ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | December 07, 2020

Healthcare: Biotechnology

Company Update

Oryzon Genomics SA | ORY.SM - €2.64 - MADRID | *Buy*

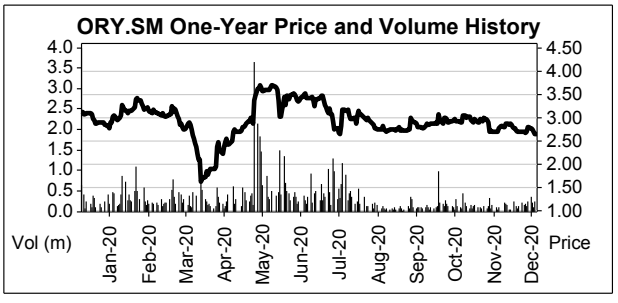
Stock Data	
52-Week Low - High	€1.48 - €3.90
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€140.09
3-Mo. Avg. Vol.	155,163
12-Mo.Price Target	€15.00
Cash (mil)	$52.2
Tot. Debt (mil)	$13.2

EPS $

Yr Dec	—2019—	—2020E—	—2021E—
		Curr	Curr
1Q	(0.04)A	(0.03)A	-
2Q	(0.02)A	0.00A	-
3Q	(0.02)A	(0.02)A	-
4Q	(0.02)A	(0.06)E	-
YEAR	(0.10)A	(0.12)E	(0.35)E
P/E	NM	NM	NM

Revenue ($ millions)

Yr Dec	—2019—	—2020E—	—2021E—
		Curr	Curr
1Q	0.0A	0.0A	0.0E
2Q	0.0A	0.0A	0.0E
3Q	0.0A	0.0A	0.0E
4Q	0.0A	0.0E	0.0E
YEAR	0.0A	0.0E	0.0E



ORY: Iadademstat Continues Delivering Robust Synergy with Azacitidine in AML

ORY presented updated results from its Phase 2 AML trial with iadademstat plus azacitidine, which still comprises the 13 evaluable patients described previously, but which now includes 11 (85% ORR), instead of 10, responding patients (7 CR/CRi, 4 PR), with 6 of the CR/CRi having a duration of >6 months and one thus far lasting almost two years. The mean time to response was only 34 days. Given the typical 27% ORR with azacitidine, we see clear synergy with iadademstat.

- **Current ASH results.** ORY's Phase 2 ALICE trial is enrolling patients >60 years old who have not received prior treatment other than hydroxyurea and are considered ineligible for, or refuse, intensive chemotherapy. These fragile patients are in clear need of safe, effective therapy having a different mechanism that facilitates combinations, and we believe that iadademstat appears able to meet that need. The ASH-2020 update included one more CR/CRi among the same 13 evaluable per protocol patients, for a total ORR of 11/13 (85%; 7 CR/CRi and 4 PR), with a rapid time to response of 34 days (equal to about one cycle) and a highly durable effect in most responders (6 CR/CRi and 2 PR lasting for >6 months). Also, median duration of response is currently 308 days, and median PFS is 270 days. In the ITT analysis (n-=19), ORR was 61%. One patient treated for only 20 weeks achieved CR and was transfusion independent for a total of 77 weeks, while another CR, who was also transfusion independent, died due to COVID-19 at week 48. Patients with longer treatment periods generally reduced or overcame their transfusion dependency. The similar pharmacodynamics and efficacy of the 60 and 90ug/m2/d iadademstat doses, but the more favorable safety at the lower dose, makes 60ug/m2/d the preferred dose in combination with azacitidine. The combination therapy demonstrates a favorable safety profile, and except for the expected hematological toxicity, it appears to be safe and well tolerated. Most of the 247 adverse events were hematological (mainly neutropenia and thrombocytopenia), and among the 41 serious adverse events, only two were considered related to iadademstat. A full 50% of the intended 36 patients have been enrolled thus far in ALICE, and we look forward to future Phase 2 updates that we believe will continue to support Phase 3 development of this mechanistically novel drug.
- **Phase 2 iadademstat results presented back at at EHA-2020.** As a reminder, ORY last released positive interim Phase 2 results from this trial at EHA-2020 in 2Q20, demonstrating strong evidence of clinical activity with reported objective responses in 10 of 13 evaluable patients (77% ORR). Of the 10 responders to the combination therapy as of that update, six were complete remissions (CR/CRi). There was also a rapid onset of clinical responses, with an average time to response of 37 days, and with the longest remission being 488 days and counting. Additionally, several patients improved or overcame their dependency on blood transfusions. Even if one included all patients *(text continued on page 2)*

(ORY traded intraday at €2.82 at 3:27PM GMT+1)

- *(continued from page 1)* except the one who died of a domestic accident without a prior bone marrow assessment, ORR in this intent-to-treat population back then was 59% (10/17). We contrast this result with the 27% historical response rate in this setting with azacitidine monotherapy, which supports a clinically meaningful synergy with iadademstat/azacitidine.

