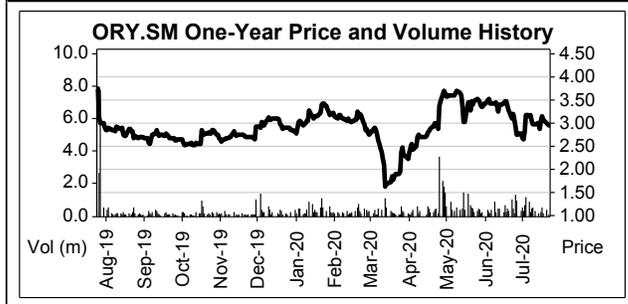


Healthcare: Biotechnology
Oryzon Genomics SA | ORY.SM - €2.95 - MADRID | Buy
Company Update

Estimates Changed

Stock Data					
52-Week Low - High	€1.48 - €3.92				
Shares Out. (mil)	53.06				
Mkt. Cap.(mil)	€156.54				
3-Mo. Avg. Vol.	587,109				
12-Mo.Price Target	€15.00				
Cash (mil)	\$54.9				
Tot. Debt (mil)	\$13.2				
EPS \$					
Yr Dec	—2019—	—2020E—		—2021E—	
		Curr	Prev	Curr	Prev
1Q	(0.04)A	(0.03)A	(0.03)A	-	-
2Q	(0.02)A	0.00A	(0.11)E	-	-
3Q	(0.02)A	(0.07)E	(0.10)E	-	-
4Q	(0.02)A	(0.08)E	(0.10)E	-	-
YEAR	(0.10)A	(0.19)E	(0.35)E	(0.38)E	(0.49)E
P/E	NM	NM	NM	NM	NM
Revenue (\$ millions)					
Yr Dec	—2019—	—2020E—		—2021E—	
		Curr	Curr	Curr	Curr
1Q	0.0A	0.0A	0.0E	0.0E	0.0E
2Q	0.0A	0.0A	0.0E	0.0E	0.0E
3Q	0.0A	0.0E	0.0E	0.0E	0.0E
4Q	0.0A	0.0E	0.0E	0.0E	0.0E
YEAR	0.0A	0.0E	0.0E	0.0E	0.0E


ORY.SM 2Q20: Cash Runway Into 1Q23, Clinical Programs on Track

ORY.SM released 2Q20 results, showing a \$54.9 million cash balance that can fund operations into 1Q23, and also reviewed its current clinical programs.

- Iadademstat.** Over 2Q20, ORY.SM released further positive results from its Phase 2 trial (ALICE trial; evaluating iadademstat plus azacitidine in AML) at EHA-2020, demonstrating strong evidence of clinical activity with reported objective responses in 10 of 13 evaluable patients (77% ORR). Of the 10 responders to combination therapy, six were complete remissions (CR or 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.
- Later in 3Q20 at the ESMO conference, we expect final results from ORY.SM's Phase 2 trial CLEPSIDRA, evaluating iadademstat plus standard-of-care platinum-etoposide therapy in patients with SCLC.
- Vafidemstat.** ORY.SM is collaborating with the Institute of Medical and Molecular Genetics at Madrid's La Paz University Hospital to evaluate vafidemstat in Phelan-McDermid Syndrome (PMS), which is believed to be one cause of autism spectrum disorder. ORY.SM's effort to evaluate vafidemstat in schizophrenia and related psychiatric disorders announced in 2Q20 will receive €0.7 million in public funding from the Spanish Ministry of Science and Innovation, and the clinical work will be performed in collaboration with the Research Institute of Vall d'Hebrón.
- ORY.SM is also continuing the ETHERAL Phase 2a trial with vafidemstat in mild and moderate AD patients. The analyses demonstrate vafidemstat's ability to statistically control agitation and aggression in AD patients, and impact biomarkers of neuroinflammation, but thus far there is no meaningful improvement in cognition. To be fair, the trials are not powered to demonstrate a cognitive benefit at six months, but nonetheless investors are always closely watching cognitive endpoints in AD. We look forward to subsequent analyses of more mature datasets.
- ORY.SM is also progressing through the extension phase of its SATEEN Phase 2a clinical trial evaluating vafidemstat in secondary progressive MS for up to a maximum of 18 months of vafidemstat treatment. The company also began a new trial in severe COVID-19 patients, an open-label, randomized, Phase 2 trial named ESCAPE, which is designed to evaluate vafidemstat plus standard of care in preventing disease progression to acute respiratory distress syndrome. The trial will enroll 20 patients per arm and is being conducted in several Spanish hospitals.

