EDISON

Oryzon Genomics

Q217 results

ORY-1001 rights back to Oryzon

Pharma & biotech

Roche's decision to discontinue the development of ORY-1001 and return the rights to Oryzon was major recent news. Roche cited portfolio reprioritisation as the reason and that the decision was not driven by data. While this is a setback in business development for Oryzon, in our view, ORY-1001's potential has not been compromised and the company indicated that it will continue developing ORY-1001 for both current indications, acute leukaemia and SCLC, before seeking a new partner for late-stage development. On a more positive note, Oryzon reported positive final Phase I data for ORY-2001, which is now ready for further development in several neurological indications. Our valuation is €295m (vs €312m previously) or €8.6/share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/15	7.2	(0.1)	(0.01)	0.0	N/A	N/A
12/16	5.0	(4.7)	(0.17)	0.0	N/A	N/A
12/17e	4.4	(6.4)	(0.20)	0.0	N/A	N/A
12/18e	7.9	(11.0)	(0.32)	0.0	N/A	N/A

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

Next steps with ORY-1001

The handover process may take several months and during this period Roche will also finalise a dose-finding Phase I study in small cell lung cancer (SCLC) and hand the data over to Oryzon, which is now free to initiate planning for further clinical activities, although it will likely take some time to present updated ORY-1001 development plans. Oryzon also mentioned that around the time ORY-1001 was out-licensed to Roche in April 2014, it was contacted by several other companies interested in epigenetic programmes in oncology. In our view, this suggests that the company could potentially replace Roche with another partner interested in epigenetics and LSD1 inhibition.

Q217 results broadly in line with expectations

Oryzon's Q217 results were broadly in line with our expectations. However, we have revised our R&D cost estimates to reflect Oryzon's plan to conduct proof-of-concept studies with ORY-1001 in acute leukaemia and SCLC. We now assume an R&D spend of €5.8m in 2017 and €13.6m in 2018 (total opex €10.4m and €18.4m in respective years). This, however, may be revised further when Oryzon provides more details about further steps with ORY-1001. Oryzon has a strong cash position and we forecast a cash reach well into 2019 (€37.5m end-Q217 cash; €16.1m net cash).

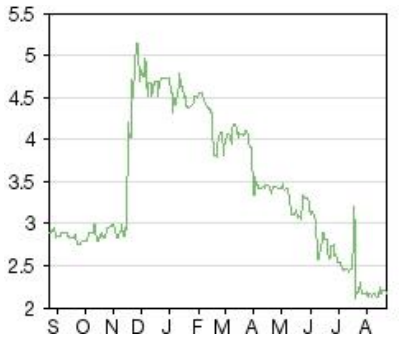
Valuation: Revised to €295m from €312m

We have revised our risk-adjusted NPV model to reflect Oryzon regaining rights to ORY-1001. While we have made changes to a number of assumptions (see below), the one of the main reasons for the lower valuation is reduced probabilities of success to reflect the partnering uncertainty. However, the additional development of ORY-1001 means that in the future Oryzon could negotiate better licensing terms than those with Roche, which could provide upside to our valuation.

22 August 2017

Price	**€2.17**
Market cap	**€74m**
Net cash (€m) at end Q217 (including term deposits)	16.1
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	(0.4)	(29.5)	(26.4)
Rel (local)	0.2	(26.3)	(40.0)
52-week high/low		€5.1	€2.1

Business description

Oryzon Genomics is a Spanish biotechnology company focused on developing novel epigenetic compounds. First clinical data with lead compound ORY-1001 have been reported in December 2016, while it is currently undergoing a Phase I clinical trial in SCLC. ORY-2001, which has potential for several neurodegenerative diseases, is finishing Phase I. ORY-3001 is a new preclinical asset.

