

Oryzon Genomics SA (ORY.SM)

MADRID

Rating	Buy
Price (05/13/26)	€2.85
12-Mo.Price Target	€12.00

Stock Data

52-Week Range	€2.96- €4.38
Shares Out. (mil)	79.89
Mkt. Cap.(mil)	€258.76
3-Mo. Avg. Vol.	64
Cash (mil)	\$25.4
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	0.0E	0.0E	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	(0.06)E	(0.07)E	(0.08)E	(0.23)E	NM
Prior	(0.05)A	(0.05)E	(0.06)E	(0.07)E		NM
2027E					(0.39)E	NM
Prior					(0.27)E	NM

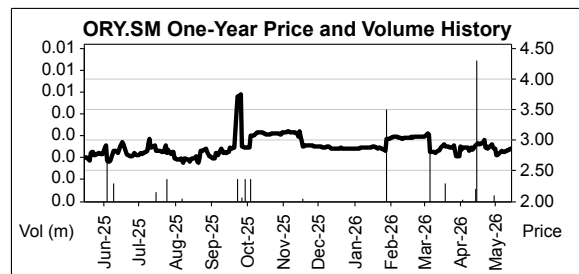
ORY.SM 1Q26: Positive Updated ALICE-2 And FRIDA Trial AML Data From Published EHA Abstracts

Estimates Changed

ORY ended 1Q26 with \$25.4M in cash, enough funding into mid-2027. Abstracts for the upcoming (June 11-14) EHA conference published, and contain updated results in AML patients taking iadademstat combination therapy. In ALICE-2, first line AML patients taking iadademstat, azacitidine, and venetoclax had favorable safety and a 100% ORR, with a CRc rate of 93% (13/14), a 79% CR rate (11/14), and estimated 12-month OS of 74%. In heavily pre-treated rel/ref FLT3mut AML patients (FRIDA trial), iadademstat plus gilteritinib demonstrated favorable safety and a 67% (12/18) CRc rate. More mature data coming at EHA.

- Updated ALICE-2 data from EHA abstract.** As of the February 2026 data cutoff, the triplet combination of iadademstat, azacitidine and venetoclax evaluated in the ALICE-2 trial (NCT06357182) continues to demonstrate favorable safety and high response rates. Among the 14 evaluable patients the overall response rate (ORR) was 100%, with a complete response (CR) rate of 79% (n=11/14) and a composite complete remission (CRc: CR+CRh+CRi) rate of 93% (n=13/14; the other patient achieved MLFS). After a median follow-up of six months, the estimated 12-month OS rate was 74%. Among the 13 MTD-evaluable patients, there were two DLTs (Grade 4 *C. difficile* colitis and Grade 4 neutropenia). Common \geq Grade 3 AEs occurring in more than one patient were febrile neutropenia (20%) and neutropenia (20%; all Grade 4). Of the three deaths, two were due to septic shock and deemed unrelated to iadademstat, and one died after hematopoietic stem cell transplantation (HSCT). Updated data with additional patients and more mature responses will be presented at the EHA.
- Prior ALICE-2 data released in February 2026.** In the prior data update released last quarter, the FRIDA trial had 10 evaluable patients, and showed the combination therapy to be safe (no DLT identified) and to deliver a 100% ORR and 90% pure CR. Also, 70% of patients transitioned to HSCT, and while median OS was not reached, 6-month OS was 66%, with seven of the patients undergoing subsequent HSCT, a highly favorable outcome. Two iadademstat doses (100 (n=3) and 150 (n=5) mcg daily) were evaluated thus far. The trial expects to enroll 21 MTD-evaluable patients overall.
- Updated FRIDA data from EHA abstract.** In 18 heavily pre-treated rel/ref FLT3mut AML patients, iadademstat plus standard of care gilteritinib demonstrated favorable safety and a 67% (12/18) CRc rate. Regarding safety, The most common \geq Grade 3 TEAEs considered related to iadademstat were thrombocytopenia and neutropenia (both 28%), leucopenia (10%) and febrile neutropenia and anemia (both 7%). There were also five serious AEs considered related to iadademstat (febrile neutropenia (2), pneumonia (1), dizziness (1) and myocarditis (1)), and of the three patients that died during the trial (from pneumonia, respiratory failure, and disease progression), none were deemed related to iadademstat. Among the 12 of 18 evaluable patients that achieved CRc, there were three CR, four CRh, and five CRi), with all responses achieved by the end of Cycle 2. FLT3mut accounts for 30-40% of AML patients. Updated data with additional patients and more mature responses will be presented at the EHA.
- Prior FRIDA data released in 4Q25.** In the prior data update released at ASH, the FRIDA trial had 15 dose-expansion phase patients evaluable out of 37 enrolled in all dose groups. There was an improved 67% (10/15; 7 CR or CRh and 3 CRi) CCR rate and a 47% (7/15) CR + CRh (*text continued on page 2*)

