

Healthcare: Biotechnology

Company Update

**Oryzon Genomics SA | ORY.SM - €2.87 - MADRID | Buy**
**Stock Data**

52-Week Low - High	€2.04 - €3.70
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€152.03
3-Mo. Avg. Vol.	134,838
12-Mo.Price Target	€15.00
Cash (mil)	\$36.0
Tot. Debt (mil)	\$25.5

Cash (mil): Pro forma cash of about \$36M includes 8M euros raised since 1Q22 via convertible debt, which also raises debt by 8M euros to about \$25.5M.

**Revenue (\$ millions)**

Yr Dec	—2021—	—2022E—	—2023E—
		Curr	Curr
1Q	0.0A	0.0A	-
2Q	0.0A	0.0E	-
3Q	0.0A	0.0E	-
4Q	0.0A	0.0E	-
YEAR	0.0A	0.0E	0.0E

**EPS \$**

Yr Dec	—2021—	—2022E—	—2023E—
		Curr	Curr
1Q	(0.04)A	(0.03)A	-
2Q	0.02A	(0.06)E	-
3Q	(0.03)A	(0.05)E	-
4Q	(0.04)A	(0.06)E	-
YEAR	(0.10)A	(0.20)E	(0.39)E
P/E	NM	NM	NM

**ORY.SM One-Year Price and Volume History**


## ORY: Establishes CRADA with NCI to Evaluate iadademstat in Several Indications

ORY entered into a Cooperative Research and Development Agreement (CRADA) with the NCI, pursuant to which ORY and the NCI will collaborate to develop iadademstat further in clinical trials in solid and hematological malignancies. Iadademstat will now be developed in new indications and in combination with other agents such as investigational and marketed immuno-oncology and molecularly-targeted agents. The CRADA increases iadademstat's chances of clinical success in mid-stage clinical trials and its recognition by potential future commercial partners, in our view.

- ORY entered into a Cooperative Research and Development Agreement (CRADA) with the NCI, pursuant to which ORY and the NCI will collaborate to develop iadademstat further in clinical trials in solid and hematological malignancies. In addition to being an endorsement of the program, the CRADA will allow ORY to significantly expand iadademstat's clinical development into new indications and in combination with other agents such as investigational and marketed immuno-oncology and molecularly-targeted agents. The CRADA also exposes iadademstat to numerous potential government agencies and academic institutions as potential trial sites, increasing the chances that the drug may succeed in mid-stage clinical trials and be recognized by potential future commercial partners. Although financial terms were not disclosed, we also note that the CRADA provides financial assistance for the drug's future development at least via facilities and personnel.
- At last month's EHA annual meeting, ORY presented updated results from its Phase 2 ALICE trial evaluating 60 or 90ug/m2/day iadademstat plus 75mg/m2 azacitadine combination therapy in elderly/unfit AML patients. The EHA poster is an update from the 4Q21 ASH poster that involves the same number of patients, and highlights include one additional CR, for an ORR of 81%, up from an ORR of 78% at ASH. Also, 12 of the 14 CR/CRi patients (86%; all 7 CRs and 5 of 7 CRi) became transfusion independent. We believe that these robust results contributed to the establishing the CRADA, and we look forward to an ALICE trial update at ASH in 4Q22.
- The Phase 1b/2 STELLAR trial in first-line SCLC is being designed, a randomized, multi-center trial of iadademstat plus a checkpoint inhibitor in this setting that could potentially support accelerated approval. ORY is also preparing a Phase 1b/2 basket trial in the U.S. of iadademstat in combination with synergistic agents in platinum rel/ref SCLC and extrapulmonary high grade neuroendocrine tumors (NET).

## 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 4x multiple of our projected 2030 operating income of \$1.34 billion. We arrive at this valuation by projecting future revenue from vafidemstat in borderline personality disorder and Kabuki syndrome, as well as iadademstat in AML and SCLC.

Factors that could impede shares of ORY.SM from achieving our price target include vafidemstat and iadademstat failing to generate statistically significant clinical results. Also, regulatory agencies could fail to approve these drugs even if pivotal clinical trials 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 the European leader in epigenetics. Oryzon has one of the strongest portfolios in the field, with two LSD1 inhibitors, iadademstat and vafidemstat, in Phase II clinical trials, and other pipeline assets directed against other epigenetic targets. In addition, Oryzon has a strong platform for biomarker identification and target validation for a variety of malignant and neurological diseases.

