ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | January 23, 2022

Healthcare: Biotechnology **Company Update**

Oryzon Genomics SA | ORY.SM - €3.12 - MADRID | *Buy*

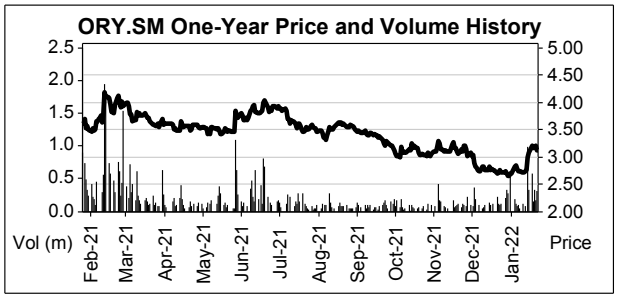
Stock Data	
52-Week Low - High	€2.63 - €4.34
Shares Out. (mil)	53.06
Mkt. Cap.(mil)	€165.56
3-Mo. Avg. Vol.	156,841
12-Mo.Price Target	€15.00
Cash (mil)	$35.8
Tot. Debt (mil)	$14.9

Revenue ($ millions)

Yr Dec	—2020—	—2021E—	—2022E—
		Curr	Curr
1Q	0.0A	0.0A	0.0E
2Q	0.0A	0.0A	0.0E
3Q	0.0A	0.0A	0.0E
4Q	0.0A	0.0E	0.0E
YEAR	0.0A	0.0E	0.0E

EPS $

Yr Dec	—2020—	—2021E—		—2022E—
		Curr	Prev	Curr
1Q	(0.03)A	(0.04)A	(0.04)A	(0.05)E
2Q	0.00A	0.02A	0.02A	(0.05)E
3Q	(0.02)A	(0.03)A	(0.03)A	(0.05)E
4Q	(0.03)A	(0.05)E	(0.04)E	(0.06)E
YEAR	(0.08)A	(0.10)E	(0.10)	(0.21)E
P/E	NM	NM	NM	NM



ORY: Not Just Cancer - Emphasizing Vafidemstat's Potential in CNS Disease

We adjusted our financial model to better describe vafidemstat and iadademstat's commercial potential in four indications we view as most likely addressable. We note that 65% of our projected 2030 revenue for ORY comes from vafidemstat from royalties on sales for borderline personality disorder (BPD) and from direct vafidemstat sales for Kabuki syndrome. Excluded from our projected revenue is schizophrenia royalties due to high competition, but we note that the potential there is almost as large as that for BPD.

- **Vafidemstat.** As a potential first-in-class LSD1 inhibitor, vafidemstat has repeatedly demonstrated its ability to enhance sociability and neuroprotection, while also reducing aggression and neuroinflammation in clinical trials and animal disease models. The drug is now the subject of two ongoing Phase 2b trials (PORTICO in BPD and EVOLUTION in schizophrenia), and a Phase 1/2 trial (HOPE) in Kabuki syndrome. PORTICO is enrolling 156 patients in the U.S. and EU, with co-primary endpoints of overall clinical BPD improvement and improvement in aggression. The potential vafidemstat market is large, with about three million BPD patients in each the U.S. and EU5 (pre-Brexit) geographies incorporated into our financial projections. Our model includes projections for BPD rather than for schizophrenia given the far lower competition in BPD, and with annual drug prices in the $25,000 to $35,000 range depending on geography, and a modeled 15% royalty rate, ORY need only gain a sliver of the market to receive substantial revenue. As for Kabuki syndrome, a monogenic loss of function condition with excess chromosomal demethylation as the core problem, vafidemstat sufficiently addressed six key elements of the disease in mice harboring a defective copy of the KMT2D gene (gene dose matters in Kabuki syndrome). The HOPE trial will soon (IND filing and first patient dosed expected in 1H22) begin enrolling 60 patients and could support accelerated approval given the absence of treatment alternatives. Our view of the market takes into consideration the roughly 5,000 patients in the U.S. and EU5, as well as a $100,000 to $125,000 pricing depending on geography, which generates almost $150 million in 2030 assuming about a 20% penetration, all of which goes to ORY.
- **Compelling REIMAGINE trial results support BPD trial.** While we believe that vafidemstat is unlikely to materially impact MS, Alzheimer's or COVID-19, given our take on those completed trials, we were particularly impressed with final Phase 2a results (REIMAGINE trial) from mid-2020 showing the drug's ability to reduce agitation and aggression in patients with BPD, ADHD, or autism spectrum disorder (ASD). REIMAGINE was an open-label trial treating agitation and aggression in 30 patients (11 ADHD, 7 ASD, and 12 BPD) with daily vafidemstat doses of 1.2mg for eight weeks. Vafidemstat was safe and well-tolerated, with no serious adverse events and no patient withdrawals due to adverse events. Per protocol, efficacy for all analyses (defined as the 23 (9 BPD, 8 ADHD, 6 ASD) of the 30 patients that completed all eight weeks of treatment) was *(text continued on page 2)*

