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COMPANY NOTE | EQUITY RESEARCH | March 15, 2023

Healthcare: Biotechnology **Company Update**

Oryzon Genomics SA | ORY.SM - €2.24 - MADRID | *Buy*

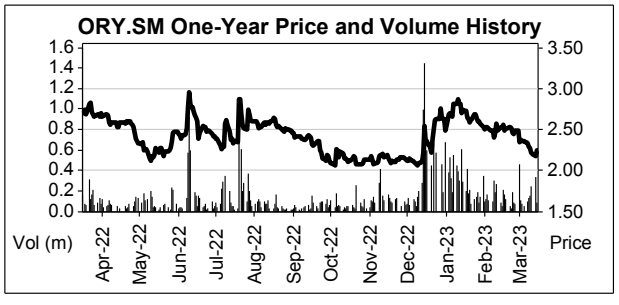
Stock Data	
52-Week Low - High	€1.98 - €3.06
Shares Out. (mil)	57.10
Mkt. Cap.(mil)	€127.89
3-Mo. Avg. Vol.	299,633
12-Mo.Price Target	€15.00
Cash (mil)	$22.7
Tot. Debt (mil)	$23.3

Rev ($M)

Yr Dec	—2022—	—2023E—	—2024E—
		Curr	Curr
1Q	0.0A	0.0E	-
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	—2022—	—2023E—	—2024E—
		Curr	Curr
1Q	(0.03)A	(0.06)E	-
2Q	0.01A	(0.06)E	-
3Q	(0.01)A	(0.08)E	-
4Q	(0.05)A	(0.09)E	-
YEAR	(0.08)A	(0.29)E	(0.60)E
P/E	NM	NM	NM



ORY: Selects HDAC-6 Inhibitor for Clinical Testing, Doses First FRIDA Patient

Earlier this week, ORY announced that it selected ORY-4001, a selective HDAC-6 inhibitor, as its drug candidate to bring into the clinic for neurological diseases such as Charcot-Marie-Tooth (CMT) and ALS, among others. HDAC-6 inhibitors are believed to be potentially effective treatments for CMT, ALS, and other neurological disorders lacking effective treatments. ORY also recently dosed the first FRIDA trial patient with combination therapy iadademstat and gilteritinib at MGH in Boston.

- Earlier this week, ORY announced that it selected ORY-4001, a selective HDAC-6 inhibitor, as its drug candidate to bring into the clinic for neurological diseases such as Charcot-Marie-Tooth (CMT) and ALS, among others. HDAC-6 inhibitors are believed to be potentially effective treatments for CMT, ALS, and other neurological disorders lacking effective treatments. Last year, ORY and the CMT Research Foundation agreed to explore ORY's HDAC-6 inhibitors, and ORY-4001 was selected due to the positive preclinical results generated under this collaboration. ORY-4001 is highly selective against other HDAC-classes, resulting in a favorable safety profile that avoids hematoxicity, as well as being strongly anti-inflammatory *in-vivo*. ORY-4001 has shown multiple positive responses in a validated CMT1A peripheral neuropathy *in vivo* model which reliably recapitulates many of the symptoms of CMT in humans, and it will now enter into IND enabling studies. CMT is a progressive, degenerative peripheral nerve disease affecting 150k U.S. patients and over 3M globally. CMT is caused by a variety of genetic mutations, with CMT1A mutation causing the disease in about half of the patients.
- ORY also recently dosed its first AML patient in FRIDA, a Phase Ib trial evaluating iadademstat plus gilteritinib in rel/ref AML that have an FMS-like tyrosine kinase mutation (FLT3mut+), at MGH in Boston. We note that the FRIDA trial is likely ORY's fastest route to market and the FLT3 mutated population it is enrolling represents about one-third of rel/ref AML. Gilteritinib is being used in FRIDA due to the drug synergy between iadademstat and gilteritinib that was observed in preclinical studies, and because gilteritinib is approved in this specific AML setting The combination therapy is an attempt to further improve patient outcome compared to gilteritinib monotherapy, which only delivers a 2.8 month PFS, CR/CRi rate of 34%, and median OS that was 9.3 months versus salvage chemotherapy OS of 5.6 months. FRIDA has primary endpoints of safety, tolerability, and determining the RP2D, and secondary endpoints of efficacy (i.e., CR/CRh, DoR, MRD).

(ORY recently traded at €2.14 at 9:41AM 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 4x multiple of our projected 2030 operating income of $1.04 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.

