ROTH Capital Partners

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

Sales (800) 933-6830, **Trading** (800) 933-6820

COMPANY NOTE | EQUITY RESEARCH | February 23, 2021

Healthcare: Biotechnology

Oryzon Genomics SA | ORY.SM - €4.13 - MADRID | *Buy*

Company Update
Estimates Changed

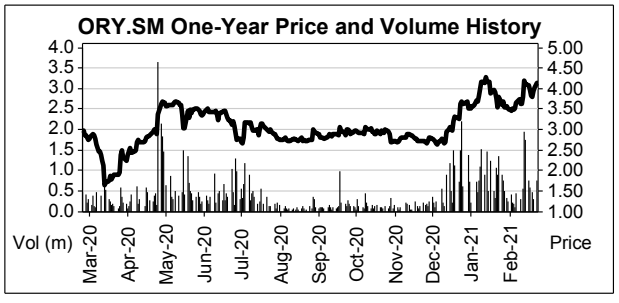
Stock Data	
52-Week Low - High	€1.48 - €4.40
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€218.88
3-Mo. Avg. Vol.	647,450
12-Mo.Price Target	€15.00
Cash (mil)	$48.6
Tot. Debt (mil)	$16.2

EPS $

Yr Dec	—2020—	—2021E—		—2022E—
		Curr	Prev	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	(0.35)E	(0.18)E
P/E	NM	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 4Q20: Clinical Programs Progressing Well Despite Pandemic, Cash Into 1H23

ORY.SM released 4Q20 results, showing a $48.6 million cash balance that should fund operations into 1H23, as per our projections, and also reviewed its current clinical programs.

- **Iadademstat.** At ASH in 4Q20, ORY released additional positive results from its ongoing Phase 2 ALICE trial investigating iadademstat in combination with azacitidine in AML, showing an 85% ORR (11/13), of which 64% (7/11) 7CR/CRi. Furthermore, 86% of patients having a CR/CRi had durable responses lasting over six months, with the longest remission lasting 690 days and counting. Several patients had also improved or overcome their dependency on blood transfusions, and the combination continued to demonstrate its favorable safety profile. We expect results from about 18-20 evaluable patients at EHA in 2Q21, and for ORY to increase its overall percentage of U.S, clinical trial sites. We also expect combination therapy with checkpoint inhibitor for the drug.

- **Vafidemstat.** ORY is cleared to begin its Phase 2b trial (PORTICO; n=156; multi-center, double-blind, 1:1 randomized, placebo-controlled) trial in Spain with vafidemstat in patients with BPD, we believe that clearance in the U.S. is imminent, and the trial will include at least two other countries in the E.U. The two primary endpoints are reduction of aggression/ agitation and overall BPD improvement, and an interim analysis will occur to adjust the sample size if necessary. ORY also began a precision medicine collaboration in schizophrenia with Columbia University in New York to perform an exhaustive functional psychometric characterization of individuals carrying mutations in the *Setd1a* gene to justify a future precision psychiatry trial with vafidemstat in SETD1A-associated psychiatric disorder patients harboring this key schizophrenia susceptibility gene. Regarding Phelan-McDermid Syndrome (PMS), initial patients have been monitored for functional impairment using a set of diverse validated scales and this analysis should conclude by 1Q21, thereby paving the way for a clinical trial with vafidemstat. ORY is also preparing for a Phase 2b trial (EVOLUTION) with vafidemstat in schizophrenia, to be performed in collaboration with Barcelona's Research Institute of Vall d'Hebrón. Finally for vafidemstat, ORY continues to rapidly enroll severe COVID-19 patients in its Phase 2 trial (ESCAPE; n=at least 40) to assess vafidemstat's utility in combination with standard of care to prevent progression to acute respiratory distress syndrome.

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)

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

	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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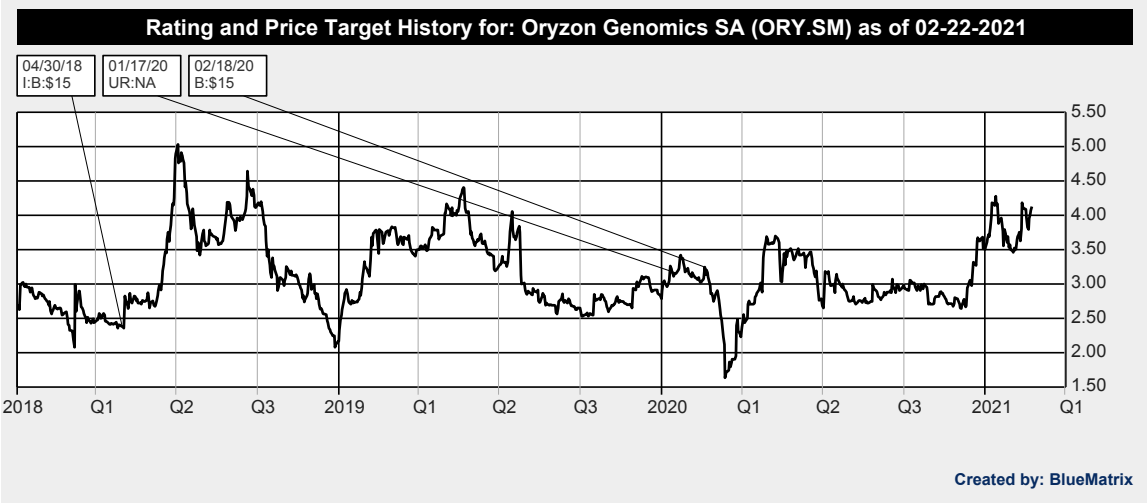
Disclosures:



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 02/23/21	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**308**	**78.57**	**191**	**62.01**
Neutral [N]	**52**	**13.27**	**22**	**42.31**
Sell [S]	**4**	**1.02**	**3**	**75.00**
Under Review [UR]	**28**	**7.14**	**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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