

Oryzon Genomics

Q123 update

Advancing on multiple clinical fronts in Q1

Pharma and biotech

11 May 2023

Price €2.08
Market cap €120m

Estimated net cash (€m) at end March 2023 0.9
Shares in issue 56.2m
Free float 80%
Code ORY
Primary exchange Madrid Stock Exchange
Secondary exchange N/A

Oryzon has **reported** Q123 results highlighting its near-term strategic priorities, including a favourable interim analysis of its lead asset study, the Phase IIb PORTICO study (vafidemstat, central nervous system, CNS), and the commencement of patient enrolment for the Phase Ib FRIDA study (iadademstat, oncology). Total operating expenses stood at \$5.6m for Q123, largely similar to Q122, with the majority (78.1%) from R&D expenses (\$4.4m) as Oryzon continues to advance its clinical pipeline. With a cash balance of \$20.0m at end Q123, we estimate a cash runway into H124. Going forward, we anticipate top-line data from the FRIDA and PORTICO studies will be key catalysts. Our valuation of Oryzon adjusts to €874.1m or €15.6/share, from €869.0m previously.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/21	10.6	(7.2)	(0.09)	0.0	N/A	N/A
12/22	15.7	(6.4)	(0.07)	0.0	N/A	N/A
12/23e	17.3	(4.2)	(0.03)	0.0	N/A	N/A
12/24e	19.0	(10.0)	(0.14)	0.0	N/A	N/A

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

Share price performance



%	1m	3m	12m
Abs	(5.9)	(16.5)	(4.1)
Rel (local)	(4.4)	(16.9)	(14.9)
52-week high/low		€2.96	€2.05

Business description

Oryzon Genomics is a Spanish biotech focused on epigenetics. Iadademstat is being explored for acute leukaemias, small-cell lung cancer and neuroendocrine tumours. Vafidemstat, its central nervous system (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

Q1 results July 2023

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PORTICO and FRIDA to remain the prime focus

Following a favourable interim analysis ([April 2023](#)) of the Phase IIb PORTICO study (borderline personality disorder, BPD), Oryzon is actively recruiting patients across Europe and the United States (expected n=188). We view the top-line data (anticipated in early 2024) as a key driving factor in shaping the future development strategy for vafidemstat. Additionally, patient enrolment is ongoing for the Phase IIb EVOLUTION trial (schizophrenia) and an investigational new drug (IND) application is expected in 2023 to support initiation of the Phase Ib/II HOPE trial (Kabuki syndrome). In oncology, the Phase Ib FRIDA study (acute myeloid leukaemia, AML) remains a key focus of Oryzon's pipeline, as the second-line AML setting may expedite iadademstat's route to market, according to management. Further, patient enrolment is ongoing for the Phase II trial in collaboration with the Fox Chase Cancer Center (neuroendocrine tumours) and preparations are underway for the Phase Ib/II trial STELLAR trial (small-cell lung cancer, SCLC).

Expanding CNS portfolio with ORY-4001

In [March 2023](#), Oryzon nominated a new clinical development candidate, ORY-4001, a histone deacetylase 6 inhibitor, for the treatment of neurological diseases and it represents the company's expansion into new epigenetic targets. Oryzon is planning IND-enabling studies to prepare the compound for clinical trials.

Valuation: €874.1m or €15.6/share

We value Oryzon at €874.1m or €15.6/share, slightly up from €869.0m or €15.6/share previously. The increased valuation comes from the combined impact of rolling our model forward, updating our FX assumption to \$1.10/€ (from \$1.07/€) and a period end net cash balance of €0.9m (vs €4.0m previously).

Valuation

Our valuation for Oryzon improves to €874.1m, marginally up from our previous valuation of €869.0m. However, the per share valuation remains the same at €15.6/share due to an increase in the total number of outstanding shares (56.2m in Q123 vs 55.6m in FY22). Though our underlying long-term assumptions remain unchanged, we have rolled our model forward, and updated our exchange rate assumption to \$1.10/€ (from \$1.07/€) as well as the net cash balance. The positive roll forward impact on the overall valuation was partially offset by FX movements and a lower net cash balance of €0.9m compared to €4.0m previously. The net cash balance of €0.9m includes gross cash of \$20.0m (€18.2m) at end Q123 and the FY22 debt balance, which is the most recent debt figure the company has reported.

