ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | June 10, 2022

Healthcare: Biotechnology **Company Update**

Oryzon Genomics SA | ORY.SM - €2.96 - MADRID | *Buy*

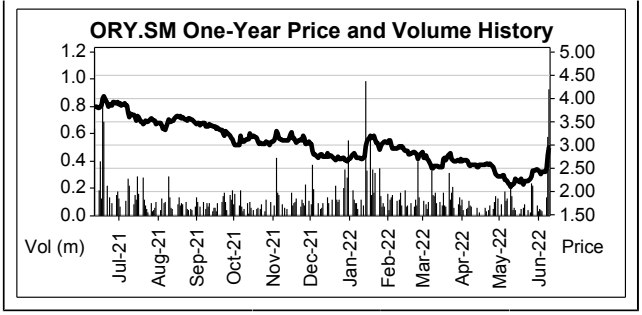
Stock Data	
52-Week Low - High	€2.04 - €4.10
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€156.80
3-Mo. Avg. Vol.	109,977
12-Mo.Price Target	€15.00
Cash (mil)	$28.0
Tot. Debt (mil)	$17.0

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: Favorable AML Trial Update at EHA - Iada Produces Rapid, Durable Responses

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.

- 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% (7 CR, 7 CRi, and 8 PR among 27 efficacy evaluable patients), 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, and of the four CR patients that were tested by flow cytometry, three (75%) were MRD negative.
- We note that median time to response remains swift, with 91% of the patients responding by the end of cycle 2 (i.e., 55 days), and duration of response remains encouraging, with three patients on study for more than one year, two patients for more than two years, and one patient for more than three years. We note that 9 of the 14 (64%) of patients with CR/CRi responded for more than six months, up from 8 of 13 (62%) reported at ASH 2021. Of note, all three evaluable patients with FLT3-ITD and six of the eight (75%) patients with p53 mutations responded, thereby justifying ORY's future trial in AML with FLT3 mutation.
- The 90µg/m2/day iadademstat dose produced a higher plasma drug concentration versus 60µg/m2/day (median C trough at steady-state 14pg/mL versus 6pg/mL, respectively; $p<0.05$) and higher and more consistent LSD1 target engagement in PBMCs at day 5 (median 91% versus 80%; $p<0.05$). At the 90µg/m2/day dose, 63% of patients achieved CR/CRi, versus 39% at the 60µg/m2/day dose. Also, the median exposure in patients with CR/CRi is higher than in those with a PR (14 versus 5pg/mL), and the median target engagement in all patients that responded is almost 90%.
- The most frequent safety event linked to treatment was platelet reduction, which was observed in 53% of patients, but we note that grade ≥3 thrombocytopenia was already present at baseline in 58% of patients. Serious adverse events occurring in more than one patient include febrile neutropenia, pneumonia, pyrexia, cellulitis, sepsis, COVID-19 pneumonia, respiratory tract infection, skin infection, urinary tract infection, septic shock, and intracranial hemorrhage. The most frequent grade 3 and 4 events include febrile neutropenia, platelet count decrease, neutrophil count decrease, anemia, asthenia, and cellulitis. There are 13 reported on-study deaths, due to infection (8), bleeding (3) or other (2). *(text continued on page 2)*

- ORY was also recently awarded the Seal of Excellence, a quality label awarded by the European Commission, and a non-refundable public grant of €1.87 million (about $2 million), which is slated to offset the cost of the iadademstat program in AML, particularly the ongoing FRIDA trial, and to develop the formulation and manufacturing processes for industrial production of iadademstat. The FRIDA trial will evaluate iadademstat plus gilteritinib in patients with rel/ref AML with FLT3 mutations.
- We note that the FDA recently granted Orphan Drug Designation (ODD) to iadademstat for small cell lung cancer (SCLC), and the drug already has ODD for AML in the U.S. and Europe. Orphan Drug Designation provides certain benefits, including market exclusivity upon regulatory approval if received, exemption of FDA application fees, and tax credits for qualified clinical trials.

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 $1.42 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	1Q21	2Q21	3Q21	4Q21	2021A	1Q22A	2Q22E	3Q22E	4Q22E	2022E	2023E
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	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
Total operating expenses	**10,865**	**11,482**	**15,823**	**17,075**	**5,580**	**4,128**	**5,052**	**5,887**	**20,647**	**5,571**	**5,894**	**6,238**	**6,605**	**24,307**	**31,600**
Operating income	**(10,845)**	**(11,482)**	**(15,823)**	**(17,075)**	**(5,580)**	**(4,128)**	**(5,052)**	**(5,887)**	**(20,647)**	**(5,571)**	**(5,894)**	**(6,238)**	**(6,605)**	**(24,307)**	**(31,600)**
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
Net income (pretax)	**(5,186)**	**(3,339)**	**(4,301)**	**(5,269)**	**(2,044)**	**(1,872)**	**(1,800)**	**(2,421)**	**(8,137)**	**(1,745)**	**(2,894)**	**(3,238)**	**(3,605)**	**(11,481)**	**(25,600)**
Net financial & tax	1,047	(1,991)	(187)	(1,098)	89	(2,823)	36	(62)	(2,760)	67	50	50	50	217	239
Net income	**(6,233)**	**(1,348)**	**(4,114)**	**(4,171)**	**(2,133)**	**951**	**(1,836)**	**(2,359)**	**(5,377)**	**(1,812)**	**(2,944)**	**(3,288)**	**(3,655)**	**(11,698)**	**(25,838)**
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

