ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | November 04, 2021

Healthcare: Biotechnology

Company Update
Estimates Changed

Oryzon Genomics SA | ORY.SM - €3.29 - MADRID | *Buy*

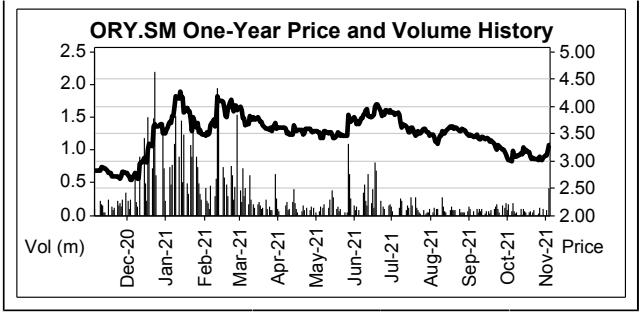
Stock Data	
52-Week Low - High	€2.61 - €4.40
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€174.58
3-Mo. Avg. Vol.	90,867
12-Mo.Price Target	€15.00
Cash (mil)	$35.8
Tot. Debt (mil)	$14.9

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	Prev
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	(0.19)E
P/E	NM	NM	NM	NM



ORY 3Q21: Solid Clinical Progress, Cash Funds Operations Well Into 1Q23

ORY released 3Q21 results, showing a $35.8 million cash balance that should fund operations to 1Q23, as per our projections and also reviewed its current clinical programs. ORY has $14.9 million in debt.

- **Iadademstat.** ORY has defined its registrational strategy in AML and extensive disease SCLC (ED-SCLC) with the potentially pivotal FRIDA and STELLAR trials that could support the accelerated approval of iadademstat as part of combination therapy in these indications. To further evaluate iadademstat in AML, FRIDA will be an open-label, multicenter Phase 1b/2 U.S. trial (n=120) using iadademstat in combination with gilteritinib in FLT3 mutated rel/ref AML. To evaluate iadademstat in ED-SCLC, STELLAR will be a randomized, multicenter Phase 1b/2 U.S. trial (n=120) using iadademstat plus a checkpoint inhibitor in the front-line setting. Thus far in AML, ORY presented at the 2021 EHA meeting a poster updating the 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. This trial is now fully enrolled at 36 patients, and we look forward to future data updates.
- **Vafidemstat in BPD.** The Phase 2b PORTICO trial, a multicenter double-blind, randomized, placebo-controlled trial to evaluate vafidemstat in borderline personality disorder (BPD) is enrolling in both the U.S. and Europe and will enroll about 156 patients at 15-20 sites. 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.
- **Vafidemstat in other indications.** 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. Several trial sites are now activated and recruitment should start soon. EVOLUTION is partially funded with public capital from the Spanish Ministry of Science and Innovation. The 18-patient Phase 2 SATEEN trial showed vafidemstat to be safe in MS patients, but efficacy signals were elusive. The 60-patient Phase 2 ESCAPE trial in serious COVID-19 patients showed safety and anti-inflammatory effects, but no clear clinical benefits. The randomized Phase 2 HOPE trial (n=50-60) in Kabuki syndrome should start in 1H22, potentially serving to support accelerated approval, and by YE21 ORY should better understand which autism and schizophrenia patients to potentially enroll into future trials focused on specific causative mutations.

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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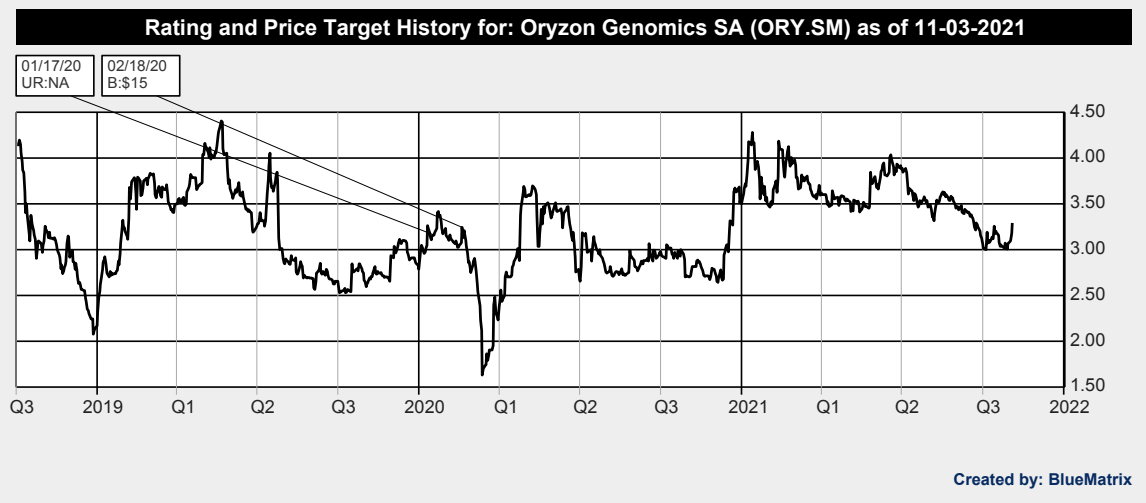
Disclosures:



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 11/04/21	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**326**	**77.99**	**220**	**67.48**
Neutral [N]	**49**	**11.72**	**27**	**55.10**
Sell [S]	**2**	**0.48**	**1**	**50.00**
Under Review [UR]	**38**	**9.09**	**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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