ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | March 22, 2019

Healthcare: Biotechnology

Oryzon Genomics SA | ORY.SM - €3.60 - MADRID | *Buy*

Company Update

Estimates Changed

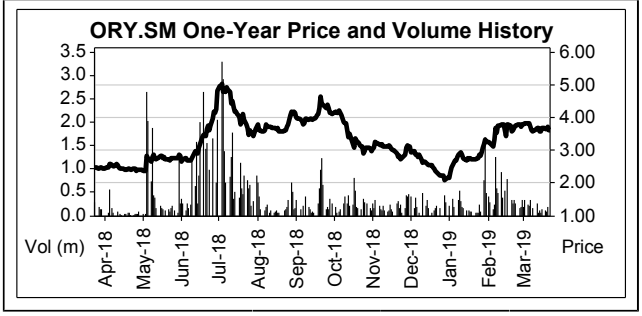
Stock Data	
52-Week Low - High	€2.06 - €5.18
Shares Out. (mil)	39.12
Mkt. Cap.(mil)	€140.84
3-Mo. Avg. Vol.	318,423
12-Mo.Price Target	€15.00
Cash (mil)	$39.3
Tot. Debt (mil)	$0.0

EPS $

Yr Dec	—2017—	—2018—		—2019E—	
		Curr	Prev	Curr	Prev
1Q	-	(0.04)A	(0.04)A	(0.05)E	(0.05)E
2Q	-	0.06A	0.06A	(0.05)E	(0.05)E
3Q	-	(0.03)A	(0.03)A	(0.05)E	(0.05)E
4Q	-	(0.09)A	(0.03)E	(0.05)E	(0.05)E
YEAR	(0.20)A	(0.04)A	(0.05)E	(0.20)E	(0.19)E
P/E	NM	NM	NM	NM	NM

Revenue ($ millions)

Yr Dec	—2017—	—2018—	—2019E—
		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	0.0A	0.0E



ORY.SM: Three Key Developments in CNS; Reiterate Buy

Topline. We continue to view Oryzon as an underappreciated member of the new wave of companies tackling neurodegeneration by engaging novel targets and using novel trial designs. In our report we dissect three recent developments (two internal, one external) which highlight the timeliness and potential value of the clinical program of Oryzon's LSD1/MAO-B inhibitor vafidemstat in CNS.

One: Alzheimer's study now extended to include the U.S. Last week, Oryzon took a first step towards becoming Americanized: the FDA approved the IND for the Phase 2a ETHERAL study of vafidemstat in mild/moderate Alzheimer's disease (AD). The study, which opened last year and expects to enroll 125 patients in Spain, France, and the U.K., will now add an extra 25 patients from the U.S. Overall, we are optimistic about vafidemstat's dual targeting of LSD1 and MAO-B in AD. In our view, the LSD1 thesis rests on a wide preclinical portfolio covering models of neuroinflammation, neuroprotection, and behavioral phenomena like aggression/agitation and social withdrawal. Meanwhile, the MAO-B thesis is supported by a string of clinical studies with older MAO-B inhibitors, suggesting a potential for clinical activity of monotherapy in earlier stages of AD.

Two: First human data in CNS are in, and they are encouraging. This week, Oryzon reported preliminary data from a cohort with Borderline Personality Disorder (BPD) in the Phase 2a REIMAGINE basket study. Vafidemstat led to improvement in several scores following just two months of treatment. Importantly, the benefit manifested in both BPD-specific scoring tools (CSSR, BPDCL) as well as scoring tools which are typically associated more broadly with CNS disorders (CGI, NPI), suggesting that the agent can exercise wide neuroactivity, We look forward to more detailed data in two weeks, at the EPA 2019 congress in Poland on 6-9 April.

Three: Aducanumab failure suggests urgent need for developers and investors to diversify away from amyloid targeting. Yesterday, the best known of all anti-amyloid Phase 3 programs (Biogen's aducanumab) was discontinued following a futility analysis. We have historically and consistently expressed skepticism around the amyloid dogma, and believe that this failure may finally become a turning point in the industry's hypotheses around AD pathogenesis. Overall, we now expect investors to turn their attention towards the new wave of targets and mechanisms underlying neurodegeneration (including epigenetics), and we expect big pharma to begin viewing this novel cohort of companies as possible BD and M&A targets.

