

Oryzon Genomics

Q118 update

Phase IIa trial in Alzheimer's disease initiated

According to the latest news from Oryzon, the first Alzheimer's disease (AD) patients (3/90) were recruited into the Phase IIa ETHERAL clinical trial testing ORY-2001, a dual LSD1/MAOB inhibitor for CNS indications. The trial is expected to be finalised in Q419, but Oryzon plans to report preliminary data in early 2019, which is one of the main catalysts in the near term. The second Phase IIa trial with ORY-2001 SATEEN in multiple sclerosis (MS) continues to enrol patients, with the preliminary readout planned in early 2019, another key catalyst for the share price. Our valuation is marginally higher at €322m or €9.4/share (vs €315m or €9.2/share previously).

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	5.0	(4.7)	(0.2)	0.0	N/A	N/A
12/17	4.3	(4.6)	(0.1)	0.0	N/A	N/A
12/18e	7.0	(5.6)	(0.2)	0.0	N/A	N/A
12/19e	6.3	(7.3)	(0.2)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

First patients enrolled into ORY-2001 AD trial

The first three patients out of 90 have been recruited at two sites in Barcelona into the randomised, double-blind, placebo-controlled, 26-week study (n=90) Phase IIa ETHERAL trial with ORY-2001 in AD after the trial was approved by the Spanish Medicines Agency (AEMPS) in April 2018. Oryzon has also recently received approval to start the trial in France and is awaiting approval for the UK, both of which should help with enrolment. In addition, it is planning to start a similar study in the US. The ETHERAL trial is expected to end in Q419, but a preliminary readout is planned in early 2019, which is one of the main catalysts in the near term.

Phase IIa SATEEN trial in MS ongoing

The second Phase IIa SATEEN trial with ORY-2001 in MS continues to enrol patients, with the first recruited in January this year. SATEEN is a randomised, double-blind, placebo-controlled, 36-week study (n=24) that will evaluate ORY-2001 in patients with relapsing-remitting MS and secondary progressive MS. The preliminary readout is planned in early 2019. Also, Oryzon reiterated its plans to submit clinical trial applications for a further two Phase IIa trials testing ORY-1001 in acute myeloid leukaemia and small cell lung cancer soon. ORY-3001 is still in preclinical stages, but has now completed regulatory toxicology studies and may move into Phase I.

Valuation: Marginally higher at €322m or €9.4/share

Our valuation is slightly up at €322m or €9.4/share from €315m or €9.2/share due to rolling our model forward, which is partially offset by lower net cash. The two near-term catalysts are the results from both Phase IIa trials with ORY-2001. We note that since the Oryzon's shares were listed on Madrid Stock Exchange in December 2015, the trading volumes have been steadily increasing (Exhibit 2).

Pharma & biotech

22 May 2018

Price €2.73

Market cap €91m

Net cash (€m) at end Q118 (including term deposits) 9.2

Shares in issue 33.5m

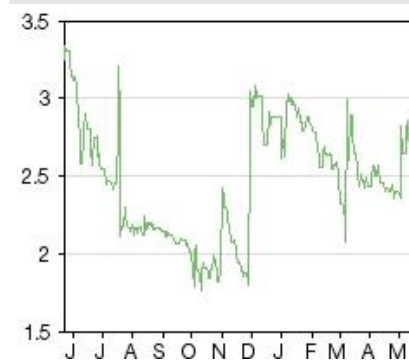
Free float 52.8%

Code ORY

Primary exchange Madrid Stock Exchange

Secondary exchange N/A

Share price performance



%	1m	3m	12m
Abs	13.3	7.3	(11.5)
Rel (local)	11.3	4.7	(4.8)

52-week high/low €3.3 €1.8

Business description

Oryzon Genomics is a Spanish biotech focused on epigenetics. ORY-1001 (Phase I/IIa) is being explored for acute leukaemias and SCLC; ORY-2001, its CNS product, is in Phase IIa trials in MS and AD. Newer asset ORY-3001 is being developed for certain orphan indications.

