EDISON

Oryzon Genomics

Q322 update

Clinical ramp in Q3; several catalysts approaching

Pharma and biotech

Oryzon Genomics reported Q322 results that are largely in line with our expectations. The clinical ramp up of its key assets, iadademstat and vafidemstat, has meant R&D expenses were higher than our estimates, largely offset by the higher R&D tax rebates. The Q322 net loss of US$0.6m (€0.7m) brought the 9M22 net loss to US$1.9m (€2.0m). As a result, we expect FY22 operating losses to decrease to €5.0m versus our previous estimates (€7.0m), reflecting the timing of R&D spend and associated tax rebates. Oryzon closed the quarter with a gross cash position, including marketable securities, of US$27.1m, implying an annual cash burn of approximately €14m, which assuming full drawdown of the €20m convertible debt facility, will see the company through into Q224 (including outstanding debts repayments). We value Oryzon at €861m or €16.2 per share, up from €802m or €15.1/share previously.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/20	9.5	(4.8)	(0.07)	0.0	N/A	N/A
12/21	10.6	(7.2)	(0.09)	0.0	N/A	N/A
12/22e	14.4	(5.2)	(0.06)	0.0	N/A	N/A
12/23e	15.9	(6.1)	(0.07)	0.0	N/A	N/A

Note: *PBT and EPS is normalised, excluding amortisation of acquired intangibles, other income and exceptional items

Positive safety data for PORTICO

The most significant Q322 clinical news for Oryzon came in form of interim safety data from its Phase IIb PORTICO study, investigating the use of vafidemstat for the treatment of borderline personality disorder. The company reported that no serious adverse events have been observed from patients enrolled in the trial and that approval for the study to continue had been granted by the PORTICO independent data monitoring committee. This positive development means the trial is on track for interim readouts in Q123, which we see as a potential catalyst for share price.

Strong cash position past key readouts

At end Q322, Oryzon had a gross cash position including securities of US$27.1m (€27.3m) and has combined short- and long-term debt obligations of €17.6m (c €6m due in FY23 and €4.5m in FY24). The company has entered a convertible bond financing agreement where it can raise up to €20m over 30 months. Based on our annual cash burn projections, we estimate that at the current annual burn rate of around €14m (c €7m cash burn rate in H122), and assuming execution of all convertible notes, will provide a cash runway into Q224 (including outstanding debts repayments).

Valuation: €861m or €16.2/share

We value Oryzon at €861m or €16.2/share, based on a risk-adjusted NPV analysis using a 12.5% discount rate and Q322e net cash of c €9.7m. The valuation has increased as we have rolled our model forward four months, updated our exchange rate assumption to $1.01/€ (from $1.05/€) and updated our estimates, but our underlying long-term assumptions remain unchanged.

3 November 2022

Price	**€2.13**
Market cap	**€113m**
	US$1.01/€
Estimated net cash (€m) at end-September 2022	9.7
Shares in issue	53.1m
Free float	80%
Code	ORY
Primary exchange	Madrid Stock Exchange
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	2.9	(17.5)	(33.1)
Rel (local)	(3.6)	(16.1)	(23.5)
52-week high/low		€3.29	€2.07

Business description

Oryzon Genomics is a Spanish biotech focused on epigenetics. Iadademstat is being explored for acute leukaemias and SCLC. Vafidemstat, its CNS asset, has completed several Phase IIa trials and a Phase IIb trial in borderline personality disorder is now the lead study, but Oryzon is rapidly expanding its CNS R&D pipeline.

Next events

Phase II PORTICO interim data	Q123
Phase II ALICE final readout	Q422

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Edison profile page

A period of catalysts on the horizon

Oryzon is gearing up for what is anticipated to be a busy six months for the clinical development of both iadademstat and vafidemstat.

For iadademstat in oncology, preliminary final data from the Phase II ALICE study will be presented at the American Society of Hematology (ASH) Annual Meeting and Exposition in December 2022. The study is investigating iadademstat in combination with azacitidine in acute myeloid leukaemia (AML) and has continued to show encouraging safety and efficacy data; the most recent readouts reported objective responses (OR) in 81% of patients.

