ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | June 15, 2021

Healthcare: Biotechnology **Company Update**

Oryzon Genomics SA | ORY.SM - €3.80 - MADRID | *Buy*

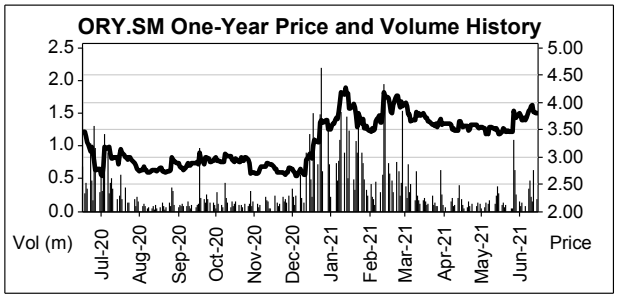
Stock Data	
52-Week Low - High	€2.61 - €4.40
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€201.64
3-Mo. Avg. Vol.	184,600
12-Mo.Price Target	€15.00
Cash (mil)	$45.2
Tot. Debt (mil)	$18.2

Revenue ($ millions)

Yr Dec	—2020—	—2021E—	—2022E—
		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	—2020—	—2021E—	—2022E—
		Curr	Curr
1Q	(0.03)A	(0.04)A	-
2Q	0.00A	(0.05)E	-
3Q	(0.02)A	(0.05)E	-
4Q	(0.03)A	(0.06)E	-
YEAR	(0.08)A	(0.20)E	(0.26)E
P/E	NM	NM	NM



ORY: FDA Clears IND for U.S. Enrollment Into Phase 2b PORTICO Trial in BPD

The FDA has approved the Phase 2b PORTICO trial's IND, a multicenter, double-blind, randomized, placebo-controlled trial to evaluate vafidemstat in borderline personality disorder (BPD) that will enroll about 160 patients at 15-20 sites in Europe and the U.S., with European enrollment already underway. PORTICO intends to demonstrate that vafidemstat can safely reduce agitation and aggression and cause an overall improvement in BPD.

- PORTICO's two primary objectives are to demonstrate that vafidemstat can reduce agitation and aggression and improve the overall disease condition in patients with BPD. ORY now has FDA confirmation that its IND for the multicenter, double-blind, 1:1 randomized, placebo-controlled Phase 2b trial is now open to include U.S. patients among its projected total enrollment of 160. An interim analysis will be conducted to adjust, if needed, the final number of patients needed to assess efficacy. Inclusion of U.S. patients will speed the trial as well as facilitate FDA dialogue regarding next clinical steps for vafidemstat in BPD. BPD is a severe mental disorder affecting about 1.6% of the general population, with patients experiencing emotional instability, impulsivity, irrational beliefs and distorted perception, and intense but unstable interpersonal relationships. Agitation, aggression, self-aggression and suicidality are also common in BPD, and there is no currently approved treatment.
- As a reminder of what vafidemstat delivered in Phase 2a, REIMAGINE was an open-label trial treating agitation and aggression in 30 patients (11 ADHD, 7 ASD, and 12 BPD) with daily vafidemstat doses of 1.2mg for eight weeks. Vafidemstat was safe and well-tolerated, with no serious adverse events and no patient withdrawals due to adverse events. Per protocol, efficacy for all analyses (defined as the 23 of the 30 patients that completed all eight weeks of treatment) was measured using the clinical global impression of severity and improvement scales (CGI-S and CGII), and the 4-item neuropsychiatric inventory agitation-aggression (NPIA/A) scale, with overall functioning assessed using the 12-item total NPI scale and individual disease-specific scales. Vafidemstat produced statistically significant reductions in CGI-S, CGI-I, NPI A/A, and total NPI, both in the 30-patient aggregated data, and in each disease group, as well as statistically improved patient scores in each disease specific scale (BPDCL and C-SSRS scales for BPD, and ADHD-RS for ADHD. There were also statistically significant efficacy correlations (linear regression analyses) for total NPI versus BPDCL, NPI-A/A versus CGI-I, and NPI-A/A versus CGI-S, demonstrating the drug's consistency of benefit.
- We believe that these results demonstrate that vafidemstat is a viable therapeutic option for treating agitation and aggression in all three of these psychiatric diseases, in addition to treating disease specific features, and has the potential to do so with less onerous adverse effects than currently used treatments.

VALUATION

Our 12-month price target of €15, 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 about $1 billion. We arrive at this valuation by only projecting future revenue from vafidemstat in borderline personality disorder and iadademstat in AML and SCLC. We view our valuation to be conservative given that it excludes revenue from vafidemstat in ASD, AD, and ADHD. Commercial success outside the three financially modeled indications would serve as upside to our valuation. We believe that ORY.SM has prudently selected areas of unmet need and therefore market demand.

