

Oryzon Genomics SA (ORY.SM)

MADRID

Rating	Buy
Price	€1.44
12-Mo.Price Target	€12.00

Stock Data

52-Week Range	€1.41- €2.29
Shares Out. (mil)	65.78
Mkt. Cap.(mil)	€100.44
3-Mo. Avg. Vol.	510
Cash (mil)	€8.4
Tot. Debt (mil)	€17.8

Rev (\$M)

Yr Dec	Q1	Q2	Q3	Q4	FY
2023A	0.0A	0.0A	0.0A	0.0A	0.0A
2024E	0.0A	0.0A	0.0A	0.0E	0.0E
2025E	0.0E	0.0E	0.0E	0.0E	0.0E

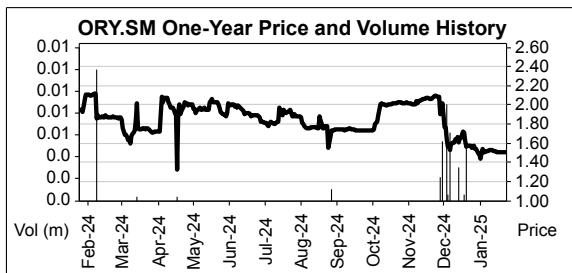
EPS \$

Yr Dec	Q1	Q2	Q3	Q4	FY	P/E
2023A	(0.03)A	0.02A	(0.02)A	(0.03)A	(0.06)A	NM
2024E	(0.02)A	0.00A	(0.02)A	(0.01)E	(0.05)E	NM
2025E	(0.01)E	(0.01)E	(0.02)E	(0.03)E	(0.07)E	NM

ORY.SM: Doses First MDS Patient In Phase 1 Investigator Initiated Trial Testing Iadademstat/Azacitidine

The first myelodysplastic syndrome (MDS) patient has been dosed in an investigator-initiated Phase 1 dose-ranging trial evaluating iadademstat plus azacitidine. The combination therapy will be evaluated for safety, tolerability, and determination of the recommended Phase 2 iadademstat dose. Iadademstat is worth evaluating in MDS, given that MDS is characterized by a block in the normal differentiation of hematopoietic progenitor cells, and that the LSD1 enzyme controls this block to differentiation.

- The first myelodysplastic syndrome (MDS) patient has been dosed in an investigator-initiated Phase 1 dose-ranging trial (led by Medical College of Wisconsin) evaluating iadademstat plus azacitidine. The combination therapy will be evaluated for safety, tolerability, and determination of the recommended Phase 2 iadademstat dose. The annual U.S. MDS incidence is over 10,000 new cases, and they are typically initially treated with azacitidine and decitabine, despite the relatively low CR rates of under 20% and poor long-term outcomes. Treatment outcomes are worse among patients with higher-risk MDS, which is highly drug resistant and saw its last drug approval in 2007. Iadademstat is worth evaluating in MDS, given that MDS is characterized by a block in the normal differentiation of hematopoietic progenitor cells, and that the LSD1 enzyme controls this block to differentiation. For supportive evidence, we refer clients to the positive outcome of the ALICE trial ([citation](#)) that showed how iadademstat irreversibly and safely inhibits LSD1 and allows immature hematopoietic cells to differentiate and function, which translated into deep and durable responses in newly diagnosed AML patients.


