Jonathan Aschoff, Ph.D., (646) 616-2795
jaschoff@roth.com
Sales (800) 933-6830, **Trading** (203) 861-9060

COMPANY NOTE | EQUITY RESEARCH | October 10, 2023

Healthcare: Biotechnology **Company Update**

Oryzon Genomics SA | ORY.SM - €2.02 - MADRID | *Buy*

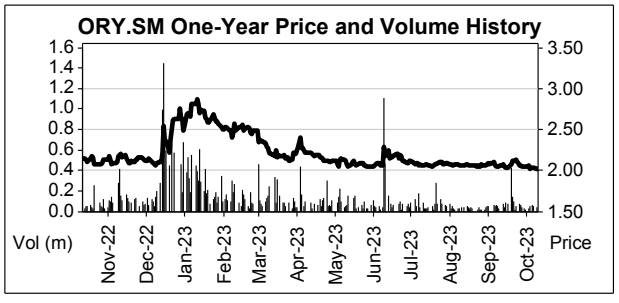
Stock Data	
52-Week Low - High	€1.98 - €2.93
Shares Out. (mil)	58.58
Mkt. Cap.(mil)	€118.34
3-Mo. Avg. Vol.	58,413
12-Mo.Price Target	€15.00
Cash (mil)	$14.6
Tot. Debt (mil)	€20.1

Rev ($M)

Yr Dec	—2022—	—2023E—	—2024E—
		Curr	Curr
1Q	0.0A	0.0A	-
2Q	0.0A	0.0A	-
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	0.02A	-
3Q	(0.01)A	(0.06)E	-
4Q	(0.05)A	(0.06)E	-
YEAR	(0.08)A	(0.13)E	(0.38)E
P/E	NM	NM	NM



ORY: Second PORTICO Trial Blinded Safety Assessment Shows Favorable Results

ORY presented a poster today that updated the blinded safety results from the ongoing Phase 2b PORTICO trial evaluating vafidemstat in BPD, which enrolled its last patient in July 2023 for a total of 210 patients, 131 of which have completed the trial, and 198 of which contributed to the new favorable safety results. We note that the one serious TEAE was severe in nature, but the patient fully recovered without dose interruption. Trial completion by YE23 should allow for topline data release in 1Q24.

- ORY presented a poster at the European College of Neuropsychopharmacology Congress today that updated the blinded safety results from the ongoing Phase 2b PORTICO trial evaluating vafidemstat in borderline personality disorder (BPD), which enrolled its last patient in July 2023 for a total of 210 patients, 131 of which have completed the trial. The prior blinded safety assessment was also favorable and involved the first 167 patients enrolled using a May 23 data cutoff, whereas this analysis used an August 23 data cutoff and has safety data from 198 patients. PORTICO enrolled a real-world BPD population by allowing common comorbidities and concomitant medications that are typically exclusionary in BPD trials, as well as allowing patients to receive concomitant psychotherapy. In aggregate, the new blinded safety data from 198 of the 210 enrolled patients demonstrates that vafidemstat is safe and well-tolerated, with a low 2% discontinuation rate due to treatment-emergent adverse events (TEAEs) and 0% rate due to serious TEAEs. The only serious TEAE that was also deemed severe was fully resolved during the trial. The PORTICO screen failure rate was low (36.6%), versus the most recent BPD trial with brexpiprazole at 62%, and the PORTICO dropout rate was likewise lower (20.7% versus 26.3%).
- More specifically regarding safety, and recall that the data are still blinded, there were 108 (54.5%) patients with TEAEs, with 54 (27.3%) experiencing treatment-related AEs, 4 (2.0%) leading to trial discontinuation, 6 (3.0%) leading to treatment withdrawal, and 6 (3.0%) leading to treatment interruption. Among the 108 patients with TEAEs, 93 had mild TEAEs, 50 had moderate TEAEs, and 9 had severe TEAEs (some patients had >1 TEAE), and the majority of patients with TEAEs have recovered or are recovering. As mentioned above, the one serious TEAE was severe in nature and not further described, but the patient fully recovered without dose interruption.
- As a reminder, PORTICO is a global, double-blind, 1:1 randomized, placebo-controlled, adaptive 14-week Phase 2b trial, which aims to analyze 150 patients who complete the trial. The Trial's primary endpoints are treatment of agitation and aggression on the Clinical Global Impression (CGI), as well as overall disease severity on the Borderline Personality Disorder Checklist (BPDCL). The last patient out is expected before YE23, allowing for topline data release in 1Q24.

