ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | November 13, 2018

Healthcare: Biotechnology

Oryzon Genomics SA | ORY.SM - €3.11 - MADRID | *Buy*

Analysis of Sales/Earnings

Estimates Changed

Stock Data	
52-Week Low - High	€1.79 - €5.18
Shares Out. (mil)	39.12
Mkt. Cap.(mil)	€121.7
3-Mo. Avg. Vol.	251,491
12-Mo.Price Target	€15.00
Cash (mil)	$41.0
Tot. Debt (mil)	$0.0

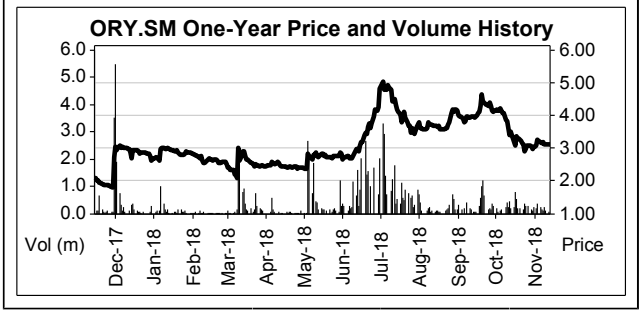
Cash (mil): Includes $26.2M in cash at the end of September and $14.8M from a private placement in October.

EPS $

Yr Dec	—2017—	—2018E—		—2019E—	
		Curr	Prev	Curr	Prev
1Q	-	(0.04)A	(0.04)A	(0.05)E	(0.06)E
2Q	-	0.06A	0.06A	(0.05)E	(0.06)E
3Q	-	(0.03)A	(0.04)E	(0.05)E	(0.06)E
4Q	-	(0.03)E	(0.04)E	(0.05)E	(0.06)E
YEAR	(0.20)A	(0.05)E	(0.06)E	(0.19)E	(0.24)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	-	0.0A	0.0E
4Q	-	0.0E	0.0E
YEAR	0.0A	0.0E	0.0E



ORY.SM: The Right Target, at the Right Time; Reiterate Buy

Our recent discussions with KOLs and our review of competitive epigenetic pipelines continue to validate Oryzon's diversified pursuit of LSD1. We remain bullish based on the development optionality ahead of multiple clinical readouts across different indications in 2019.

LSD1 target validation: KOLs. Our recent conversations with two veterans in epigenetics (one from academia and one from industry) have reinforced our interest in LSD1: independently and unsolicited, both experts singled out LSD1 as the most interesting target out there in epigenetics.

LSD1 target validation: big pharma. While a few companies are pursuing LSD1 in oncology, we highlight that Takeda has advanced an LSD1 inhibitor into neuro. The agent, TAK-418, has been dosing in healthy volunteers (see studies here and here), although based on our review of Takeda's issued patents we believe that the agent is likely to be positioned in one or more orphan neuro disorders, such as Kabuki and Kleefstra syndromes (both are associated with deletion or mutation of specific histone methyltransferases). Meanwhile, at the SFN conference last week in San Diego, Takeda presented preclinical data from a new LSD1 inhibitor (TAK-448) in CNS mouse models, suggesting that it is doubling down on this target in neuro. We view all this as strong validation of Oryzon's target and direction. In perspective, Takeda is now where Oryzon was three years ago.

The neuro program is marching on. We remain fans of Oryzon's vafidemstat as the top LSD1 targeting agent in neuro. As a reminder, vafidemstat also has lateral anti-MAO-B activity, which was selected deliberately for the neuro program, and in our view is likely to provide an important point of differentiation from other LSD1 inhibitors. Currently, Oryzon's Phase 2 studies in mild/moderate Alzheimer's and multiple sclerosis are actively recruiting. Meanwhile, recently Oryzon also started enrollment in an open-label study exploring aggression in a basket of neuro and psych disorders (REIMAGINE).

Far from quiet on the oncology front. Yesterday, Oryzon reported enrollment of the first patient in the Phase 2 study of ladademstat in combo with aza in elderly unfit AML patients (ALICE; N=36). We are believers in the potential of this agent in AML: in our view, the Phase 1 data from former partner Roche looks promising when dissected correctly (call us to discuss), and we are optimistic about epigenetic targeting in combination with HMAs (ladademstat has also shown preclinical synergy with several other anti-leukemic classes such as nucleoside analogues, retinoids, FLT3 inhibitors). Meanwhile, in addition to ALICE, the Phase 2 study of ladademstat in second line SCLC (CLEPSIDRA; N=36) is poised to begin following approval in October. Of note, these patients will be enrolled based on a screen for proprietary biomarkers.

