ORYZON GENOMICS

BUY

TARGET PRICE : 6,6€ +181%

ECMH 2022

PORTICO CONFIRMS GOOD SAFETY PROFILE FOR VAFIDEMSTAT

At the European Conference for Mental Health (ECMH) held from 13-16 September 2022 in Lisbon, as part of an oral communication on Friday, Oryzon Genomics presented the first safety data obtained so far in the PORTICO study. This Phase IIb trial aims to assess the potential of vafidemstat (vafi) in improving borderline personality disorder (BPD). The results taken from 43 patients confirmed the product's good safety profile already demonstrated in various Ph I and Ph II clinical trials concerning more than 300 healthy volunteers and patients over periods of up to 24 months. We are maintaining our Buy recommendation and our TP of €6.6.

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No serious adverse event signalled at this stage

At the 10th European Conference for Mental Health (ECMH), held in Lisbon from 13-16 September, in an oral communication, ORYZON GENOMICS presented the first preliminary safety data from its Phase IIb PORTICO trial assessing the potential of vafidemstat in borderline personality disorder (BPD).

Aggregate blinded safety results were based on data collected from 43 randomised patients (cut-off on 30 June 2022). No serious adverse event was signalled, 41 adverse reactions were reported affecting 12 out of the 43 patients analysed, the majority of which were classed as minor, with none leading to a halt to treatment or patient withdrawal (see table on next page). As such, the safety data stemming from the PORTICO trial confirmed the good safety profile of vafidemstat already known and demonstrated under the framework of seven clinical trials that have included 300 patients so far.

Note that the DSMB recommended continuing the PORTICO trial in July 2022 based on available safety data. An intermediary independent analysis to assess the size and futility of the signal is due to be undertaken in Q1 2023 on the basis of data obtained from the first 90 patients to conclude at least two-thirds of the trial.

PORTICO is a multicentric (EU + US), randomised and double-blind vs placebo Ph IIb trial, aimed at assessing the efficacy and innocuity of vafidemstat in 160 adult patients suffering from BPD. The trial has two main independent objectives:

(i) Reduce agitation and aggressiveness.
(ii) Enable an overall improvement in the borderline disorder.

Given the lack of approved treatments and a high rate of self-mutilation and suicidal tendency, BPD remains a significant unmet medical need. Studies estimate that the suicide rate in people suffering from BPD is around 10%, 50 times higher than the general population. BPD patients are being treated with off-label drugs (i.e. not approved for BPD) that have limited efficacy and/or significant side effects (e.g. weight gain, somnolence, extrapyramidal symptoms).

Invest Securities and the issuer have signed an analyst coverage agreement.

in € / share	2022e	2023e	2024e
Adjusted EPS	0,57	0,48	0,81
chg.	*n.s.*	*-15,6%*	*+67,1%*
estimates chg.	*-937%*	*-517%*	*n.s.*

au 31/12	2022e	2023e	2024e
PE	0,0x	0,0x	0,0x
EV/Sales	0,2x	-0,2x	-0,3x
EV/Adjusted EBITD	0,2x	-0,2x	-0,7x
EV/Adjusted EBITA	0,2x	-0,2x	-0,7x
FCF yield*	198,8%	######	-86,2%
Div. yield (%)	n.s.	n.s.	n.s.

* After tax op. FCF before WCR

key points	
Closing share price 19/09/2022	2,3
Number of Shares (m)	54,0
Market cap. (€m)	127
Free float (€m)	102
ISIN	ES0167733015
Ticker	ORY-ES
DJ Sector	Health Technology

	1m	3m	Ytd
Absolute perf.	-7,7%	-4,5%	-13,1%
Relative perf.	-1,6%	-6,1%	+6,7%

Source : Factset, Invest Securities estimates

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PORTICO preliminary safety data: adverse events