In our view, final positive readouts from ALICE would bode well for Oryzon's Phase Ib FRIDA trial investigating iadademstat in combination with gilteritinib (FDA-approved FLT3 inhibitor) for treating patients with relapsed/refractory (r/r) FLT3-mutated AML in a second-line setting. The latest ALICE data reported that patients possessing the FLT3 mutation also responded to treatment, providing promise for this further sub-population of AML patients in FRIDA. Having received IND approval, Oryzon will look to discuss with the FDA the plans for trial initiation, but has communicated that it expects the first patient to be recruited (FPI) in FRIDA in H222.

The IND for the Phase Ib/II STELLAR study in extensive disease small cell lung cancer (ED-SCLC) with iadademstat in combination with an immune checkpoint inhibitor (ICI) is also expected in in H222. If approved, we anticipate FPI in H123. In our view, ICI combination studies are critical in the development of new oncology treatment regimes. Additionally, Oryzon is planning a further combination Phase II trial for iadademstat in platinum r/r SCLC and extrapulmonary high-grade neuroendocrine tumours (NET); it expects FPI in H222.

In addition to the upcoming interim readouts from the PORTICO study, the most significant development for vafidemstat will be the initiation of the Phase Ib/II HOPE study in Kabuki syndrome. An IND is expected to be submitted in H222, with FPI in H123. The HOPE study represents Oryzon's first clinical efforts in developing a precision medicine approach in tackling a monogenic central nervous system (CNS) indication. With the clinical successes achieved in targeting monogenic CNS diseases and potential upside from pursuing an orphan indication, we believe this represents a significant opportunity for Oryzon. For more information, please see our recent sector report on the field of neuroscience.

Valuation

We value Oryzon at €861m or €16.2/share, based on a risk-adjusted NPV analysis using a 12.5% discount rate and Q322e net cash of c €9.7m. Our underlying long-term assumptions remain unchanged, and we roll our model forward in time by four months. We have also updated our fx assumptions to $1.01/€ (from $1.05/€). Our model includes five rNPV projects (Exhibit 2, for more details see our Outlook note).

Exhibit 1: Valuation of Oryzon

Product	Indication	Launch	Peak sales ($m)	Value (€m)	Probability	rNPV (€m)	NPV/share (€/share)
Iadademstat	2L AML	2026	490	771.7	30%	225.7	4.3
	1L SCLC	2026	720	814.5	25%	197.4	3.7
Vafidemstat	BPD	2027	1,580	1,271.2	20%	243.3	4.6
	Schizophrenia, negative symptoms	2027	690	640.2	15%	88.1	1.7
	Aggression in Alzheimer's disease	2028	890	681.8	15%	97.7	1.8
Estimated net cash end Q322				9.7	100%	9.1	0.2
Valuation				**3,931.2**		**861**	**16.2**

Source: Edison Investment Research

Financials

As a result of Oryzon's ramp up in clinical development activities, the company reported research and development (R&D) expenses for Q322 of US$4.3m (€4.4m), bringing total R&D expenses for FY22 to date up to US$11.9m (€12.0m). With the increase in R&D spend, Oryzon will receive income associated with R&D tax credits, which we estimate will reach €14.4m by end FY22. In light of the quarterly update, we have updated our full year estimates and now forecast total operating expenses for FY22 to amount to €18.9m (previously €16.4m), with R&D expenses totalling €15.6m (previously €12.0m). We estimate free cash outflows of c €15.9m in FY22 and €17.1m in FY23, in line with current spending in operations and increased R&D activity. In our model, we project that Oryzon will launch its first product into the market in FY26. Based on the current annual cash burn projections (c €14m), we estimate that it will be required to raise a further c €30m, in addition to the €20m convertible bond financing, to continue to fund operations up to this point, which we model as illustrative debt. Based on our annual cash burn projections, we estimate that excluding debt repayment obligations and assuming execution of all convertible notes, Oryzon has a cash runway into Q224 (including outstanding debts repayments).

