BIOTECHNOLOGY

ORYZON GENOMICS

BUY

TARGET PRICE : 10,9€ +235%

NEWS FLOW + COMPANY CONTACT

FDA RECOMMENDATIONS TRIGGER PHASE III PROTOCOL UPDATES

The company received written feedback from the FDA last week regarding the pivotal PORTICO-2 Phase III protocol in borderline personality disorder. The Agency issued several technical recommendations, notably related to endpoints and certain non-clinical aspects. The company intends to address these comments and submit a revised version of the protocol as soon as possible, with no specific timeline provided at this stage. Given the support already expressed by the FDA during the End-of-Phase II meeting one year ago, particularly on the selection of endpoints and target population, we believe that the required adjustments should be limited in scope. We therefore expect a resubmission of the revised protocol in early 2026, followed by a final FDA response in Q1 2026. Accordingly, we maintain our current time-to-market assumptions. Our Buy rating is reiterated with an unchanged target price of €10.9.

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Document completed on 23/10/2025 09:45

Document published on 23/10/2025 09:45

FDA written feedback: multiple recommendations issued

On Friday after market close, Oryzon Genomics announced that it had received written feedback from the FDA regarding the Phase III clinical trial protocol evaluating vafidemstat in borderline personality disorder (BPD). The Agency issued several recommendations, notably regarding the selection of endpoints and certain non-clinical aspects. The company plans to incorporate these comments and submit a revised version of the protocol shortly, although no specific timeline has been provided at this stage. Additional updates will be communicated once the revised protocol has been submitted to the FDA and further discussions are underway.

What changes might the FDA have requested?

The company emphasized that this type of exchange with regulatory authorities is common during the clinical development process. While an immediate validation would have been viewed as a highly positive signal, the FDA's recommendations nonetheless provide an opportunity to optimize the study design and enhance the probability of success for vafidemstat, which is being developed as a potential first approved treatment for agitation and aggression associated with borderline personality disorder.

During the End-of-Phase II meeting held with the FDA in late August 2024, various aspects of vafidemstat's development plan were evaluated and discussed in depth. The meeting minutes issued by the FDA highlighted the relevance and robustness of the vafidemstat program across several key areas: (i) preclinical data, (ii) toxicology, (iii) clinical pharmacology, and (iv) clinical studies.

It was jointly agreed that agitation and aggression in borderline personality disorder could be considered an acceptable target indication. The Agency also agreed that the company could proceed with a Phase III trial using the STAXI-2 "Trait Anger" score as the primary efficacy endpoint, while noting that the company would need to provide additional information to demonstrate that the STAXI-2 trait anger measure is clinically meaningful in this indication — specifically through qualitative research on the scale in patients with BPD.

in € / share	2025e	2026e	2027e
Adjusted EPS	-0,03	-0,04	-0,04
chg.	*n.s.*	*n.s.*	*n.s.*
estimates chg.	*-1,7%*	*+0,0%*	*+0,0%*

au 31/12	2025e	2026e	2027e
PE	n.s.	n.s.	n.s.
EV/Sales	n.s.	n.s.	n.s.
EV/Adjusted EBITDA	n.s.	n.s.	n.s.
EV/Adjusted EBITA	n.s.	n.s.	n.s.
FCF yield*	n.s.	n.s.	n.s.
Div. Yield	n.s.	n.s.	n.s.

* After tax op. FCF before WCR

key points		
Closing share price	22/10/2025	3,3
Number of Shares (m)		79,9
Market cap. (€m)		260
Free float (€m)		185
ISIN		ES0167733015
Ticker		ORY-ES
DJ Sector		Health Technology

	1m	3m	Ytd
Absolute perf.	-9,6%	+17,1%	+132,5%
Relative perf.	-12,7%	+9,8%	+101,9%

Source : Factset, Invest Securities estimates

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This is likely the aspect currently under discussion and adjustment. Since the main elements of the protocol had already been reviewed and validated during the August 2024 meeting, we believe that the required modifications should remain minor and should not lead to any significant delay in the program's timeline.

