ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | July 10, 2019

Healthcare: Biotechnology

Oryzon Genomics SA | ORY.SM - €3.25 - MADRID | *Buy*

Transferring Coverage

Estimates Changed

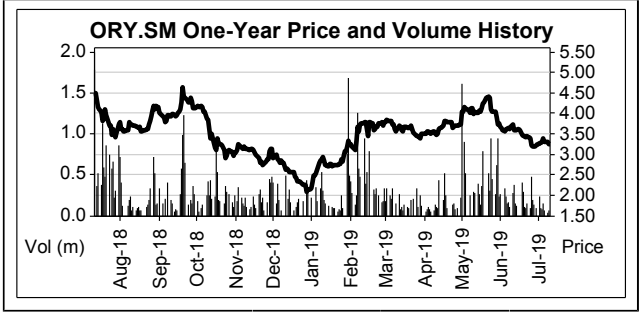
Stock Data	
52-Week Low - High	€2.06 - €5.02
Shares Out. (mil)	39.12
Mkt. Cap.(mil)	€127.15
3-Mo. Avg. Vol.	304,308
12-Mo.Price Target	€15.00
Cash (mil)	$39.3
Tot. Debt (mil)	$0.0

EPS $

Yr Dec	—2018—	—2019E—		—2020E—
		Curr	Prev	Curr
1Q	(0.04)A	(0.04)A	(0.05)E	(0.05)E
2Q	0.06A	(0.06)E	(0.05)E	(0.06)E
3Q	(0.03)A	(0.06)E	(0.05)E	(0.06)E
4Q	(0.02)A	(0.06)E	(0.05)E	(0.06)E
YEAR	(0.04)A	(0.21)E	(0.20)E	(0.24)E
P/E	NM	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: LSD1-Mediated Oncology Programs

We remain fans of Oryzon's LSD1 targeting pipeline and its utility in lateral expansion of its epigenetic portfolio into multiple indications. While the previous clinical updates took shape on the neuro side of its pipeline, we view Oryzon's ALICE and CLEPSIDRA oncology programs as essential value drivers for the company leading the LSD1-targeted oncology space. Effective with this report, coverage is transferred to Jerry Isaacson Ph.D.; we maintain our Buy rating and €15/share price target.

Phase 2 ALICE. Reminder, ALICE is a phase 2 iadademstat study (potent and selective LSD1 inhibitor) in combo with hypomethylating agent, azacitidine, in elderly unfit AML patients (n=36). Safety and tolerability comprise the primary, while the secondary endpoints include time to response, duration, and overall survival. The EHA update demonstrated good safety profile, target engagement, and established [90 µg/m2] dose going forward. Iadademstat showed meaningful 75% CRi, 25% PR, and 1.5 months median time to response. We view this as a positive efficacy signal serving a significant step for Oryzon by: (i) further validating efficacy and utility of LSD1 in oncology, and (ii) shaping a regulatory path for further iadademstat development in AML. To this end, this data and the vast body of literature supporting LSD1 as a promising oncology therapeutic, we are optimistic about iadademstat clinical development and look forward to a significant update in December at ASH'19.

Phase 2 CLEPSIDRA. In the emerging era of biomarker pre-specification for targeted oncology, we believe Oryzon's iadademstat opportunity is well positioned within the SCLC space. As a reminder, SCLC is plagued by ASCL1 transcription factor hyperactivity, classically known to be difficult to drug. Recent evidence showed iadademstat: (i) indirectly repressing ASCL1 by reactivating NOTCH1 signaling, (ii) demonstrating efficacy in SCLC preclinical models using therapeutically-relevant doses, and (iii) providing insight into genetically resistant, intermediate, and sensitive SCLC tumors. Together these support our view that a positive efficacy signal could emerge from CLEPSIDRA Phase 2 biomarker predefined SCLC patient study. We look forward to ESMO'19 in September and anticipate a clean safety primary endpoint along with a preview indicating positive efficacy signal (RECIST) as the upside.

The LSD1 Landscape. Historically, epigenetic modulating compounds were plagued by unacceptable safety profiles, though new generation compounds are superior and bode well on the safety profile making them a promising approach in the oncology therapeutic landscape. Other clinical stage oncology LSD1 entrants we are keeping in sight are Imago BioSciences (Private), Incyte (INCY-NC), and Celgene (CELG-NC). We believe Oryzon holds the torch as the leader in clinical stage of LSD1 inhibitors and could be first to validate LSD1 as a putative mechanism in the AML and SCLC therapeutic space.

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)

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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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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
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

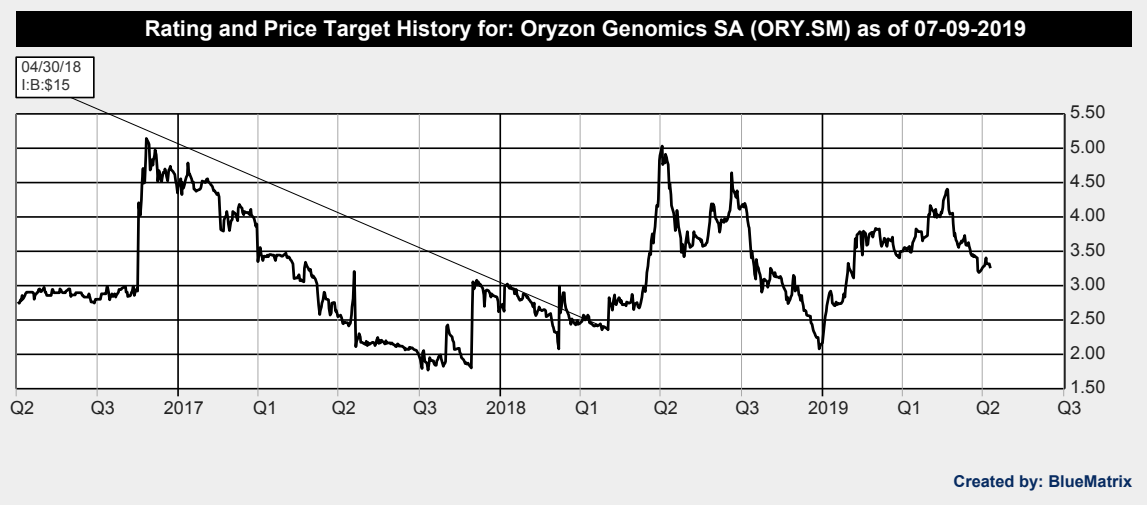
Source: ROTH Capital Partners.

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 07/10/19	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**266**	**74.51**	**141**	**53.01**
Neutral [N]	**46**	**12.89**	**20**	**43.48**
Sell [S]	**4**	**1.12**	**2**	**50.00**
Under Review [UR]	**40**	**11.20**	**21**	**52.50**

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.