ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | September 16, 2022

Healthcare: Biotechnology **Company Update**

Oryzon Genomics SA | ORY.SM - €2.32 - MADRID | *Buy*

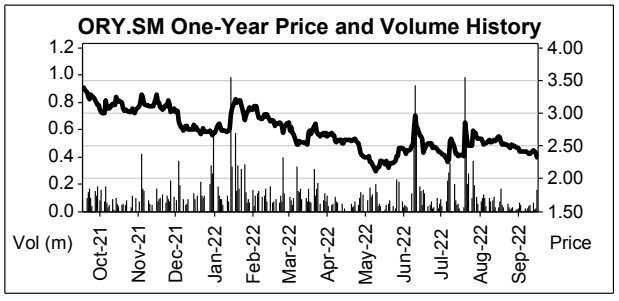
Stock Data	
52-Week Low - High	€2.04 - €3.41
Shares Out. (mil)	53.96
Mkt. Cap.(mil)	€125.20
3-Mo. Avg. Vol.	108,889
12-Mo.Price Target	€15.00
Cash (mil)	$31.6
Tot. Debt (mil)	$26.2

Revenue ($ millions)

Yr Dec	—2021—	—2022E—	—2023E—
		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	—2021—	—2022E—	—2023E—
		Curr	Curr
1Q	(0.04)A	(0.03)A	-
2Q	0.02A	0.01A	-
3Q	(0.03)A	(0.05)E	-
4Q	(0.04)A	(0.05)E	-
YEAR	(0.10)A	(0.14)E	(0.34)E
P/E	NM	NM	NM



ORY: Initial PORTICO Trial Blinded Safety Data Underscores Vafidemstat's Safety

ORY presented initial blinded safety data from the first 43 patients enrolled in its Phase 2b PORTICO trial evaluating vafidemstat in borderline personality disorder at the European Conference on Mental Health. In short, no serious or severe adverse reactions were reported, with 41 mostly mild adverse reactions reported in 12 patients (blinded, so unknown if vafidemstat or placebo), and with no reactions leading to treatment discontinuation or patient withdrawal. We look forward to results from an interim analysis in 1Q23.

- The blinded safety results were reported in an oral presentation at the European Conference on Mental Health and encompass data up to the June 30 cutoff date. For these initial 43 borderline personality disorder (BPD) patients, no serious or severe adverse reactions were reported, with 41 mostly mild adverse reactions reported in 12 patients (blinded, so unknown if vafidemstat or placebo patients), and with no reactions leading to treatment discontinuation or patient withdrawal. Adverse reactions are a subset of adverse events that are characterized as having a reasonable causal relationship to vafidemstat, with the remaining reported adverse events being less likely to have been caused by the drug. Regarding the broader adverse event count, there were a total of 74 reported in 17 patients, but again, with only 41 of them having a reasonable causal relationship to vafidemstat. Adverse reactions reported for more than one patient include tension headache (18 in 7 patients), dizziness (2 in 2 patients), platelet count reduction (3 in 3 patients), and subcutaneous hematoma (3 in 5 patients).
- The highly favorable initial PORTICO safety results data replicate the safety and tolerability observed in the prior seven vafidemstat clinical trials involving almost 400 people that received vafidemstat (about 300 patients and 87 healthy volunteers), the longest exposure of which was 24 months. In addition to the favorable safety from several prior trials, vafidemstat was also shown to cross the blood-brain barrier and in the REIMAGINE trial in BPD, the drug provided some patients with observable clinical benefit such as reduced aggression, improved BPD symptoms, and reduced suicidal ideation. We note that BPD patients have about a 10% rate of successful suicide, which is about 50 times higher than in the general population. We look forward to results from the interim analysis to be performed in 1Q23, which is when at least the first 90 patients are expected to complete at least two-thirds of the 14-week PORTICO dosing period.
- As a reminder, PORTICO is a multi-center, double-blind, randomized, and placebo-controlled trial in the E.U. (Spain, Germany, Serbia, and Bulgaria) and the U.S. having two primary independent endpoints: 1) to reduce agitation and aggression as per the Clinical Global Impression-Severity-Agitation/Aggression (CGI-S-A/A), and 2) an overall improvement of BPD as per the Borderline Personality Disorder Checklist (BPDCL). About 156 adult patients are expected to enroll in PORTICO, unless the interim analysis in 1Q23 determines that more patients are required due to excessive variability around the two primary endpoints.

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 $1.33 billion. 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 considered as the European leader in epigenetics. Oryzon has one of the strongest portfolios in the field, with two LSD1 inhibitors, iadademstat and vafidemstat, in Phase II clinical trials, and 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.