Oryzon Genomics SA - Revenue Build
Iadademstat AML

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U.S. second-line AML market	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Incidence of second-line AML patients in U.S. (000)		6.4	6.4	6.4	6.5	6.5	6.5
Percent market penetration		1.0%	2.5%	4.5%	6.3%	6.6%	6.7%
Number of patients treated (000)		0.06	0.16	0.29	0.41	0.43	0.43
Annual iadademstat net price		90,000	91,800	93,636	95,509	97,419	99,367
U.S. iadademstat AML revenue to Oryzon (000)		**5,740**	**14,694**	**27,087**	**38,835**	**41,758**	**43,191**

EU5 second-line AML market	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Incidence of second-line AML patients in EU5 (000)			6.4	6.4	6.4	6.4	6.4
Percent market penetration			1.0%	2.0%	3.4%	4.4%	4.6%
Number of patients treated (000)			0.1	0.1	0.2	0.3	0.3
Annual iadademstat net price			70,000	70,000	70,000	70,000	70,000
EU5 iadademstat AML revenue to Oryzon (000)			**4,468**	**8,954**	**15,253**	**19,868**	**20,903**

Total iadademstat AML revenue to Oryzon (000)	**$ 5,740**	**$ 19,163**	**$ 36,041**	**$ 54,087**	**$ 61,627**	**$ 64,095**

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

Oryzon Genomics SA - Revenue Build
Iadademstat SCLC

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U.S. first-line SCLC market	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Incidence of first-line SCLC in U.S. (000)		30	30	30	31	31	31
Percent market penetration		0.5%	2.5%	6.3%	9.4%	11.3%	11.8%
Number of patients treated (000)		0	1	2	3	3	4
Annual iadademstat net price		90,000	91,800	93,636	95,509	97,419	99,367
U.S. iadademstat SCLC revenue to Oryzon (000)		**13,594**	**69,605**	**178,203**	**273,741**	**336,399**	**361,724**

EU5 first-line SCLC market	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Incidence of first-line SCLC in EU5 (000)			30	30	30	30	30
Percent market penetration			0.5%	2.0%	5.0%	7.0%	8.1%
Number of patients treated (000)			0.1	0.6	1.5	2.1	2.4
Annual iadademstat net price			70,000	70,000	70,000	70,000	70,000
EU5 iadademstat SCLC revenue to Oryzon (000)			**10,426**	**41,787**	**104,676**	**146,839**	**169,203**

Total iadademstat SCLC revenue to Oryzon (000)	**$ 13,594**	**$ 80,031**	**$ 219,989**	**$ 378,416**	**$ 483,238**	**$ 530,927**

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

Oryzon Genomics SA - Revenue Build
Vafidemstat BPD

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U.S. BPD market	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Incidence of BPD in U.S. (000)		3,356	3,370	3,383	3,397	3,410	3,424
Percent market penetration		1.0%	2.0%	2.5%	2.8%	2.9%	3.0%
Number of patients treated (000)		34	67	85	93	98	104
Annual vafidemstat net price (capsule formulation)		35,000	35,700	36,414	37,142	37,885	38,643
EU5 BPD revenue to future partner (000)		1,174,760	2,406,097	3,080,044	3,469,633	3,730,841	4,011,713
royalty rate		15%	15%	15%	15%	15%	15%
U.S. vafidemstat BPD royalty revenue to Oryzon (000)		**176,214**	**360,914**	**462,007**	**520,445**	**559,626**	**601,757**

EU5 BPD market	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Incidence of BPD in EU5 (000)			3,273	3,280	3,287	3,293	3,300
Percent market penetration			1.0%	2.0%	2.5%	2.8%	2.9%
Number of patients treated (000)			32.7	65.6	82.2	90.6	95.3
Annual vafidemstat net price (capsule formulation)			25,000	25,000	25,000	25,000	25,000
EU5 BPD revenue to future partner (000)			818,355	1,639,984	2,054,080	2,264,007	2,381,962
royalty rate			15%	15%	15%	15%	15%
EU5 vafidemstat BPD royalty revenue to Oryzon (000)			**122,753**	**245,998**	**308,112**	**339,601**	**357,294**

