ROTH Capital Partners

Jerry Isaacson, Ph.D., (406) 425-0563
jisaacson@roth.com

Sales (800) 933-6830, **Trading** (800) 933-6820

COMPANY NOTE | EQUITY RESEARCH | July 18, 2019

Healthcare: Biotechnology

Oryzon Genomics SA | ORY.SM - €3.68 - MADRID | *Buy*

Company Update

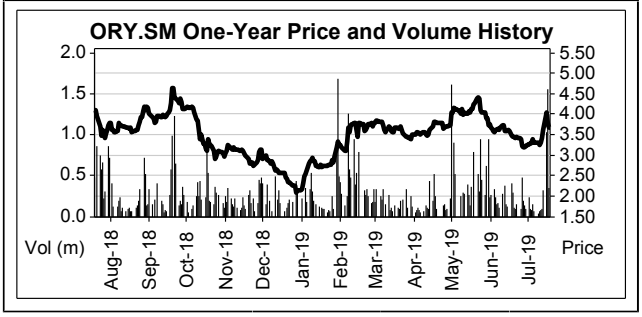
Stock Data	
52-Week Low - High	€2.06 - €4.83
Shares Out. (mil)	39.12
Mkt. Cap.(mil)	€143.78
3-Mo. Avg. Vol.	337,711
12-Mo.Price Target	€15.00
Cash (mil)	$39.3
Tot. Debt (mil)	$0.0

EPS $

Yr Dec	—2018—	—2019E—	—2020E—
		Curr	Curr
1Q	(0.04)A	(0.04)A	(0.05)E
2Q	0.06A	(0.06)E	(0.06)E
3Q	(0.03)A	(0.06)E	(0.06)E
4Q	(0.02)A	(0.06)E	(0.06)E
YEAR	(0.04)A	(0.21)E	(0.24)E
P/E	NM	NM	NM

Revenue ($ millions)

Yr Dec	—2018—	—2019E—	—2020E—
		Curr	Curr
1Q	0.0A	0.0E	0.0E
2Q	0.0A	0.0E	0.0E
3Q	0.0A	0.0E	0.0E
4Q	0.0A	0.0E	0.0E
YEAR	0.0A	0.0E	0.0E



ORY.SM: Positive Alzheimer's News for a Change

Topline. In light of yet another BACE1 inhibitor, CNP520, trial suspended, we reiterate our continued interest in the emerging non-Amyloid Alzheimer's disease-modifying therapeutic landscape. With this in mind, we continue to to be excited about Oryzon's vafidemstat Phase 2a Alzheimer's ETHERAL LSD1/MAO-B targeted study. The AAIC-2019 update reinforced vafidemstat's clinical path, cultivating potential value upside for the stock.

Key Takeaways and what we like about ETHERAL. Briefly, vafidemstat is Oryzon's lead epigenetic LSD1/MAO-B inhibitor being evaluated in a Phase 2a, 24-week, double-blind, placebo-controlled study for the treatment of patients with mild-to-moderate Alzheimer's disease (AD). The trial is evaluating the drug's safety profile as well as symptomatic and potential disease modifying benefits in 125 EU and 30 U.S. patients. The trial design will measure the clinically relevant AD biomarkers including: CSF Aß42/40 ratio, Tau, p-Tau, YKL-40, neurogranin, NfL chain. We believe a positive biomarker signal emerging from vafidemstat treatment could establish vafidemstat as the first safe epigenetic Alzheimer's disease-modifying therapeutic agent.

What's important so far? We are pleased to see that vafidemstat has, thus far, illustrated a clean safety profile. More importantly, though, we look forward seeing data from the clinically meaningful measures such as the Clinical Dementia Rating Scale Sum of Boxes (CDR-SB), Alzheimer's Disease Assessment Scale-Cognitive (ADAS-cog), Mini-mental State Examination (MMSE) and Computerized Cognitive Test Battery (Cogstate). We note that the MMSE results, while blinded, could indicate a positive cognitive signal emerging.

Why Safety Matters. Vafidemstat is a brain-penetrating epigenetic dual LSD1/MAO-B inhibitor. Epigenetic modulators first emerged for the treatment of various cancers. These assets are historically plagued by SAEs, thus creating a barrier for the drugs' utility outside of oncology. However, next-generation compounds have enjoyed success by producing a cleaner safety profile, thereby paving a regulatory path towards their use in neurological disorders. We believe that because ~90% of the enrolled patients have been treated for >1 month without hematological signs indicates vafidemstat's safety profile is favorable for chronic dosing in AD. Moreover, while the cognitive outcome measures are clinically relevant to AD, we view agitation and depression measures embedded within secondary outcomes with equal commercial potential and conceivable value-driving upside to the stock.