Oryzon Genomics SA
Income Statement
Fiscal Year ends December
(in 000, except per share items)

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	2017A	2018A	2019A	2020A	2021A	1Q22	2Q22	3Q22	4Q22	2022A	1Q23E	2Q23E	3Q23E	4Q23E	2023E	2024E
Global iadademstat revenue																
Global vafidemstat revenue																
Collaboration revenue	20															
Total revenue	**20**															
Cost of revenue																-
R&D	6,363	8,489	12,647	13,591	15,118	4,228	4,166	4,274	5,033	17,701	5,184	5,340	5,500	5,665	21,688	27,110
G&A	4,502	2,993	3,176	3,484	5,529	1,343	1,520	659	1,249	4,771	1,261	1,274	1,287	1,300	5,122	11,269
Total operating expenses	**10,865**	**11,482**	**15,823**	**17,075**	**20,647**	**5,571**	**5,686**	**4,933**	**6,282**	**22,472**	**6,445**	**6,614**	**6,787**	**6,964**	**26,810**	**38,379**
Operating income	**(10,845)**	**(11,482)**	**(15,823)**	**(17,075)**	**(20,647)**	**(5,571)**	**(5,686)**	**(4,933)**	**(6,282)**	**(22,472)**	**(6,445)**	**(6,614)**	**(6,787)**	**(6,964)**	**(26,810)**	**(38,379)**
Other income (net)	5,659	8,143	11,522	11,805	12,510	3,826	3,894	4,248	4,693	16,661	3,000	3,000	2,000	2,000	10,000	
Net income (pretax)	**(5,186)**	**(3,339)**	**(4,301)**	**(5,269)**	**(8,137)**	**(1,745)**	**(1,792)**	**(685)**	**(1,589)**	**(5,811)**	**(3,445)**	**(3,614)**	**(4,787)**	**(4,964)**	**(16,810)**	**(38,379)**
Net financial & tax	1,047	(1,991)	(187)	(1,098)	(2,760)	67	(2,139)	(67)	863	(1,276)	(250)	(250)	(250)	(250)	(1,000)	(1,100)
Net income	**(6,233)**	**(1,348)**	**(4,114)**	**(4,171)**	**(5,377)**	**(1,812)**	**347**	**(618)**	**(2,452)**	**(4,535)**	**(3,195)**	**(3,364)**	**(4,537)**	**(4,714)**	**(15,810)**	**(37,279)**
EPS basic	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.10)**	**(0.03)**	**0.01**	**(0.01)**	**(0.05)**	**(0.08)**	**(0.06)**	**(0.06)**	**(0.08)**	**(0.09)**	**(0.29)**	**(0.60)**
EPS diluted	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.10)**	**(0.03)**	**0.01**	**(0.01)**	**(0.05)**	**(0.08)**	**(0.06)**	**(0.06)**	**(0.08)**	**(0.09)**	**(0.29)**	**(0.60)**
Basic shares outstanding	31,711	34,638	41,589	49,235	52,762	52,762	52,762	53,609	54,284	53,354	54,338	54,393	54,447	54,502	54,420	62,583
Diluted shares outstanding	31,711	34,638	41,565	49,235	52,762	52,762	52,762	53,609	54,284	53,354	54,338	54,393	54,447	54,502	54,420	62,583

Source: SEC filings, company press releases, and ROTH MKM

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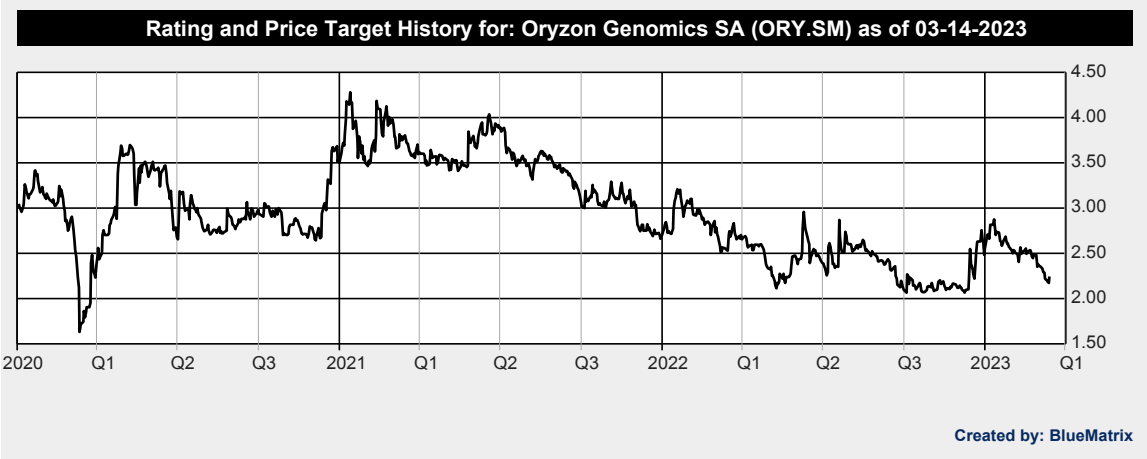
Disclosures:

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 03/15/23	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**369**	**74.40**	**221**	**59.89**
Neutral [N]	**97**	**19.56**	**29**	**29.90**
Sell [S]	**3**	**0.60**	**0**	**0**
Under Review [UR]	**25**	**5.04**	**9**	**36.00**

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.

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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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