ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | March 15, 2021

Healthcare: Biotechnology

Company Update

Oryzon Genomics SA | ORY.SM - €3.75 - MADRID | *Buy*

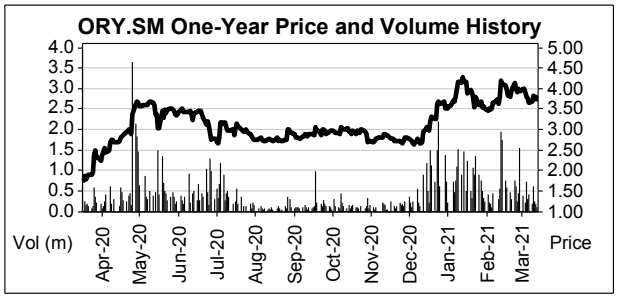
Stock Data	
52-Week Low - High	€1.48 - €4.40
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€198.72
3-Mo. Avg. Vol.	722,871
12-Mo.Price Target	€15.00
Cash (mil)	$48.6
Tot. Debt (mil)	$16.2

EPS $

Yr Dec	—2020—	—2021E—	—2022E—
		Curr	Curr
1Q	(0.03)A	(0.03)E	-
2Q	0.00A	(0.03)E	-
3Q	(0.02)A	(0.03)E	-
4Q	(0.03)A	(0.04)E	-
YEAR	(0.08)A	(0.13)E	(0.18)E
P/E	NM	NM	NM

Revenue ($ millions)

Yr Dec	—2020—	—2021E—	—2022E—
		Curr	Curr
1Q	0.0A	0.0E	-
2Q	0.0A	0.0E	-
3Q	0.0A	0.0E	-
4Q	0.0A	0.0E	-
YEAR	0.0A	0.0E	0.0E



ORY.SM: Successful Pre-IND Meeting with FDA for Vafidemstat in BPD

ORY's constructive pre-IND meeting allows the company to file an IND in the U.S. to make U.S. trial sites a part of its PORTICO Phase 2b trial of its selective LSD1 inhibitor vafidemstat in borderline personality disorder (BPD). The trial is already approved in Europe by the Spanish Medicinal Agency (AEMPS) and is expected to enroll 156 BPD patients randomized to either vafidemstat or placebo. PORTICO was planned after positive results from ORY's REIMAGINE Phase 2a trial in three indications.

- ORY's successful pre-IND meeting for vafidemstat in BPD allows the company to confidently file an IND for its Phase 2b PORTICO so the trial can include U.S. as well as E.U. sites. The IND will be filed in the next few weeks with the expectation that ORY can start enrolling U.S. patients in 1H21. PORTICO is a multicenter, double-blind, randomized, placebo-controlled Phase 2b trial having primary objectives of reduction of aggression/agitation and overall improvement of BPD. Although initial enrollment is to be 156 patients (78 per arm), the trial has an adaptive design with a pre-defined interim analysis to adjust the sample size in case of excessive variability around the endpoints or an unexpectedly high placebo rate.
- We remind investors of the successful prior REIMAGINE Phase 2a trial results, where the drug reduced agitation/aggression in patients with attention deficit hyperactivity disorder (ADHD), autism spectrum disorder (ASD) and BPD after two months of treatment. 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.
- Vafidemstat also performed well in the Phase 2a REIMAGINE-AD trial, where the drug reduced agitation/aggression in patients with severe and moderate Alzheimer's disease after six months of treatment. Vafidemstat has proven safe and well-tolerated in several trials in a total of about 300 patients, some of whom took the drug continuously for 18 months.