VALUATION

We maintain our rating, price target and valuation: our 12-month price target of €15/share (rounded: €4/share for ORY-1001 in AML + €10/share for ORY-2001 in AD + €1/share in cash) is based on a DCF-SoP analysis using a 12% discount rate and 1% growth rate. Factors which could impede the achievement of our target price include, but are not limited to: (1) failure and/ or setbacks of the drugs in clinical studies; (2) failure of the drugs to gain regulatory approval; and (3) smaller than projected commercial opportunity due to changes in market size, competitive landscape, and drug pricing and reimbursement.

RISKS

Experimental therapeutic product risk. The company's risk profile is based primarily, in our belief, on the company's thesis being based on the clinical and commercial prospects of pipeline candidates. Current funding at the company is being directed toward these programs and should there be any missteps, negative trial data or delays, this could impact the stock negatively. Adding additional risk to both programs is their early stage nature. Drug development is fraught with failures and this risk is increased significantly during the earlier stages of development.

Development timeline risk. The company's shares could be subject to increased volatility, in our belief, based on the time frame required to get meaningful proof of concept data from the planned clinical program. Positive clinical data could yield a potential accelerated path toward approval, however we currently project that our modeled drug candidates ORY-1001 and ORY-2001 may only reach the market in 2023 and 2024, respectively. Investors may choose to delay investment in the company, despite potential excitement, until meaningful clinical data is generated.

Financing risk. As with a majority of development-stage biotechnology companies, the ability to maintain sufficient funding is critical to the progress of pipeline candidates. Should the company experience problems raising sufficient capital, its development programs' progress could be significantly impeded, leading to both delays in development timelines as well as potential negative effects on investor confidence. Each of these could have a negative impact on share price.

COMPANY DESCRIPTION

Oryzon Genomics S.A., headquartered in Barcelona, Spain, is a clinical stage biotechnology company focused on the discovery and development of epigenetic therapies in oncology and neurodegenerative diseases. Its first clinical asset, ORY-1001, an inhibitor of the histone demethylase LSD1, is currently advancing into a Phase 2 study in acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS), and a Phase 1 study in small cell lung cancer (SCLC). Its second clinical asset, ORY-2001, a dual inhibitor of LSD1 and MAO-B, is currently in proof-of-concept Phase 2 studies in Alzheimer's disease (AD) and multiple sclerosis (MS).

Oryzon Genomics, S.A.
Income Statement
(in $'1000s)

Jerry Isaacson, Ph.D.
ROTH Capital Partners, LLC
jisaacson@roth.com
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	2015	2016	2017	Mar Q1:18	Jun Q2:18	Sep Q3:18	Dec Q4:18	2018	Mar Q1:19	Jun Q2:19E	Sep Q3:19E	Dec Q4:19E	2019E	Mar Q1:20E	Jun Q2:20E	Sep Q3:20E	Dec Q4:20E	2020E
Collaborations	4,647	775	20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total revenues	4,647	775	20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Research and development	4053	5,492	6,363	2,334	2,113	1,942	2,324	8,489	2,610	2,741	2,878	3,021	11,249	3,172	3,331	3,498	3,673	13,674
General and administrative	4624	5,011	4,502	887	838	816	539	2,993	876	920	966	1,014	3,776	1,065	1,118	1,174	1,233	4,589
Total operating expenses	8,677	10,503	10,865	3,221	2,951	2,758	2,863	11,482	3,486	3,660	3,843	4,035	15,025	4,237	4,449	4,672	4,905	18,263
Loss from operations	(4,030)	(9,728)	(10,845)	(3,221)	(2,951)	(2,758)	(2,863)	(11,482)	(3,486)	(3,660)	(3,843)	(4,035)	(15,025)	(4,237)	(4,449)	(4,672)	(4,905)	(18,263)
Other income	3774	4,903	5,659	2,458	1,960	1,776	2,177	8,143	2,497	967	977	987	5,428	2,497	967	977	987	5,428
Tax	-829	(918)	(1,047)	(499)	2,835	(153)	(178)	1,991	(368)	330	440	550	952	(368)	330	440	550	952
Net loss	(1,085)	(5,743)	(6,233)	(1,262)	1,844	(1,135)	(864)	(1,348)	(1,357)	(2,363)	(2,426)	(2,498)	(8,645)	(2,108)	(3,152)	(3,255)	(3,368)	(11,883)
Net loss per share	(0.04)	(0.21)	(0.20)	(0.04)	0.06	(0.03)	(0.02)	(0.04)	(0.04)	(0.06)	(0.06)	(0.06)	(0.21)	(0.05)	(0.06)	(0.06)	(0.06)	(0.24)
Weighted average shares	24,729	27,569	31,711	33,493	33,493	33,493	37,214	34,638	38,455	40,378	42,397	44,516	41,436	46,742	49,079	51,533	52,564	49,980

Source: www.oryzon.com and ROTH Capital Partners.

