ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | September 11, 2018

Healthcare: Biotechnology

Oryzon Genomics SA | ORY.SM - €3.92 - MADRID | *Buy*

Company Update

Estimates Changed

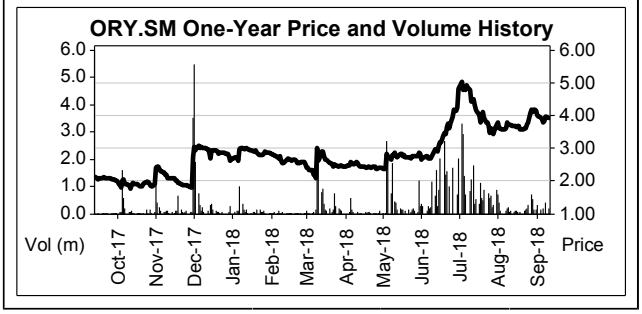
Stock Data	
52-Week Low - High	€1.75 - €5.18
Shares Out. (mil)	34.16
Mkt. Cap.(mil)	€133.7
3-Mo. Avg. Vol.	739,405
12-Mo.Price Target	€15.00
Cash (mil)	$31.2
Tot. Debt (mil)	$0.0

EPS $

Yr Dec	—2017—	—2018E—		—2019E—	
		Curr	Prev	Curr	Prev
1Q	-	(0.04)A	(0.05)E	(0.06)E	--
2Q	-	0.06A	(0.05)E	(0.06)E	--
3Q	-	(0.04)E	(0.06)E	(0.06)E	--
4Q	-	(0.04)E	(0.06)E	(0.06)E	--
YEAR	(0.20)A	(0.06)E	(0.22)E	(0.24)E	(0.26)E
P/E	NM	NM	NM	NM	NM

Revenue ($ millions)

Yr Dec	—2017—	—2018E—	—2019E—
		Curr	Curr
1Q	-	0.0A	0.0E
2Q	-	0.0A	0.0E
3Q	-	0.0E	0.0E
4Q	-	0.0E	0.0E
YEAR	0.0A	0.0E	0.0E



ORY.SM: Epigenetic Pipeline Advancing On Multiple Fronts

We reiterate our Buy rating and €15 price target. Our top key words about Oryzon are "epigenetic" and "diversified". In our view, the company's most interesting program is the ongoing Phase 2a study in Alzheimer's, representing the first clinical epigenetic approach to this disease. Meanwhile, below we highlight two developments from the last week which show parallel progress in two additional clinical directions: oncology and psychiatry.

O**RY-1001 (Iadademstat): Phase 2a in AML (ALICE).** Yesterday, Oryzon reported the CTA approval for a Phase 2a study in front-line AML. Here is what we like about this new direction: (a) we believe that the front-line is the ideal stage to test epigenetic agents in oncology (ALICE will enroll 36 newly-diagnosed elderly/unfit AML patients); (b) we believe that combination of a targeted agent with low intensity treatment in unfit patients is a good way to flush out anti-tumor activity in AML (ALICE will combine Iadademstat with azacitidine and look for response benefit); (c) we believe that aza is the best strategic choice relative to deci or LDAC (although deci and LDAC are used in Europe, only aza is likely to make the results appetizing to the American audience), and; (d) in the larger picture, we believe that the combination potential of this agent extends well beyond chemo and into immuno-oncology (read about it here). As such, this combo study is an important step forward for Oryzon's LSD1 inhibitor in oncology.

ORY-2001 (Vafidemstat): Phase 2a in neuro-psych aggression (REIMAGINE). Last week, Oryzon reported the CTA approval for a Phase 2a study in aggression across five different indications: two neurodegenerative (Alzheimer's and Lewy Body Dementia), and three psychiatric (adult ADHD, Autism Spectrum Syndrome, and Borderline Personality Disorder). Here is what we like about this new direction: (a) to the extent that manifestations of aggression across the neuro-psych spectrum may have common roots, this agent has shown reduction in exacerbated aggression in the SAMP8 mouse model; (b) we believe that a basket approach is a smart way to explore effects on aggression across indications at this stage (the study will enroll six patients per indication, open-label, eight-week treatment), and; (c) beyond the two neurodegenerative cohorts (remember that the agent is already in a Phase 2a in mild/moderate Alzheimer's), the venture into psych cohorts is a completely new step forward which could expand the drug's optionality. For example, we find the inclusion of personality disorders an especially engaging move with paradigm-shifting potential (remember that patients with a personality disorder do not even have insight into their condition, by definition, and have historically been challenging prospects for neuroactive agents, such as antipsychotics or anticonvulsants).

