ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | June 12, 2020

Healthcare: Biotechnology

Oryzon Genomics SA | ORY.SM - €3.24 - MADRID | *Buy*

Company Update

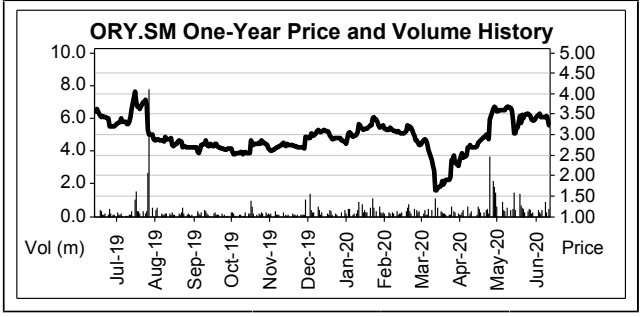
Stock Data	
52-Week Low - High	€1.48 - €4.21
Shares Out. (mil)	45.79
Mkt. Cap.(mil)	€148.13
3-Mo. Avg. Vol.	511,642
12-Mo.Price Target	€15.00
Cash (mil)	$32.3
Tot. Debt (mil)	$13.2

EPS $

Yr Dec	—2019—	—2020E—	—2021E—
		Curr	Curr
1Q	(0.04)A	(0.03)A	-
2Q	(0.02)A	(0.11)E	-
3Q	(0.02)A	(0.12)E	-
4Q	(0.02)A	(0.12)E	-
YEAR	(0.10)A	(0.38)E	(0.56)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	0.0E	0.0E
3Q	0.0A	0.0E	0.0E
4Q	0.0A	0.0E	0.0E
YEAR	0.0A	0.0E	0.0E



ORY.SM: Iadademstat Shows Promising Efficacy in Phase 2 AML Trial at EHA

ALICE, a Phase 2 first-line AML trial presented at EHA, has shown that combination therapy with iadademstat/azacitidine provides clinically meaningful benefit in this fragile, elderly population. We look forward to further updates at the RP2D, likely at ASH in 4Q20.

- The ALICE trial has enrolled 18 of its intended 36 patients (18 dose ranging, 18 dose expansion). The RP2D of iadademstat in combination with azacitidine is 60µg/m^2/day. ALICE is enrolling patients >60 years old who have not received prior treatment other than hydroxyurea and are considered ineligible for, or refuse, intensive chemotherapy.
- Robust signals of clinical efficacy, with ORR of 77% (10 of 13 evaluable patients having had at least one bone marrow evaluation), of which 60% (6/10) are CR/CRi (4CR/2CRi) and 40% (4/10) are PR. One of the CRs lasted for one assessment (cycle 3), and changed to a PR (cycle 4) before the patient was withdrawn at cycle 7 after having two dosing interruptions while on study. Iadademstat/azacitidine drove rapid clinical responses, with a mean time to response of 37 days, and the longest remission being 488 days and counting. Two of the CR patients also converted to red cell transfusion independence. Given that ALICE is being conducted entirely in Spain, a country hit hard by COVID-19, we note that the patient with the second longest remission died due to COVID-19 and that a patient that achieved SD left the trial due to COVID-19. Even if one includes all patients except the one who died of a domestic accident without a prior bone marrow assessment, ORR in this intent-to-treat population 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. The combination therapy demonstrates a favorable safety profile, and except for the expected hematological toxicity, it appears to be safe and well tolerated.
- By demonstrating the plausibility of using this combination therapy in first-line elderly AML patients, the ALICE trial also serves as a prelude to broader application in other leukemia settings, and to that end we note the likely ability of iadademstat to be safely combined with other anti-leukemic agents. As expected, the regimen's toxicity seems predictable, manageable, and restricted to hematologic events. We view the ORR improvement versus historical results to be due to the synergistic effect arising from the combination. These fragile patients are in clear need of safe, effective therapy having a different mechanism that facilitates combinations. LSD1, iadademstat's target, has a well characterized mechanistic role in MLL-r leukemia and erythroleukemia subtypes, and the ALICE trial support the notion that LSD1 inhibition is also relevant in the current setting.

