ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | July 30, 2021

Healthcare: Biotechnology

Company Update
Estimates Changed

Oryzon Genomics SA | ORY.SM - €3.53 - MADRID | *Buy*

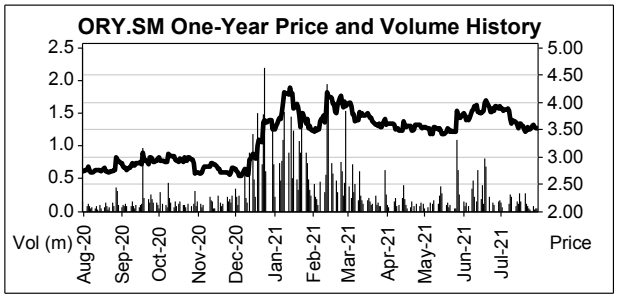
Stock Data	
52-Week Low - High	€2.61 - €4.40
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€187.31
3-Mo. Avg. Vol.	193,907
12-Mo.Price Target	€15.00
Cash (mil)	$40.1
Tot. Debt (mil)	$16.1

Revenue ($ millions)

Yr Dec	—2020—	—2021E—	—2022E—
		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	—2020—	—2021E—		—2022E—	
		Curr	Prev	Curr	Prev
1Q	(0.03)A	(0.04)A	(0.04)A	-	-
2Q	0.00A	0.02A	(0.05)E	-	-
3Q	(0.02)A	(0.03)E	(0.05)E	-	-
4Q	(0.03)A	(0.04)E	(0.06)E	-	-
YEAR	(0.08)A	(0.10)E	(0.20)E	(0.19)E	(0.26)E
P/E	NM	NM	NM	NM	NM



ORY 2Q21: Solid Clinical Progress, Cash Funds Operations Well Into 1Q23

ORY released 2Q21 results, showing a $40.1 million cash balance that should fund operations into 1Q23, as per our projections and also reviewed its current clinical programs.

- In a recent 2021 EHA poster, ORY released updated positive results (83% ORR, 67% CR/CRi) from its ongoing single-arm Phase 2a ALICE trial of iadademstat/azacitidine combination therapy in 27 elderly or unfit treatment-naive AML patients, of whom 18 were evaluable for per protocol efficacy. The 62% (15/24) ORR rate in the intent-to-treat population was also highly encouraging, considering the historical azacitidine data. Of particular note was one patient with a difficult to treat M5b (monocytic) AML that achieved CRi in 29 days. We starkly contrast the robust ORR with the historical ORR of 28% in this fragile population when taking standard of care azacitidine monotherapy (19% CR/CRi and 9% PR), underscoring a highly likely synergy between the two drugs. There was a rapid average onset of response (29 days) and five patients responded for >1 year, with the longest remission being 858 days and counting. Also critical is that the therapy continued to show its favorable safety profile, which is important given the fragility of those enrolled. New combination therapy trials in AML and solid tumors are planned, with more details coming in 2H21.
- 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 156 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. 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. Agitation, aggression, self-aggression and suicidality are common in BPD, and there is no currently approved treatment.
- ORY also received CTA approval in Spain to conduct a Phase 2b trial with vafidemstat in schizophrenia, called EVOLUTION, and intended to evaluate vafidemstat in the negative symptoms and cognitive impairment that is associated with the disease. Recruitment should start in the next month or two and is partially funded with public capital from the Spanish Ministry of Science and Innovation.
- Lastly, in its latest ECCMID e-poster, ORY presented preliminary Phase 2 ESCAPE trial data, highlighting vafidemstat's anti-inflammatory effect in hospitalized, severe COVID-19. We note that a vafidemstat dose of 2.4mg/day for five days durably and substantially occupied its target LSD1, and was well tolerated. Rapidly improved hospital management of serious COVID-19 over the May 2020 to March 2021 enrollment period likely led to the miss of the mortality primary endpoint.