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 Q4:18E	2018E	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	2,039	8,428	2,141	2,248	2,361	2,479	9,228
General and administrative	4624	5,011	4,502	887	838	816	857	3,398	900	945	992	1,041	3,878
Total operating expenses	8,677	10,503	10,865	3,221	2,951	2,758	2,896	11,826	3,041	3,193	3,352	3,520	13,106
Loss from operations	(4,030)	(9,728)	(10,845)	(3,221)	(2,951)	(2,758)	(2,896)	(11,826)	(3,041)	(3,193)	(3,352)	(3,520)	(13,106)
Other income	3774	4,903	5,659	2,458	1,960	1,776	987	7,181	957	967	977	987	3,888
Tax	-829	(918)	(1,047)	(499)	2,835	(153)	770	2,953	220	330	440	550	1,540
Net loss	(1,085)	(5,743)	(6,233)	(1,262)	1,844	(1,135)	(1,139)	(1,692)	(1,864)	(1,896)	(1,935)	(1,983)	(7,678)
Net loss per share	(0.04)	(0.21)	(0.20)	(0.04)	0.06	(0.03)	(0.03)	(0.05)	(0.05)	(0.05)	(0.05)	(0.05)	(0.19)
Weighted average shares	24,729	27,569	31,711	33,493	33,493	33,493	38,455	34,733	39,224	40,597	42,018	43,488	41,332

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)	(3)	(3)	(8)	(12)	21	90	133	158	181	186
Periods	0.00	0.25	1.25	2.25	3.25	4.25	5.25	6.25	7.25	8.25	9.25
Discounted income	(3)	(3)	(3)	(8)	(12)	13	51	67	71	74	68

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)	(8)	(8)	(13)	(19)	(35)	196	688	1,475	1,969	2,071
Periods	0.00	0.25	1.25	2.25	3.25	4.25	5.25	6.25	7.25	8.25	9.25
Discounted income	(7)	(8)	(8)	(13)	(13)	(21)	106	330	630	748	699

ORY-1001, AML Valuation		
Discount Rate		12%
Growth Rate		1%
CPV		963.14
CPV/share	€	22.40
Adj CPV/share	€	4.48

ORY-2001, AD Valuation		
Discount Rate		12%
Growth Rate		1%
CPV		8,611.81
CPV/share	€	200.27
Adj CPV/share	€	10.01

Share Valuation					
	Probability		Adj Value		Full Value
ORY-1001, AML	20%	€	4	€	22
ORY-2001, AD	5%	€	10	€	200
Cash		€	1	€	1
Price Target		**€**	**15**	€	224

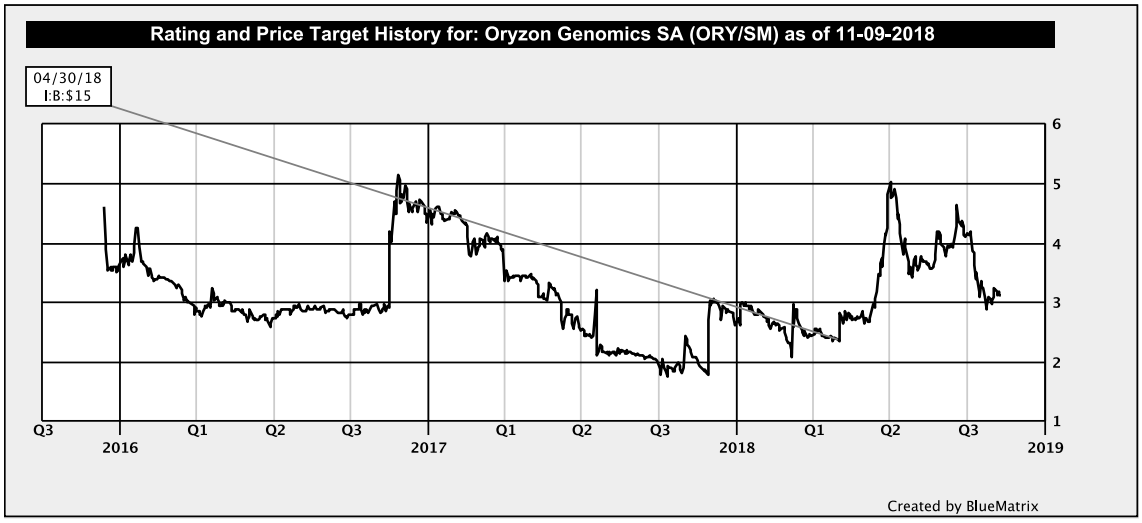
Source: ROTH Capital Partners research.

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 11/13/18	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**271**	**79.71**	**148**	**54.61**
Neutral [N]	**42**	**12.35**	**25**	**59.52**
Sell [S]	**4**	**1.18**	**2**	**50.00**
Under Review [UR]	**23**	**6.76**	**10**	**43.48**

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.