Factors that could impede shares of ORY.SM from achieving our price target include vafidemstat and iadademstat failing to generate statistically significant Phase 3 results in AD and AML, respectively. Also, regulatory agencies could fail to approve these drugs even if both Phase 3 programs 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 a European champion in epigenetics. Oryzon has one of the strongest portfolios in the field. Oryzon's LSD1 program has rendered clinical stage vafidemstat and iadademstat. In addition, Oryzon has ongoing programs for developing inhibitors against other epigenetic targets. Oryzon has a strong technological platform for biomarker identification and performs biomarker and target validation for a variety of malignant and neurodegenerative diseases. Oryzon has offices in Spain and the United States

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

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	2017A	2018A	2019A	1Q20	2Q20	3Q20	4Q20	2020A	1Q21A	2Q21E	3Q21E	4Q21E	2021E	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	4,316	2,731	2,279	3,376	13,591	4,278	4,492	4,716	4,952	18,439	23,048	28,810
G&A	4,502	2,993	3,176	846	906	733	776	3,484	1,302	1,107	1,118	1,129	4,655	4,888	11,243
Total operating expenses	**10,865**	**11,482**	**15,823**	**5,162**	**3,637**	**3,012**	**4,152**	**17,075**	**5,580**	**5,599**	**5,834**	**6,081**	**23,094**	**27,937**	**40,053**
Operating income	**(10,845)**	**(11,482)**	**(15,823)**	**(5,162)**	**(3,637)**	**(3,012)**	**(4,152)**	**(17,075)**	**(5,580)**	**(5,599)**	**(5,834)**	**(6,081)**	**(23,094)**	**(27,937)**	**(40,053)**
Other income (net)	5,659	8,143	11,522	4,013	2,312	1,787	2,904	11,805	3,536	2,800	2,800	2,800	11,936	12,533	
Net income (pretax)	**(5,186)**	**(3,339)**	**(4,301)**	**(1,149)**	**(1,324)**	**(1,225)**	**(1,248)**	**(5,269)**	**(2,044)**	**(2,799)**	**(3,034)**	**(3,281)**	**(11,158)**	**(15,404)**	**(40,053)**
Net financial & tax	1,047	(1,991)	(187)	116	(1,102)	(155)	143	(1,098)	89	(100)	(100)	(100)	(211)	(300)	
Net income	**(6,233)**	**(1,348)**	**(4,114)**	**(1,265)**	**(222)**	**(1,070)**	**(1,391)**	**(4,171)**	**(2,133)**	**(2,699)**	**(2,934)**	**(3,181)**	**(10,947)**	**(15,104)**	**(40,053)**
EPS basic	**(0.20)**	**(0.04)**	**(0.10)**	**(0.03)**	**(0.00)**	**(0.02)**	**(0.03)**	**(0.08)**	**(0.04)**	**(0.05)**	**(0.05)**	**(0.06)**	**(0.20)**	**(0.26)**	**(0.67)**
EPS diluted	**(0.20)**	**(0.04)**	**(0.10)**	**(0.03)**	**(0.00)**	**(0.02)**	**(0.03)**	**(0.08)**	**(0.04)**	**(0.05)**	**(0.05)**	**(0.06)**	**(0.20)**	**(0.26)**	**(0.67)**
Basic shares outstanding	31,711	34,638	41,589	45,489	45,808	52,762	52,762	49,235	52,762	53,289	53,822	54,360	53,558	57,078	59,932
Diluted shares outstanding	31,711	34,638	41,565	45,489	45,808	52,762	52,762	49,235	52,762	53,289	53,822	54,360	53,558	57,078	59,932

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

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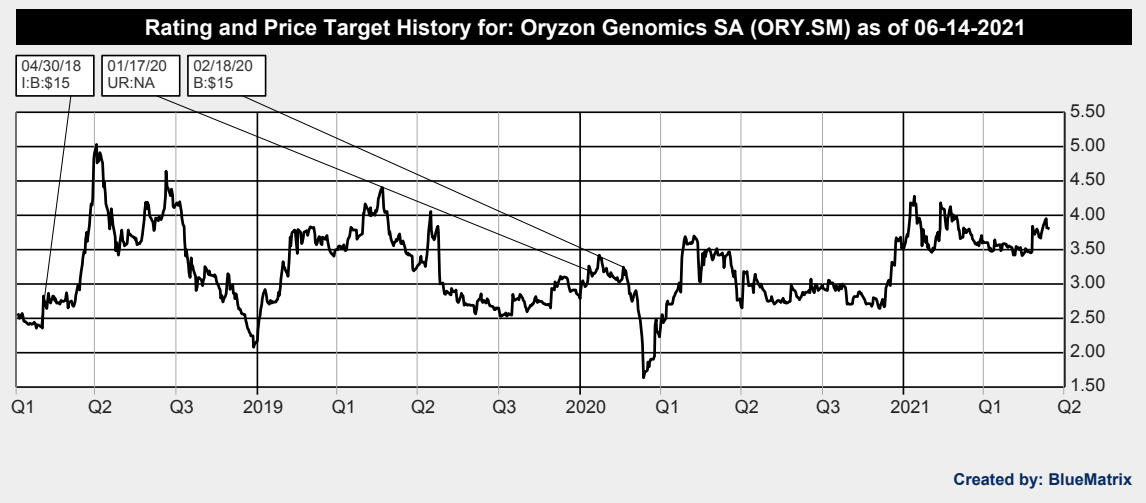
Disclosures:



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 06/14/21	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**298**	**76.21**	**191**	**64.09**
Neutral [N]	**52**	**13.30**	**26**	**50.00**
Sell [S]	**1**	**0.26**	**1**	**100.00**
Under Review [UR]	**39**	**9.97**	**27**	**69.23**

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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