Likely delay to early 2026 based on our estimates

With only a few weeks left in the year, we consider it unlikely that the company will be able to submit a revised version of its Phase III protocol before the end of December 2025. However, we remain confident that the additional elements requested by the FDA will not materially alter the key aspects of the protocol that were already discussed and validated.
We therefore assume the following indicative timeline (Invest Securities estimates):

- Revised protocol submission: Early Q1 2026
- FDA acknowledgment / final design alignment: Q1–Q2 2026
- Patient screening and first-in-patient (FPI): H2 2026

Typical Sequence Before Regulatory Green Light

Although the market reacted negatively to the FDA's request for additional information, it is important to remember that the program is progressing along standard regulatory pathways, following a typical sequence in such procedures:

Positive EoP2 → Protocol submission → FDA feedback → Announced revisions.

Key milestones and elements related to the PORTICO-2 protocol:

- **Oct 1, 2024** – End-of-Phase 2 (EoP2) meeting minutes: The FDA supported the initiation of the Phase III PORTICO-2 trial and clarified key design elements (population, endpoints, etc.).

"The FDA feedback supports the initiation of the Phase 3 PORTICO-2 study and provides clarity on key design aspects."
"The company and the FDA reached alignment on endpoints and target population."

- **Mar 3, 2025** – Oryzon specifies Phase III endpoints for agitation/aggression (corporate pre-submission announcement).

- **Jun 23, 2025** – PORTICO-2 protocol submitted to the FDA: Primary endpoint STAXI-2 Trait Anger (patient-reported); and key secondary endpoint OAS-M (clinician-assessed).

"PORTICO-2 is designed to confirm vafidemstat's efficacy in reducing aggression in Borderline Personality Disorder (BPD); primary endpoint: STAXI-2 'Trait Anger.'"
"Key secondary endpoints include clinician-rated scales for agitation/anger (e.g., OAS-M)."

- **Oct 17, 2025** – Written FDA feedback: The Agency requested adjustments related to endpoints and certain non-clinical aspects.

"ORYZON receives FDA feedback on its Phase 3 protocol; the company will incorporate comments and submit a revised version."

Key upcoming catalysts (short / medium Term)

- H2 2025: FDA IND approval to initiate a Phase Ib/II study in Autism Spectrum Disorder (ASD) focused on evaluating aggression.
- Q4 2025: Launch of the Phase Ib/II trial in ASD – First Patient In (FPI).
- December 2025: Updated oncology results expected at the ASH 2025 conference.
- Early 2026 (IS est.): Updated Phase III PORTICO-2 protocol incorporating FDA recommendations following initial feedback received in mid-October 2025.
- H1 2026 (IS est.): FDA feedback/approval on the Phase III PORTICO-2 protocol in Borderline Personality Disorder (BPD).
- H1 2026 (IS est.): Launch of the pivotal Phase III trial in BPD – FPI / **potential FDA agreement to support registration based on a single Phase III study.**

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Rating maintained at Buy, TP unchanged at €10.9

In light of the ongoing clinical developments with vafidemstat in borderline personality disorder, as well as iadademstat in oncology and more recently in sickle cell disease, we continue to view the company as offering an attractive value proposition. We therefore maintain our Buy recommendation, with an unchanged target price of €10.9, as the anticipated delay, currently estimated at only a few months, has no material impact on our model, which assumes completion of the pivotal study by end-2029 and a potential approval in 2030.

Should commercialization be delayed by one year, our target price could be adjusted to €10.0, reflecting:

- –€2.2 from a longer time-to-market;
- +€1.3 from the annual model roll as we enter 2026 in two months.