- *(text continued from page 1)* measured using the clinical global impression of severity and improvement scales (CGI-S and CGII), and the 4-item neuropsychiatric inventory agitation-aggression (NPIA/A) scale, with overall functioning assessed using the 12-item total NPI scale and individual disease-specific scales. Vafidemstat produced statistically significant reductions in CGI-S, CGI-I, NPI A/A, and total NPI, both in the full aggregated dataset, and in each disease group, as well as statistically improved patient scores in each disease specific scale (BPDCL and C-SSRS (suicidal ideation) scales for BPD, and ADHD-RS for ADHD. There were also statistically significant efficacy correlations (linear regression analyses) for total NPI versus BPDCL, NPI-A/A versus CGI-I, and NPI-A/A versus CGI-S, demonstrating the drug's consistency of benefit.
- **Safety across the board.** Vafidemstat's safety record is highly favorable, with the drug having already been given to more than 300 subjects and the initial Phase 1 trial (n=110; 87 received vafidemstat) showing a placebo-like safety profile. We believe that the growing clinical evidence in favor of vafidemstat should attract an increasing amount of business development interest.
- **Iadademstat in rel/ref AML.** We have not lost sight of oncology asset iadademstat, especially with the most recent compelling results last month at ASH. Iadademstat plus azacitadine (Phase 2 ALICE trial) delivered robust results in 27 evaluable elderly/unfit AML patients, with a 78% ORR (62% CR/CRi, 38% PR), and 77% of the CR/CRi patients having durable responses lasting >six months (one ongoing response lasting >1,000 days). Looking only at patients receiving 90ug/m2/d of iadademstat, a 77% ORR and 80% CR/CRi rate was achieved. There were only two serious AEs reported as being probably related to the combination therapy treatment, one grade 3 differentiation syndrome and one fatal intracranial hemorrhage. The most frequent AE was platelet reduction, which was observed in 44% of patients, although grade 3 or lower thrombocytopenia was already present at baseline in 61% of patients. This safety profile is consistent with ALICE trial results shown at ASH 2020 and at EHA 2021. There were no other significant non-hematological toxicities or other organ-related toxicities observed, and we emphasize that ALICE enrolled a fragile median patient age of 77 years. ALICE enrollment is complete and 90ug/m2/d is the dose for future combination therapy evaluation. Next up for iadademstat is the Phase 1b/2 FRIDA trial (IND filing and first patient dosed in 1H22), which will treat rel/ref AML patients with iadademstat/gilteritinib versus gilteritinib alone in the Phase 2 portion once Phase 1b establishes the best iadademstat dose for the combination. Should Phase 2 demonstrate the combination's superiority over gilteritinib regarding CR rate, response duration, and minimal residual disease, the trial could support accelerated approval.
- **Iadademstat in first-line SCLC.** After demonstrating a strong preclinical rationale (drug synergy) for combining iadademstat with a checkpoint inhibitor, ORY plans to conduct the randomized, controlled Phase 1b/2 STELLAR trial in first-line, metastatic SCLC (IND filing and first patient dosed in 1H22), especially given the modest two-month survival benefit observed with checkpoint inhibitor/chemotherapy in this setting and iadademstat's far better safety profile than chemotherapy. Upon establishing the best Phase 2 combination dose, Phase 2 will test the combination against a checkpoint inhibitor alone as maintenance therapy after standard of care chemotherapy, with PFS as the endpoint. The STELLAR trial can also potentially support an application for accelerated approval.