Next events

Initiation of POC trials with ORY-1001 and ORY-2001 in selected indications	2018

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Edison profile page

Final Phase I results support ORY-2001's safety

Oryzon's Q217 report described progress with its other two lead drug candidates. ORY-2001 (a dual LSD1/MAOB inhibitor) is being developed for neurodegenerative diseases. We discussed ORY-2001's preclinical data and positive preliminary Phase I results released in March 2017 in detail in our outlook report. The final data released in July 2017 confirmed ORY-2001 safety using selected doses in all patients including the elderly. PK/PD data showed that the drug is able to penetrate the blood-brain barrier and allowed Oryzon to model the long-term administration scheme to be used in subsequent efficacy trials. Oryzon now aims to ramp up the clinical programme and initiate trials in several neurological indications, with the leading ones being multiple sclerosis, Alzheimer's disease and Huntington's disease. ORY-3001 (a selective LSD1 inhibitor) is in advanced preclinical studies in as yet undisclosed, orphan, non-cancer indications and should be ready for filing for the investigational new drug application in 2017.

Valuation

Oryzon indicated they will continue to develop ORY-1001 in the acute leukaemia and SCLC indications and will conduct proof-of-concept studies before seeking a new partner, which is in line with its general strategy to partner with larger companies that are able to invest in large-scale studies. In line with this, we now assume that the company will invest €10m in two studies for both indications over the next two years and will then partner for further development in 2019. We now assume an R&D spend of €5.8m in 2017 and €13.6m in 2018. Going forward, virtually all of Oryzon's revenues will account for the capitalisation of the development costs (Oryzon follows Spanish GAAP). Therefore, higher R&D costs have also prompted us to increase our revenue estimates in 2017 and 2018.

We use the Roche deal as a benchmark and include similar terms in our model in 2019. As a reminder, the deal involved a $21m upfront payment and near-term milestones, $435m in development-related milestones, $90m in sales-related milestones and a tiered royalty rate of up to 15% on global sales. $235m of development-related milestones could have been triggered by events related to oncology projects, with the rest to non-oncologic indications. Since Roche was free to expand into more oncologic indications, we have assumed that one-third of $235m and $90 could have been triggered in the acute leukaemia project and another third in the SCLC project. Therefore, the total amount we use currently is $238m. Of that we include $21m in an upfront payment as in the Roche deal, $113m in development milestones, while the rest can be triggered by achieved sales.

In our view, there is potential for Oryzon to negotiate better terms if the POC data are positive because of additional investments in R&D and the fact that the asset is later stage. On the other hand, finding a partner requires time and business development efforts, and we therefore reduce our success probabilities from 20% to 15% for acute leukaemia and from 12% to 8% for SCLC to reflect the partnering uncertainty. This was likely the main reason behind the share price drop following the Roche news, although it stated that the decision was not data driven. The adjustments led us also to delay the launch date for acute leukaemia and SCLC by one year.

With regards to ORY-2001 development, Oryzon's plans were to initiate proof-of-concept studies in several neurological disorders, with the leading studies being multiple sclerosis (MS) and Alzheimer's disease (AD). We previously included AD and MS in our model and make no changes to our assumptions, as the company indicated that there should not be any changes or delays to these programmes. Given the additional investment in ORY-1001, Oryzon has stated that it could

reprioritise and delay ORY-2001 for other neurological indications and the development of ORY-3001. These projects, however, are early stage and we have not yet included them in our valuation.

We have lowered our rNPV from €312m to €295m or from €9.1/share to €8.6/share. We note that the additional ORY-1001 development could create more value for Oryzon. If the next studies are successful, the company could negotiate higher deal terms than those in the Roche agreement, which is still not reflected in our forecast and therefore provides potential upside.

Exhibit 1: Oryzon rNPV valuation

Product	Indication	Launch	Peak sales* (US$m)	Value (€m)	Probability (%)	rNPV (€m)	NPV/share (€/share)
ORY-1001	AML	2023	930	231.5	15%	42.0	1.2
ORY-1001	SCLC	2026	570	113.0	8%	19.2	0.6
ORY-2001	AD	2026	4,510	844.0	15%	128.8	3.8
ORY-2001	MS	2027	1,940	374.6	20%	88.8	2.6
Net cash (end-Q217)				16.1	100%	16.1	0.5
Valuation				**1,579.2**		**294.9**	**8.6**