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FINANCIAL DATA

Share information	2020	2021	2022	2023	2024	2025e	2026e	2027e
Published EPS (€)	-0,04	-0,06	-0,05	-0,04	-0,06	-0,03	-0,04	-0,04
Adjusted EPS (€)	**-0,04**	**-0,06**	**-0,05**	**-0,04**	**-0,06**	**-0,03**	**-0,04**	**-0,04**
chg.	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*
Consensus EPS)	**-0,07**	**-0,09**	**-0,08**	**-0,06**	**-0,06**	**-0,04**	**0,05**	**0,01**
Diff. I.S. vs Consensus	*-44,5%*	*-33,5%*	*-27,1%*	*-21,7%*	*-3,4%*	*-30,6%*	*-172,3%*	*-440,1%*
Dividend	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Pay-out ratio	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Operating FCF	-3,22	-4,22	-2,83	-1,49	-2,38	-0,58	-0,58	-0,58
Book Value	0,81	0,88	0,87	0,95	1,14	1,28	1,55	1,51

Valuation ratios	2020	2021	2022	2023	2024	2025e	2026e	2027e
P/E	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Price to Book Value	3,6x	3,9x	2,9x	2,3x	2,9x	2,5x	2,1x	2,2x
EV/Sales	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
EV/Adjusted EBITDA	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
EV/Adjusted EBITA	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Op. FCF bef. WCR yield	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Op. FCF yield	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Div. yield (%)	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

NB : valuation based on annual average price for past exercise

Entreprise Value (€m)	2020	2021	2022	2023	2024	2025e	2026e	2027e
Average number of shares (m)	93,2	80,7	77,4	77,4	65,8	79,9	64,7	64,7
Share price in €	*3,0*	*3,5*	*2,5*	*2,2*	*3,3*	*3,3*	*3,3*	*3,3*
Market cap.	275,8	280,4	192,3	168,5	214,1	260,0	210,5	210,5
Net Debt	-26	-24	-19	2	9	-22	-23	-24
Minorities	0	0	0	0	0	0	0	0
Provisions/ near-debt	0	0	0	0	0	0	0	0
Financial assets	0	0	0	0	0	0	0	0
+/- Adjustments	0	0	0	0	0	0	0	1
Entreprise Value (EV)	**249,8**	**256,0**	**172,9**	**171,0**	**223,2**	**238,3**	**187,8**	**187,9**

NB : valuation based on annual average price for past exercise

Financial ratios	2020	2021	2022	2023	2024	2025e	2026e	2027e
Adjusted EBITDA margin	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Adjusted EBITA margin	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Tax rate	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Adjusted Net Profit/Sales	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
FCF/EBITDA adjusted	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Capex/Revenue	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
WCR in % of sales	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
DSO (days)	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
ROCE	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
ROCE exc. Intangible assets	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
ROE adjusted	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Gearing	n.s.	n.s.	n.s.	3,3%	12,1%	n.s.	n.s.	n.s.
Net Debt/Adjusted EBITDA (in x)	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Interest cover ratio	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

Source : company, Invest Securities Estimates

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FINANCIAL DATA

Income statement (€m)	2020	2021	2022	2023	2024	2025e	2026e	2027e
Revenue	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**
Organic growth.	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*
chg.	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*
Adjusted EBITDA	**-4,1**	**-6,9**	**-5,3**	**-4,4**	**-4,4**	**-3,5**	**-3,5**	**-3,5**
chg.	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***
Adjusted depreciation	-0,1	-0,1	-0,2	-0,2	-0,1	-0,2	-0,2	-0,2
Adjusted EBITA	**-4,1**	**-6,9**	**-5,3**	**-4,4**	**-4,4**	**-3,5**	**-3,5**	**-3,5**
chg.	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***
Exceptional items	0,6	0,0	0,0	0,0	0,0	0,0	0,0	0,0
EBIT	**-4,3**	**-7,0**	**-5,5**	**-4,5**	**-4,4**	**-3,6**	**-3,6**	**-3,6**
chg.	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***
Financial result	-0,5	-0,2	-1,1	-1,6	-1,1	-1,6	-1,6	-1,6
Profit before taxes	**-4,8**	**-7,2**	**-6,6**	**-6,1**	**-5,6**	**-5,2**	**-5,2**	**-5,2**
chg.	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***
Corp. tax	1,4	2,5	2,3	2,8	1,9	2,8	2,8	2,8
Minorities & affiliates	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
Net attributable profit	**-3,4**	**-4,7**	**-4,2**	**-3,4**	**-3,7**	**-2,4**	**-2,4**	**-2,4**
chg.	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***
Adjusted net profit	**-3,4**	**-4,7**	**-4,2**	**-3,4**	**-3,7**	**-2,4**	**-2,4**	**-2,4**
chg.	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***