(ORY.SM recently traded intraday at €3.42 at 10:54AM EDT)

VALUATION

Our 12-month price target of €15, is based on a DCF analysis using a 40% 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 $1.4 billion. 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	2Q20E	3Q20E	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	4,402	4,490	4,580	17,789	24,015
G&A	4,502	2,993	876	1,042	742	516	3,176	846	854	863	872	3,435	3,607
Total operating expenses	**10,865**	**11,482**	**3,486**	**4,064**	**4,204**	**4,069**	**15,823**	**5,162**	**5,257**	**5,353**	**5,452**	**21,224**	**27,622**
Operating income	**(10,845)**	**(11,482)**	**(3,486)**	**(4,064)**	**(4,204)**	**(4,069)**	**(15,823)**	**(5,162)**	**(5,257)**	**(5,353)**	**(5,452)**	**(21,224)**	**(27,622)**
Other income (net)	5,659	8,143	2,497	2,516	3,208	3,301	11,522	4,013				4,013	
Net income (pretax)	**(5,186)**	**(3,339)**	**(989)**	**(1,548)**	**(996)**	**(768)**	**(4,301)**	**(1,149)**	**(5,257)**	**(5,353)**	**(5,452)**	**(17,211)**	**(27,622)**
Net financial & tax	1,047	(1,991)	368	(924)	73	296	(187)	116				116	
Net income	**(6,233)**	**(1,348)**	**(1,357)**	**(624)**	**(1,069)**	**(1,064)**	**(4,114)**	**(1,265)**	**(5,257)**	**(5,353)**	**(5,452)**	**(17,327)**	**(27,622)**
EPS basic	**(0.20)**	**(0.04)**	**(0.04)**	**(0.02)**	**(0.02)**	**(0.02)**	**(0.10)**	**(0.03)**	**(0.11)**	**(0.12)**	**(0.12)**	**(0.38)**	**(0.56)**
EPS diluted	**(0.20)**	**(0.04)**	**(0.04)**	**(0.02)**	**(0.02)**	**(0.02)**	**(0.10)**	**(0.03)**	**(0.11)**	**(0.12)**	**(0.12)**	**(0.38)**	**(0.56)**
Basic shares outstanding	31,711	34,638	38,455	38,638	43,677	45,489	41,589	45,489	45,943	46,403	46,867	46,175	49,210
Diluted shares outstanding	31,711	34,638	38,455	38,638	43,677	45,489	41,565	45,489	45,943	46,403	46,867	46,175	49,210

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

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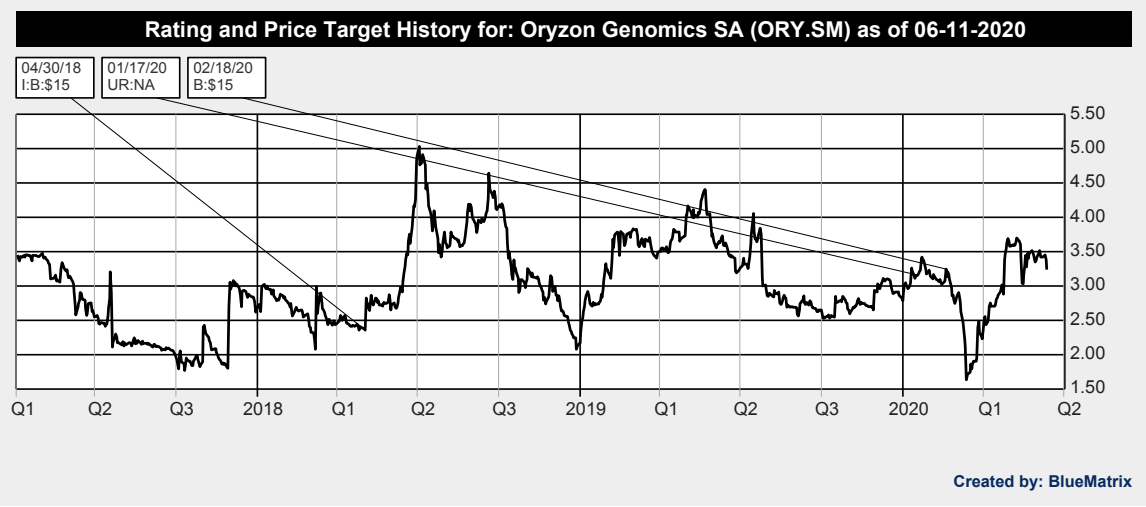
Disclosures:



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 06/12/20	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**275**	**77.03**	**154**	**56.00**
Neutral [N]	**57**	**15.97**	**24**	**42.11**
Sell [S]	**3**	**0.84**	**1**	**33.33**
Under Review [UR]	**22**	**6.16**	**12**	**54.55**

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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