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 almost $1.1 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 of 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	1Q21E	2Q21E	3Q21E	4Q21E	2021E	2022E
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	3,545	3,722	3,908	4,104	15,279	19,098
G&A	4,502	2,993	3,176	846	906	733	776	3,484	792	807	823	840	3,262	3,425
Total operating expenses	**10,865**	**11,482**	**15,823**	**5,162**	**3,637**	**3,012**	**4,152**	**17,075**	**4,336**	**4,529**	**4,732**	**4,944**	**18,541**	**22,524**
Operating income	**(10,845)**	**(11,482)**	**(15,823)**	**(5,162)**	**(3,637)**	**(3,012)**	**(4,152)**	**(17,075)**	**(4,336)**	**(4,529)**	**(4,732)**	**(4,944)**	**(18,541)**	**(22,524)**
Other income (net)	5,659	8,143	11,522	4,013	2,312	1,787	2,904	11,805	2,800	2,800	2,800	2,800	11,200	11,760
Net income (pretax)	**(5,186)**	**(3,339)**	**(4,301)**	**(1,149)**	**(1,324)**	**(1,225)**	**(1,248)**	**(5,269)**	**(1,536)**	**(1,729)**	**(1,932)**	**(2,144)**	**(7,341)**	**(10,764)**
Net financial & tax	1,047	(1,991)	(187)	116	(1,102)	(155)	143	(1,098)	(100)	(100)	(100)	(100)	(400)	(300)
Net income	**(6,233)**	**(1,348)**	**(4,114)**	**(1,265)**	**(222)**	**(1,070)**	**(1,391)**	**(4,171)**	**(1,436)**	**(1,629)**	**(1,832)**	**(2,044)**	**(6,941)**	**(10,464)**
EPS basic	**(0.20)**	**(0.04)**	**(0.10)**	**(0.03)**	**(0.00)**	**(0.02)**	**(0.03)**	**(0.08)**	**(0.03)**	**(0.03)**	**(0.03)**	**(0.04)**	**(0.13)**	**(0.18)**
EPS diluted	**(0.20)**	**(0.04)**	**(0.10)**	**(0.03)**	**(0.00)**	**(0.02)**	**(0.03)**	**(0.08)**	**(0.03)**	**(0.03)**	**(0.03)**	**(0.04)**	**(0.13)**	**(0.18)**
Basic shares outstanding	31,711	34,638	41,589	45,489	45,808	52,762	52,762	49,235	53,289	53,822	54,360	54,904	54,094	57,649
Diluted shares outstanding	31,711	34,638	41,565	45,489	45,808	52,762	52,762	49,235	53,289	53,822	54,360	54,904	54,094	57,649

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

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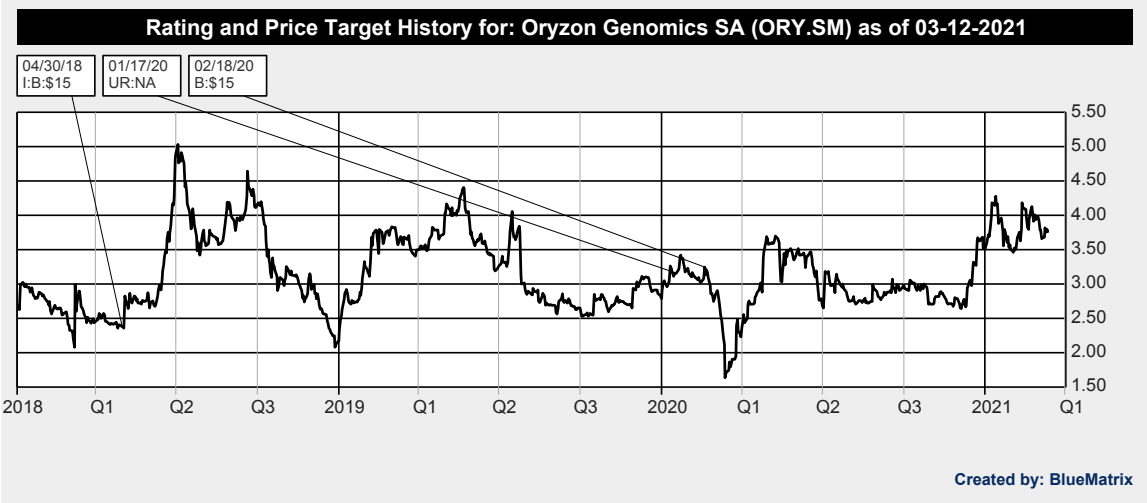
Disclosures:



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 03/15/21	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**315**	**79.55**	**196**	**62.22**
Neutral [N]	**51**	**12.88**	**22**	**43.14**
Sell [S]	**2**	**0.51**	**1**	**50.00**
Under Review [UR]	**28**	**7.07**	**20**	**71.43**

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 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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