Cash flow statement (€m)	2020	2021	2022	2023	2024	2025e	2026e	2027e
Adjusted EBITDA	-4,1	-6,9	-5,3	-4,4	-4,4	-3,5	-3,5	-3,5
Theoretical Tax / Adjusted EBITA	-0,3	-0,4	-0,5	-0,6	-0,4	-0,8	-0,8	-0,8
Capex	0,6	0,0	0,0	0,0	0,0	0,0	0,0	0,0
Operating FCF bef. WCR	**-3,9**	**-7,2**	**-5,8**	**-5,0**	**-4,8**	**-4,3**	**-4,3**	**-4,3**
Change in WCR	-1,2	0,0	0,0	0,0	0,0	0,0	0,0	0,0
Operating FCF	**-5,1**	**-7,2**	**-5,8**	**-5,0**	**-4,8**	**-4,3**	**-4,3**	**-4,3**
Acquisitions/disposals	-9,1	0,0	0,0	0,0	-10,4	0,0	0,0	0,0
Capital increase/decrease	18,4	-0,2	-1,1	10,0	5,0	30,0	-1,6	-1,6
Dividends paid	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
Other adjustments	-1,6	2,6	1,5	0,9	1,2	1,5	1,5	1,5
Published Cash-Flow	**2,6**	**-4,8**	**-5,4**	**5,8**	**-9,0**	**27,2**	**-4,4**	**-4,4**

Balance Sheet (€m)	2020	2021	2022	2023	2024	2025e	2026e	2027e
Assets	51,7	62,2	77,7	91,8	99,1	113,9	131,0	150,7
- of which Intangible assets/GW	49,2	59,7	75,2	89,2	96,5	111,4	128,5	148,2
- of which tangible assets	0,6	0,6	0,6	0,6	0,6	0,6	0,6	0,6
WCR	-1,9	-1,9	-1,9	-1,9	-1,9	-1,9	-1,9	-1,9
- of which trade receivables	2,4	2,4	2,4	2,4	2,4	2,4	2,4	2,4
- of which inventories	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3
Group equity capital	75,9	71,2	67,0	73,7	75,0	102,6	100,1	97,7
Minority shareholders	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
Provisions	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
Net financial debt	**-26,1**	**-24,4**	**-19,5**	**2,5**	**9,0**	**-21,8**	**-22,7**	**-23,6**
- of which gross financial debt	13,5	13,4	16,0	16,0	16,0	16,0	14,4	12,8
- of which gross cash	39,6	37,8	35,4	13,5	6,9	37,8	37,1	36,5

Source : company, Invest Securities Estimates

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INVESTMENT CASE

ORYZON GENOMICS is a Spanish biotechnology company specializing in the treatment of neurodegenerative diseases and cancer. Specializing in the field of epigenetics, the company aims, across all its development programs, to identify biomarkers through its genetic and proteomic platforms in order to develop small molecule drugs with differentiated therapeutic potential. The company has delivered interesting results with its most advanced programs in areas with varying levels of global R&D investment, including cancer, but also Covid-19 and cognitive disorders associated with neurodegenerative diseases or personality disorders. Its most advanced program in borderline personality disorder has delivered promising Ph IIb results with game-changing potential for the company.