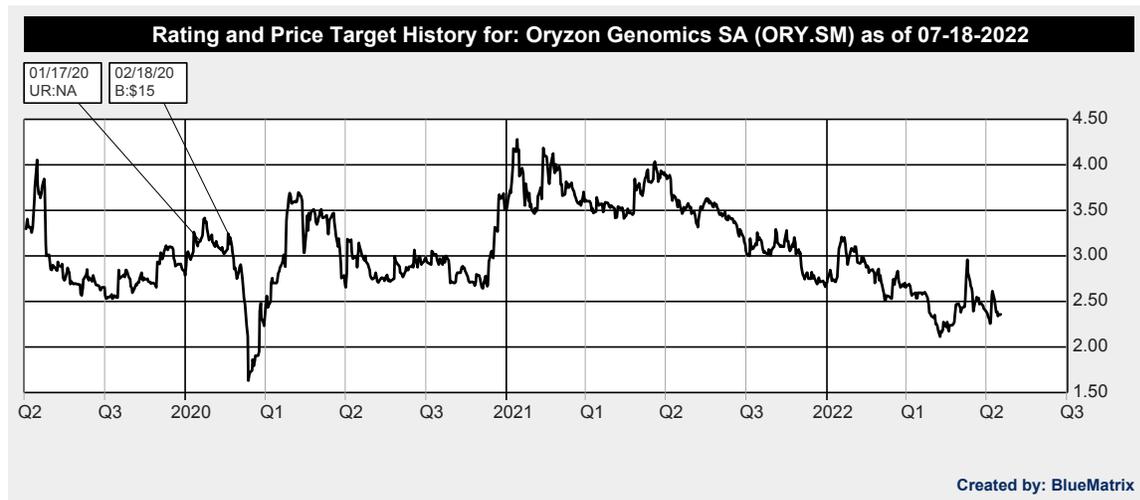
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Income Statement															
Fiscal Year ends December															
(in 000, except per share items)															
	2017A	2018A	2019A	2020A	1Q21	2Q21	3Q21	4Q21	2021A	1Q22A	2Q22E	3Q22E	4Q22E	2022E	2023E
Global iadademstat revenue															
Global vafidemstat revenue															
Collaboration revenue	20														
<b>Total revenue</b>	<b>20</b>														
Cost of revenue															
R&D	6,363	8,489	12,647	13,591	4,278	2,928	3,982	3,930	15,118	4,228	4,524	4,841	5,179	18,772	24,404
G&A	4,502	2,993	3,176	3,484	1,302	1,200	1,070	1,957	5,529	1,343	1,370	1,397	1,425	5,535	7,196
<b>Total operating expenses</b>	<b>10,865</b>	<b>11,482</b>	<b>15,823</b>	<b>17,075</b>	<b>5,580</b>	<b>4,128</b>	<b>5,052</b>	<b>5,887</b>	<b>20,647</b>	<b>5,571</b>	<b>5,894</b>	<b>6,238</b>	<b>6,605</b>	<b>24,307</b>	<b>31,600</b>
<b>Operating income</b>	<b>(10,845)</b>	<b>(11,482)</b>	<b>(15,823)</b>	<b>(17,075)</b>	<b>(5,580)</b>	<b>(4,128)</b>	<b>(5,052)</b>	<b>(5,887)</b>	<b>(20,647)</b>	<b>(5,571)</b>	<b>(5,894)</b>	<b>(6,238)</b>	<b>(6,605)</b>	<b>(24,307)</b>	<b>(31,600)</b>
Other income (net)	5,659	8,143	11,522	11,805	3,536	2,256	3,252	3,466	12,510	3,826	3,000	3,000	3,000	12,826	6,000
<b>Net income (pretax)</b>	<b>(5,186)</b>	<b>(3,339)</b>	<b>(4,301)</b>	<b>(5,269)</b>	<b>(2,044)</b>	<b>(1,872)</b>	<b>(1,800)</b>	<b>(2,421)</b>	<b>(8,137)</b>	<b>(1,745)</b>	<b>(2,894)</b>	<b>(3,238)</b>	<b>(3,605)</b>	<b>(11,481)</b>	<b>(25,600)</b>
Net financial & tax	1,047	(1,991)	(187)	(1,098)	89	(2,823)	36	(62)	(2,760)	67	50	50	50	217	239
<b>Net income</b>	<b>(6,233)</b>	<b>(1,348)</b>	<b>(4,114)</b>	<b>(4,171)</b>	<b>(2,133)</b>	<b>951</b>	<b>(1,836)</b>	<b>(2,359)</b>	<b>(5,377)</b>	<b>(1,812)</b>	<b>(2,944)</b>	<b>(3,288)</b>	<b>(3,655)</b>	<b>(11,698)</b>	<b>(25,838)</b>
EPS basic	(0.20)	(0.04)	(0.10)	(0.08)	(0.04)	0.02	(0.03)	(0.04)	(0.10)	(0.03)	(0.06)	(0.05)	(0.06)	(0.20)	(0.39)
EPS diluted	(0.20)	(0.04)	(0.10)	(0.08)	(0.04)	0.02	(0.03)	(0.04)	(0.10)	(0.03)	(0.06)	(0.05)	(0.06)	(0.20)	(0.39)
Basic shares outstanding	31,711	34,638	41,589	49,235	52,762	52,762	52,762	52,762	52,762	52,762	52,762	63,314	63,377	58,054	66,546
Diluted shares outstanding	31,711	34,638	41,565	49,235	52,762	52,762	52,762	52,762	52,762	52,762	52,762	63,314	63,377	58,054	66,546

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

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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**

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 07/19/22	
			Count	Percent
Buy [B]	349	84.91	225	64.47
Neutral [N]	50	12.17	30	60.00
Sell [S]	2	0.49	1	50.00
Under Review [UR]	10	2.43	5	50.00

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