

Oryzon Genomics

Q116 results

Second product enters Phase I

Q116 results and the corporate update on 12 May showed that Oryzon is on track with its both clinical stage assets. Preliminary efficacy data from Part 2 Phase I/IIa study with ORY-1001 for acute leukaemia is expected to be announced at ASH in December 2016. Oryzon's second product, ORY-2001, targets Alzheimer's disease (AD) with preclinical data potentially indicating a disease-modifying effect. A Phase I trial started in Q116 and we expect data in early 2017. Our valuation is largely unchanged at €160m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14	15.5	11.3	0.48	0.0	N/A	N/A
12/15	7.2	(0.1)	(0.01)	0.0	N/A	N/A
12/16e	3.0	(3.6)	(0.11)	0.0	N/A	N/A
12/17e	2.2	(4.7)	(0.17)	0.0	N/A	N/A

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

New debt boosts cash position

Oryzon reported its Q116 results on 12 May. Operating costs amounted to €1.8m (of which R&D expenses were €1.2m), which largely met our expectations. The cash position was significantly boosted (by €10.5m in new debt) to €29.0m and the additional funds will mainly be used to support existing operations. Oryzon has a history of efficient use of available public grants, which could further provide non-dilutive financing. In total, during the past 12 months Oryzon has managed to attract €27m in new funding from various sources.

Phase I/IIa ongoing to plan; ORY-2001 enters Phase I

The main event for Oryzon this year is the preliminary efficacy data from Part 2 of the ongoing Phase I/IIa study with lead product ORY-1001 in different subsets of acute leukaemia patients. The results are expected to be presented at the American Society of Hematology (ASH) annual meeting on 3-6 December 2016. ORY-1001 is a first-in-class inhibitor of lysine specific demethylase 1 (LSD1), partnered with Roche, and can be best described as a second-generation epigenetic therapeutic agent with increased specificity and novel target compared to a handful of approved first generation HDAC inhibitors. A second product, ORY-2001, entered Phase I trial in Q116 with healthy volunteers to establish safety/tolerability. Phase II with AD patients could start in H117. ORY-2001 has a dual activity, inhibiting LSD1 and monoamine oxidase B (MAO B), so represents a refreshingly novel mode of action in AD research.

Valuation: Largely unchanged at €160m, €5.6/share

Our valuation of Oryzon is largely unchanged at €160m or €5.6m/share with the only changes being the updated net cash position and rolling our model further in time, which offsets the decrease in net cash. The main catalyst for the stock this year is the expected preliminary ORY-1001 efficacy results from the ongoing Phase I/IIa trial. Early next year, if positive, safety and tolerability data read-out from Phase I with ORY-2001 will be a major de-risking event.

Pharma & biotech

20 May 2016

Price €2.90

Market cap €83m

Net cash (€m) at end of Q116 10.9

Shares in issue 28.47m

Free float 30%

Code ORY

Primary exchange Madrid Stock Exchange

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (10.3) (10.0) N/A

Rel (local) (7.3) (19.3) N/A

52-week high/low €4.60 €2.77

Business description

Oryzon is a Spanish biotechnology company focused on developing novel epigenetic compounds. Lead compound ORY-1001 is partnered with Roche and is undergoing a Phase I/IIa study for acute leukaemia. ORY-2001 has potential for Alzheimer's disease and has entered Phase I.

Next events

ORY-1001 Phase I/IIa results Dec 2016 (ASH)

ORY-2001 Phase I results H117

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Financials

In Q116 Oryzon reported income of €957k to account for the capitalization of the development costs. Oryzon follows Spanish GAAP and research costs are expensed, while development costs can be capitalised. This is achieved by recognising the costs as revenue in the P&L, cash outflow from investing activities and a subsequent increase in intangible assets. The remaining income of €302k consists of a reimbursement payment from Roche according to the R&D collaboration agreement separate to the ORY-1001 licensing deal, and recognition of deferred income after a milestone payment of \$4m from Roche in July 2015.