SWOT ANALYSIS

STRENGHTS

- Epigenetic platform (cutting-edge domain)
- Extensive clinical development pipeline
- Differentiating positioning
- Asset class enjoying strong momentum

WEAKNESSES

- No industrial partnership to date
- Clinically risky indications (CNS)
- Intense competition in oncology

OPPORTUNITIES

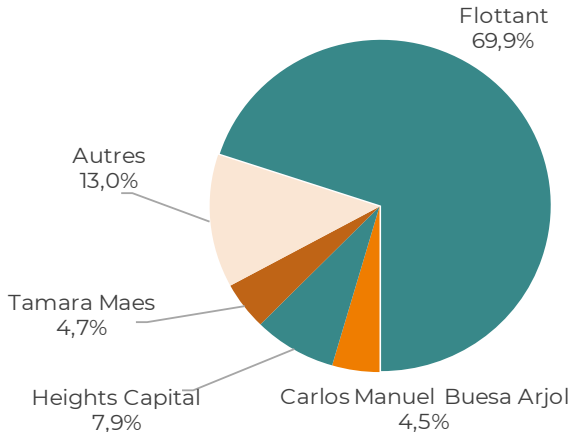
- Potential partnership
- Expansion of indications in both franchises
- Industrial interest in neuropsychiatric disorders
- $1.3 billion deal made by Merck for the same target = valuation benchmark for Oryzon

THREATS

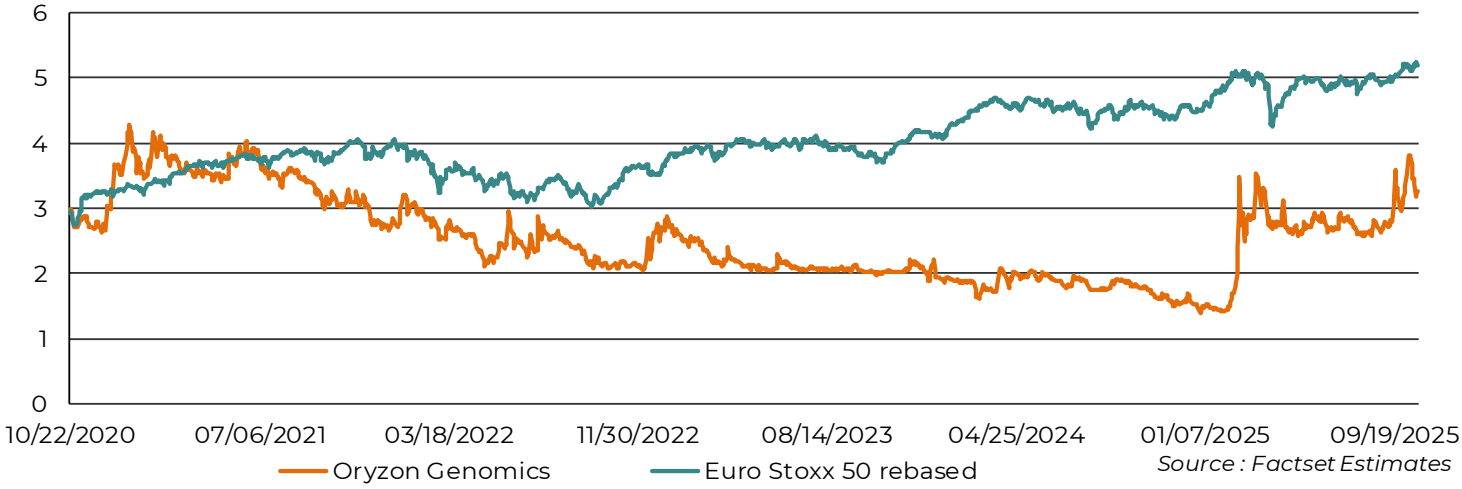
- Clinical and regulatory risk
- Commercial risks
- Legal risks