Next events

Initiation of POC trials with ORY-1001 in selected indications	H218
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Results of Phase IIa with ORY-2001 in MS	H119
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Results of Phase IIa with ORY-2001 in AD	H119
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Financials and valuation

Oryzon's Q118 financial results came in largely in line with our expectations. Q118 R&D expenses were €1.9m (\$2.3m) compared with €1.3m (\$1.6m) in Q117. The increase is related to more intensive clinical R&D activities, mainly the initiation of the two new trials. Q118 G&A costs were €0.7m (\$0.9m) compared with €0.8 (\$1.0m) a year ago. We leave our R&D cost estimates of €8.5m for FY18 and €9.5m for FY19 unchanged; these are the main cost drivers. €1.8m was booked as income and represents capitalised R&D costs (Oryzon follows local GAAP). The reported Q118 cash position was €30.9m (cash and short-term investments; net cash €9.2m). Our model suggests this should be sufficient to reach 2020.

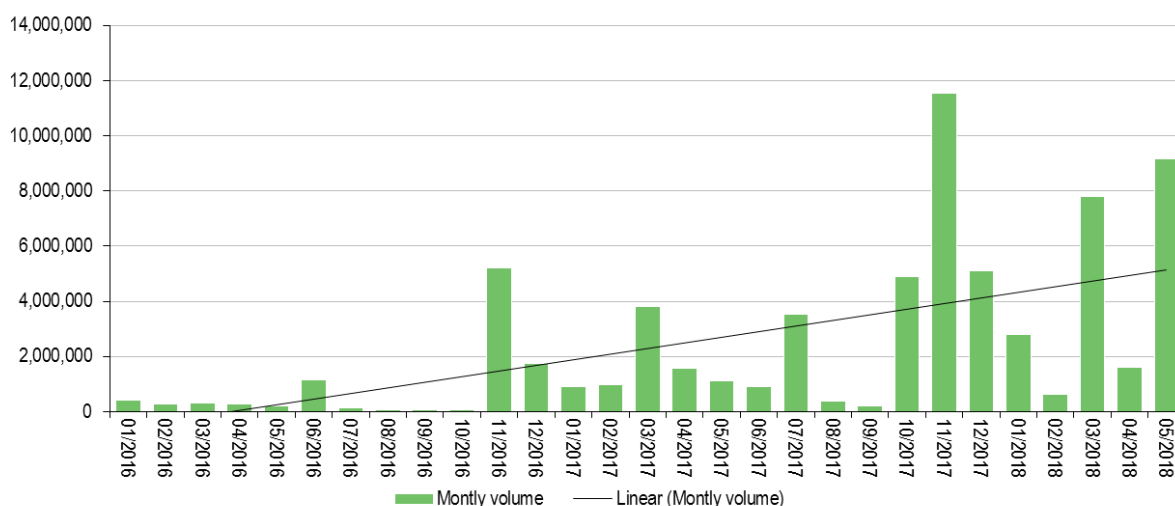
As Oryzon is on track to develop its assets in all the indications we currently include in our valuation, we leave our [assumptions unchanged](#). Our new valuation is €322m or €9.4/share, marginally up from €315m or €9.2/share due to rolling our model forward, which was partially offset by a lower net cash position.

Exhibit 1: Oryzon rNPV valuation

Product	Indication	Launch	Peak sales* (US\$m)	Value (€m)	Probability (%)	rNPV (€m)	rNPV/share (€/share)
ORY-1001	AML	2023	927	257.1	15%	47.0	1.4
ORY-1001	SCLC	2026	571	125.7	8%	21.8	0.6
ORY-2001	AD	2026	4,510	938.1	15%	145.2	4.3
ORY-2001	MS	2027	1,940	415.1	20%	98.4	2.9
Net cash (end-Q118)				9.2	100%	9.2	0.3
Valuation				1,745.1		321.7	9.4

Source: Edison Investment Research. Note: *Peak sales are rounded to the nearest US\$10m, shown in US dollars. SCLC = small cell lung cancer; AML = acute myeloid leukaemia; AD = Alzheimer's disease; MS = multiple sclerosis. Net cash includes term deposits.