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)

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	2015	2016	2017	Mar Q1:18	Jun Q2:18	Sep Q3:18	Dec Q4:18	2018	Mar Q1:19E	Jun Q2:19E	Sep Q3:19E	Dec Q4:19E	2019E
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	2,382	2,442	2,503	2,565	9,892
General and administrative	4624	5,011	4,502	887	838	816	539	2,993	857	900	945	992	3,693
Total operating expenses	8,677	10,503	10,865	3,221	2,951	2,758	2,863	11,482	3,239	3,341	3,447	3,557	13,585
Loss from operations	(4,030)	(9,728)	(10,845)	(3,221)	(2,951)	(2,758)	(2,863)	(11,482)	(3,239)	(3,341)	(3,447)	(3,557)	(13,585)
Other income	3774	4,903	5,659	2,458	1,960	1,776	2,177	8,143	957	967	977	987	3,888
Tax	-829	(918)	(1,047)	(499)	2,835	(153)	(178)	1,991	220	330	440	550	1,540
Net loss	(1,085)	(5,743)	(6,233)	(1,262)	1,844	(1,135)	(864)	(1,348)	(2,062)	(2,044)	(2,030)	(2,020)	(8,157)
Net loss per share	(0.04)	(0.21)	(0.20)	(0.04)	0.06	(0.03)	(0.09)	(0.04)	(0.05)	(0.05)	(0.05)	(0.05)	(0.20)
Weighted average shares	24,729	27,569	31,711	33,493	33,493	33,493	37,214	34,638	37,958	38,718	41,234	43,915	40,456

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

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

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ORY-1001 in AML	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Total Revenue	0	0	0	0	0	50	156	221	256	290	297
Net Income	(3)	(4)	(4)	(9)	(14)	18	87	131	155	179	183
Periods	0.00	0.00	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00
Discounted income	(3)	(4)	(4)	(9)	(14)	12	51	68	72	75	69

ORY-2001 in AD	2018E	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	(7)	(10)	(10)	(15)	(24)	(43)	190	682	1,468	1,962	2,063
Periods	0.00	0.00	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00
Discounted income	(7)	(10)	(10)	(15)	(17)	(27)	106	337	646	767	718

ORY-1001, AML Valuation		
Discount Rate		12%
Growth Rate		1%
CPV		969.44
CPV/share	€	22.03
Adj CPV/share	€	4.41

ORY-2001, AD Valuation		
Discount Rate		12%
Growth Rate		1%
CPV		8,825.85
CPV/share	€	200.59
Adj CPV/share	€	10.03

Share Valuation					
	Probability		Adj Value		Full Value
ORY-1001, AML	20%	€	4	€	22
ORY-2001, AD	5%	€	10	€	201
Cash		€	1	€	1
Price Target		**€**	**15**	€	224

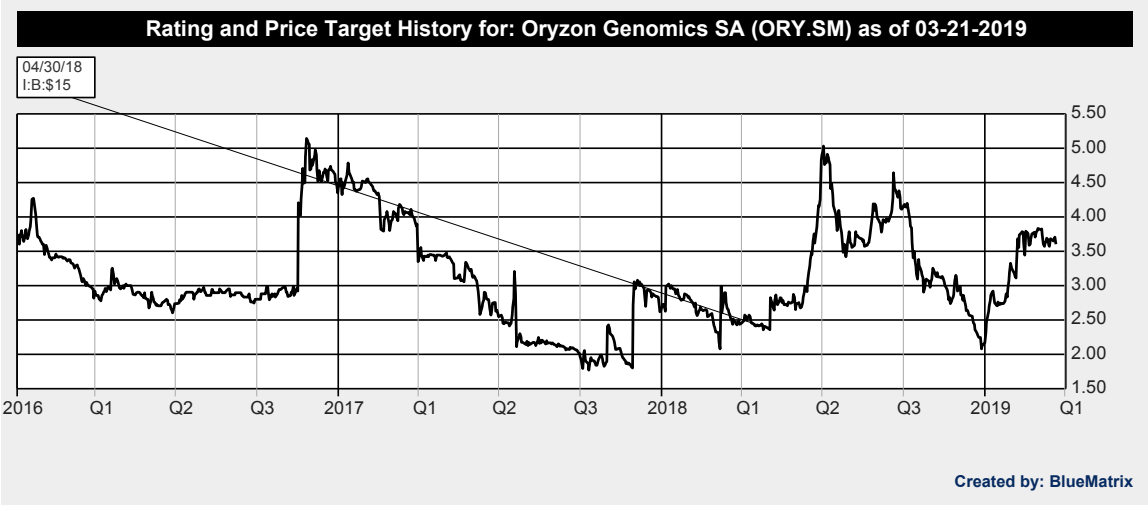
Source: ROTH Capital Partners research.

Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject company or companies and its or their securities. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

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 03/22/19	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**266**	**76.44**	**141**	**53.01**
Neutral [N]	**52**	**14.94**	**30**	**57.69**
Sell [S]	**3**	**0.86**	**1**	**33.33**
Under Review [UR]	**26**	**7.47**	**12**	**46.15**

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.