ORY Intraday Price: €2.81 at 10:57ET



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- *(text continued from page 1)* rate in the 15 evaluable dose-expansion phase patients. Four patients were able to undergo HSCT, a highly favorable outcome, despite 47% (7/15) of patients at this dose having already failed venetoclax.
- **Other 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) has started to enroll patients. Patients will then take maintenance therapy with atezolizumab and iadademstat. Regarding the RESTORE trial in sickle cell disease (SCD), we expect to see initial data later in 2026 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, small cell lung cancer, and as an investigator-initiated trial in myelodysplastic syndrome. ORY is also preparing a Phase 2 trial to evaluate iadademstat in essential thrombocythemia (ET), following the trial's recent approval by the European Medicines Agency (EMA). The primary endpoints of the multicenter, single-arm trial are safety, tolerability, and efficacy (reduction of the percentage of patients with abnormal platelet counts).
- **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. ORY's recently established U.S.-centric CNS Clinical Advisory Board and new CNS savvy Chief Medical Officer should be taken as a strong sign that the CNS program is still very much alive. In addition to BPD, vafidemstat is being evaluated in schizophrenia in the ongoing EVOLUTION trial, with readout expected in 2027.
- **EVOLUTION trial.** The Phase 2b EVOLUTION trial evaluating vafidemstat in schizophrenia continues to enroll patients in Spain and now 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 of vafidemstat in treating BPD, the company increased EVOLUTION's enrollment target to 84 patients. EVOLUTION is partially funded by the Spanish Ministry of Science.
- **HOPE-2 trial.** ORY is planning a 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, and be supported by ORY's Med4Cure IPCEI EU initiative.

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Income Statement																		jaschoff@roth.com	
Fiscal Year ends December																			
(in 000, except per share items)																			
	2020A	2021A	2022A	2023A	2024A	1Q25	2Q25	3Q25	4Q25	2025A	1Q26A	2Q26E	3Q26E	4Q26E	2026E	2027E	2028E	2029E	2030E
Global iadademstat sales										-					-	-	75,340	88,139	92,466
Global vafidemstat royalty										-					-	-	293,855	452,897	534,242
Total revenue										-					-	-	369,195	541,036	626,708
Cost of revenue										-					-	-	13,839	16,690	18,190
R&D	13,591	15,118	17,701	16,324	8,992	2,582	2,962	3,857	5,171	14,805	5,171	5,688	6,257	6,883	23,999	28,798	30,238	30,541	30,846
G&A	3,484	5,529	4,771	4,180	3,830	1,173	1,382	1,232	1,701	5,594	1,495	1,525	1,555	1,587	6,162	12,324	12,940	13,587	14,266
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	7,213	7,812	8,469	30,160	41,122	57,017	60,817	63,302
Operating income	(17,075)	(20,647)	(22,472)	(20,504)	(12,822)	(3,755)	(4,344)	(5,089)	(6,872)	(20,399)	(6,666)	(7,213)	(7,812)	(8,469)	(30,160)	(41,122)	312,178	480,219	563,406
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	2,000	2,000	2,000	10,673	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)	(5,213)	(5,812)	(6,469)	(19,487)	(34,122)	319,178	486,219	568,406
Net financial & tax	(1,098)	(2,760)	(1,276)	(1,299)	(810)	252	(1,842)	(1,590)	(484)	(3,648)	(585)	(300)	(300)	(300)	(1,485)	(1,500)	79,794	121,555	142,101
Net income	(4,171)	(5,377)	(4,535)	(3,648)	(3,953)	(1,836)	121	395	(1,584)	(3,062)	(1,408)	(4,913)	(5,512)	(6,169)	(18,002)	(32,622)	239,383	364,664	426,304
EPS basic	(0.08)	(0.10)	(0.08)	(0.06)	(0.06)	(0.03)	0.00	0.01	(0.02)	(0.04)	(0.02)	(0.06)	(0.07)	(0.08)	(0.23)	(0.39)	2.72	3.94	4.39
EPS diluted	(0.08)	(0.10)	(0.08)	(0.06)	(0.06)	(0.03)	0.00	0.01	(0.02)	(0.04)	(0.02)	(0.06)	(0.07)	(0.08)	(0.23)	(0.39)	2.72	3.94	4.39
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	78,289	79,071	79,862	78,684	83,855	88,048	92,450	97,073
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	78,289	79,071	79,862	78,684	83,855	88,048	92,450	97,073