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 $1.46 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. We view our valuation to be conservative given that it excludes revenue from vafidemstat in schizophrenia. 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 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 is a clinical stage biopharmaceutical company considered as the European champion 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 ongoing programs for developing inhibitors against other epigenetic targets. In addition, Oryzon has a strong platform for biomarker identification and performs biomarker and target validation for a variety of malignant and neurological diseases.

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

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	2017A	2018A	2019A	2020A	1Q21A	2Q21A	3Q21A	4Q21E	2021E	1Q22E	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	4,380	15,568	4,599	4,829	5,071	5,324	19,823	25,770
G&A	4,502	2,993	3,176	3,484	1,302	1,200	1,070	1,081	4,653	1,092	1,102	1,113	1,125	4,432	5,762
Total operating expenses	**10,865**	**11,482**	**15,823**	**17,075**	**5,580**	**4,128**	**5,052**	**5,461**	**20,221**	**5,691**	**5,932**	**6,184**	**6,449**	**24,255**	**31,532**
Operating income	**(10,845)**	**(11,482)**	**(15,823)**	**(17,075)**	**(5,580)**	**(4,128)**	**(5,052)**	**(5,461)**	**(20,221)**	**(5,691)**	**(5,932)**	**(6,184)**	**(6,449)**	**(24,255)**	**(31,532)**
Other income (net)	5,659	8,143	11,522	11,805	3,536	2,256	3,252	3,000	12,044	3,000	3,000	3,000	3,000	12,000	6,000
Net income (pretax)	**(5,186)**	**(3,339)**	**(4,301)**	**(5,269)**	**(2,044)**	**(1,872)**	**(1,800)**	**(2,461)**	**(8,177)**	**(2,691)**	**(2,932)**	**(3,184)**	**(3,449)**	**(12,255)**	**(25,532)**
Net financial & tax	1,047	(1,991)	(187)	(1,098)	89	(2,823)	36	50	(2,648)	50	50	50	50	200	220
Net income	**(6,233)**	**(1,348)**	**(4,114)**	**(4,171)**	**(2,133)**	**951**	**(1,836)**	**(2,511)**	**(5,529)**	**(2,741)**	**(2,982)**	**(3,234)**	**(3,499)**	**(12,455)**	**(25,752)**
EPS basic	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.04)**	**0.02**	**(0.03)**	**(0.05)**	**(0.10)**	**(0.05)**	**(0.05)**	**(0.05)**	**(0.06)**	**(0.21)**	**(0.41)**
EPS diluted	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.04)**	**0.02**	**(0.03)**	**(0.05)**	**(0.10)**	**(0.05)**	**(0.05)**	**(0.05)**	**(0.06)**	**(0.21)**	**(0.41)**
Basic shares outstanding	31,711	34,638	41,589	49,235	52,762	52,762	52,762	52,762	52,762	55,400	60,386	60,446	60,506	59,184	63,532
Diluted shares outstanding	31,711	34,638	41,565	49,235	52,762	52,762	52,762	52,762	52,762	55,400	60,386	60,446	60,506	59,184	63,532

