ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | May 07, 2021

Healthcare: Biotechnology

Company Update
Estimates Changed

Oryzon Genomics SA | ORY.SM - €3.42 - MADRID | *Buy*

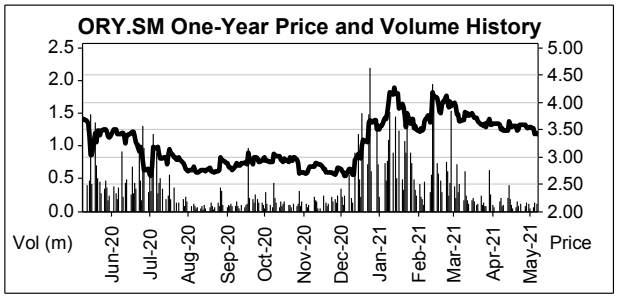
Stock Data	
52-Week Low - High	€2.61 - €4.40
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€181.48
3-Mo. Avg. Vol.	320,576
12-Mo.Price Target	€15.00
Cash (mil)	$45.2
Tot. Debt (mil)	$16.2

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	Prev	Curr	Prev
1Q	(0.03)A	(0.04)A	(0.03)E	-	-
2Q	0.00A	(0.05)E	(0.03)E	-	-
3Q	(0.02)A	(0.05)E	(0.03)E	-	-
4Q	(0.03)A	(0.06)E	(0.04)E	-	-
YEAR	(0.08)A	(0.20)E	(0.13)E	(0.26)E	(0.18)E
P/E	NM	NM	NM	NM	NM



ORY 1Q21: Clinical Programs Progressing Well Despite Pandemic, Cash into 1Q23

ORY released 1Q21 results, showing a $45.2 million cash balance that should fund operations into 1Q23, 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 85.7% ORR, of which 58.3% were CR/CRi. Furthermore, four patients with CR/CRi had durable responses lasting more than one year, with the longest remission lasting more than two years and counting. Of patients on therapy for more than 120 days, 40% have 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 trials with checkpoint inhibitors and iadademstat to be conducted in AML and solid tumors.
- **Vafidemstat.** ORY started enrolling patients in 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 a U.S. IND filing will occur in 2Q21, and that PORTICO 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 is collaborating with the Seaver Autism Center to explore the effects of vafidemstat in animal models defective for Shank3, which recapitulate many symptoms of a variety of autism known as Phelan-McDermid Syndrome (PMS). A pilot study is ongoing with INGEMM to phenotypically characterize up to 40 PMS patients, and results are expected in 3Q21 that should inform a future clinical trial with vafidemstat.
- ORY is also preparing for a Phase 2b trial (EVOLUTION) to evaluate vafidemstat's efficacy on negative symptoms and cognition in schizophrenia. The trial will be conducted in collaboration with Barcelona's Research Institute of Vall d'Hebrón and should start dosing patients in 2Q21.
- ORY has completed enrollment of severe COVID-19 patients in its Phase 2 trial (ESCAPE; n=60) to assess vafidemstat's utility in combination with standard of care to prevent progression to acute respiratory distress syndrome. The data are being analyzed and preliminary results are expected in 2Q21.
- ORY also began a precision medicine collaboration in schizophrenia with Columbia University in New York to perform an exhaustive functional psychometric characterization of up to 60 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. Results of this analysis are expected in 3Q21.

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 aboutt $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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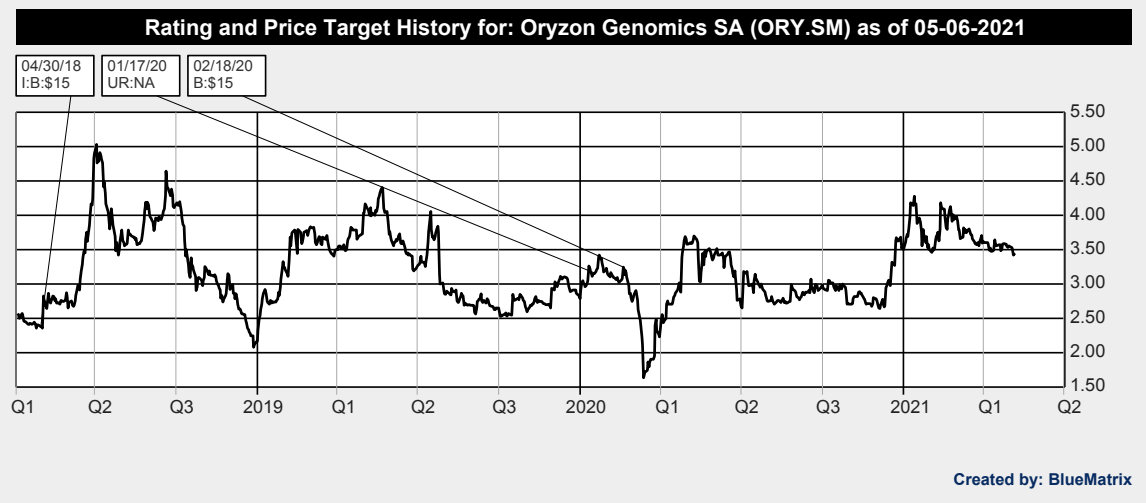
Disclosures:



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 05/07/21	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**299**	**76.67**	**194**	**64.88**
Neutral [N]	**51**	**13.08**	**23**	**45.10**
Sell [S]	**1**	**0.26**	**1**	**100.00**
Under Review [UR]	**39**	**10.00**	**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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