System Organ Class Preferred Term	Number of Patients (%) Event Count			
	Adverse Events (AEs)	Adverse Reactions (ARs)	Serious Adverse Events (SAEs)	Serious Adverse Reactions (SARs)
Nervous system disorders	**10 (23.3) 31**	**9 (20.9) 22**	**0 (0.0) 0**	**0 (0.0) 0**
Tension headache	7 (16.3) 26	7 (16.3) 18	0 (0.0) 0	0 (0.0) 0
Dizziness	2 (4.7) 2	2 (4.7) 2	0 (0.0) 0	0 (0.0) 0
Cognitive disorder	1 (2.3) 1	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0
Headache	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Hypersomnia	1 (2.3) 1	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0
Infections and infestations	**7 (16.3) 7**	**0 (0.0) 0**	**0 (0.0) 0**	**0 (0.0) 0**
Nasopharyngitis	3 (7.0) 3	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
COVID-19	2 (4.7) 2	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Influenza	2 (4.7) 2	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Investigations	**5 (11.6) 6**	**5 (11.6) 6**	**0 (0.0) 0**	**0 (0.0) 0**
Platelet count decreased	3 (7.0) 3	3 (7.0) 3	0 (0.0) 0	0 (0.0) 0
Blood creatine phosphokinase increased	1 (2.3) 1	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0
Liver function test increased	1 (2.3) 1	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0
Neutrophil count decreased	1 (2.3) 1	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0
Gastrointestinal disorders	**4 (9.3) 5**	**1 (2.3) 2**	**0 (0.0) 0**	**0 (0.0) 0**
Abdominal pain	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Diarrhoea	1 (2.3) 1	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0
Nausea	1 (2.3) 1	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0
Odynophagia	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Teething	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Psychiatric disorders	**4 (9.3) 9**	**0 (0.0) 0**	**0 (0.0) 0**	**0 (0.0) 0**
Intentional self-injury	3 (7.0) 7	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Insomnia	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Panic attack	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Injury, poisoning and procedural complications	**3 (7.0) 5**	**3 (7.0) 5**	**0 (0.0) 0**	**0 (0.0) 0**
Subcutaneous haematoma	3 (7.0) 5	3 (7.0) 5	0 (0.0) 0	0 (0.0) 0
Blood and lymphatic system disorders	**2 (4.7) 2**	**0 (0.0) 0**	**0 (0.0) 0**	**0 (0.0) 0**
Anaemia	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Microcytic anaemia	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Metabolism and nutrition disorders	**2 (4.7) 2**	**1 (2.3) 1**	**0 (0.0) 0**	**0 (0.0) 0**
Decreased appetite	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Increased appetite	1 (2.3) 1	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0
Musculoskeletal and connective tissue disorders	**2 (4.7) 2**	**1 (2.3) 1**	**0 (0.0) 0**	**0 (0.0) 0**
Fibromyalgia	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Pain in extremity	1 (2.3) 1	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0
Respiratory, thoracic and mediastinal disorders	**2 (4.7) 3**	**1 (2.3) 2**	**0 (0.0) 0**	**0 (0.0) 0**
Cough	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0	0 (0.0) 0
Epistaxis	1 (2.3) 2	1 (2.3) 2	0 (0.0) 0	0 (0.0) 0
Reproductive system and breast disorders	**1 (2.3) 1**	**1 (2.3) 1**	**0 (0.0) 0**	**0 (0.0) 0**
Heavy menstrual bleeding	1 (2.3) 1	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0
Vascular disorders	**1 (2.3) 1**	**1 (2.3) 1**	**0 (0.0) 0**	**0 (0.0) 0**
Hypertension	1 (2.3) 1	1 (2.3) 1	0 (0.0) 0	0 (0.0) 0
TOTAL	**17 (39.5) 74**	**12 (27.9) 41**	**0 (0.0) 0**	**0 (0.0) 0**

Number of patients included 43, Cut-off date June 30th 2022. A patient with more than one finding in the specific category Preferred Term (PT) was only counted once; a patient with more than one finding in the specific category System Organ Class (SOC) was only counted once;; Table is sorted by descending patient count on the SOC and PT level driven by first column "AEs"; Drug related: AEs with causal relationship to medication not documented as unlikely and not related, and not applicable.

Source: Oryzon Genomics, ECMH 2022

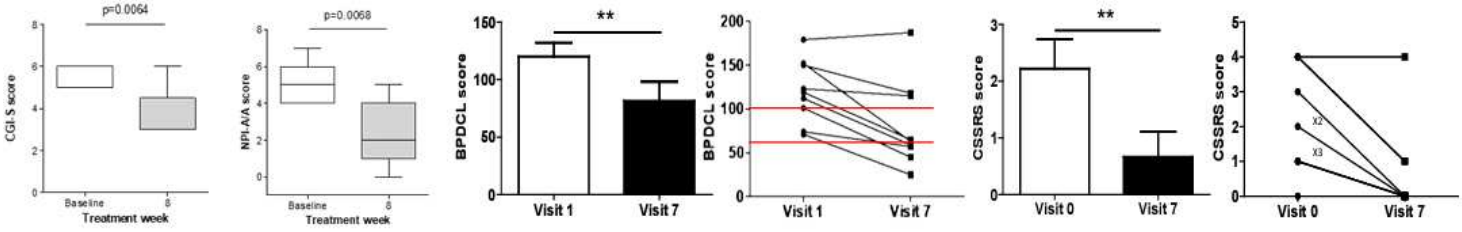
Efficiency signs identified during the REIMAGINE trial