ORY traded intraday at €2.03 at 11:54AM EDT)

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 $992 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)

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

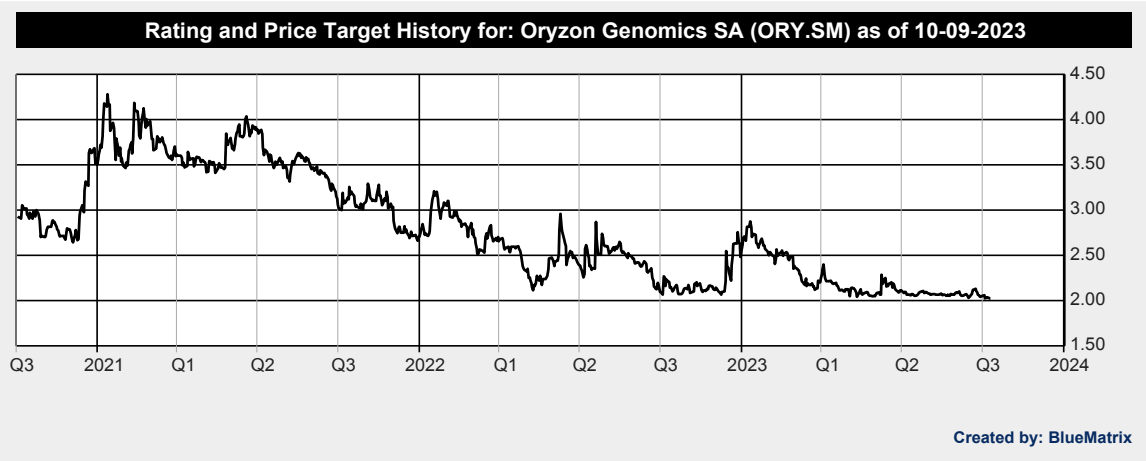
	2017A	2018A	2019A	2020A	2021A	1Q22	2Q22	3Q22	4Q22	2022A	1Q23A	2Q23A	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Global iadademstat revenue																	25,778	99,451	209,468	313,934	372,470	389,751
Global vafidemstat revenue																	98,463	342,237	520,351	615,106	684,577	721,921
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	4,264	4,477	4,701	17,814	21,377	25,653	28,218	29,629	29,925	30,224	30,526
G&A	4,502	2,993	3,176	3,484	5,529	1,343	1,520	659	1,249	4,771	1,223	1,096	1,107	1,118	4,544	6,816	12,269	18,403	20,243	22,268	23,381	24,550
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**	**5,360**	**5,584**	**5,819**	**22,358**	**28,193**	**43,341**	**63,687**	**84,813**	**101,183**	**113,211**	**119,680**
Operating income	**(10,845)**	**(11,482)**	**(15,823)**	**(17,075)**	**(20,647)**	**(5,571)**	**(5,686)**	**(4,933)**	**(6,282)**	**(22,472)**	**(5,595)**	**(5,360)**	**(5,584)**	**(5,819)**	**(22,358)**	**(28,193)**	**80,899**	**378,001**	**645,006**	**827,857**	**943,836**	**991,991**
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	4,054	2,000	2,000	12,269							
Net income (pretax)	**(5,186)**	**(3,339)**	**(4,301)**	**(5,269)**	**(8,137)**	**(1,745)**	**(1,792)**	**(685)**	**(1,589)**	**(5,811)**	**(1,380)**	**(1,306)**	**(3,584)**	**(3,819)**	**(10,089)**	**(28,193)**	**80,899**	**378,001**	**645,006**	**827,857**	**943,836**	**991,991**
Net financial & tax	1,047	(1,991)	(187)	(1,098)	(2,760)	67	(2,139)	(67)	863	(1,276)	392	(2,459)	(250)	(250)	(2,567)	(2,824)	(3,106)	94,500	161,251	206,964	235,959	247,998
Net income	**(6,233)**	**(1,348)**	**(4,114)**	**(4,171)**	**(5,377)**	**(1,812)**	**347**	**(618)**	**(2,452)**	**(4,535)**	**(1,772)**	**1,153**	**(3,334)**	**(3,569)**	**(7,522)**	**(25,369)**	**84,005**	**283,501**	**483,754**	**620,893**	**707,877**	**743,994**
EPS basic	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.10)**	**(0.03)**	**0.01**	**(0.01)**	**(0.05)**	**(0.08)**	**(0.03)**	**0.02**	**(0.06)**	**(0.06)**	**(0.13)**	**(0.38)**	**1.20**	**3.85**	**6.26**	**7.65**	**8.30**	**8.31**
EPS diluted	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.10)**	**(0.03)**	**0.01**	**(0.01)**	**(0.05)**	**(0.08)**	**(0.03)**	**0.02**	**(0.06)**	**(0.06)**	**(0.13)**	**(0.38)**	**1.00**	**3.23**	**5.29**	**6.52**	**7.13**	**7.18**
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	57,339	57,397	57,454	57,095	66,801	70,141	73,649	77,331	81,198	85,257	89,520
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	57,339	57,397	57,454	57,095	66,801	84,179	87,686	91,368	95,235	99,295	103,557

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

Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject company or companies and its or their securities. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

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 10/10/23	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**355**	**72.90**	**218**	**61.41**
Neutral [N]	**85**	**17.45**	**30**	**35.29**
Sell [S]	**2**	**0.41**	**1**	**50.00**
Under Review [UR]	**42**	**8.62**	**9**	**21.43**

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.

Ratings System Definitions - ROTH MKM employs a rating system based on the following:

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

ROTH Capital Partners, LLC expects to receive or intends to seek compensation for investment banking or other business relationships with the covered companies mentioned in this report in the next three months. The material, information and facts discussed in this report other than the information regarding ROTH Capital Partners, LLC and its affiliates, are from sources believed to be reliable, but are in no way guaranteed to be complete or accurate. This report should not be used