ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | November 17, 2021

Healthcare: Biotechnology **Company Update**

Oryzon Genomics SA | ORY.SM - €3.16 - MADRID | *Buy*

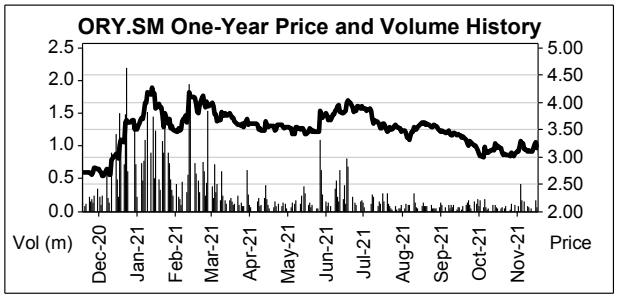
Stock Data	
52-Week Low - High	€2.61 - €4.40
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€167.68
3-Mo. Avg. Vol.	88,467
12-Mo.Price Target	€15.00
Cash (mil)	$35.8
Tot. Debt (mil)	$14.9

Revenue ($ millions)

Yr Dec	—2020—	—2021E—	—2022E—
		Curr	Curr
1Q	0.0A	0.0A	-
2Q	0.0A	0.0A	-
3Q	0.0A	0.0A	-
4Q	0.0A	0.0E	-
YEAR	0.0A	0.0E	0.0E

EPS $

Yr Dec	—2020—	—2021E—	—2022E—
		Curr	Curr
1Q	(0.03)A	(0.04)A	(0.05)E
2Q	0.00A	0.02A	(0.05)E
3Q	(0.02)A	(0.03)A	(0.05)E
4Q	(0.03)A	(0.04)E	(0.06)E
YEAR	(0.08)A	(0.10)E	(0.21)E
P/E	NM	NM	NM



ORY: EVOLUTION Trial with Vafidemstat in Schizophrenia Begins Enrollment

ORY enrolled the first patient in its Phase 2b EVOLUTION trial (n=100) evaluating vafidemstat in schizophrenia, which will ascertain the drug's ability to improve the negative symptoms and cognitive impairment of the disease (i.e., co-primary endpoints) in six-to-10 Spanish centers. The trial incorporates an efficient adaptive design and will assess the endpoints at 24 weeks. Vafidemstat has shown promising results in BPD, ASD, and ADHD, and we believe the drug has a real shot at improving the lives of schizophrenics.

- ORY enrolled the first patient in its Phase 2b EVOLUTION trial evaluating vafidemstat in adult schizophrenia patients under stable antipsychotic therapy. The multi-center trial (n=100) is double-blind, randomized, placebo-controlled, and will evaluate its endpoints at 24-weeks. Co-primary endpoints include improvement in negative symptoms and cognitive impairment associated with schizophrenia. The trial will also assess secondary endpoints focusing on positive schizophrenia symptoms, as well as cognition. The 1:1 randomized trial will be conducted in six-to-10 sites in Spain and an interim analysis will be performed to determine the final patient number needed for proper efficacy powering.
- As a reminder of what vafidemstat delivered in Phase 2a, ORY's REIMAGINE trial was open-label and treated 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 CGII), 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. Over only eight weeks of dosing, 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 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 psychiatric diseases, and has the potential to do so with less onerous adverse effects than currently used treatments. Vafidemstat has shown a favorable safety and tolerability profile in several Phase 1/2 trials involving more than 300 individuals, some of whom received the drug for up to 24 months. Vafidemstat has not been associated with sedation, weight gain or extrapyramidal side effects, which are common problems with current antipsychotic therapy.

(ORY.SM traded intraday at €3.16 at 4:38 PM GMT+1)

