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COMPANY NOTE | EQUITY RESEARCH | July 05, 2023

Healthcare: Biotechnology **Company Update**

Oryzon Genomics SA | ORY.SM - €2.10 - MADRID | *Buy*

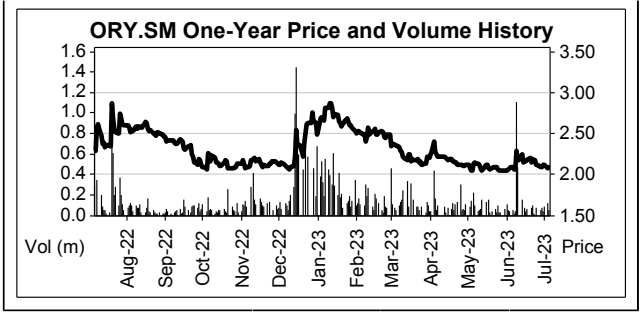
Stock Data	
52-Week Low - High	€1.98 - €2.94
Shares Out. (mil)	57.85
Mkt. Cap.(mil)	€121.20
3-Mo. Avg. Vol.	109,380
12-Mo.Price Target	€15.00
Cash (mil)	$20.0
Tot. Debt (mil)	$21.9

Rev ($M)

Yr Dec	—2022—	—2023E—	—2024E—
		Curr	Curr
1Q	0.0A	0.0A	-
2Q	0.0A	0.0E	-
3Q	0.0A	0.0E	-
4Q	0.0A	0.0E	-
YEAR	0.0A	0.0E	0.0E

EPS $

Yr Dec	—2022—	—2023E—	—2024E—
		Curr	Curr
1Q	(0.03)A	(0.03)A	-
2Q	0.01A	(0.05)E	-
3Q	(0.01)A	(0.07)E	-
4Q	(0.05)A	(0.07)E	-
YEAR	(0.08)A	(0.22)E	(0.46)E
P/E	NM	NM	NM



ORY: Vafidemstat Appears Safe Thus Far in PORTICO Phase 2b BPD Trial As Per DMC

Recent preliminary blinded aggregate safety data (data cutoff of May 23 involving data from 167 BPD patients) from ORY's ongoing Phase 2b PORTICO trial evaluating vafidemstat in borderline personality disorder (BDP) was reviewed by the trial's independent Data Monitoring Committee (DMC) on June 26. The DMC characterized the aggregate safety results as positive and recommended that the PORTICO trial continue as planned to its ultimate enrollment of 188 patients.

- More specifically about the blinded safety results, no treatment-related serious adverse events or deaths were observed. A total of 306 adverse events among 98 patients treated either with vafidemstat or placebo were reported, with most of the events being mild (216) or moderate (78), and only 12 events reported as severe among in nine patients, which led to six treatment discontinuations or patient withdrawals. Overall, the PORTICO safety data thus far showing vafidemstat to be safe and well tolerated aligns well with prior aggregated safety data from seven completed vafidemstat trials, in which almost 400 patients and healthy volunteers have received vafidemstat.

- After the DMC reviewed and reported upon the blinded safety data, the committee then reviewed the unblinded safety data, which prompted it to recommend trial continuation without protocol modification through its full anticipated enrollment of 188, which should occur in early 3Q23. PORTICO has now passed its initial futility analysis in 1Q23 with the data from the first 90 patients that had completed at least two-thirds of the trial, and a subsequent blinded and unblinded safety assessment. Enrolling in the U.S. and Europe, PORTICO is a multi-center, double-blind, randomized, placebo-controlled trial that has two primary endpoints: to reduce agitation and aggression and to produce an overall improvement in BPD severity.

VALUATION

Our 12-month price target of €15, is based on a DCF analysis using a 40% 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 $988 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

- **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

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, NYC and San Diego. Oryzon has an advanced clinical portfolio with two LSD1 inhibitors, vafidemstat in CNS and iadademstat in oncology, in several Phase II clinical trials. The company has other pipeline assets directed against other epigenetic targets. 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