According to the news this week, Oryzon and Roche will extend the R&D collaboration agreement by one more year. The goal of the original agreement, which ended in April this year, was to further explore the potential of ORY-1001 in oncology and haematology following the licensing agreement for ORY-1001. We believe the extension shows a fruitful relationship between the companies, as four new patents were filed based on the discoveries. The extension means that Oryzon will continue to receive R&D cost reimbursement at least until the end of the extension in March 2017. Oryzon received reimbursement in the amount of €776k for the period 1 January to 30 September 2015. The scale of the new agreement in relation to the original is not clear yet, therefore we estimate a more conservative €500k in reimbursed costs for Oryzon in 2016, which is the main cause behind our somewhat increased 2016 revenue estimate, while the bottom line was mostly impacted by the increased estimates of interest expenses after inclusion of the new debt.

Exhibit 1: Changes to our forecasts

€m	2015	2016e	2016e	% Chng	2017e	2017e	% Chng
	Actual	Old	New		Old	New	
Revenue	7.185	2.755	3.047	+11%	2.077	2.170	+4%
Operating Profit reported	(0.233)	(3.921)	(4.022)	N/M	(4.732)	(5.052)	N/M
Profit Before Tax reported	(0.955)	(3.641)	(4.391)	N/M	(4.510)	(5.574)	N/M
EPS reported (€)	(0.04)	(0.13)	(0.14)	N/M	(0.16)	(0.20)	N/M

Source: Edison Investment Research

At the end of Q116, Oryzon had cash and short-term liquid investments of €29.0m. In May 2016, Oryzon raised new debt of €10.5m in long term loans at current market rates (between 2% and 3%). In total, during the past 12 months Oryzon has managed to attract €27m in new funding from various sources.

Valuation

We value Oryzon at €160m or €5.6/share, based on risk-adjusted NPV analysis, which includes €10.9m net cash at end Q116 and uses a 12.5% discount rate. The only changes to our valuation are the updated net cash position and rolling out model by one quarter, which offsets the decrease in net cash after the new debt. We use a 12.5% discount rate with a 15% and 12% probability for reaching the market for ORY-1001 and ORY-2001 respectively.

Exhibit 2: Oryzon rNPV valuation

Product	Indication	Launch	Peak sales (US\$m)	Value (€m)	Probability	rNPV (€m)	NPV/Share (€/share)
ORY-1001	AML	2022	900	236.6	15%	42.6	1.5
ORY-1001	SCLC	2025	630*	111.8	8%	15.8	0.6
ORY-2001	AD	2026	4,500*	743.7	12%	90.5	3.2
Net cash				10.9	100%	10.9	0.4
Valuation				1,103.0		159.7	5.6

Source: Edison Investment Research. Note: *Peak sales are rounded to the nearest US\$100m, shown in US\$.

Currently our valuation is based on clinical stage compounds and one preclinical indication (Exhibit 1). After completion of the ongoing Phase I/IIa, Roche will be solely responsible for further clinical development and commercialisation of ORY-1001 and could expand beyond acute leukaemia. We assume small cell lung cancer (SCLC) as the most likely indication (see our [initiation](#) report for more details). Notably, Oryzon participated at the American Association for Cancer Research (AACR) Annual meeting in New Orleans in April. Roche and Oryzon jointly presented data describing gene expression profile that predict responses to ORY-1001 in SCLC cell lines. This was an early stage *in vitro* study, but indicates Roche's active interest in SCLC indication, in our view.

ORY-2001 is still unpartnered, yet Oryzon's strategy is to develop the asset until clinical proof-of-concept stage and then seek to out-license it. We assumed a licensing deal for this asset as well in our model.