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

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	2017A	2018A	2019A	2020A	1Q21	2Q21	3Q21	4Q21	2021A	1Q22A	2Q22A	3Q22E	4Q22E	2022E	2023E
Global iadademstat revenue															
Global vafidemstat revenue															
Collaboration revenue	20														
Total revenue	**20**														
Cost of revenue															
R&D	6,363	8,489	12,647	13,591	4,278	2,928	3,982	3,930	15,118	4,228	4,166	4,458	4,770	17,621	22,908
G&A	4,502	2,993	3,176	3,484	1,302	1,200	1,070	1,957	5,529	1,343	1,520	1,566	1,613	6,041	7,854
Total operating expenses	**10,865**	**11,482**	**15,823**	**17,075**	**5,580**	**4,128**	**5,052**	**5,887**	**20,647**	**5,571**	**5,686**	**6,023**	**6,382**	**23,662**	**30,761**
Operating income	**(10,845)**	**(11,482)**	**(15,823)**	**(17,075)**	**(5,580)**	**(4,128)**	**(5,052)**	**(5,887)**	**(20,647)**	**(5,571)**	**(5,686)**	**(6,023)**	**(6,382)**	**(23,662)**	**(30,761)**
Other income (net)	5,659	8,143	11,522	11,805	3,536	2,256	3,252	3,466	12,510	3,826	3,894	3,000	3,000	13,720	6,000
Net income (pretax)	**(5,186)**	**(3,339)**	**(4,301)**	**(5,269)**	**(2,044)**	**(1,872)**	**(1,800)**	**(2,421)**	**(8,137)**	**(1,745)**	**(1,792)**	**(3,023)**	**(3,382)**	**(9,942)**	**(24,761)**
Net financial & tax	1,047	(1,991)	(187)	(1,098)	89	(2,823)	36	(62)	(2,760)	67	(2,139)	50	50	(1,972)	(2,169)
Net income	**(6,233)**	**(1,348)**	**(4,114)**	**(4,171)**	**(2,133)**	**951**	**(1,836)**	**(2,359)**	**(5,377)**	**(1,812)**	**347**	**(3,073)**	**(3,432)**	**(7,970)**	**(22,592)**
EPS basic	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.04)**	**0.02**	**(0.03)**	**(0.04)**	**(0.10)**	**(0.03)**	**0.01**	**(0.05)**	**(0.05)**	**(0.14)**	**(0.34)**
EPS diluted	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.04)**	**0.02**	**(0.03)**	**(0.04)**	**(0.10)**	**(0.03)**	**0.01**	**(0.05)**	**(0.05)**	**(0.14)**	**(0.34)**
Basic shares outstanding	31,711	34,638	41,589	49,235	52,762	52,762	52,762	52,762	52,762	52,762	52,762	63,314	63,377	58,054	66,546
Diluted shares outstanding	31,711	34,638	41,565	49,235	52,762	52,762	52,762	52,762	52,762	52,762	52,762	63,314	63,377	58,054	66,546

Source: SEC filings, company press releases, and ROTH Capital Partners

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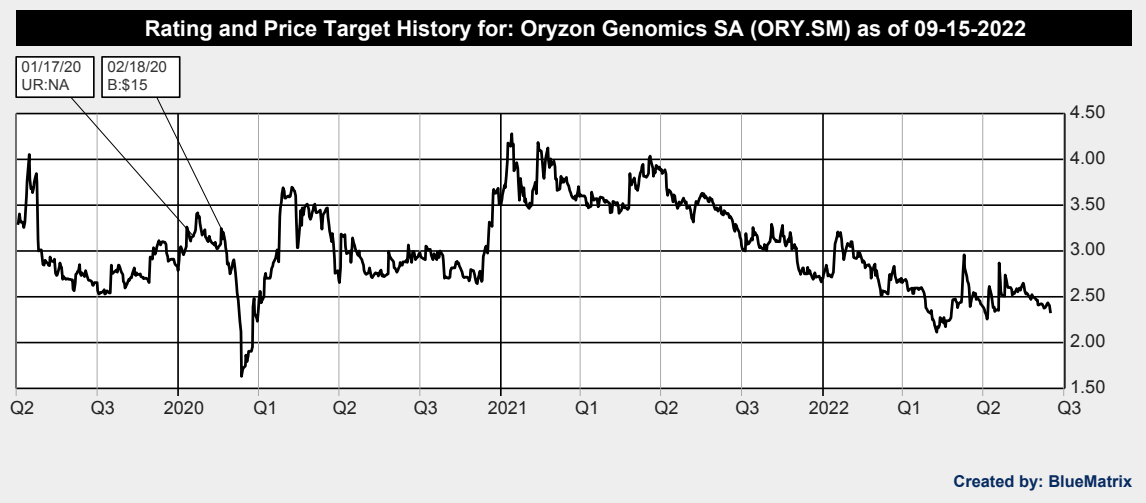
Disclosures:

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 09/16/22	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**334**	**82.47**	**220**	**65.87**
Neutral [N]	**54**	**13.33**	**30**	**55.56**
Sell [S]	**2**	**0.49**	**1**	**50.00**
Under Review [UR]	**15**	**3.70**	**8**	**53.33**

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

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