ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | May 12, 2020

Healthcare: Biotechnology

Oryzon Genomics SA | ORY.SM - €3.65 - MADRID | *Buy*

Company Update

Estimates Changed

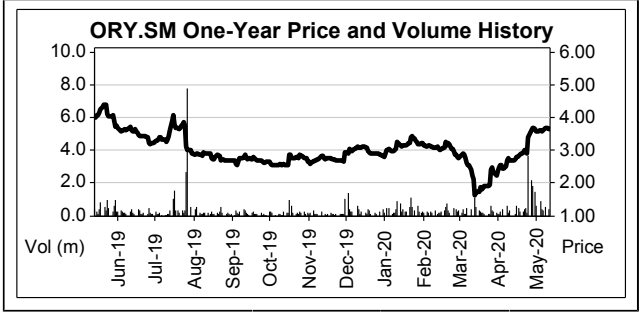
Stock Data	
52-Week Low - High	€1.48 - €4.47
Shares Out. (mil)	45.79
Mkt. Cap.(mil)	€167.13
3-Mo. Avg. Vol.	461,482
12-Mo.Price Target	€15.00
Cash (mil)	$32.3
Tot. Debt (mil)	$13.2

EPS $

Yr Dec	—2019—	—2020E—		—2021E—	
		Curr	Prev	Curr	Prev
1Q	(0.04)A	(0.03)A	(0.10)E	-	-
2Q	(0.02)A	(0.11)E	(0.10)E	-	-
3Q	(0.02)A	(0.12)E	(0.11)E	-	-
4Q	(0.02)A	(0.12)E	(0.11)E	-	-
YEAR	(0.10)A	(0.38)E	(0.42)E	(0.56)E	(0.51)E
P/E	NM	NM	NM	NM	NM

Revenue ($ millions)

Yr Dec	—2019—	—2020E—	—2021E—
		Curr	Curr
1Q	0.0A	0.0A	0.0E
2Q	0.0A	0.0E	0.0E
3Q	0.0A	0.0E	0.0E
4Q	0.0A	0.0E	0.0E
YEAR	0.0A	0.0E	0.0E



ORY.SM: Still Relatively Minor Covid-19 Related Clinical Delays - Reports 1Q20

ORY.SM reported 1Q20 results and gave clinical updates on its iadademstat and vafidemstat programs. The Covid-19 related clinical delays discussed were all previously disclosed last month. ORY.SM reported cash of $32.3 million at the end of 1Q20, enough to fund operations through 2021, as per our projections.

- **Covid-19 impact.** ORY.SM has already disclosed that the Covid-19 pandemic has impacted its clinical activities, specifically that it has not canceled or postponed recruitment in ongoing trials, but that it is postponing the start of its Phase 2b vafidemstat trial, named PORTICO, in agitation-aggression in borderline personality disorder until lock-down conditions are scaled back. To assist in fighting SARS-CoV2, ORY.SM started a Phase 2 trial, named ESCAPE, in severe Covid-19 patients to improve their condition by preventing ARDS.
- **Iadademstat update.** ORY.SM reported positive efficacy results at ASH 2019 from its Phase 2 trial, named ALICE, testing iadademstat in AML, and the trial continues, with the company anticipating that visits, evaluations, and recruitment will progressively return to normal in the next few weeks as lock-downs ease, and we expect ORY.SM to present new efficacy data at EHA later in 2Q20. Also, positive preliminary efficacy results from Part 1 in the CLEPSIDRA Phase 2 trial in second-line SCLC were presented at ESMO 2019, and once the company obtains the necessary safety data regarding hematological toxicity, and finalizing recruitment, it will present new efficacy and safety data at ESMO in 2H20.
- **Vafidemstat update.** In REIMAGINE-AD, we highlight the reduction of aggression as per CGI-I scale ($p<0.05$), the reduction of aggression as per CMAI scale ($p<0.05$), the reduction of aggression as per NPI 4-item Agitation/Aggression subscale ($p<0.05$ for both severity x frequency and emotional distress), the global improvement on the NPI total score ($p<0.05$ for both severity x frequency and emotional distress), and the global improvement on the caregiver burden as measured by the ZBI scale ($p<0.05$).

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Preliminary results from the ongoing Phase-2a trial in mild and moderate AD treated for six months in Europe (ETHERAL-EU) were also presented at AAT-AD/PD, and while six months of therapy showed that vafidemstat was safe and well tolerated, with significant reduction in YKL40, a CSF biomarker of inflammation for drug versus placebo (p=0.007 for all patients), preliminary analysis of ADASCog showed no significant differences between groups, thereby supporting ORY.SM's decision to conduct the next AD trials specifically using endpoints of agitation-aggression, especially given the positive results in ASD, BPD, and ADHD. The ETHERAL_US arm of the trial continues, and we look forward to full six-month ETHERAL trial data at AAIC-2020 in early 3Q20.