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 $889 million. 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	2Q20A	3Q20A	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	2,731	2,279	2,507	11,833	15,974
G&A	4,502	2,993	876	1,042	742	516	3,176	846	906	733	740	3,225	3,386
Total operating expenses	**10,865**	**11,482**	**3,486**	**4,064**	**4,204**	**4,069**	**15,823**	**5,162**	**3,637**	**3,012**	**3,247**	**15,058**	**19,360**
Operating income	**(10,845)**	**(11,482)**	**(3,486)**	**(4,064)**	**(4,204)**	**(4,069)**	**(15,823)**	**(5,162)**	**(3,637)**	**(3,012)**	**(3,247)**	**(15,058)**	**(19,360)**
Other income (net)	5,659	8,143	2,497	2,516	3,208	3,301	11,522	4,013	2,312	1,787		8,112	
Net income (pretax)	**(5,186)**	**(3,339)**	**(989)**	**(1,548)**	**(996)**	**(768)**	**(4,301)**	**(1,149)**	**(1,324)**	**(1,225)**	**(3,247)**	**(6,945)**	**(19,360)**
Net financial & tax	1,047	(1,991)	368	(924)	73	296	(187)	116	(1,102)	(155)		(1,141)	
Net income	**(6,233)**	**(1,348)**	**(1,357)**	**(624)**	**(1,069)**	**(1,064)**	**(4,114)**	**(1,265)**	**(222)**	**(1,070)**	**(3,247)**	**(5,804)**	**(19,360)**
EPS basic	**(0.20)**	**(0.04)**	**(0.04)**	**(0.02)**	**(0.02)**	**(0.02)**	**(0.10)**	**(0.03)**	**(0.00)**	**(0.02)**	**(0.06)**	**(0.12)**	**(0.35)**
EPS diluted	**(0.20)**	**(0.04)**	**(0.04)**	**(0.02)**	**(0.02)**	**(0.02)**	**(0.10)**	**(0.03)**	**(0.00)**	**(0.02)**	**(0.06)**	**(0.12)**	**(0.35)**
Basic shares outstanding	31,711	34,638	38,455	38,638	43,677	45,489	41,589	45,489	45,808	52,762	53,290	49,337	55,954
Diluted shares outstanding	31,711	34,638	38,455	38,638	43,677	45,489	41,565	45,489	45,808	52,762	53,290	49,337	55,954

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

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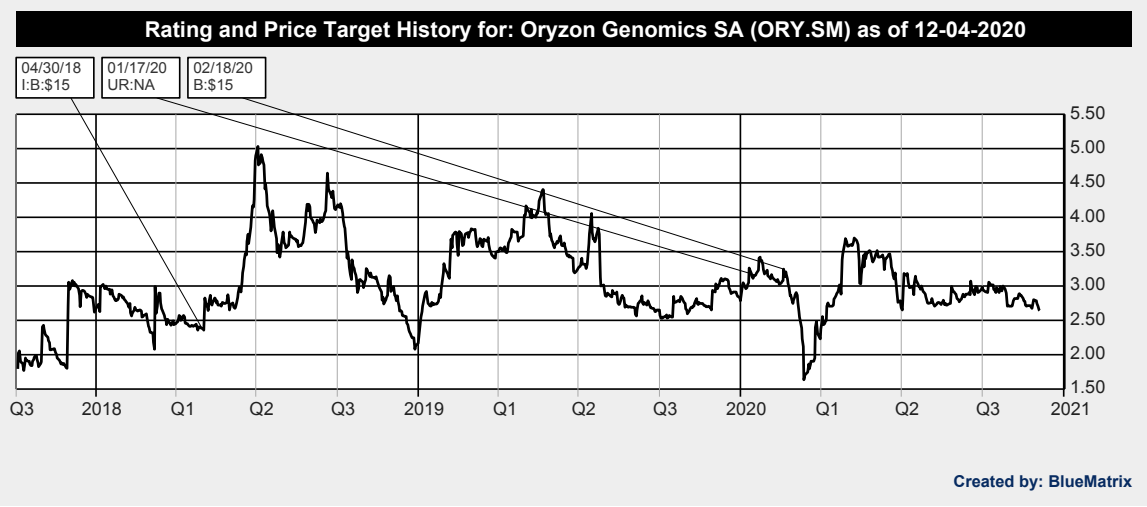
Disclosures:



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 12/07/20	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**280**	**75.07**	**166**	**59.29**
Neutral [N]	**53**	**14.21**	**20**	**37.74**
Sell [S]	**3**	**0.80**	**2**	**66.67**
Under Review [UR]	**37**	**9.92**	**21**	**56.76**

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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