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

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

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	2017A	2018A	2019A	2020A	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Global iadademstat revenue									19,333	99,193	256,030	432,504	544,865	595,022
Global vafidemstat revenue								3,761	189,925	513,815	762,193	913,971	1,016,738	1,105,910
Collaboration revenue	20													
Total revenue	**20**								**209,258**	**613,008**	**1,018,224**	**1,346,474**	**1,561,602**	**1,700,932**
Cost of revenue								564	4,957	18,108	43,431	67,329	86,109	89,026
R&D	6,363	8,489	12,647	13,591	15,568	19,823	25,770	34,790	41,748	43,835	44,273	44,716	45,163	45,615
G&A	4,502	2,993	3,176	3,484	4,653	4,432	5,762	12,675	31,688	79,221	87,143	95,858	100,651	105,683
Total operating expenses	**10,865**	**11,482**	**15,823**	**17,075**	**20,221**	**24,255**	**31,532**	**48,029**	**78,393**	**141,164**	**174,847**	**207,903**	**231,923**	**240,324**
Operating income	**(10,845)**	**(11,482)**	**(15,823)**	**(17,075)**	**(20,221)**	**(24,255)**	**(31,532)**	**(48,029)**	**130,865**	**471,844**	**843,376**	**1,138,571**	**1,329,680**	**1,460,608**
Other income (net)	5,659	8,143	11,522	11,805	12,044	12,000	6,000							
Net income (pretax)	**(5,186)**	**(3,339)**	**(4,301)**	**(5,269)**	**(8,177)**	**(12,255)**	**(25,532)**	**(48,029)**	**130,865**	**471,844**	**843,376**	**1,138,571**	**1,329,680**	**1,460,608**
Net financial & tax	1,047	(1,991)	(187)	(1,098)	(2,648)	200	220	242	266	117,961	210,844	284,643	332,420	365,152
Net income	**(6,233)**	**(1,348)**	**(4,114)**	**(4,171)**	**(5,529)**	**(12,455)**	**(25,752)**	**(48,271)**	**130,599**	**353,883**	**632,532**	**853,929**	**997,260**	**1,095,456**
EPS basic	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.10)**	**(0.21)**	**(0.41)**	**(0.72)**	**1.86**	**4.81**	**8.19**	**10.53**	**11.71**	**12.25**
EPS diluted	**(0.20)**	**(0.04)**	**(0.10)**	**(0.08)**	**(0.10)**	**(0.21)**	**(0.41)**	**(0.60)**	**1.55**	**4.04**	**6.93**	**8.98**	**10.06**	**10.59**
Basic shares outstanding	31,711	34,638	41,589	49,235	52,762	59,184	63,532	66,708	70,044	73,546	77,223	81,084	85,139	89,396
Diluted shares outstanding	31,711	34,638	41,565	49,235	52,762	59,184	63,532	80,746	84,081	87,583	91,260	95,122	99,176	103,433

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

Contribution to Revenue By Indication

Drug/Indication	2030 Revenue (million)	Percent Total Revenue
Iadademstat	**$595**	**35%**
AML	$64	4%
SCLC	$531	31%
Vafidemstat	**$1,106**	**65%**
BPD	$959	56%
Kabuki syndrome	$147	9%

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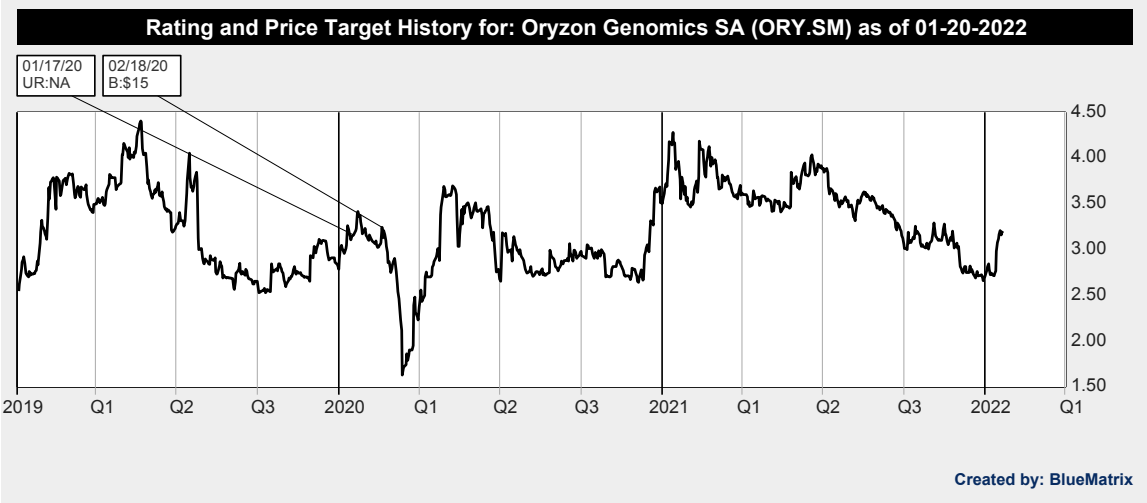

Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of 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 01/24/22	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**344**	**81.90**	**232**	**67.44**
Neutral [N]	**47**	**11.19**	**24**	**51.06**
Sell [S]	**1**	**0.24**	**0**	**0**
Under Review [UR]	**28**	**6.67**	**17**	**60.71**

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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