REIMAGINE was a Phase IIa open proof-of-concept trial. This was a basket trial concerning 30 people suffering from various disorders (ADHD, ASD and BPD), with around one-third suffering from BPD. Under the framework of the study Oryzon Genomics demonstrated:

- A reduction in aggressiveness,
- An improvement in BPD symptoms,
- A reduction in suicidal thoughts.

These results demonstrated an overall improvement in the BPDCL scale at the diagnosis threshold level, and underpin the rationale behind overall treatment of the disorder.

Efficacy data from the Ph IIa REIMAGINE trial



Source: Oryzon Genomics, ECMH 2022

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Clinical trials underway and to come with vafidemstat

Several clinical trials assessing vafidemstat are currently underway or in preparation to assess the efficacy of various psychiatric and neurodevelopmental disorders:

- Ph IIb underway
  - PORTICO: randomised, double-blind, controlled vs placebo, adaptive trial in BPD
  - EVOLUTION: randomised, double-blind, controlled vs placebo, adaptive trial in negative symptoms and cognitive deficiency associated with schizophrenia.
- Ph Ib/II to come
  - IND in preparation for a randomised, double-blind, controlled vs. placebo trial in patients suffering from Kabuki syndrome.

BPD: a disorder with no satisfactory solution to date

Prevalence of the disorder is estimated at between 0.5% and 5.9% of adults in the general population with a greater concentration in hospital environments:

- 6% in primary clinical care,
- 10% in external psychiatric clinics,
- 20% in hospitalised psychiatric clinics.

Diagnosis is made according to the standard DSM-5 (American Psychiatric Association, 2013) test, which establishes BPD through “a pervasive pattern of instability in interpersonal relationships, self-image, and emotion, as well as marked impulsivity beginning by early adulthood and present in a variety of contexts”. BPD has nine criteria or clinical characteristics, and diagnosis is based on the presence of at least five out of nine criteria in the BPD patient.

The cause of the disorder remains vague with the accepted etiology being an interaction between biological factors and psychosocial factors (e.g. adverse events in childhood) in the initial stages of human development. On the genetic front, hereditability has been established as standing at 40% within families and in twins for BPD. According to some studies, gene-environment interactions and epigenetic changes could explain more the expression of a BPD phenotype relative to the presence of a concrete polymorphism.

At present, there is no approved drug treatment for borderline personality disorder. Drugs used off-label used have limited efficacy and/or significant side-effects (e.g. weight-gain, somnolence, EPS etc.). First-line treatment remains psychotherapy, especially dialectic behaviour therapy, but this presents limited efficacy and a variable response duration. In addition, the majority of BPD patients do not have access to this type of therapy due to a lack of resources (access to therapists/lack of financial resources). As such, BPD presents an unmet medical need with significant consequences given the associated suicide rate (50x higher than in the general population).

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FINANCIAL DATA

Share information	2017	2018	2019	2020	2021	2022e	2023e	2024e
Published EPS (€)	-0,15	-0,03	-0,08	-0,08	-0,14	0,57	0,48	0,81
Adjusted EPS (€)	**-0,15**	**-0,03**	**-0,08**	**-0,08**	**-0,14**	**0,57**	**0,48**	**0,81**
Diff. I.S. vs Consensus	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*
Dividend	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00