VALUATION

Our 12-month price target of €15, is based on a DCF analysis using a 40% discount rate that is applied to all cash flows and the terminal value, which is based on a 5x multiple of our projected 2030 operating income of $1.4 billion. We arrive at this valuation by only projecting future revenue from vafidemstat in AD and iadademstat in AML. We view our valuation to be conservative given that it excludes revenue from vafidemstat in ASD, BPD, and ADHD, and from iadademstat in SCLC. Commercial success outside of the two 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	1Q19	2Q19	3Q19	4Q19	2019A	1Q20A	2Q20E	3Q20E	4Q20E	2020E	2021E
Global iadademstat revenue													
Global vafidemstat revenue													
Collaboration revenue	20												
Total revenue	**20**												
Cost of revenue													
R&D	6,363	8,489	2,610	3,022	3,462	3,553	12,647	4,316	4,402	4,490	4,580	17,789	24,015
G&A	4,502	2,993	876	1,042	742	516	3,176	846	854	863	872	3,435	3,607
Total operating expenses	**10,865**	**11,482**	**3,486**	**4,064**	**4,204**	**4,069**	**15,823**	**5,162**	**5,257**	**5,353**	**5,452**	**21,224**	**27,622**
Operating income	**(10,845)**	**(11,482)**	**(3,486)**	**(4,064)**	**(4,204)**	**(4,069)**	**(15,823)**	**(5,162)**	**(5,257)**	**(5,353)**	**(5,452)**	**(21,224)**	**(27,622)**
Other income (net)	5,659	8,143	2,497	2,516	3,208	3,301	11,522	4,013				4,013	
Net income (pretax)	**(5,186)**	**(3,339)**	**(989)**	**(1,548)**	**(996)**	**(768)**	**(4,301)**	**(1,149)**	**(5,257)**	**(5,353)**	**(5,452)**	**(17,211)**	**(27,622)**
Net financial & tax	1,047	(1,991)	368	(924)	73	296	(187)	116				116	
Net income	**(6,233)**	**(1,348)**	**(1,357)**	**(624)**	**(1,069)**	**(1,064)**	**(4,114)**	**(1,265)**	**(5,257)**	**(5,353)**	**(5,452)**	**(17,327)**	**(27,622)**
EPS basic	**(0.20)**	**(0.04)**	**(0.04)**	**(0.02)**	**(0.02)**	**(0.02)**	**(0.10)**	**(0.03)**	**(0.11)**	**(0.12)**	**(0.12)**	**(0.38)**	**(0.56)**
EPS diluted	**(0.20)**	**(0.04)**	**(0.04)**	**(0.02)**	**(0.02)**	**(0.02)**	**(0.10)**	**(0.03)**	**(0.11)**	**(0.12)**	**(0.12)**	**(0.38)**	**(0.56)**
Basic shares outstanding	31,711	34,638	38,455	38,638	43,677	45,489	41,589	45,489	45,943	46,403	46,867	46,175	49,210
Diluted shares outstanding	31,711	34,638	38,455	38,638	43,677	45,489	41,565	45,489	45,943	46,403	46,867	46,175	49,210

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

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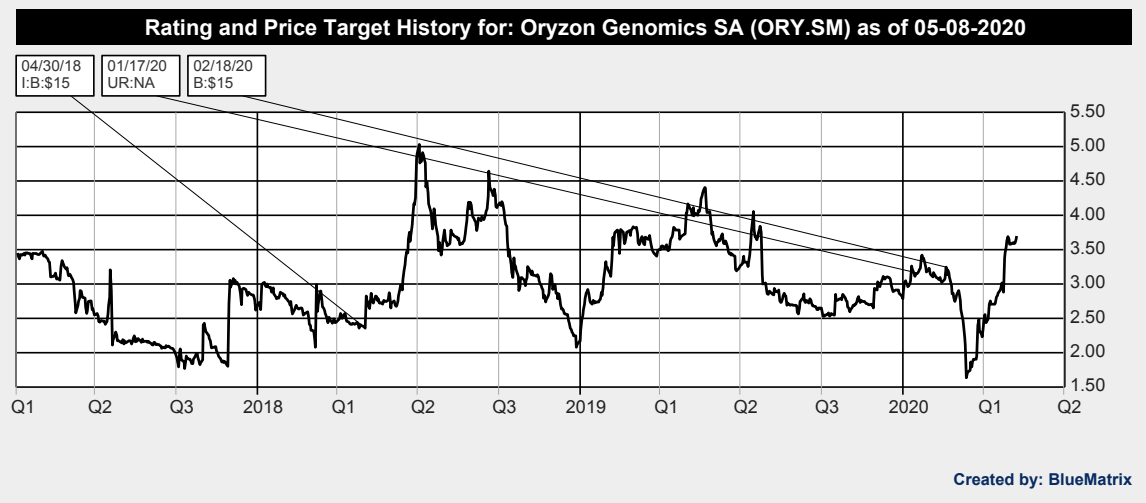
Disclosures:



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 05/12/20	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**265**	**75.28**	**152**	**57.36**
Neutral [N]	**58**	**16.48**	**25**	**43.10**
Sell [S]	**3**	**0.85**	**1**	**33.33**
Under Review [UR]	**26**	**7.39**	**13**	**50.00**

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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