VALUATION

Our 12-month price target of €15/share (€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 Q3:18E	Dec Q4:18E	2018E	Mar Q1:19E	Jun Q2:19E	Sep Q3:19E	Dec Q4:19E	2019E
Collaborations	4,647	775	20	-	-	-	-	-	-	-	-	-	-
Other revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Total revenues	4,647	775	20	-	-	-	-	-	-	-	-	-	-
Research and development	4053	5,492	6,363	2,334	2,113	2,219	2,330	8,995	2,446	2,568	2,697	2,832	10,543
General and administrative	4624	5,011	4,502	887	838	880	924	3,529	970	1,019	1,070	1,123	4,181
Total operating expenses	8,677	10,503	10,865	3,221	2,951	3,099	3,253	12,524	3,416	3,587	3,766	3,955	14,724
Loss from operations	(4,030)	(9,728)	(10,845)	(3,221)	(2,951)	(3,099)	(3,253)	(12,524)	(3,416)	(3,587)	(3,766)	(3,955)	(14,724)
Other income	3774	4,903	5,659	2,458	1,960	977	987	6,382	957	967	977	987	3,888
Tax	-829	(918)	(1,047)	(499)	2,835	880	770	3,986	220	330	440	550	1,540
Net loss	(1,085)	(5,743)	(6,233)	(1,262)	1,844	(1,242)	(1,496)	(2,156)	(2,239)	(2,290)	(2,349)	(2,418)	(9,296)
Net loss per share	(0.04)	(0.21)	(0.20)	(0.04)	0.06	(0.04)	(0.04)	(0.06)	(0.06)	(0.06)	(0.06)	(0.06)	(0.24)
Weighted average shares	24,729	27,569	31,711	33,493	33,493	34,163	34,846	33,999	36,588	38,418	40,339	41,145	39,122

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	246	284	292	297
Net Income	(10)	(15)	(15)	(18)	(20)	15	84	144	170	177	179
Periods	0.00	0.50	1.50	2.50	3.50	4.50	5.50	6.50	7.50	8.50	9.50
Discounted income	(10)	(15)	(15)	(18)	(20)	9	46	71	75	70	63

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	(10)	(18)	(18)	(28)	(33)	(35)	196	688	1,475	1,969	2,071
Periods	0.00	0.50	1.50	2.50	3.50	4.50	5.50	6.50	7.50	8.50	9.50
Discounted income	(10)	(18)	(18)	(28)	(22)	(20)	103	321	612	726	679

ORY-1001, AML Valuation		
Discount Rate		12%
Growth Rate		1%
CPV		894
CPV/share	€	22.35
Adj CPV/share	€	4.47

ORY-2001, AD Valuation		
Discount Rate		12%
Growth Rate		1%
CPV		8,066
CPV/share	€	201.64
Adj CPV/share	€	10.08

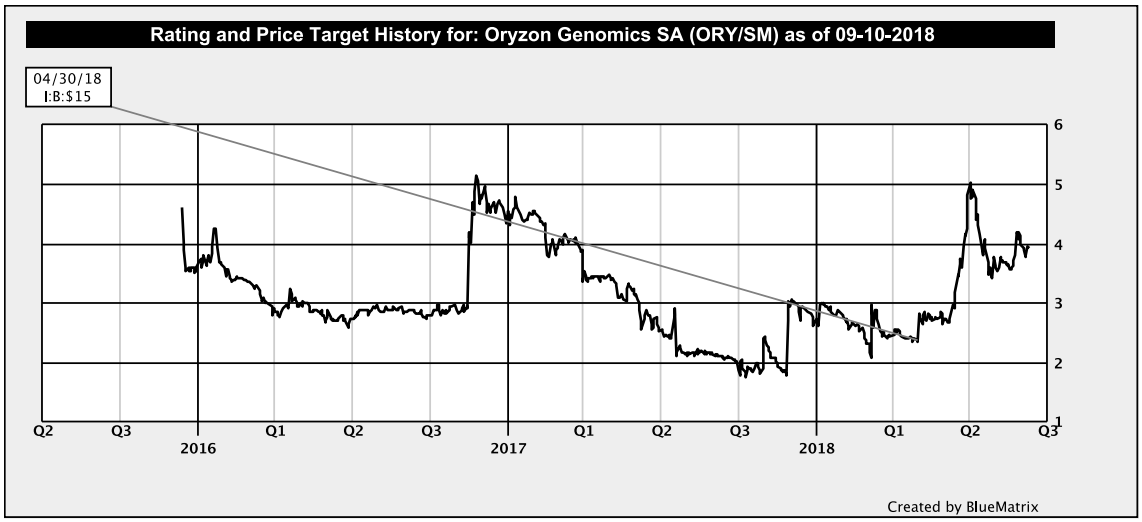
Share Valuation	Probability		Adj Value		Full Value
ORY-1001, AML	20%	€	4	€	22
ORY-2001, AD	5%	€	10	€	202
Cash		€	1	€	1
Price Target		**€**	**15**	€	225

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:

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 09/11/18	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**255**	**75.89**	**140**	**54.90**
Neutral [N]	**46**	**13.69**	**26**	**56.52**
Sell [S]	**4**	**1.19**	**2**	**50.00**
Under Review [UR]	**31**	**9.23**	**15**	**48.39**

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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