Total vafidemstat BPD royalty revenue to Oryzon (000)	**$ 176,214**	**$ 483,668**	**$ 708,004**	**$ 828,557**	**$ 899,227**	**$ 959,051**
Source: SEC filings, company press releases, and ROTH Capital Partners							

Oryzon Genomics SA - Revenue Build
Vafidemstat Kabuki syndrome

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U.S. Kabuki syndrome market	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Incidence of Kabuki syndrome in U.S. (000)	3.0	3.0	3.0	3.0	3.1	3.1	3.1
Percent market penetration	1.0%	3.0%	6.0%	10.2%	15.3%	19.9%	23.9%
Number of patients treated (000)	0.03	0.1	0.2	0.3	0.5	0.6	0.7
Annual vafidemstat net price (pediatric liquid formulation)	125,000	127,500	130,050	132,651	135,304	138,010	140,770
U.S. vafidemstat Kabuki syndrome revenue to Oryzon (000)	**3,761**	**11,555**	**23,666**	**41,200**	**63,289**	**84,257**	**103,543**

EU5 Kabuki syndrome market	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Incidence of Kabuki syndrome in EU5 (000)		2.2	2.2	2.2	2.2	2.2	2.2
Percent market penetration		1.0%	3.0%	6.0%	10.2%	15.3%	19.9%
Number of patients treated (000)		0.02	0.1	0.1	0.2	0.3	0.4
Annual vafidemstat net price (pediatric liquid formulation)		100,000	100,000	100,000	100,000	100,000	100,000
EU5 vafidemstat Kabuki syndrome revenue to Oryzon (000)		**2,156**	**6,481**	**12,989**	**22,125**	**33,254**	**43,316**

Total Kabuki syndrome revenue to Oryzon (000)	**$ 3,761**	**$ 13,711**	**$ 30,147**	**$ 54,189**	**$ 85,414**	**$ 117,510**	**$ 146,859**
Source: SEC filings, company press releases, and ROTH Capital Partners							

Oryzon Genomics SA - Discounted Cash Flow Model

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	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023	12/31/2024	12/31/2025	12/31/2026	12/31/2027	12/31/2028	12/31/2029	12/31/2030
EBIT	(11,482)	(15,823)	(17,075)	(20,647)	(24,307)	(31,600)	(49,340)	125,190	454,446	824,029	1,117,078	1,307,017	1,429,298
Taxes	(1,991)	(187)	(1,098)	(2,760)	217	239	263	289	113,612	206,007	279,270	326,754	357,324
NOPAT	(9,491)	(15,636)	(15,977)	(17,887)	(24,524)	(31,838)	(49,603)	124,901	340,835	618,022	837,809	980,262	1,071,973
Dep. & Amor.	-	-	-	-	-	-	-	-	-	-	-	-	-
EBITDA	(11,482)	(15,823)	(17,075)	(20,647)	(24,307)	(31,600)	(49,340)	125,190	454,446	824,029	1,117,078	1,307,017	1,429,298

TP date	6/3/2023

-0.42	0.58	1.58	2.58	3.58	4.58	5.58	6.58	7.58

Discount rate	A: PV of CF's 2017 - 2025	+	B: PV of TV as a Multiple of Ebitda 2	3	4	5	6	7	=	C: Enterprise Value 2	3	4	5	6	7
30.0%	$ 810,400		391,454	587,181	782,908	978,635	1,174,362	1,370,089		1,201,854	1,397,581	1,593,308	1,789,035	1,984,762	2,180,489
35.0%	$ 648,531		294,085	441,127	588,170	735,212	882,255	1,029,297		942,616	1,089,659	1,236,701	1,383,744	1,530,786	1,677,829
40.0%	$ 522,648		223,245	334,868	446,491	558,113	669,736	781,359		745,893	857,516	969,139	1,080,761	1,192,384	1,304,007
45.0%	$ 423,626		171,117	256,675	342,234	427,792	513,351	598,909		594,743	680,302	765,860	851,418	936,977	1,022,535
50.0%	$ 344,908		132,348	198,523	264,697	330,871	397,045	463,219		477,256	543,431	609,605	675,779	741,953	808,127

	D: Net Debt	=	Total Equity Value 2	3	4	5	6	7	Value Per Diluted Share 2	3	4	5	6	7
30.0%	(10,500)		1,212,354	1,408,081	1,603,808	1,799,535	1,995,262	2,190,989	$19.13	$22.22	$25.31	$28.39	$31.48	$34.57
35.0%	(10,500)		953,116	1,100,159	1,247,201	1,394,244	1,541,286	1,688,329	$15.04	$17.36	$19.68	$22.00	$24.32	$26.64
40.0%	(10,500)		756,393	868,016	979,639	1,091,261	1,202,884	1,314,507	$11.93	$13.70	$15.46	$17.22	$18.98	$20.74
45.0%	(10,500)		605,243	690,802	776,360	861,918	947,477	1,033,035	$9.55	$10.90	$12.25	$13.60	$14.95	$16.30
50.0%	(10,500)		487,756	553,931	620,105	686,279	752,453	818,627	$7.70	$8.74	$9.78	$10.83	$11.87	$12.92