Oryzon Genomics, S.A.
Revenue Model
(in €'MM except patient numbers)

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ROTH Capital Partners, LLC
jisaacson@roth.com
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ORY-1001	**2018**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
ORY-1001 WW Sales	€ -	€ -	€ -	€ -	€ -	€ 50	€ 185	€ 333	€ 417	€ 442	€ 450
ORY-1001 WW Revenue to Oryzo	€ -	€ -	€ -	€ -	€ -	€ 50	€ 156	€ 246	€ 284	€ 292	€ 297
ORY-1001 US Sales											
US new AML cases per year	21,666	21,833	22,001	22,170	22,341	22,513	22,686	22,861	23,037	23,215	23,393
Growth Rate	*0.77%*	*0.77%*	*0.77%*	*0.77%*	*0.77%*	*0.77%*	*0.77%*	*0.77%*	*0.77%*	*0.77%*	*0.77%*
Percent patients eventually R/R	*55%*	*55%*	*55%*	*55%*	*55%*	*55%*	*55%*	*55%*	*55%*	*55%*	*55%*
Patients eligible for ORY-1001	11,916	12,008	12,101	12,194	12,288	12,382	12,478	12,574	12,670	12,768	12,866
Penetration of eligible patients						*4%*	*12%*	*18%*	*20%*	*20%*	*20%*
Number of patients on ORY-1001					-	495	1,497	2,263	2,534	2,554	2,573
Avg Annual Cost (x €1000)						100	101	102	103	104	105
YoY price increase							*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*
ORY-1001 US Revenue	€ -	€ -	€ -	€ -	€ -	€ 50	€ 151	€ 231	€ 261	€ 266	€ 270
ORY-1001 EU Sales	**€ -**	**€ -**	**€ -**	**€ -**		**€ -**	**€ 33**	**€ 102**	**€ 156**	**€ 176**	**€ 179**
EU Royalty	€ -	€ -	€ -	€ -	€ -	€ -	€ 5	€ 15	€ 23	€ 26	€ 27
EU royalty rate	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*
Source: www.oryzon.com and RO	*68%*	*68%*	*68%*	*68%*	*68%*	*68%*	*68%*	*68%*	*68%*	*68%*	*68%*
% of US market	*120%*	*120%*	*120%*	*120%*	*120%*	*120%*	*120%*	*120%*	*120%*	*120%*	*120%*
% of US penetration	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*
% of US treatment cost	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*

ORY-2001	**2018**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
ORY-2001 WW Sales	€ -	€ -	€ -	€ -	€ -	€ -	€ 350	€ 1,308	€ 2,911	€ 4,265	€ 4,727
ORY-2001 WW Revenue to Oryzo	€ -	€ -	€ -	€ -	€ -	€ -	€ 350	€ 1,107	€ 2,296	€ 3,010	€ 3,127
ORY-2001 US Sales											
AD prevalence (x 1000)	5,500	5,555	5,611	5,667	5,723	5,781	5,838	5,897	5,956	6,015	6,075
Growth Rate	*1.00%*	*1.00%*	*1.00%*	*1.00%*	*1.00%*	*1.00%*	*1.00%*	*1.00%*	*1.00%*	*1.00%*	*1.00%*
Percent mild/moderate disease	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*
Patients eligible for ORY-2011 (x	3,300	3,333	3,366	3,400	3,434	3,468	3,503	3,538	3,573	3,609	3,645
Penetration of eligible patients							*1%*	*3%*	*6%*	*8%*	*8%*
Number of patients on ORY-2001 (x 1000)					-		35	106	214	271	273
Avg Annual Cost (x €1000)							10	10	10	10	10
YoY price increase								*1.0%*	*1.0%*	*1.0%*	*1.0%*
US Revenue	€ -	€ -	€ -	€ -	€ -	€ -	€ 350	€ 1,072	€ 2,187	€ 2,789	€ 2,845
ORY-2001 EU Sales	**€ -**	**€ -**	**€ -**	**€ -**		**€ -**	**€ -**	**€ 236**	**€ 724**	**€ 1,476**	**€ 1,883**
EU Royalty	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ 35	€ 109	€ 221	€ 282
EU royalty rate	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*
EU/US adjustment factor	*68%*	*68%*	*68%*	*68%*	*68%*	*68%*	*68%*	*68%*	*68%*	*68%*	*68%*
% of US market	*120%*	*120%*	*120%*	*120%*	*120%*	*120%*	*120%*	*120%*	*120%*	*120%*	*120%*
% of US penetration	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*
% of US treatment cost	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*

Source: ROTH Capital Partners.