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

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	2017A	2018A	2019A	2020A	2021A	1Q22	2Q22	3Q22	4Q22	2022A	1Q23A	2Q23E	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Global iadademstat revenue																	25,778	99,451	209,468	313,934	372,470	389,751
Global vafidemstat revenue																	98,463	342,237	520,351	615,106	684,577	721,921
Collaboration revenue	20																					
Total revenue	**20**																**124,241**	**441,689**	**729,819**	**929,040**	**1,057,047**	**1,111,672**
Cost of revenue																-	5,420	17,066	34,941	48,990	59,606	64,604
R&D	6,363	8,489	12,647	13,591	15,118	4,228	4,166	4,274	5,033	17,701	4,372	4,591	4,820	5,061	18,844	22,613	27,135	29,849	31,341	31,655	31,971	32,291
G&A	4,502	2,993	3,176	3,484	5,529	1,343	1,520	659	1,249	4,771	1,223	1,235	1,248	1,260	4,966	7,449	13,408	20,112	22,123	24,335	25,552	26,830
Total operating expenses	**10,865**	**11,482**	**15,823**	**17,075**	**20,647**	**5,571**	**5,686**	**4,933**	**6,282**	**22,472**	**5,595**	**5,826**	**6,068**	**6,321**	**23,810**	**30,061**	**45,963**	**67,027**	**88,405**	**104,980**	**117,129**	**123,724**
Operating income	**(10,845)**	**(11,482)**	**(15,823)**	**(17,075)**	**(20,647)**	**(5,571)**	**(5,686)**	**(4,933)**	**(6,282)**	**(22,472)**	**(5,595)**	**(5,826)**	**(6,068)**	**(6,321)**	**(23,810)**	**(30,061)**	**78,278**	**374,662**	**641,414**	**824,060**	**939,918**	**987,948**
Other income (net)	5,659	8,143	11,522	11,805	12,510	3,826	3,894	4,248	4,693	16,661	4,215	3,000	2,000	2,000	11,215							
Net income (pretax)	**(5,186)**	**(3,339)**	**(4,301)**	**(5,269)**	**(8,137)**	**(1,745)**	**(1,792)**	**(685)**	**(1,589)**	**(5,811)**	**(1,380)**	**(2,826)**	**(4,068)**	**(4,321)**	**(12,595)**	**(30,061)**	**78,278**	**374,662**	**641,414**	**824,060**	**939,918**	**987,948**
Net financial & tax	1,047	(1,991)	(187)	(1,098)	(2,760)	67	(2,139)	(67)	863	(1,276)	392	(250)	(250)	(250)	(358)	(394)	(433)	93,665	160,354	206,015	234,980	246,987
Net income	**(6,233)**	**(1,348)**	**(4,114)**	**(4,171)**	**(5,377)**	**(1,812)**	**347**	**(618)**	**(2,452)**	**(4,535)**	**(1,772)**	**(2,576)**	**(3,818)**	**(4,071)**	**(12,237)**	**(29,668)**	**78,711**	**280,996**	**481,061**	**618,045**	**704,939**	**740,961**
EPS basic	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.10)**	**(0.03)**	**0.01**	**(0.01)**	**(0.05)**	**(0.08)**	**(0.03)**	**(0.05)**	**(0.07)**	**(0.07)**	**(0.22)**	**(0.46)**	**1.16**	**3.94**	**6.42**	**7.86**	**8.53**	**8.54**
EPS diluted	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.10)**	**(0.03)**	**0.01**	**(0.01)**	**(0.05)**	**(0.08)**	**(0.03)**	**(0.05)**	**(0.07)**	**(0.07)**	**(0.22)**	**(0.46)**	**0.96**	**3.29**	**5.41**	**6.67**	**7.30**	**7.35**
Basic shares outstanding	31,711	34,638	41,589	49,235	52,762	52,762	52,762	53,609	54,284	53,354	56,190	56,247	56,303	56,359	56,275	64,716	67,952	71,349	74,917	78,663	82,596	86,725
Diluted shares outstanding	31,711	34,638	41,565	49,235	52,762	52,762	52,762	53,609	54,284	53,354	56,190	56,247	56,303	56,359	56,275	64,716	81,989	85,386	88,954	92,700	96,633	100,763

Source: SEC filings, company press releases, and ROTH MKM

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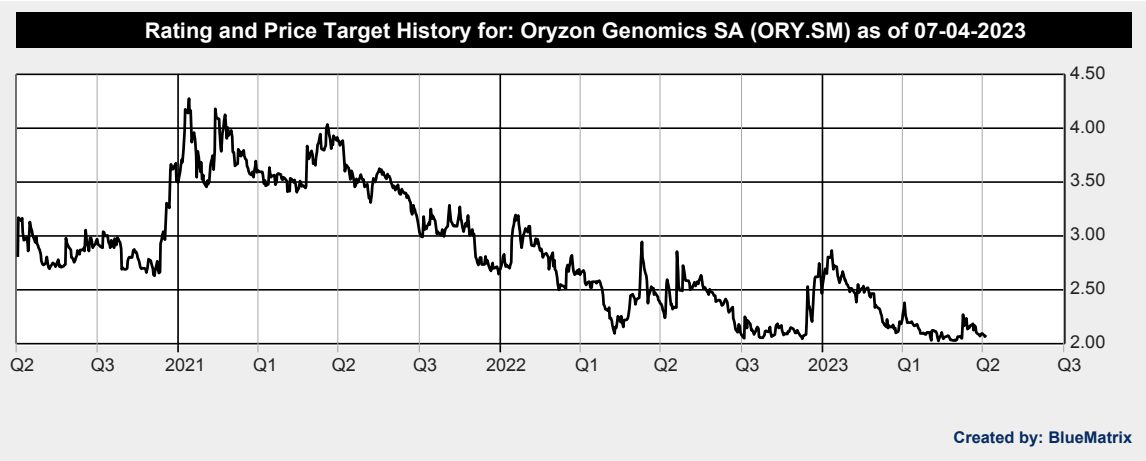
Disclosures:

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 07/05/23	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**379**	**76.26**	**224**	**59.10**
Neutral [N]	**96**	**19.32**	**32**	**33.33**
Sell [S]	**3**	**0.60**	**0**	**0**
Under Review [UR]	**19**	**3.82**	**4**	**21.05**

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 MKM does not publish research or have an opinion about this security.

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