ADDITIONAL INFORMATION

Shareholders



SHARE PRICE CHANGE FOR 5 YEARS



Source : Factset Estimates

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TARGET PRICE AND RECOMMENDATION

Our analyst ratings are dependent on the expected absolute performance of the stock on a 6- to 12-month horizon. They are based on the company’s risk profile and the target price set by the analyst, which takes into account exogenous factors related to the market environment that may vary considerably. The Invest Securities analysis office sets target prices based on a multi-criteria fundamental analysis, including, but not limited to, discounted cash flows, comparisons based on peer companies or transaction multiples, sum-of-the-parts value, restated net asset value, discounted dividends.

Ratings assigned by the Invest Securities analysis office are defined as follows:

- BUY: Upside potential of more than 10% (the minimum upside required may be revised upward depending on the company’s risk profile)
- NEUTRAL: Between -10% downside and +10% upside potential (the maximum required may be revised upward depending on the company’s risk profile)
- SELL: Downside potential of more than 10%
- TENDER or DO NOT TENDER: Recommendations used when a public offer has been made for the issuer (takeover bid, public exchange offer, squeeze-out, etc.)
- SUBSCRIBE or DO NOT SUBSCRIBE: Recommendations used when a company is raising capital
- UNDER REVIEW: Temporary recommendation used when an exceptional event that has a substantial impact on the company’s results or our target price makes it impossible to assign a BUY, NEUTRAL or SELL rating to a stock

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12-MONTH HISTORY OF OPINION

The table below reflects the history of price recommendation and target changes made by the financial analysis office of Invest Securities over the past 12 months.

Company Name	Main Author	Release Date	Rating	Target Price	Current Share price	Potential
Oryzon Genomics	Jamila El Bougrini	24-avr.-25	ACHAT	10,9	2,8	+296%
Oryzon Genomics	Jamila El Bougrini	24-mars.-25	ACHAT	12,6	3,0	+314%
Oryzon Genomics	Jamila El Bougrini	17-janv.-25	ACHAT	3,1	1,5	+112%

DETECTION OF CONFLICTS OF INTEREST

	Oryzon Genomics
Invest Securities was lead manager or co-lead manager in a public offer concerning the financial instruments of this issuer during the last twelve months.	No
Invest Securities has signed a liquidity contract with the issuer.	No
Invest Securities and the issuer have signed a research service agreement.	Yes
Invest Securities and the issuer have signed a Listing Sponsor agreement.	No
Invest Securities has been remunerated by this issuer in exchange for the provision of other investment services during the last twelve months (RTO, Execution on behalf of third parties, advice, placement, underwriting).	No
This document was sent to the issuer prior to its publication. This rereading did not lead the analyst to modify the valuation.	No
This document was sent to the issuer for review prior to its publication. This rereading led the analyst to modify the valuation.	No
The financial analyst has an interest in the capital of the issuer.	No
The financial analyst acquired equity securities of the issuer prior to the public offering transaction.	No
The financial analyst receives remuneration directly linked to the transaction or to an investment service provided by Invest Securities.	No
An executive officer of Invest Securities is in a conflict of interest with the issuer and was given access to this document prior to its completion.	No
Invest Securities or the All Invest group owns or controls 5% or more of the share capital issued by the issuer.	No
Invest Securities or the All Invest group holds, on a temporary basis, a net long position of more than 0.5% of the issuer's capital.	No
Invest Securities or the All Invest group holds, on a temporary basis, a net short position of more than 0.5% of the issuer's capital.	No
The issuer owns or controls 5% or more of the capital of Invest Securities or the All Invest group.	No

Invest Securities's conflict of interest management policy is available on the Invest Securities website in the Complicance section. A list of all recommendations released over 12 months as well as the quarterly publication of "BUY, SELL, NEUTRAL, OTHERS" over 12 months, are available on the Invest Securities research platform.

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