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 \$563 million. We arrive at this valuation by projecting future revenue from vafidemstat in borderline personality disorder and Kabuki syndrome, as well as 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)

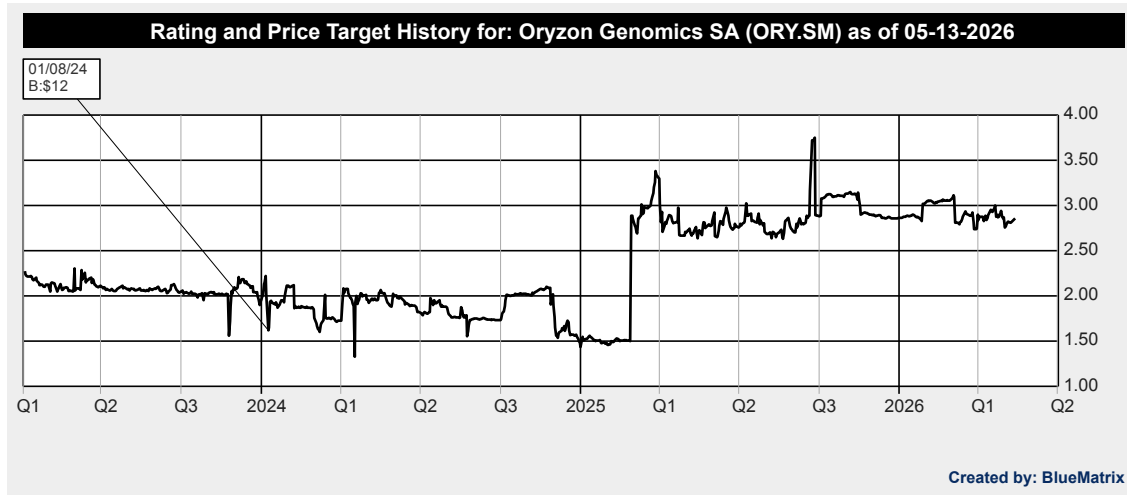
Founded in 2000 in Barcelona, Spain, Oryzon (ISIN Code: ES0167733015) is a clinical stage biopharmaceutical company and the European leader in epigenetics, with a strong focus on personalized medicine in CNS disorders and oncology. Oryzon's team is composed of highly qualified professionals from the pharma industry located in Barcelona, Boston, and San Diego. Oryzon has an advanced clinical portfolio with two LSD1 inhibitors, vafidemstat in CNS (Phase III-ready) and iadademstat in oncology (Phase II). The company has other pipeline assets directed against other epigenetic targets like HDAC-6 where a clinical candidate ORY-4001, has been nominated for its possible development in CMT and ALS. In addition, Oryzon has a strong platform for biomarker identification and target validation for a variety of malignant and neurological diseases.

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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

Rating	Count	Percent	IB Serv./Past 12 Mos. as of May 12, 2026	
			Count	Percent
Buy [B]	369	74.70	102	27.64
Neutral [N]	86	17.41	7	8.14
Sell [S]	3	0.61	1	33.33
Under Review [UR]	36	7.29	17	47.22

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

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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