ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | April 24, 2020

Healthcare: Biotechnology

Oryzon Genomics SA | ORY.SM - €2.88 - MADRID | *Buy*

Company Update

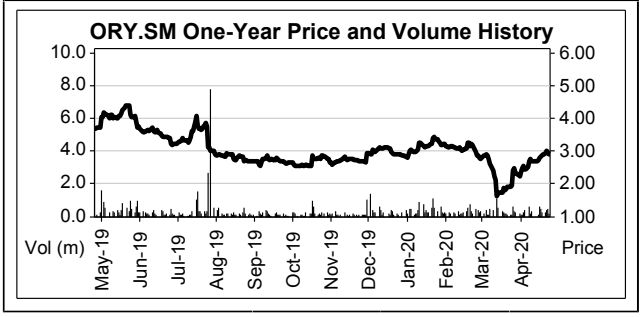
Stock Data	
52-Week Low - High	€1.48 - €4.47
Shares Out. (mil)	45.79
Mkt. Cap.(mil)	€131.87
3-Mo. Avg. Vol.	315,083
12-Mo.Price Target	€15.00
Cash (mil)	$39.6
Tot. Debt (mil)	$13.2

EPS $

Yr Dec	—2019—	—2020E—	—2021E—
		Curr	Curr
1Q	(0.04)A	(0.10)E	-
2Q	(0.02)A	(0.10)E	-
3Q	(0.02)A	(0.11)E	-
4Q	(0.02)A	(0.11)E	-
YEAR	(0.10)A	(0.42)E	(0.51)E
P/E	NM	NM	NM

Revenue ($ millions)

Yr Dec	—2019—	—2020E—	—2021E—
		Curr	Curr
1Q	0.0A	0.0E	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: Decides to Conduct a Phase 2 Trial with Vafidemstat in Severe COVID-19

ORY.SM will initiate a Phase 2 trial with its vafidemstat, its oral LSD1 inhibitor, currently in trials for several neurological conditions that can potentially benefit from its anti-inflammatory effects. The trial rationale is that vafidemstat could potentially reduce the cytokine storm that underpins the acute respiratory distress syndrome (ARDS) that claims many lives. Vafidemstat will be added to standard of care COVID-19 therapy, and the trial already has CTA approval to begin human testing in Spain via an accelerated procedure.

- The open-label COVID-19 trial, named ESCAPE, will randomize 20 patients to each of its two arms (standard of care with or without vafidemstat), with the primary efficacy endpoint being prevention of progression to ARDS in severely ill adult COVID-19 patients. The Spanish trial will initially enroll patients at two hospitals in Barcelona, but more trial centers can be added as required. The swiftness of the trial set up was facilitated by certain urgency provisions related to the COVID-19 pandemic put in place by the Spanish Drug Agency.
- The result of an overactive inflammatory response, ARDS is an unnecessarily extreme systemic reaction to coronavirus that often causes multiple organ failure. For example, the high 34% death rate with the MERS virus was shown to be closely correlated with over expression of the cytokines IL-6 and IL-1B, which are central to triggering the cytokine storm, along with other inflammatory factors, notably TNFα. In preclinical animal models of acute inflammation, vafidemstat produced a rapid and strong reduction in IL-6, IL-1B, TNFα, and IFN-y, and the drug has also reduced brain markers of inflammation in Alzheimer's disease patients. We view inflammation as an ideal process to reduce in treating COVID-19 patients because the virus appears to us to be like so many viruses, causing unnecessary inflammation that does far more harm than good, and therefore mitigating the event should not necessarily compromise the patient's ability to fight the virus. The safety and tolerability of vafidemstat has already been established in an elderly population with Alzheimer's disease for treatment durations that were far longer than what is expected in COVID-19, so we are not expecting any material adverse reactions to sideline the trial.
- ORY.SM has sufficient manufactured vafidemstat to supply all ongoing clinical trials and is preparing for new clinical trials in CNS and cancer to start once the pandemic allows. With $39.6 million in cash as of the end of 2019, ORY.SM has enough cash to fund its operations through 2021, as per our projections.

