Oryzon Genomics SA (ORY.SM)

MADRID

Rating	Buy
Price (02/26/25)	€1.50
12-Mo.Price Target	€12.00

Stock Data

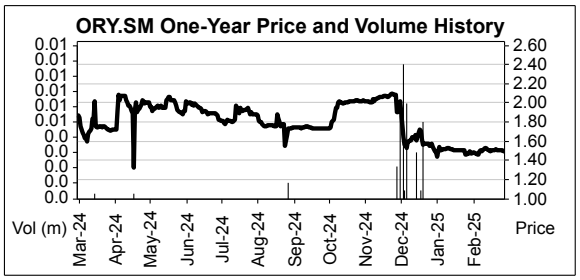
52-Week Range	€1.41- €2.25
Shares Out. (mil)	65.78
Mkt. Cap.(mil)	€188.53
3-Mo. Avg. Vol.	529
Cash (mil)	€8.4
Tot. Debt (mil)	€17.8

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



Jonathan Aschoff, Ph.D., Managing Director, Sr. Research Analyst
jaschoff@roth.com
(646) 616-2795

Sales (800) 933-6830, **Trading** (203) 861-9060

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ORY.SM: Recent Share Price Rally Not Unfounded

We discuss some recent and near future developments related to ORY, developments that have led to about a 100% share price increase since early February (vs. NBI flat). Should the company execute on a big pharma licensure of vafidemstat or an outright sale of the company, we believe that the current share price increase still does not nearly capture that value. We believe that the most important driver of collaborative/acquisitive interest in ORY stems from the FDA's view of acceptable pivotal trial endpoints for vafidemstat in BPD.

- **Recent optimistic Spanish press.** On February 19, in an article titled "Oryzon Attracts U.S. Pharmaceutical Companies Following Its Latest Research" in *elEconomista*, ORY's CEO Carlos Buesa was featured discussing the potential outlicensing of vafidemstat or outright sale of ORY, given the favorable PORTICO trial results and the favorable EoP2 meeting between ORY and the FDA during which the agency opined that ORY could use a secondary endpoint (STAXI-2; p=0.007 in Phase 2b as a secondary endpoint) it comfortably achieved in Phase 2b as primary endpoints in a pivotal program. The article discusses ORY being in confidential talks with several big pharma companies, which makes sense given the absence of an FDA approved treatment for borderline personality disorder (BPD), and the absence of any established primary endpoints for a pivotal BPD program that ORY could have possibly missed in Phase 2b. Alleviation of any one of the major symptoms afflicting BPD patients would be of value. ORY must also conduct a Qualitative Research Study using a subset of future Phase 3 PORTICO-2 trial patients to provide further validation of the proposed endpoints, and the company will submit the Qualitative Research Study protocol prior to Phase 3 initiation to obtain regulatory feedback. ORY will also provide the psychometric properties and performance for the selected primary and key secondary endpoints for FDA review prior to Phase 3 initiation. A Special Protocol Assessment is unlikely to be sought given the useful clarity received from the FDA, and likely also given the absence of any FDA approved therapy for BPD. The two Phase 3 trials may be conducted in sequence or in parallel, depending on funding/partnering.
- **BoD changes involving appointing three new directors from the Bay Area.** The article (and a press release from January 27, 2025) also mentions ORY's recently proposed substantial BoD changes that we believe will increase investor interest in the company, and for which a special shareholder vote will occur tomorrow that we believe will formalize the addition of four new directors, three of whom are from the Bay Area.
- **Imminent European grant.** ORY stands to likely receive a grant of about €15 to €17 million. There was a recent public announcement by the Spanish Government regarding the correction processes of the grant applications, which confirmed that the administrative process is ongoing and that its resolution is imminent, and we believe that the time lag due to the required corrections may have decreased investor optimism for the potential near future non-dilutive funding.
- **Recent publication of REIMAGINE trial clinical data.** Earlier this month, the final publication of data on aggression in autism, ADHD, and BPD from the Phase 2a REIMAGINE trial (citation), allowed investors and the pharmaceutical community to better contextualize and highlight the relevance of PORTICO's data and ORY's favorable interactions with the FDA thereafter.

ORY recently traded at €2.94 at 9:05AM EST

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

Jonathan Aschoff, Ph.D. (646) 616-2795
jaschoff@roth.com

	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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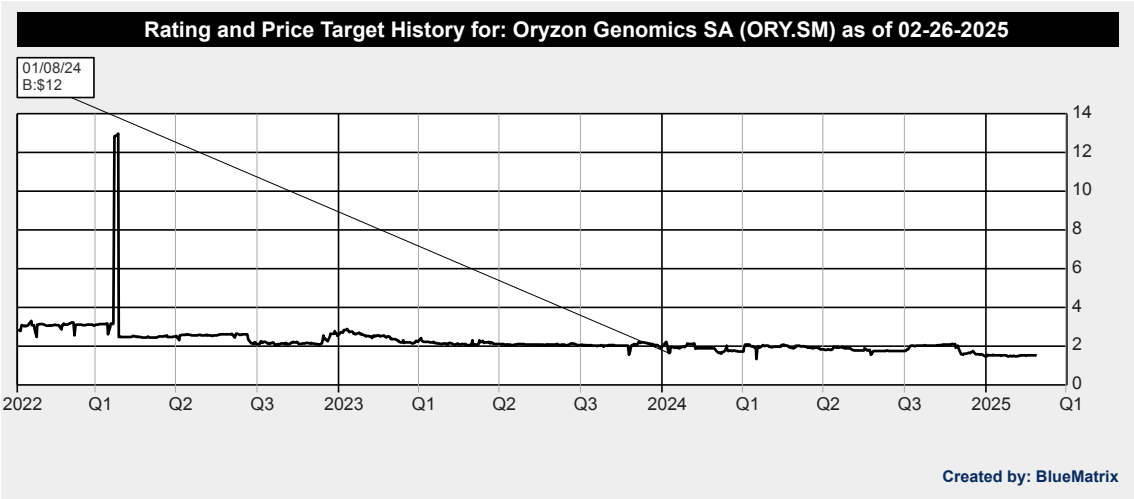
Disclosures:

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

			IB Serv./Past 12 Mos. as of February 27, 2025	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**360**	**78.09**	**111**	**30.83**
Neutral [N]	**79**	**17.14**	**5**	**6.33**
Sell [S]	**1**	**0.22**	**0**	**0**
Under Review [UR]	**20**	**4.34**	**2**	**10.00**

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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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