SUMMARY

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 \$1.1 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

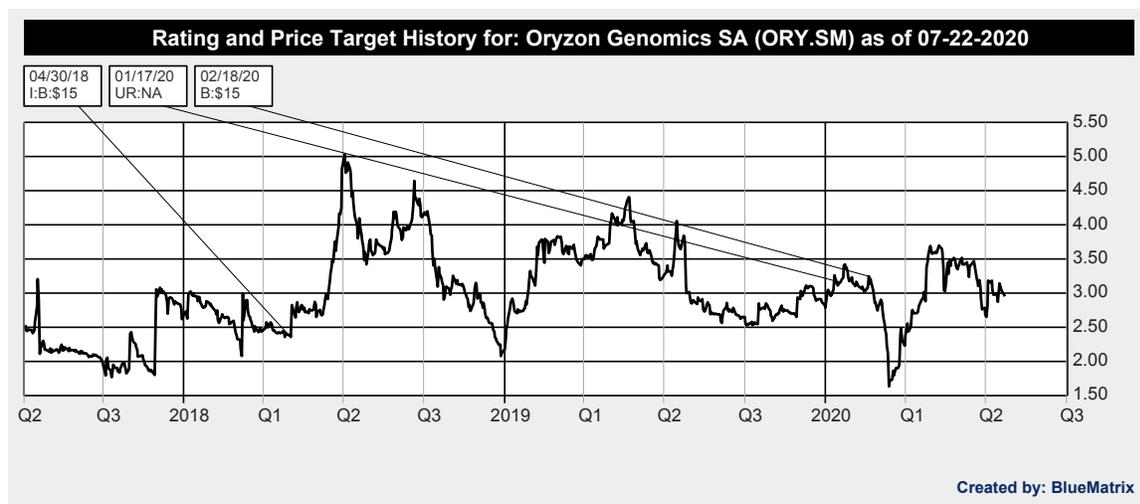
Founded in 2000 in Barcelona, Spain, Oryzon (ISIN Code: ES0167733015) is a clinical stage biopharmaceutical company considered as a European champion in epigenetics. Oryzon has one of the strongest portfolios in the field. Oryzon's LSD1 program has rendered clinical stage vafidemstat and iadademstat. 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		Jonathan Aschoff, Ph.D. (646) 616-2795 jaschoff@roth.com											
Income Statement													
Fiscal Year ends December													
(in 000, except per share items)													
	2017A	2018A	1Q19	2Q19	3Q19	4Q19	2019A	1Q20A	2Q20A	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	2,731	3,004	3,305	13,356	18,030
G&A	4,502	2,993	876	1,042	742	516	3,176	846	906	915	924	3,590	3,769
Total operating expenses	10,865	11,482	3,486	4,064	4,204	4,069	15,823	5,162	3,637	3,919	4,228	16,945	21,799
Operating income	(10,845)	(11,482)	(3,486)	(4,064)	(4,204)	(4,069)	(15,823)	(5,162)	(3,637)	(3,919)	(4,228)	(16,945)	(21,799)
Other income (net)	5,659	8,143	2,497	2,516	3,208	3,301	11,522	4,013	2,312			6,325	
Net income (pretax)	(5,186)	(3,339)	(989)	(1,548)	(996)	(768)	(4,301)	(1,149)	(1,324)	(3,919)	(4,228)	(10,620)	(21,799)
Net financial & tax	1,047	(1,991)	368	(924)	73	296	(187)	116	(1,102)			(986)	
Net income	(6,233)	(1,348)	(1,357)	(624)	(1,069)	(1,064)	(4,114)	(1,265)	(222)	(3,919)	(4,228)	(9,634)	(21,799)
EPS basic	(0.20)	(0.04)	(0.04)	(0.02)	(0.02)	(0.02)	(0.10)	(0.03)	(0.00)	(0.07)	(0.08)	(0.19)	(0.38)
EPS diluted	(0.20)	(0.04)	(0.04)	(0.02)	(0.02)	(0.02)	(0.10)	(0.03)	(0.00)	(0.07)	(0.08)	(0.19)	(0.38)
Basic shares outstanding	31,711	34,638	38,455	38,638	43,677	45,489	41,589	45,489	45,808	53,539	54,075	49,728	56,778
Diluted shares outstanding	31,711	34,638	38,455	38,638	43,677	45,489	41,565	45,489	45,808	53,539	54,075	49,728	56,778

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

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 07/23/20	
			Count	Percent
Buy [B]	266	74.72	142	53.38
Neutral [N]	54	15.17	21	38.89
Sell [S]	3	0.84	2	66.67
Under Review [UR]	33	9.27	23	69.70

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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.

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