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Oryzon Genomics SA																	Jonathan Aschoff, Ph.D. (646) 616-2795				
Income Statement																	jaschoff@roth.com				
Fiscal Year ends December																					
(in 000, except per share items)																					
	2018A	2019A	2020A	2021A	2022A	2023A	1Q24A	2Q24A	3Q24A	4Q24E	2024E	1Q25E	2Q25E	3Q25E	4Q25E	2025E	2026E	2027E	2028E	2029E	2030E
Global iadademstat revenue																-	-	93,669	143,784	171,389	179,742
Global vafidemstat revenue																-	-	100,935	271,856	427,073	505,511
Total revenue																-	-	194,604	415,640	598,461	685,253
Cost of revenue																-	-	16,769	25,810	29,372	29,566
R&D	8,489	12,647	13,591	15,118	17,701	16,324	2,636	2,325	1,915	1,934	8,810	2,031	2,335	2,803	3,363	10,532	11,059	11,169	11,281	11,394	11,508
G&A	2,993	3,176	3,484	5,529	4,771	4,180	863	1,222	879	888	3,852	906	924	942	961	3,732	6,345	6,979	7,677	8,061	8,464
Total operating expenses	11,482	15,823	17,075	20,647	22,472	20,504	3,499	3,547	2,794	2,822	12,662	2,936	3,259	3,745	4,324	14,264	17,404	34,918	44,768	48,827	49,538
Operating income	(11,482)	(15,823)	(17,075)	(20,647)	(22,472)	(20,504)	(3,499)	(3,547)	(2,794)	(2,822)	(12,662)	(2,936)	(3,259)	(3,745)	(4,324)	(14,264)	(17,404)	159,686	370,872	549,635	635,715
Other income (net)	8,143	11,522	11,805	12,510	16,661	15,557	2,400	2,061	1,671	2,000	8,132	2,000	2,000	2,000	2,000	8,000	8,000	7,000	7,000	6,000	5,000
Net income (pretax)	(3,339)	(4,301)	(5,269)	(8,137)	(5,811)	(4,947)	(1,099)	(1,486)	(1,123)	(822)	(4,530)	(936)	(1,259)	(1,745)	(2,324)	(6,264)	(9,404)	166,686	377,872	555,635	640,715
Net financial & tax	(1,991)	(187)	(1,098)	(2,760)	(1,276)	(1,299)	140	(1,599)	256	(250)	(1,453)	(300)	(300)	(300)	(300)	(1,200)	(1,000)	41,672	94,468	138,909	160,179
Net income	(1,348)	(4,114)	(4,171)	(5,377)	(4,535)	(3,648)	(1,239)	113	(1,379)	(572)	(3,077)	(636)	(959)	(1,445)	(2,024)	(5,064)	(8,404)	125,015	283,404	416,726	480,536
EPS basic	(0.04)	(0.10)	(0.08)	(0.10)	(0.08)	(0.06)	(0.02)	0.00	(0.02)	(0.01)	(0.05)	(0.01)	(0.01)	(0.02)	(0.03)	(0.07)	(0.12)	1.65	3.56	4.99	5.48
EPS diluted	(0.04)	(0.10)	(0.08)	(0.10)	(0.08)	(0.06)	(0.02)	0.00	(0.02)	(0.01)	(0.05)	(0.01)	(0.01)	(0.02)	(0.03)	(0.07)	(0.12)	1.39	3.03	4.27	4.72
Basic shares outstanding	34,638	41,589	49,235	52,762	53,354	57,616	61,216	62,215	63,384	68,455	63,817	68,523	68,592	68,660	68,729	68,626	72,165	75,774	79,562	83,540	87,717
Diluted shares outstanding	34,638	41,565	49,235	52,762	53,354	57,616	61,216	62,215	63,384	68,455	63,817	68,523	68,592	68,660	68,729	68,626	72,165	89,811	93,599	97,578	101,755

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 \$636 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.

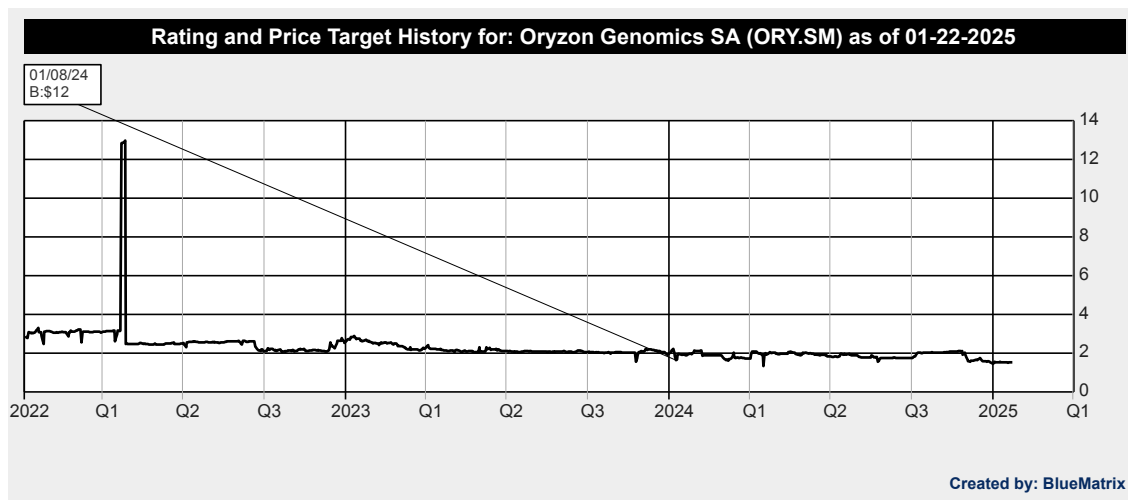
Company Description: Oryzon Genomics SA (ORY.SM)

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 ORY4001, 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. For more information, visit www.oryzon.com

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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 month.

Distribution of IB Services Firmwide

Rating	Count	Percent	IB Serv./Past 12 Mos. as of January 23, 2025	
			Count	Percent
Buy [B]	355	78.37	107	30.14
Neutral [N]	75	16.56	5	6.67
Sell [S]	2	0.44	0	0
Under Review [UR]	21	4.64	2	9.52

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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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