ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | December 13, 2021

Healthcare: Biotechnology **Company Update**

Oryzon Genomics SA | ORY.SM - €2.75 - MADRID | *Buy*

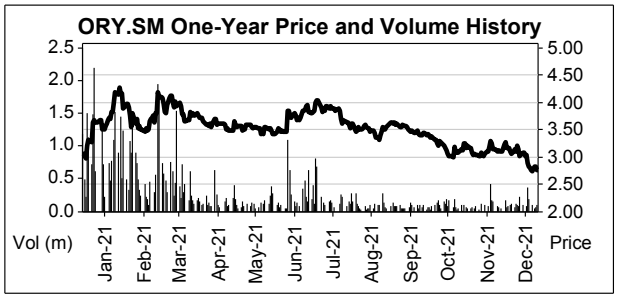
Stock Data	
52-Week Low - High	€2.67 - €4.40
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€145.66
3-Mo. Avg. Vol.	99,645
12-Mo.Price Target	€15.00
Cash (mil)	$35.8
Tot. Debt (mil)	$14.9

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: Iadademstat Plus Azacitadine Shows Clear Utility in Elderly/Unfit with AML

Iadademstat plus azacitadine (Phase 2 ALICE trial) delivered robust results in 27 evaluable elderly/unfit AML patients, with a 78% ORR (62% CR/CRi, 38% PR), and 77% of the CR/CRi patients having durable responses lasting >six months (one ongoing response lasting >1,000 days). The regimen's safety profile remains favorable and consistent with earlier reports. ALICE enrollment is complete and 90ug/m2/d is the dose for future evaluattion.

- ORY's poster at the ongoing virtual ASH annual meeting demonstrates iadademstat's utility in elderly/unfit AML patients (34 treated, 27 efficacy evaluable) in combination with azacitidine. The poster contains new results from ORY's ongoing Phase 2a ALICE trial and is titled “Iadademstat in Combination with Azacitidine Generates Robust and Long Lasting Responses in AML Patients (ALICE Trial)”. Iadademstat's new positive combination therapy results are consistent with previously released robust results from the trial, continuing to show a robust synergy between both drugs. Enrollment in ALICE is now complete.
- ORY reported an ORR of 78% (21/27 evaluable), of which there was 62% (13/21) CR/CRi and 38% (8/21) PR. Six were CR and seven were CRi. We favorably compare this to the historical 28% ORR in this same population of AML treated with azacitidine monotherapy. We also note that among AML subgroups, both patients with M5b AML and all three patients with TP53-mutant AML achieved CR/CRi. Median time to response remains swift at two cycles of therapy (i.e., 55 days), and duration of response remains encouraging, with 77% (10/13) of the CR/CRi lasting more than six months (six lasting >one year; longest thus far at the October 15, ASH data cutoff was >1,000 days and ongoing), with the patient remaining transfusion independent and MRD-negative. The ALICE trial has determined that iadademstat should be dosed 90ug/m2/d in future trials when combined with azacitidine. Preliminary data indicates a direct correlation between quality of response and iadademstat exposure/LSD1 target engagement. The 90ug/m2/d dose more consistently achieved the exposure and LSD1 target engagement observed in CR/CRi patients than did the 60ug/m2/d dose that some ALICE patients received, and importantly did so without increasing toxicity. Looking only at patients receiving 90ug/m2/d of iadademstat, a 77% ORR and 80% CR/CRi rate was achieved. There were only two serious AEs reported as being probably related to the combination therapy treatment, one grade 3 differentiation syndrome and one fatal intracranial hemorrhage. The most frequent AE was platelet reduction, which was observed in 44% of patients, although grade 3 or lower thrombocytopenia was already present at baseline in 61% of patients. This safety profile is consistent with ALICE trial results shown at ASH last year and at this year's EHA conference. There were no other significant non-hematological toxicities or other organ-related toxicities observed, and we emphasize that ALICE enrolled a median patient age of 77 years.

ORY traded intraday at €2.75 at 4:32 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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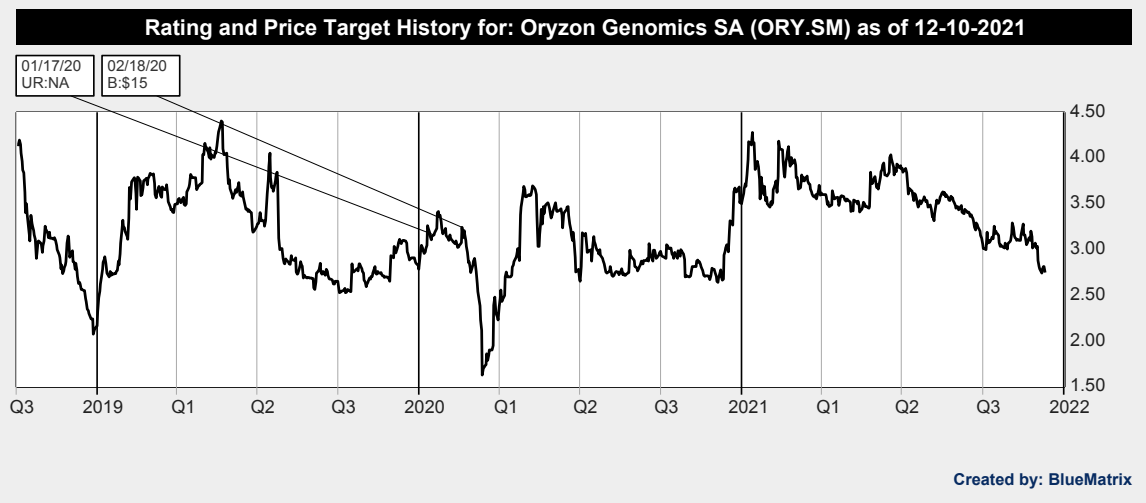
Disclosures:



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 12/13/21	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**328**	**78.28**	**225**	**68.60**
Neutral [N]	**53**	**12.65**	**29**	**54.72**
Sell [S]	**1**	**0.24**	**0**	**0**
Under Review [UR]	**37**	**8.83**	**24**	**64.86**

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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