Exhibit 2: Monthly trading volumes in Oryzon's share



Source: Edison Investment Research

Exhibit 3: Financial summary

	€000s	2014	2015	2016	2017	2018e	2019e
December		Local GAAP	Local GAAP	Local GAAP	Local GAAP	Local GAAP	Local GAAP
PROFIT & LOSS							
Revenue		15,536	7,185	5,009	4,317	7,034	6,301
Cost of Sales		0	0	0	0	0	0
Gross Profit		15,536	7,185	5,009	4,317	7,034	6,301
Research and development		(1,108)	(3,191)	(5,210)	(5,306)	(8,502)	(9,454)
EBITDA		11,659	688	(3,721)	(3,498)	(4,678)	(6,350)
Operating Profit (before amort. and except.)		11,398	448	(3,879)	(3,660)	(4,789)	(6,461)
Intangible Amortisation		(657)	(657)	(695)	(664)	(767)	(887)
Exceptionals		(4,617)	(24)	(4)	0	0	0
Other		0	0	0	0	0	0
Operating Profit		6,124	(233)	(4,578)	(4,324)	(5,556)	(7,348)
Exceptionals		667	(169)	(58)	0	0	0
Net Interest		(52)	(553)	(844)	(928)	(793)	(802)
Profit Before Tax (norm)		11,346	(105)	(4,724)	(4,588)	(5,582)	(7,263)
Profit Before Tax (reported)		6,739	(955)	(5,480)	(5,252)	(6,349)	(8,150)
Tax		(88)	(37)	32	55	0	0
Profit After Tax (norm)		11,258	(142)	(4,692)	(4,533)	(5,582)	(7,263)
Profit After Tax (reported)		6,651	(992)	(5,448)	(5,197)	(6,349)	(8,150)
Average Number of Shares Outstanding (m)		23.3	24.7	27.6	31.7	34.2	34.2
EPS - normalised (€)		0.48	(0.01)	(0.17)	(0.14)	(0.16)	(0.21)
EPS - reported (€)		0.29	(0.04)	(0.20)	(0.16)	(0.19)	(0.24)
Dividend per share (€)		0.0	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		100.0	100.0	100.0	100.0	100.0	100.0
EBITDA Margin (%)		75.0	9.6	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		73.4	6.2	N/A	N/A	N/A	N/A
BALANCE SHEET							
Fixed Assets		16,059	18,050	21,269	24,914	31,070	36,373
Intangible Assets		12,928	15,188	18,810	22,458	28,725	34,139
Tangible Assets		981	854	696	638	527	417
Investments		2,150	2,008	1,763	1,818	1,818	1,818
Current Assets		9,999	22,681	28,475	36,130	24,013	10,366
Stocks		9	4	8	7	8	8
Debtors		704	940	978	857	517	687
Cash		3,633	19,467	22,028	34,950	23,488	9,671
Other*		5,654	2,270	5,461	316	0	0
Current Liabilities		(3,969)	(5,296)	(7,597)	(8,696)	(9,084)	(8,890)
Creditors		(1,299)	(2,401)	(2,119)	(1,343)	(1,731)	(1,537)
Short term borrowings		(2,670)	(2,895)	(5,477)	(7,354)	(7,354)	(7,354)
Long Term Liabilities		(8,196)	(7,841)	(19,419)	(17,915)	(17,915)	(17,915)
Long term borrowings		(6,420)	(6,177)	(17,723)	(16,041)	(16,041)	(16,041)
Other long term liabilities		(1,776)	(1,664)	(1,696)	(1,874)	(1,874)	(1,874)
Net Assets		13,893	27,594	22,729	34,432	28,083	19,933
CASH FLOW							
Operating Cash Flow		12,178	1,076	(4,536)	(4,281)	(4,621)	(7,393)
Net Interest		(52)	(553)	(471)	(426)	(793)	(802)
Tax		0	0	0	0	0	0
Capex		0	0	(28)	(105)	0	0
Acquisitions/disposals		798	0	0	0	0	0
Financing		0	14,725	287	16,887	0	0
Other*		(9,579)	605	(6,819)	653	(6,048)	(5,622)
Dividends		0	0	0	0	0	0
Net Cash Flow		3,345	15,853	(11,567)	12,728	(11,462)	(13,817)
Opening net debt/(cash)		8,803	5,458	(10,395)	1,172	(11,555)	(93)
HP finance leases initiated		0	0	0	0	0	0
Other		0	0	0	0	0	0
Closing net debt/(cash)		5,458	(10,395)	1,172	(11,555)	(93)	13,724

Source: Oryzon accounts, Edison Investment Research. Note: Oryzon reports in Spanish GAAP. *Includes cash outflows related to development costs that were capitalised.

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