Considering the anticipated debt repayments due in FY23, we estimate the need to raise a total of €50m (€8m in FY23, €20m in FY24 and €22m in FY25), currently shown as illustrative debt in our model. Alternatively, if the funding is realised through an equity issue instead (assuming at the current trading price of €2.08/share), Oryzon would have to issue 23.7m shares, resulting in our per share valuation coming down to €10.9/share from \$15.6 currently (shares outstanding would increase from 56.2m to 79.9m). A breakdown of our risk-adjusted net present value (NPV) valuation is shown in Exhibit 1:

Exhibit 1: Valuation of Oryzon							
Product	Indication	Launch	Peak sales (\$m)	Value (€m)	Probability	rNPV (€m)	NPV/share (€/share)
Iadademstat	2L AML	2026	510	781.2	30%	231.0	4.1
	1L SCLC	2026	740	826.8	25%	203.0	3.6
Vafidemstat	BPD	2027	1,640	1,291.7	20%	250.5	4.5
	Schizophrenia, negative symptoms	2027	710	649.9	15%	90.9	1.6
	Aggression in Alzheimer's disease	2028	920	690.9	15%	97.8	1.7
Estimated net cash end Q123				0.9	100%	0.9	0.0
Valuation				4,241.5		874.1	15.6

Source: Edison Investment Research

Exhibit 2: Financial summary

Accounts: Year end 31 December (€000s)	2021	2022	2023e	2024e
INCOME STATEMENT				
Total revenues	10,615	15,698	17,268	18,995
Cost of sales	(746)	(464)	(487)	(512)
Gross profit	9,869	15,234	16,781	18,483
Gross margin %	93%	97%	97%	97%
SG&A (expenses)	(3,782)	(3,163)	(3,479)	(3,827)
R&D costs	(9,746)	(13,681)	(16,975)	(23,975)
Other income/(expense)	(3,203)	(3,714)	0	0
Exceptionals and adjustments	(4)	0	0	0
Reported EBITDA	(6,866)	(5,323)	(3,673)	(9,318)
Depreciation and amortisation	144	167	149	131
Reported EBIT	(7,011)	(5,490)	(3,822)	(9,450)
Finance income/(expense)	(169)	(871)	(426)	(579)
Other income/(expense)	0	(195)	0	0
Reported PBT	(7,180)	(6,557)	(4,248)	(10,029)
Income tax expense (includes exceptionals)	2,493	2,325	2,409	2,367
Reported net income	(4,687)	(4,231)	(1,839)	(7,662)
Basic average number of shares, m	53.1	55.6	56.2	56.2
Basic EPS (€)	(0.09)	(0.08)	(0.03)	(0.14)
Adjusted EBITDA	(6,862)	(5,323)	(3,673)	(9,318)
Adjusted EBIT	(7,007)	(5,490)	(3,822)	(9,450)
Adjusted PBT	(7,176)	(6,361)	(4,248)	(10,029)
Adjusted EPS (€)	(0.09)	(0.07)	(0.03)	(0.14)
Adjusted diluted EPS (€)	(0.09)	(0.07)	(0.03)	(0.14)
BALANCE SHEET				
Property, plant and equipment	682	611	538	482
Intangible assets	60,254	75,843	87,460	99,926
Investments	29	31	31	31
Deferred tax assets	1,812	2,050	2,050	2,050
Total non-current assets	62,778	78,535	90,078	102,489
Cash and equivalents	28,725	21,317	5,152	496
Trade and other receivables	3,645	3,709	3,677	3,693
Inventories	104	10	10	10
Other current assets	132	129	129	129
Total current assets	32,606	25,165	8,968	4,328
Deferred tax liabilities	1,812	2,050	2,050	2,050
Long term debt	13,354	10,346	14,486	31,877
Other non-current liabilities	285	0	0	0
Total non-current liabilities	15,451	12,396	16,536	33,927
Trade and other payables	3,518	5,742	4,630	5,186
Short term debt	4,306	12,920	7,077	4,562
Other current liabilities	847	70	70	70
Total current liabilities	8,672	18,732	11,777	9,818
Equity attributable to company	71,262	72,572	70,733	63,071
	0	0	0	0
CASH FLOW STATEMENT				
Profit before tax	(7,180)	(6,557)	(4,248)	(10,029)
Cash from operations (CFO)	(3,626)	(1,848)	(2,770)	(6,991)
Capex	(175)	(76)	(76)	(76)
Acquisitions & disposals net	0	0	0	0
Acquisition of intangible assets	(11,586)	(14,195)	(11,617)	(12,466)
Other investing activities	37	(1)	0	0
Cash used in investing activities (CFIA)	(11,724)	(14,271)	(11,693)	(12,542)
Net proceeds from issue of shares	0	(932)	0	0
Movements in debt	4,123	9,642	(1,703)	14,877
Other financing activities	0	0	0	0
Cash from financing activities (CFF)	4,123	8,710	(1,703)	14,877
Increase/(decrease) in cash and equivalents	(10,880)	(7,408)	(16,165)	(4,656)
Currency translation differences and other	348	1	0	0
Cash and equivalents at start of period	39,605	28,725	21,317	5,152
Cash and equivalents at end of period	28,725	21,317	5,152	496
Net (debt) cash	14,954	3,975	(3,094)	(2,648)

Source: Company reports, Edison Investment Research

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