Oryzon Genomics, S.A.
Valuation
(in €'MM, except per share values)

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ORY-1001 in AML	2018	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Total Revenue	0	0	0	0	0	50	156	246	284	292	297
COGS	-	-	-	-	-	(7)	(20)	(28)	(29)	(27)	(27)
% of revenue	0%	0%	0%	0%	0%	14%	13%	12%	11%	10%	10%
OpEx	(10)	(6)	(9)	(10)	(11)	(12)	(13)	(13)	(14)	(15)	(15)
% of revenue						24%	8%	5%	5%	5%	5%
Operating Income	(10)	(6)	(9)	(10)	(11)	31	124	205	242	251	255
Tax Rate	0%	0%	0%	0%	0%	26%	26%	26%	26%	26%	26%
Net Income	(10)	(6)	(9)	(10)	(11)	23	92	152	179	186	189
Periods	0.00	0.00	0.75	1.75	2.75	3.75	4.75	5.75	6.75	7.75	8.75
Discounted income	(10)	(6)	(9)	(10)	(11)	15	55	81	86	80	73

ORY-2001 in AD	2018	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Total Revenue	0	0	0	0	0	0	350	1,107	2,296	3,010	3,127
Net Income	(10)	(9)	(14)	(14)	(17)	(18)	209	702	1,489	1,985	2,087
Periods	0.00	0.00	0.75	1.75	2.75	3.75	4.75	5.75	6.75	7.75	8.75
Discounted income	(10)	(9)	(14)	(14)	(12)	(12)	120	357	675	799	747

ORY-1001, AML Valuation		
Discount Rate		12%
Growth Rate		1%
CPV		1,044
CPV/share	€	22.22
Adj CPV/share	€	4

ORY-2001, AD Valuation		
Discount Rate		12%
Growth Rate		1%
CPV		8,944
CPV/share	€	190.29
Adj CPV/share	€	10

Share Valuation	Probability		Adj Value		Full Value
ORY-1001, AML	20%	€	4	€	22
ORY-2001, AD	5%	€	10	€	190
Cash		€	1	€	1
Price Target		**€**	**15**	€	213

Source: ROTH Capital Partners.

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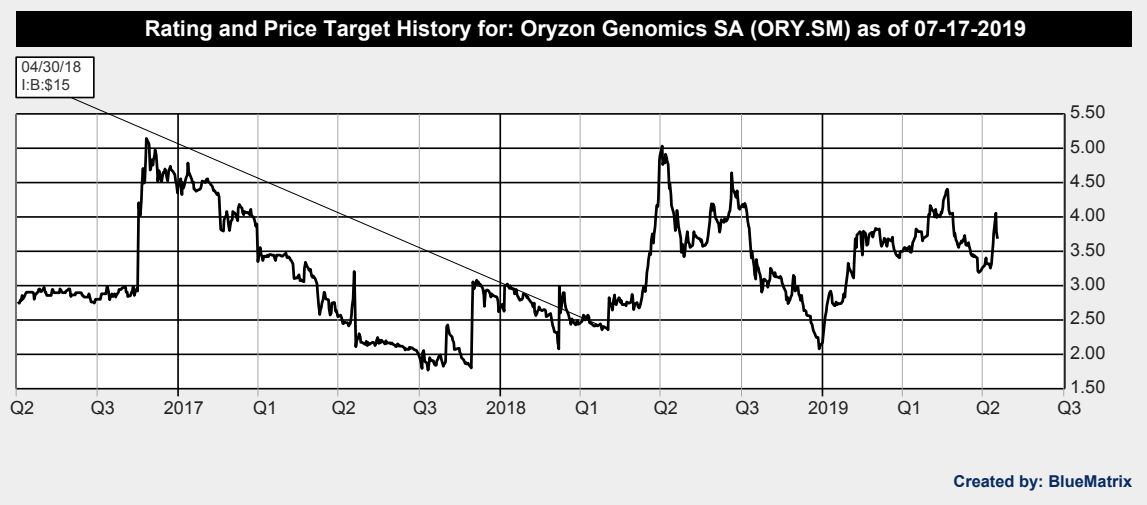
Disclosures:

Within the last twelve months, ROTH has received compensation for investment banking services from Oryzon Genomics SA.

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 07/18/19	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**270**	**75.21**	**146**	**54.07**
Neutral [N]	**45**	**12.53**	**20**	**44.44**
Sell [S]	**5**	**1.39**	**2**	**40.00**
Under Review [UR]	**39**	**10.86**	**19**	**48.72**

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.