

Oryzon Genomics

Company update

Multiple data readouts in 2019 within cash reach

Oryzon is ramping up its R&D programme and plans to conduct a total of four mid-stage clinical trials with lead assets ORY-1001 (a specific LSD1 inhibitor for cancers) and ORY-2001 (a dual LSD1/MAOB inhibitor for CNS indications). If all goes according to plan, data readouts are expected from all four trials in 2019 and these key catalysts are reachable with current cash, as per our calculations. The most advanced studies are the two Phase IIa trials with ORY-2001 in multiple sclerosis (MS) and Alzheimer's disease with the MS study, SATEEN, enrolling patients since January 2018. Our valuation is marginally higher at €315m or €9.2/share.

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.

ORY-1001 for blood and small cell lung cancer

Oryzon regained the rights from Roche for ORY-1001 in January 2018 and in its Q417 report reiterated its plans to continue the development of ORY-1001 in both clinical-stage indications (Phase I dose-finding data for SCLC; Phase I/IIa data for acute leukaemias, as discussed in our [August report](#)). R&D plans are still at an early stage, but initially Oryzon expects to start a new Phase I/IIa study in SCLC and a follow-on Phase IIa in acute myeloid leukaemia (AML) in H218 with results deliverable later in 2019. Recent news also includes a fresh peer-reviewed [publication](#) in the prestigious Cancer Cell detailing the pharmacology of ORY-1001.

ORY-2001 for MS and mild-to-moderate AD

Two trials with ORY-2001 are underway. A randomised, double-blind, placebo-controlled, 36-week study (n=24) will evaluate ORY-2001 in patients with relapsing-remitting MS and secondary progressive MS. The Phase IIa SATEEN study with ORY-2001 in MS started enrolling patients in January 2018 and the preliminary readout is planned in early 2019. A second Phase IIa ETHERAL trial (n=90) with ORY-2001 in mild-to-moderate AD will start in H118 and is expected to end in Q419, but the preliminary readout is planned in early 2019. This means that data readouts from the four trials with ORY-1001 and ORY-2001 are expected in 2019 and all are reachable with current cash.

Valuation: Marginally higher at €315m or €9.2/share

Our valuation is up slightly at €315m or €9.2/share from €305m or €8.9/share due to rolling our model forward, which is partially offset by lower net cash. The reported year-end cash position was €35.3m (cash and short-term investments; net cash €11.6m). Our model suggests this should be sufficient to reach 2020.

Pharma & biotech

8 March 2018

Price €2.08

Market cap €71m

Net cash (€m) at end Q417 (including term deposits) 11.6

Shares in issue 34.2m

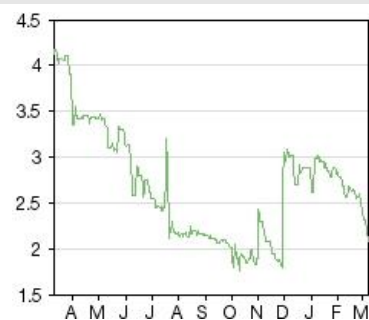
Free float 50%

Code ORY

Primary exchange Madrid Stock Exchange

Secondary exchange N/A

Share price performance



%	1m	3m	12m
Abs	(24.3)	(30.8)	(48.0)
Rel (local)	(21.3)	(26.1)	(46.9)

52-week high/low €4.2 €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 a Phase IIa trial in MS and due to enter a Phase IIa trial in 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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Oryzon Genomics is a research client of Edison Investment Research Limited

Financials and valuation

Oryzon's FY17 financial results came in somewhat better than our estimates, mainly due to lower R&D costs of €5.3m vs our estimate of €5.8m. Total operating expenses decreased y-o-y to €8.6m from €9.6m in FY16. However, we expect this to pick up again in 2018 as Oryzon has initiated the two Phase II trials with ORY-2001 and plans to conduct smaller studies with ORY-1001. We leave our R&D cost estimates of €8.5m for FY18 and €9.5m for FY19 unchanged; these are the main cost drivers. €4.3m was booked as income and represents capitalised R&D costs (Oryzon follows local GAAP). We fine-tune our forecasts by slightly increasing G&A to €3.0m from €2.7m. The reported year-end cash position was €35.3m (cash and short-term investments; net cash €11.6m). Our model suggests this should be sufficient to reach 2020.

Exhibit 1: Key changes to our financial forecasts

€000s	2017			2018e			2019e
	Est.	Act	Change (%)	Old	New	Change (%)	New
Revenue	4,742	4,317	-9%	7,014	7,034	+0%	6,301
Gross profit	4,742	4,317	-9%	7,014	7,034	+0%	6,301
R&D costs	(5,774)	(5,306)	-8%	(8,502)	(8,502)	+0%	(9,454)
Operating profit (rep)	(4,883)	(4,324)	-11%	(5,005)	(5,556)	+11%	(7,348)
Profit before tax (rep)	(6,152)	(5,252)	-15%	(5,799)	(6,349)	+9%	(8,150)
Profit after tax (rep)	(6,152)	(5,197)	-16%	(5,799)	(6,349)	+9%	(8,150)
EPS reported (€)	(0.20)	(0.16)	-17%	(0.17)	(0.19)	+9%	(0.24)

Source: Oryzon Genomics accounts, Edison Investment Research

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 €315m or €9.2/share, marginally up from €305m or €8.9/share due to rolling our model forward, which is partially offset by a lower net cash position.

Exhibit 2: Oryzon rNPV valuation

Product	Indication	Launch	Peak sales* (US\$m)	Value (€m)	Probability (%)	rNPV (€m)	rNPV/share (€/share)
ORY-1001	AML	2023	930	251.3	15%	45.9	1.3
ORY-1001	SCLC	2026	570	122.9	8%	21.3	0.6
ORY-2001	AD	2026	4,510	917.1	15%	142.0	4.2
ORY-2001	MS	2027	1,940	405.8	20%	96.2	2.8
Net cash (est. end-Q118)				9.6	100%	9.6	0.3
Valuation				1,706.7		315.0	9.2

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 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 Genomics accounts, Edison Investment Research

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