NOPAT	PV	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
	$ 810,400						$ (27,395)	$ (27,358)	$ (32,786)	$ 63,505	$ 133,305	$ 185,935	$ 193,892	$ 174,507	$ 146,795
	$ 648,531						$ (27,835)	$ (26,767)	$ (30,891)	$ 57,618	$ 116,466	$ 156,432	$ 157,084	$ 136,143	$ 110,282
	$ 522,648						$ (28,265)	$ (26,211)	$ (29,168)	$ 52,461	$ 102,255	$ 132,440	$ 128,242	$ 107,177	$ 83,717
	$ 423,626						$ (28,687)	$ (25,684)	$ (27,596)	$ 47,923	$ 90,189	$ 112,784	$ 105,444	$ 85,084	$ 64,169
	$ 344,908						$ (29,100)	$ (25,186)	$ (26,159)	$ 43,913	$ 79,887	$ 96,570	$ 87,276	$ 68,077	$ 49,631

EBITDA	PV	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
	$ 1,089,313						$ (27,153)	$ (27,153)	$ (32,613)	$ 63,652	$ 177,739	$ 247,914	$ 258,522	$ 232,676	$ 195,727
	$ 874,744						$ (27,589)	$ (26,567)	$ (30,727)	$ 57,751	$ 155,288	$ 208,576	$ 209,446	$ 181,524	$ 147,042
	$ 707,980						$ (28,015)	$ (26,014)	$ (29,013)	$ 52,582	$ 136,340	$ 176,586	$ 170,989	$ 142,902	$ 111,623
	$ 576,886						$ (28,433)	$ (25,492)	$ (27,450)	$ 48,034	$ 120,253	$ 150,379	$ 140,592	$ 113,446	$ 85,558
	$ 472,741						$ (28,843)	$ (24,997)	$ (26,020)	$ 44,014	$ 106,516	$ 128,760	$ 116,368	$ 90,769	$ 66,174

ROTH

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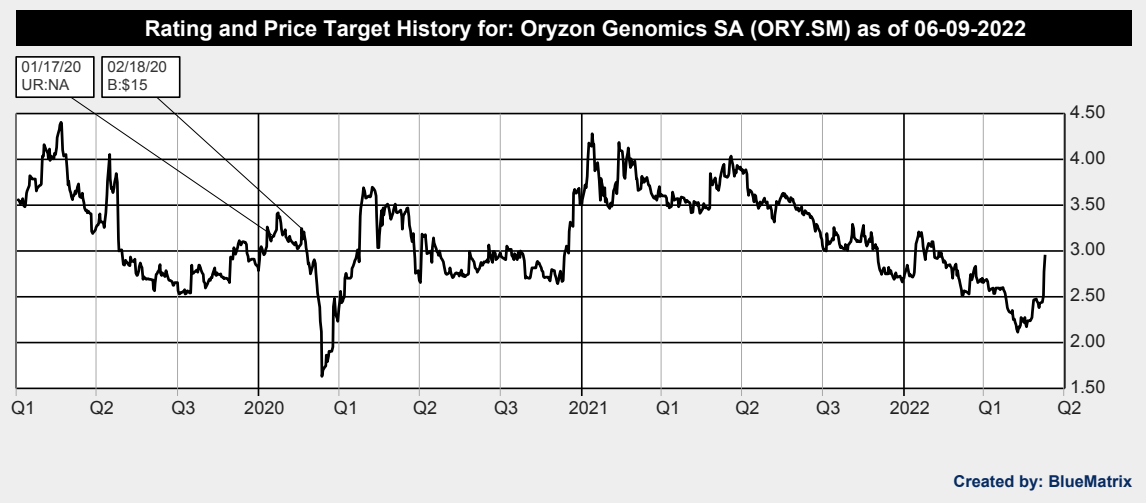
Disclosures:

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 06/10/22	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**343**	**81.86**	**226**	**65.89**
Neutral [N]	**46**	**10.98**	**27**	**58.70**
Sell [S]	**2**	**0.48**	**1**	**50.00**
Under Review [UR]	**25**	**5.97**	**17**	**68.00**

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.

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.

ROTH Capital Partners, LLC expects to receive or intends to seek compensation for investment banking or other business relationships with the covered companies mentioned in this report in the next three months. The material, information and facts discussed in this report other than the information regarding ROTH Capital Partners, LLC and its affiliates, are from