Exhibit 3: Financial summary

	EUR'000s	2012	2013	2014	2015	2016e	2017e
December		Local GAAP					
PROFIT & LOSS							
Revenue		4,353	2,360	15,536	7,185	3,047	2,170
Cost of Sales		0	0	0	0	0	0
Gross Profit		4,353	2,360	15,536	7,185	3,047	2,170
Research and development		(876)	(873)	(1,108)	(3,191)	(2,874)	(2,949)
EBITDA		856	(94)	11,659	688	(3,110)	(4,085)
Operating Profit (before amort. and except.)		559	(370)	11,398	448	(3,228)	(4,203)
Intangible Amortisation		(455)	(657)	(657)	(657)	(794)	(849)
Exceptionals		0	(186)	(4,617)	(24)	0	0
Other		0	0	0	0	0	0
Operating Profit		104	(1,213)	6,124	(233)	(4,022)	(5,052)
Exceptionals		(220)	0	667	(169)	0	0
Net Interest		(582)	(672)	(52)	(553)	(368)	(522)
Profit Before Tax (norm)		(23)	(1,042)	11,346	(105)	(3,597)	(4,725)
Profit Before Tax (reported)		(698)	(1,885)	6,739	(955)	(4,391)	(5,574)
Tax		90	89	(88)	(37)	338	0
Profit After Tax (norm)		67	(953)	11,258	(142)	(3,259)	(4,725)
Profit After Tax (reported)		(608)	(1,796)	6,651	(992)	(4,053)	(5,574)
Average Number of Shares Outstanding (m)		23.0	23.0	23.3	24.5	28.5	28.5
EPS - normalised (EUR)		0.00	(0.04)	0.48	(0.01)	(0.11)	(0.17)
EPS - normalised and fully diluted (EUR)		0.00	(0.04)	0.48	(0.01)	(0.11)	(0.17)
EPS - (reported) (EUR)		(0.03)	(0.08)	0.29	(0.04)	(0.14)	(0.20)
Dividend per share (EUR)		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 (%)		19.7	N/A	75.0	9.6	N/A	N/A
Operating Margin (before GW and except.) (%)		12.8	N/A	73.4	6.2	N/A	N/A
BALANCE SHEET							
Fixed Assets		18,765	20,128	16,059	18,050	19,728	20,931
Intangible Assets		15,062	15,825	12,928	15,188	16,646	17,967
Tangible Assets		1,485	1,159	981	854	736	618
Investments		2,217	3,145	2,150	2,008	2,346	2,346
Current Assets		3,808	2,851	9,999	22,681	24,582	16,399
Stocks		19	2	9	4	10	7
Debtors		977	663	704	940	769	855
Cash		2,302	2,033	3,633	19,467	18,561	10,296
Other		510	153	5,654	2,270	5,242	5,242
Current Liabilities		(2,283)	(2,724)	(3,969)	(5,296)	(3,567)	(3,752)
Creditors		(765)	(1,005)	(1,299)	(2,401)	(932)	(1,487)
Short term borrowings		(1,519)	(1,719)	(2,670)	(2,895)	(2,635)	(2,265)
Long Term Liabilities		(9,949)	(11,251)	(8,196)	(7,841)	(17,202)	(15,610)
Long term borrowings		(7,963)	(9,117)	(6,420)	(6,177)	(15,237)	(14,167)
Other long term liabilities		(1,986)	(2,134)	(1,776)	(1,664)	(1,965)	(1,443)
Net Assets		10,341	9,004	13,893	27,594	23,541	17,967
CASH FLOW							
Operating Cash Flow		1,420	(113)	12,178	1,076	(7,528)	(4,135)
Net Interest		(582)	(672)	(52)	(553)	(368)	(522)
Tax		0	0	0	0	338	0
Capex		0	0	0	0	0	0
Acquisitions/disposals		107	(677)	798	0	0	0
Financing		0	0	0	14,725	0	0
Other		(8,125)	(161)	(9,579)	605	(2,147)	(2,170)
Dividends		0	0	0	0	0	0
Net Cash Flow		(7,180)	(1,623)	3,345	15,853	(9,706)	(6,826)
Opening net debt/(cash)		0	7,180	8,803	5,458	(10,395)	(689)
HP finance leases initiated		0	0	0	0	0	0
Other		0	0	0	0	0	0
Closing net debt/(cash)		7,180	8,803	5,458	(10,395)	(689)	6,136

Source: Edison Investment Research, Oryzon Genomics. Note: Oryzon reports in Spanish GAAP. *Represents cash outflows related to development costs that were capitalised. **Term deposits classed as other current assets.

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