ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | July 06, 2020

Healthcare: Biotechnology

Oryzon Genomics SA | ORY.SM - €3.18 - MADRID | *Buy*

Company Update

Estimates Changed

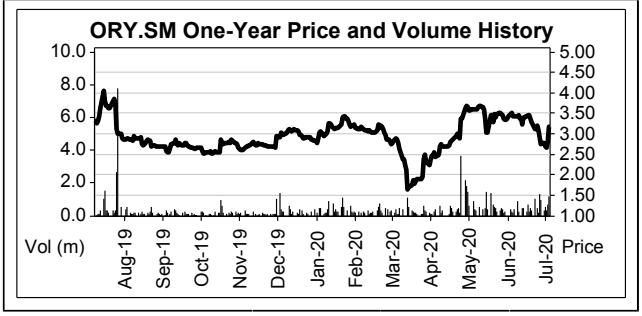
Stock Data	
52-Week Low - High	€1.48 - €4.21
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€168.74
3-Mo. Avg. Vol.	576,779
12-Mo.Price Target	€15.00
Cash (mil)	$50.9
Tot. Debt (mil)	$13.2

EPS $

Yr Dec	—2019—	—2020E—		—2021E—	
		Curr	Prev	Curr	Prev
1Q	(0.04)A	(0.03)A	(0.03)A	-	-
2Q	(0.02)A	(0.11)E	(0.11)E	-	-
3Q	(0.02)A	(0.10)E	(0.12)E	-	-
4Q	(0.02)A	(0.10)E	(0.12)E	-	-
YEAR	(0.10)A	(0.35)E	(0.38)E	(0.49)E	(0.56)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: Final Phase 2a Vafidemstat Data Shown at EPA 2020 - Aggression Reduced

Vafidemstat was found to reduce agitation and aggression in three psychiatric disorders (autistic spectrum disorder (ASD), attention deficit hyperactivity disorder (ADHD), and borderline personality disorder (BPD)). Later this year, we expect ORY.SM to begin Phase 2b, specifically in BPD given the relatively more compelling results in those patients.

- 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 CGI-I), 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.
- We believe that these results demonstrate that vafidemstat is a viable therapeutic option for treating agitation and aggression in all three of these psychiatric diseases, in addition to treating disease specific features, and has the potential to do so with less onerous adverse effects than currently used treatments.
- ORY.SM will publish more detailed REIMAGINE data in a peer-reviewed international medical journal. The upcoming Phase 2b trial in agitation and aggressiveness in BPD, named PORTICO, will be double-blind, placebo controlled, and multicenter. PORTICO will start in Spain and then in other European countries and the U.S.
- With its recent capital raise of €20 million in gross proceeds, ORY.SM has more than €50 million in cash, enough to fund operations into 1H22.

(ORY.SM recently traded at €3.20 at 11:34AM ET)

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 5x multiple of our projected 2030 operating income of $1.1 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)**	**(0.10)**	**(0.10)**	**(0.35)**	**(0.49)**
EPS diluted	**(0.20)**	**(0.04)**	**(0.04)**	**(0.02)**	**(0.02)**	**(0.02)**	**(0.10)**	**(0.03)**	**(0.11)**	**(0.10)**	**(0.10)**	**(0.35)**	**(0.49)**
Basic shares outstanding	31,711	34,638	38,455	38,638	43,677	45,489	41,589	45,489	45,943	53,676	54,213	49,830	56,923
Diluted shares outstanding	31,711	34,638	38,455	38,638	43,677	45,489	41,565	45,489	45,943	53,676	54,213	49,830	56,923
share growth rate		9%		0%	13%	4%	20.0%	0.0%	1.0%	1.0%	1.0%	19.9%	5.0%

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

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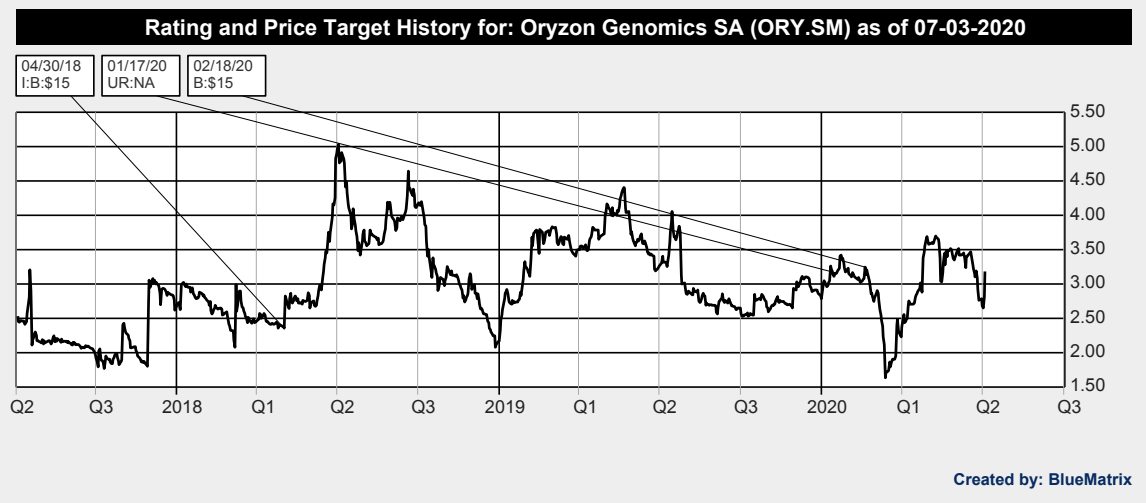
Disclosures:



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 07/06/20	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**269**	**76.42**	**147**	**54.65**
Neutral [N]	**53**	**15.06**	**21**	**39.62**
Sell [S]	**4**	**1.14**	**2**	**50.00**
Under Review [UR]	**26**	**7.39**	**17**	**65.38**

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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