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 $915 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	2020A	1Q21A	2Q21A	3Q21A	4Q21E	2021E	1Q22E	2Q22E	3Q22E	4Q22E	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	13,591	4,278	2,928	3,982	4,380	15,568	4,599	4,829	5,071	5,324	19,823	25,770
G&A	4,502	2,993	3,176	3,484	1,302	1,200	1,070	1,081	4,653	1,092	1,102	1,113	1,125	4,432	7,978
Total operating expenses	**10,865**	**11,482**	**15,823**	**17,075**	**5,580**	**4,128**	**5,052**	**5,461**	**20,221**	**5,691**	**5,932**	**6,184**	**6,449**	**24,255**	**33,748**
Operating income	**(10,845)**	**(11,482)**	**(15,823)**	**(17,075)**	**(5,580)**	**(4,128)**	**(5,052)**	**(5,461)**	**(20,221)**	**(5,691)**	**(5,932)**	**(6,184)**	**(6,449)**	**(24,255)**	**(33,748)**
Other income (net)	5,659	8,143	11,522	11,805	3,536	2,256	3,252	3,000	12,044	3,000	3,000	3,000	3,000	12,000	
Net income (pretax)	**(5,186)**	**(3,339)**	**(4,301)**	**(5,269)**	**(2,044)**	**(1,872)**	**(1,800)**	**(2,461)**	**(8,177)**	**(2,691)**	**(2,932)**	**(3,184)**	**(3,449)**	**(12,255)**	**(33,748)**
Net financial & tax	1,047	(1,991)	(187)	(1,098)	89	(2,823)	36	50	(2,648)	50	50	50	50	200	
Net income	**(6,233)**	**(1,348)**	**(4,114)**	**(4,171)**	**(2,133)**	**951**	**(1,836)**	**(2,511)**	**(5,529)**	**(2,741)**	**(2,982)**	**(3,234)**	**(3,499)**	**(12,455)**	**(33,748)**
EPS basic	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.04)**	**0.02**	**(0.03)**	**(0.04)**	**(0.10)**	**(0.05)**	**(0.05)**	**(0.05)**	**(0.06)**	**(0.21)**	**(0.54)**
EPS diluted	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.04)**	**0.02**	**(0.03)**	**(0.04)**	**(0.10)**	**(0.05)**	**(0.05)**	**(0.05)**	**(0.06)**	**(0.21)**	**(0.54)**
Basic shares outstanding	31,711	34,638	41,589	49,235	52,762	52,762	52,762	59,093	54,344	59,152	59,211	59,270	59,330	59,241	62,296
Diluted shares outstanding	31,711	34,638	41,565	49,235	52,762	52,762	52,762	59,093	54,344	59,152	59,211	59,270	59,330	59,241	62,296

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

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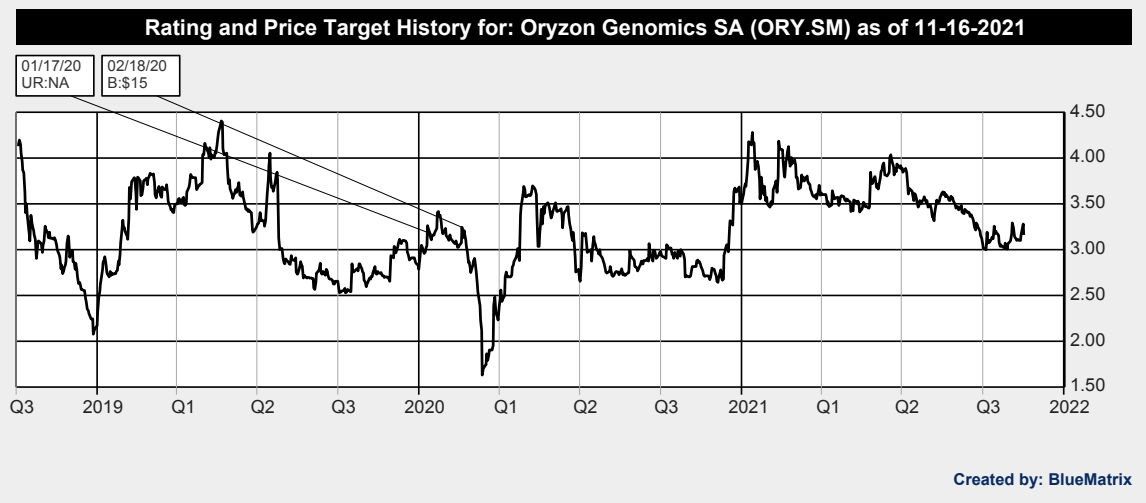
Disclosures:



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 11/17/21	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**326**	**78.37**	**220**	**67.48**
Neutral [N]	**51**	**12.26**	**29**	**56.86**
Sell [S]	**1**	**0.24**	**0**	**0**
Under Review [UR]	**38**	**9.13**	**25**	**65.79**

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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