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	1Q20E	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	3,731	4,104	4,309	4,524	16,668	22,501
G&A	4,502	2,993	876	1,042	742	516	3,176	697	704	711	718	2,828	2,970
Total operating expenses	**10,865**	**11,482**	**3,486**	**4,064**	**4,204**	**4,069**	**15,823**	**4,427**	**4,807**	**5,020**	**5,242**	**19,496**	**25,471**
Operating income	**(10,845)**	**(11,482)**	**(3,486)**	**(4,064)**	**(4,204)**	**(4,069)**	**(15,823)**	**(4,427)**	**(4,807)**	**(5,020)**	**(5,242)**	**(19,496)**	**(25,471)**
Other income (net)	5,659	8,143	2,497	2,516	3,208	3,301	11,522					-	
Net income (pretax)	**(5,186)**	**(3,339)**	**(989)**	**(1,548)**	**(996)**	**(768)**	**(4,301)**	**(4,427)**	**(4,807)**	**(5,020)**	**(5,242)**	**(19,496)**	**(25,471)**
Net financial & tax	1,047	(1,991)	368	(924)	73	296							
Net income	**(6,233)**	**(1,348)**	**(1,357)**	**(624)**	**(1,069)**	**(1,064)**	**(4,301)**	**(4,427)**	**(4,807)**	**(5,020)**	**(5,242)**	**(19,496)**	**(25,471)**
EPS basic	**(0.20)**	**(0.04)**	**(0.04)**	**(0.02)**	**(0.02)**	**(0.02)**	**(0.10)**	**(0.10)**	**(0.10)**	**(0.11)**	**(0.11)**	**(0.42)**	**(0.51)**
EPS diluted	**(0.20)**	**(0.04)**	**(0.04)**	**(0.02)**	**(0.02)**	**(0.02)**	**(0.10)**	**(0.10)**	**(0.10)**	**(0.11)**	**(0.11)**	**(0.42)**	**(0.51)**
Basic shares outstanding	31,711	34,638	38,455	38,638	43,677	45,489	41,589	45,943	46,403	46,867	47,336	46,637	49,702
Diluted shares outstanding	31,711	34,638	38,455	38,638	43,677	45,489	41,565	45,943	46,403	46,867	47,336	46,637	49,702

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

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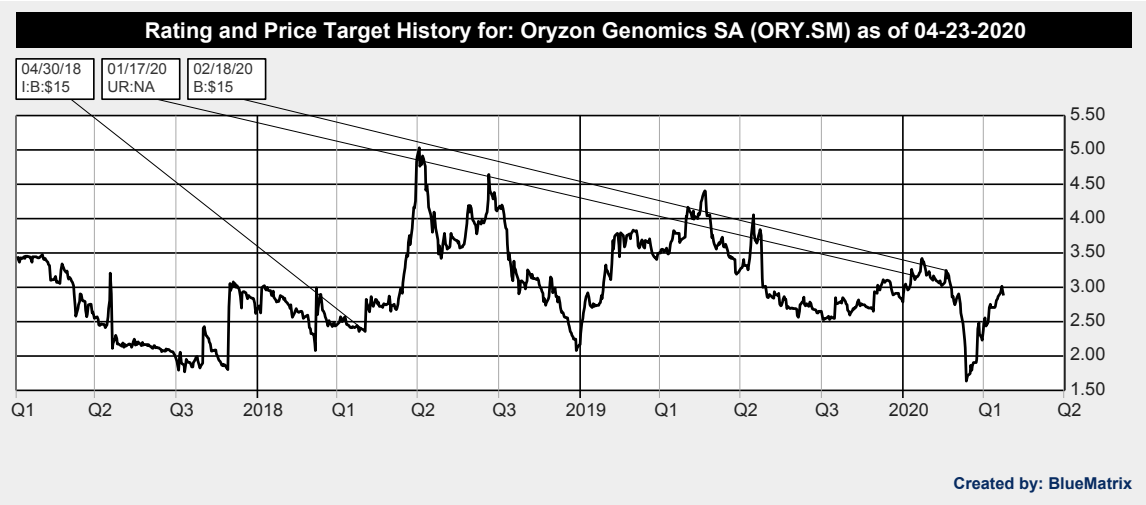
Disclosures:

Shares of Oryzon Genomics SA may be subject to the Securities and Exchange Commission's Penny Stock Rules, which may set forth sales practice requirements for certain low-priced securities.



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 04/24/20	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**263**	**74.29**	**151**	**57.41**
Neutral [N]	**60**	**16.95**	**26**	**43.33**
Sell [S]	**3**	**0.85**	**1**	**33.33**
Under Review [UR]	**28**	**7.91**	**13**	**46.43**

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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