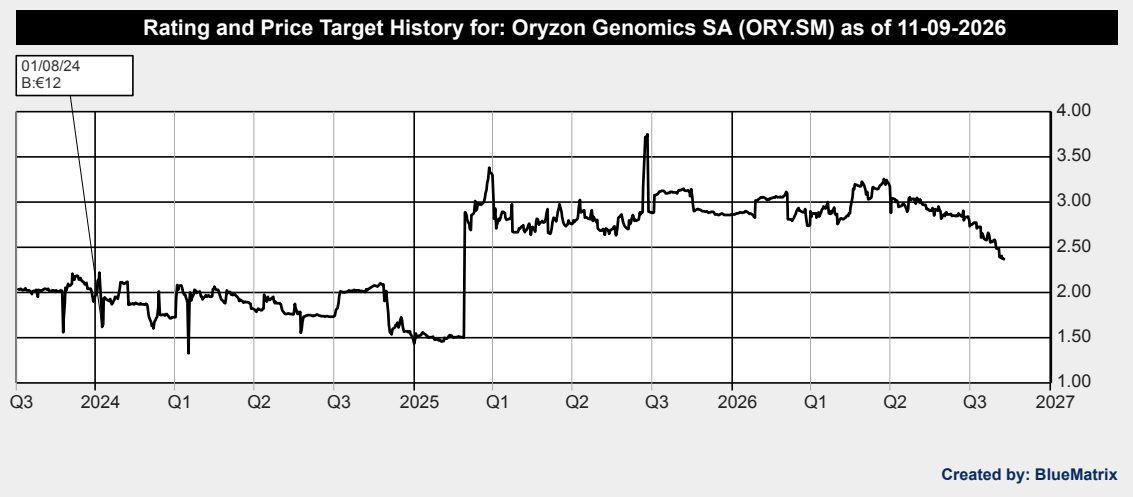
Company Description: Oryzon Genomics SA (ORY.SM)

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.

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Disclosures:

Shares of Oryzon Genomics SA may be subject to the Securities and Exchange Commission's Penny Stock Rules, which may set forth sales practice requirements for certain low-priced securities.



Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 months.

Distribution of IB Services Firmwide

			IB Serv./Past 12 Mos. as of November 10, 2026	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**413**	**78.07**	**110**	**26.63**
Neutral [N]	**70**	**13.23**	**4**	**5.71**
Sell [S]	**1**	**0.19**	**0**	**0**
Under Review [UR]	**44**	**8.32**	**12**	**27.27**

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

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Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

Under Review [UR]: A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

Not Covered [NC]: ROTH Capital does not publish research or have an opinion about this security.

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