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 $913 million. 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	2Q21A	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	2,928	3,367	3,872	14,445	18,057	23,474
G&A	4,502	2,993	3,176	846	906	733	776	3,484	1,302	1,200	1,212	1,224	4,938	5,185	9,333
Total operating expenses	**10,865**	**11,482**	**15,823**	**5,162**	**3,637**	**3,012**	**4,152**	**17,075**	**5,580**	**4,128**	**4,579**	**5,096**	**19,384**	**23,242**	**32,807**
Operating income	**(10,845)**	**(11,482)**	**(15,823)**	**(5,162)**	**(3,637)**	**(3,012)**	**(4,152)**	**(17,075)**	**(5,580)**	**(4,128)**	**(4,579)**	**(5,096)**	**(19,384)**	**(23,242)**	**(32,807)**
Other income (net)	5,659	8,143	11,522	4,013	2,312	1,787	2,904	11,805	3,536	2,256	2,800	2,800	11,392	11,962	
Net income (pretax)	**(5,186)**	**(3,339)**	**(4,301)**	**(1,149)**	**(1,324)**	**(1,225)**	**(1,248)**	**(5,269)**	**(2,044)**	**(1,872)**	**(1,779)**	**(2,296)**	**(7,992)**	**(11,280)**	**(32,807)**
Net financial & tax	1,047	(1,991)	(187)	116	(1,102)	(155)	143	(1,098)	89	(2,823)	(100)	(100)	(2,934)	(300)	
Net income	**(6,233)**	**(1,348)**	**(4,114)**	**(1,265)**	**(222)**	**(1,070)**	**(1,391)**	**(4,171)**	**(2,133)**	**951**	**(1,679)**	**(2,196)**	**(5,058)**	**(10,980)**	**(32,807)**
EPS basic	**(0.20)**	**(0.04)**	**(0.10)**	**(0.03)**	**(0.00)**	**(0.02)**	**(0.03)**	**(0.08)**	**(0.04)**	**0.02**	**(0.03)**	**(0.04)**	**(0.10)**	**(0.19)**	**(0.55)**
EPS diluted	**(0.20)**	**(0.04)**	**(0.10)**	**(0.03)**	**(0.00)**	**(0.02)**	**(0.03)**	**(0.08)**	**(0.04)**	**0.02**	**(0.03)**	**(0.04)**	**(0.10)**	**(0.19)**	**(0.55)**
Basic shares outstanding	31,711	34,638	41,589	45,489	45,808	52,762	52,762	49,235	52,762	52,762	53,289	53,822	53,159	56,513	59,339
Diluted shares outstanding	31,711	34,638	41,565	45,489	45,808	52,762	52,762	49,235	52,762	52,762	53,289	53,822	53,159	56,513	59,339

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

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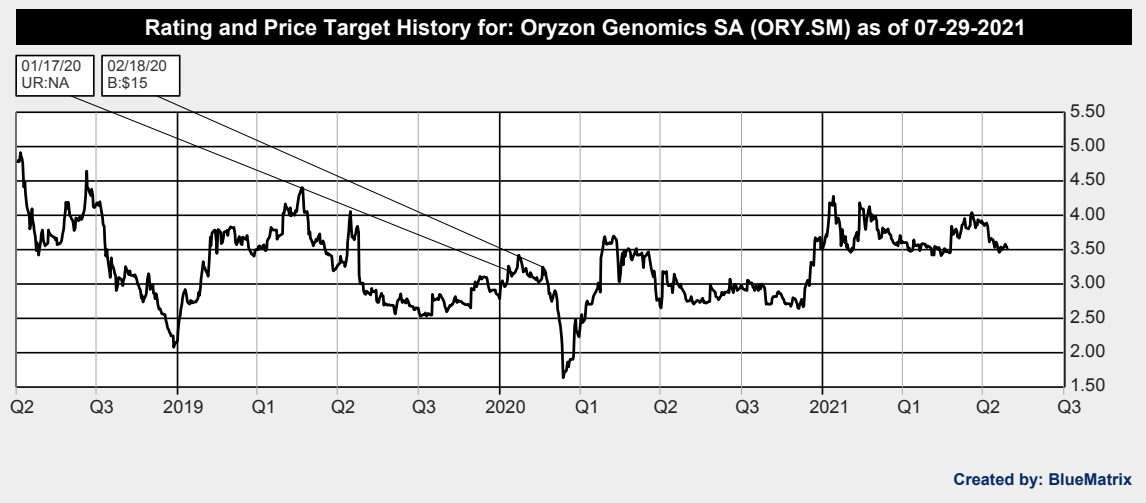
Disclosures:



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 07/30/21	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**315**	**77.78**	**206**	**65.40**
Neutral [N]	**51**	**12.59**	**26**	**50.98**
Sell [S]	**1**	**0.25**	**1**	**100.00**
Under Review [UR]	**38**	**9.38**	**27**	**71.05**

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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