ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | March 09, 2021

Healthcare: Biotechnology

Company Update

Oryzon Genomics SA | ORY.SM - €3.68 - MADRID | *Buy*

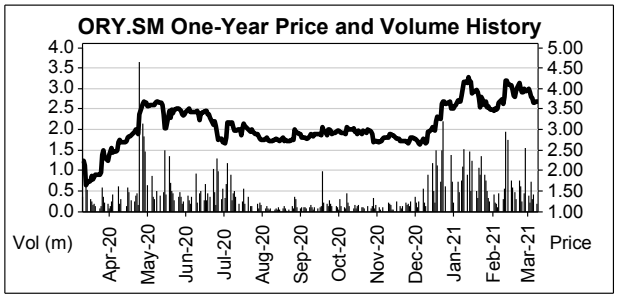
Stock Data	
52-Week Low - High	€1.48 - €4.40
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€195.01
3-Mo. Avg. Vol.	720,482
12-Mo.Price Target	€15.00
Cash (mil)	$48.6
Tot. Debt (mil)	$16.2

EPS $

Yr Dec	—2020—	—2021E—	—2022E—
		Curr	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	(0.18)E
P/E	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: Vafidemstat Can Lower AD-Related Agitation/Aggression, Favorable Safety

ORY reported results after up to 12 months of vafidemstat treatment from its Phase 2a ETHERAL and REIMAGINE-AD trials, showing the drug's favorable safety profile and ability to reduce AD-related agitation/aggression. In ETHERAL (n=140), although CSF levels of inflammation (YKL40) and neuronal damage (NFL) biomarkers were reduced, cognition was not statistically improved. In REIMAGINE-AD (n=12), reduction of AD-related agitation and aggression was the main efficacy finding, with cognitive benefit seen in a small subset of this small trial.

- **ETHERAL.** Vafidemstat was safe and well tolerated, with two drug-related serious AEs observed for placebo and two in the combined treatment arms, and no clinically relevant differences observed in the number of drop-outs, AEs or serious AEs across treatment groups. The trial was placebo-controlled through six months, with placebo patients divided between doses groups thereafter. Of the 140 mild/moderate AD patients that enrolled and were treated with either 0.6mg vafidemstat, 1.2mg vafidemstat, or placebo, 116 finished six months and 72 finished 12 months of therapy. Regarding cognitive measures, there were no statistically significant differences between treatment groups during the placebo-controlled six-month period on the ADAS-Cog14, MMSE, or CMAI scores. Vafidemstat significantly reduced overall levels of proinflammatory YKL40 in CSF during the six-month controlled period (p=0.0150), and these levels appeared to remain lower out to 12 months, but there was no placebo group for further comparison. Vafidemstat also lowered CSF levels of neurofilament light chain (NFL), a marker of neuronal damage, in the high dose group at six months, although the level appears to have increased at 12 months. There were no significant differences in CSF measured neurogranin resulting from vafidemstat treatment.
- **REIMAGINE-AD.** With vafidemstat not appearing to stem cognitive decline in mild/moderate AD, we turn to the open-label 12-patient REIMAGINE-AD trial in moderate/severe AD and note a significant (compared to baseline) reduction of agitation/aggression after 6 and 12 months of treatment, but only a cognitive benefit in two patients from an already small trial and only as compared to baseline, given the absence of a control group. There appear to be clear signs that vafidemstat can lower agitation/aggression, when assessing patients with NPI-Total, NPI-AA, CMAI, CGI-I, and ZBI scales, but we view the cognitive benefit as elusive, even though the trials were only 12 months long and uncontrolled or controlled for only six months, versus the more accepted fully controlled AD trial duration of 18 months. We believe that a much larger and fully controlled trial is needed to draw any firm conclusions on agitation/aggression.
- Both of these datasets were presented in posters today at the virtual AD/PD-2021 conference.

(ORY recently traded at $3.80 at 9:38 EST)

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)

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	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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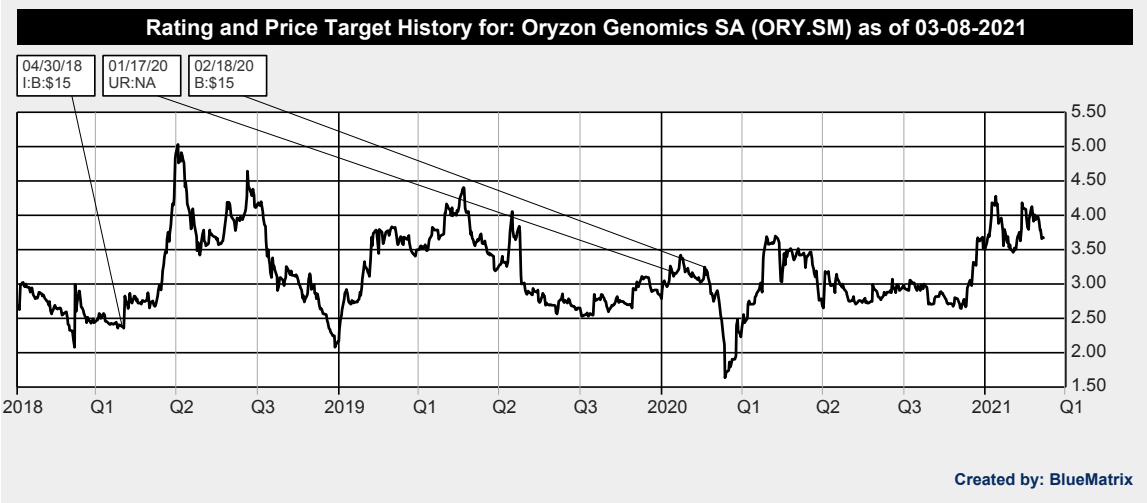
Disclosures:



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 03/09/21	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**312**	**79.39**	**193**	**61.86**
Neutral [N]	**51**	**12.98**	**23**	**45.10**
Sell [S]	**2**	**0.51**	**1**	**50.00**
Under Review [UR]	**28**	**7.12**	**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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