Exhibit 2: Financial summary

Accounts: Year end 31 December (€000s)	2019	2020	2021	2022e	2023e
INCOME STATEMENT					
Total revenues	10,278	9,521	10,615	14,418	15,860
Cost of sales	(430)	(526)	(746)	(473)	(497)
Gross profit	9,847	8,995	9,869	13,945	15,363
Gross margin %	96%	94%	93%	97%	97%
SG&A (expenses)	(2,983)	(3,541)	(3,782)	(3,513)	(3,864)
R&D costs	(11,322)	(11,075)	(13,023)	(15,607)	(17,253)
Other income/(expense)	779	1,476	73	6	6
Exceptionals and adjustments	(11)	(5)	(4)	0	0
Reported EBITDA	(3,690)	(4,149)	(6,866)	(5,169)	(5,748)
Depreciation and amortisation	150	145	144	180	179
Reported EBIT	(3,839)	(4,294)	(7,011)	(4,989)	(5,569)
Finance income/(expense)	(737)	(485)	(169)	(236)	(511)
Other income/(expense)	0	0	0	0	0
Reported PBT	(4,576)	(4,779)	(7,180)	(5,225)	(6,080)
Income tax expense (includes exceptionals)	892	1,379	2,493	2,138	2,316
Reported net income	(3,685)	(3,400)	(4,687)	(3,087)	(3,764)
Basic average number of shares, m	45.8	53.1	53.1	53.0	53.0
Basic EPS (€)I	(0.09)	(0.07)	(0.09)	(0.06)	(0.07)
Adjusted EBITDA	(3,679)	(4,145)	(6,862)	(5,169)	(5,748)
Adjusted EBIT	(3,829)	(4,290)	(7,007)	(4,989)	(5,569)
Adjusted PBT	(4,566)	(4,774)	(7,176)	(5,225)	(6,080)
Adjusted EPS (€)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
Adjusted diluted EPS (€)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
BALANCE SHEET					
Property, plant and equipment	631	644	682	677	674
Intangible assets	39,938	49,216	60,254	70,811	81,216
Investments	67	66	29	29	29
Deferred tax assets	1,721	1,803	1,812	1,812	1,812
Total non-current assets	42,357	51,729	62,778	73,330	83,731
Cash and equivalents	35,111	39,605	28,725	15,394	9,075
Trade and other receivables	2,071	2,351	3,645	2,998	3,321
Inventories	289	317	104	104	104
Other current assets	267	105	132	132	132
Total current assets	37,738	42,377	32,606	18,628	12,633
Deferred tax liabilities	1,721	1,803	1,812	1,812	1,812
Long term debt	6,699	8,680	13,354	13,354	21,354
Other non-current liabilities	0	0	285	285	285
Total non-current liabilities	8,420	10,483	15,451	15,451	23,451
Trade and other payables	4,000	2,839	3,518	3,179	3,349
Short term debt	6,547	4,854	4,306	4,306	4,306
Other current liabilities	0	0	847	847	847
Total current liabilities	10,546	7,693	8,672	8,332	8,502
Equity attributable to company	61,129	75,931	71,262	68,175	64,411
	0	0	0	0	0
CASH FLOW STATEMENT					
Profit before tax	(4,576)	(4,779)	(7,180)	(5,225)	(6,080)
Cash from operations (CFO)	(3,934)	(4,817)	(3,626)	(2,599)	(3,739)
Capex	(9,585)	(9,223)	(11,761)	(10,732)	(10,580)
Acquisitions & disposals net	0	0	0	0	0
Acquistion of intangible assets	(9,469)	(9,070)	(11,586)	(10,557)	(10,404)
Other investing activities	8	142	37	0	0
Cash used in investing activities (CFIA)	(19,046)	(18,152)	(23,310)	(21,289)	(20,984)
Net proceeds from issue of shares	18,374	18,181	0	0	0
Movements in debt	(4,112)	200	4,123	0	8,000
Other financing activities	0	0	0	0	0
Cash from financing activities (CFF)	14,262	18,382	4,123	0	8,000
Increase/(decrease) in cash and equivalents	791	4,494	(10,880)	(13,331)	(6,318)
Currency translation differences and other	40	11	348	0	0
Cash and equivalents at start of period	34,320	35,111	39,605	28,725	15,394
Cash and equivalents at end of period	35,111	39,605	28,725	15,394	9,075
Net (debt) cash	21,866	26,071	11,065	(2,266)	(24,584)

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

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