Valuation ratios	2017	2018	2019	2020	2021	2022e	2023e	2024e
P/E	n.s.	n.s.	n.s.	n.s.	n.s.	0,0x	0,0x	0,0x
EV/Sales	n.s.	n.s.	n.s.	n.s.	n.s.	0,16x	-0,16x	-0,32x
EV/Adjusted EBITDA	n.s.	n.s.	n.s.	n.s.	n.s.	0,2x	-0,2x	-0,7x
EV/Adjusted EBITA	n.s.	n.s.	n.s.	n.s.	n.s.	0,2x	-0,2x	-0,7x
Op. FCF bef. WCR yield	n.s.	n.s.	n.s.	n.s.	n.s.	198,8%	-292,2%	-86,2%
Op. FCF yield	n.s.	n.s.	n.s.	n.s.	n.s.	198,8%	-292,2%	-86,2%
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)	2017	2018	2019	2020	2021	2022e	2023e	2024e
Share price in €	*4,6*	*0,0*	*1464,2*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*
Market cap.	156	0	50 058	39	39	39	39	39
Net Debt	-17	-23	-27	-29	-15	-31	-43	-70
Minorities	0	0	0	0	0	0	0	0
Provisions/ near-debt	0	0	0	0	0	0	0	0
+/- Adjustments	0	0	0	0	0	0	0	0
Entreprise Value (EV)	**139**	**-22**	**50 031**	**10**	**24**	**8**	**-4**	**-31**

Income statement (€m)	2017	2018	2019	2020	2021	2022e	2023e	2024e
Sales	0,0	0,0	0,0	0,0	0,0	50,0	26,5	96,3
chg.	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*
Adjusted EBITDA	-4	-3	-4	-4	-6	35	22	41
adjusted EBITA	**-4**	**-3**	**-4**	**-4**	**-6**	**35**	**22**	**41**
chg.	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***-36,3%***	***+87,6%***
EBIT	-4,7	-3,3	-3,8	-4,3	-6,8	34,1	21,5	40,7
Financial result	-1	-1	-1	0	0	0	0	0
Corp. tax	0	3	1	1	1	-9	0	-5
Minorities+affiliates	0	0	0	0	0	0	0	0
Net attributable profit	-5,2	-1,2	-3,7	-3,4	-5,9	25,0	21,1	35,2
Adjusted net att. profit	**-5,2**	**-1,2**	**-3,7**	**-3,4**	**-5,9**	**25,0**	**21,1**	**35,2**
chg.	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***-15,6%***	***+67,1%***

Cash flow statement (€m)	2017	2018	2019	2020	2021	2022e	2023e	2024e
EBITDA	-3,9	-3,1	-3,7	-4,1	-6,5	34,5	22,0	41,2
Theoretical Tax / EBITA	0,1	2,5	0,9	1,4	1,4	-8,7	0,0	-5,1
Capex	0,6	-7,0	-9,6	-9,1	-9,5	-9,5	-9,5	-9,5
Operating FCF bef. WCR	**-3,2**	**-7,6**	**-12,4**	**-11,8**	**-14,6**	**16,3**	**12,5**	**26,7**
Change in WCR	-0,2	0,3	0,3	-1,2	0,0	0,0	0,0	0,0
Operating FCF	**-3,4**	**-7,3**	**-12,1**	**-13,1**	**-14,6**	**16,3**	**12,5**	**26,7**
Acquisitions/disposals	5,1	0,1	0,5	0,1	0,0	0,0	0,0	0,0
Capital increase/decrease	16,9	11,9	18,4	18,2	0,0	0,0	0,0	0,0
Dividends paid	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
Other adjustments	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
Published Cash-Flow	**18,5**	**4,7**	**6,7**	**5,3**	**-14,6**	**16,3**	**12,5**	**26,7**

Balance Sheet (€m)	2017	2018	2019	2020	2021	2022e	2023e	2024e
Assets	25	32	42	52	61	70	79	88
Intangible assets/GW	22	29	40	49	58	68	77	86
WCR	-8	-9	-8	-5	-5	-5	-5	-5
Group equity capital	34	45	61	76	70	95	116	151
Minority shareholders	0	0	0	0	0	0	0	0
Provisions	0	0	0	0	0	0	0	0
Net financial debt	**-17,2**	**-22,6**	**-26,7**	**-29,1**	**-14,5**	**-30,8**	**-43,3**	**-69,9**

Financial ratios	2017	2018	2019	2020	2021	2022e	2023e	2024e
EBITDA margin	n.s.	n.s.	n.s.	n.s.	n.s.	69,0%	83,1%	42,8%
EBITA margin	n.s.	n.s.	n.s.	n.s.	n.s.	69,0%	83,1%	42,8%
Adjusted Net Profit/Sales	n.s.	n.s.	n.s.	n.s.	n.s.	49,9%	79,6%	36,5%
ROCE	n.s.	n.s.	n.s.	n.s.	n.s.	53,0%	29,6%	49,5%
ROE adjusted	n.s.	n.s.	n.s.	n.s.	n.s.	26,3%	18,1%	23,3%
Gearing	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
ND/EBITDA (in x)	n.s.	n.s.	n.s.	n.s.	n.s.	-0,9x	-2,0x	-1,7x

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, in all of its development programs, to identify biomarkers through its genetic and proteomic platforms in order to develop small molecule drugs. The company has delivered interesting results with its most advanced programs in areas more or less invested in terms of overall R&D efforts, cancer but also Covid-19 and cognitive disorders associated with neurodegenerative diseases or disorders of the personality.