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

Exhibit 2: Financial summary

December €000s	2013	2014	2015	2016	2017e	2018e
PROFIT & LOSS	Local GAAP	Local GAAP	Local GAAP	Local GAAP	Local GAAP	Local GAAP
Revenue	2,360	15,536	7,185	5,009	4,381	7,906
Cost of Sales	0	0	0	0	0	0
Gross Profit	2,360	15,536	7,185	5,009	4,381	7,906
Research and development	(873)	(1,108)	(3,191)	(5,210)	(5,774)	(13,577)
EBITDA	(94)	11,659	688	(3,721)	(5,024)	(9,681)
Operating Profit (before amort. and except.)	(370)	11,398	448	(3,879)	(5,120)	(9,778)
Intangible Amortisation	(657)	(657)	(657)	(695)	(941)	(1,098)
Exceptionals	(186)	(4,617)	(24)	(4)	0	0
Other	0	0	0	0	0	0
Operating Profit	(1,213)	6,124	(233)	(4,578)	(6,061)	(10,875)
Exceptionals	0	667	(169)	(58)	0	0
Net Interest	(672)	(52)	(553)	(844)	(1,269)	(1,214)
Profit Before Tax (norm)	(1,042)	11,346	(105)	(4,724)	(6,390)	(10,992)
Profit Before Tax (reported)	(1,885)	6,739	(955)	(5,480)	(7,330)	(12,090)
Tax	89	(88)	(37)	32	0	0
Profit After Tax (norm)	(953)	11,258	(142)	(4,692)	(6,390)	(10,992)
Profit After Tax (reported)	(1,796)	6,651	(992)	(5,448)	(7,330)	(12,090)
Average Number of Shares Outstanding (m)	23.0	23.3	24.7	27.6	31.3	34.2
EPS - normalised (EUR)	(0.04)	0.48	(0.01)	(0.17)	(0.20)	(0.32)
EPS - (reported) (EUR)	(0.08)	0.29	(0.04)	(0.20)	(0.23)	(0.35)
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 (%)	N/A	75.0	9.6	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	73.4	6.2	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets	20,128	16,059	18,050	21,269	24,612	31,324
Intangible Assets	15,825	12,928	15,188	18,810	22,250	29,058
Tangible Assets	1,159	981	854	696	600	503
Investments	3,145	2,150	2,008	1,763	1,763	1,763
Current Assets	2,851	9,999	22,681	28,475	31,573	11,577
Stocks	2	9	4	8	6	7
Debtors	663	704	940	978	959	969
Cash	2,033	3,633	19,467	22,028	29,468	10,601
Other*	153	5,654	2,270	5,461	1,140	0
Current Liabilities	(2,724)	(3,969)	(5,296)	(7,597)	(8,726)	(8,746)
Creditors	(1,005)	(1,299)	(2,401)	(2,119)	(2,080)	(2,100)
Short term borrowings	(1,719)	(2,670)	(2,895)	(5,477)	(6,646)	(6,646)
Long Term Liabilities	(11,251)	(8,196)	(7,841)	(19,419)	(16,478)	(16,478)
Long term borrowings	(9,117)	(6,420)	(6,177)	(17,723)	(14,782)	(14,782)
Other long term liabilities	(2,134)	(1,776)	(1,664)	(1,696)	(1,696)	(1,696)
Net Assets	9,004	13,893	27,594	22,729	30,981	17,677
CASH FLOW						
Operating Cash Flow	(113)	12,178	1,076	(4,536)	(6,311)	(10,887)
Net Interest	(672)	(52)	(553)	(471)	(1,269)	(1,214)
Tax	0	0	0	0	0	0
Capex	0	0	0	(28)	0	0
Acquisitions/disposals	(677)	798	0	0	0	0
Financing	0	0	14,725	287	16,853	0
Other**	(161)	(9,579)	605	(6,819)	(60)	(6,766)
Dividends	0	0	0	0	0	0
Net Cash Flow	(1,623)	3,345	15,853	(11,567)	9,212	(18,867)
Opening net debt/(cash)	7,180	8,803	5,458	(10,395)	1,172	(8,040)
HP finance leases initiated	0	0	0	0	0	0
Other	0	0	0	0	0	0
Closing net debt/(cash)	8,803	5,458	(10,395)	1,172	(8,040)	10,827

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

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