SWOT ANALYSIS

STRENGTHS

- Epigenetic platform
- Extensive development pipeline
- Differentiating positioning

WEAKNESSES

- No partnership
- Risky indications (CNS)
- Intense competition in oncology

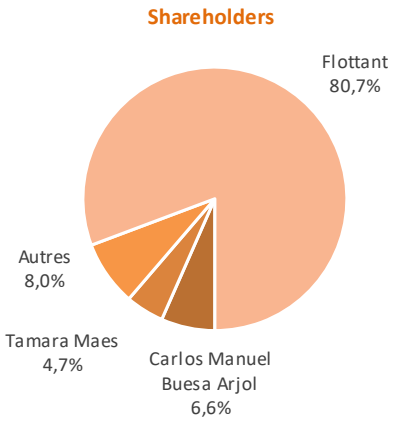
OPPORTUNITIES

- Potential partnership
- Extension of indications

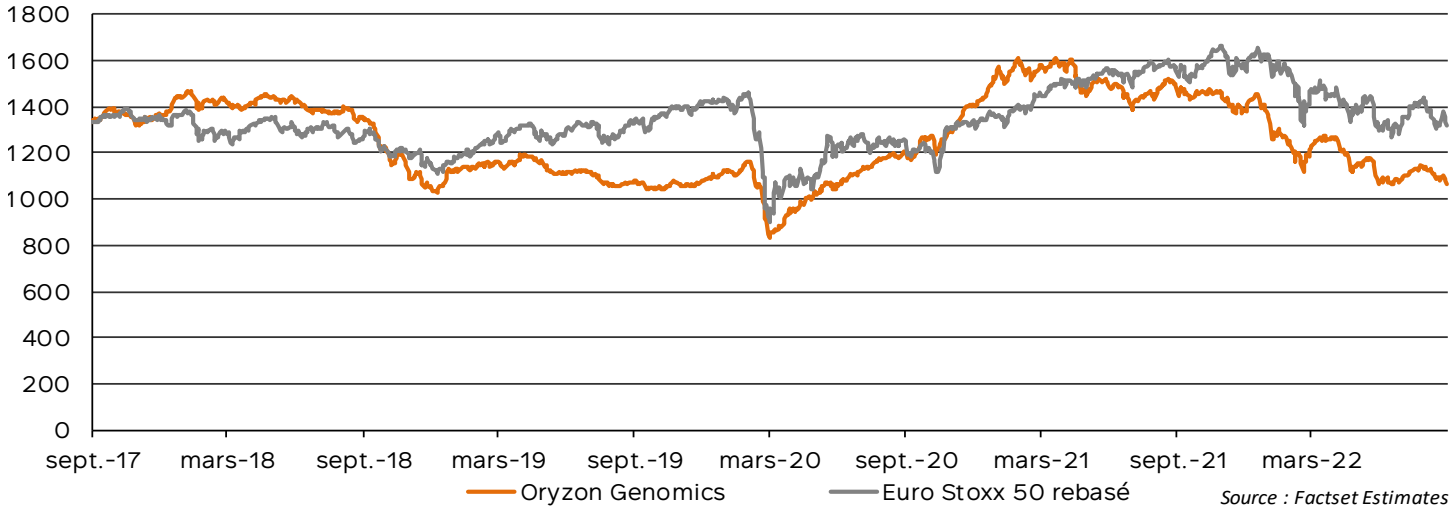
THREATS

- Clinical and regulatory risk
- Commercial risks
- Legal risks

ADDITIONAL INFOMATION



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.

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- 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-MONTHS HISTORY OF OPINION

The table below reflects the history of recommendation and price target changes made by Invest Securities' research department over the last 12 months.

Company Name	Main Author	Release Date	Rating	Target Price	Potential

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
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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
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