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BIOTECH

ORYZON GENOMICS

BUY

TARGET PRICE : 6,6€ +214%

ASH 2022 CONGRESS

PHASE IIA ALICE TRIAL: POSITIVE FOUR-YEAR RESULTS IN AML

Yesterday at the ASH congress (held from 10 to 13 December), Oryzon presented the final data from its Phase IIa clinical trial ALICE in acute myeloid leukaemia in an oral communication. Four-year data confirmed the observations noted so far in terms of safety, the trial's primary end-point, and efficacy, with promising signs at this stage. The company confirmed its aim to continue the programme in combination with other treatments, especially in sub-groups of patients presenting specific genetic patterns that seem to have better responder profiles. Oryzon is currently carrying out four trials in its oncology franchise in three different indications. We reiterate our Buy recommendation with a TP of €6.6.

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ASH 2022: presentation of end-results after four years in the Phase IIa trial ALICE

The last results presented at the EHA 2022 (European Hematology Association) congress in June based on data collected as of 15 April 2022, showed an objective response rate (ORR) of 81% (or 22 patients out of 27 assessable), of which 64% in complete remission (14 CR/CRi) and 36% partial remissions (eight PR). This data is all the more encouraging in that the literature shows an ORR of around 28% with standard chemotherapy (CT), azacitidine, in this target population of elderly or inapt for chemotherapy patients suffering from AML.

In all, the ALICE data at 48 months show that:

- 81% of patients obtained an objective response (vs. 81% at 42 weeks): 14 complete responses (64% CR) and eight partial responses (36% PR), bearing in mind that 71% of CR patients are no long dependent on transfusion (vs. 86%);
- 82% of samples tested in CR were MRD (Minimal Residual Disease) negative by flow cytometry (vs. 75% at 42 weeks), which means that the cancer was no longer detectable after treatment;
- 68% of the CRs were durable, namely more than six months (vs. 64%) [36% more than 12 months and 30% more than 18 months];
- 86% of patients had responded at the end of cycle 2 (vs. 91% at 42 weeks);
- After 48 weeks of follow-up, six patients are still alive, three of which entered treatment through compassionate usage, and four out of the 10 patients still alive at the last visit have an unknown survival status at this stage.

Primary end-point of ALICE trial: safety of the iada/aza combo confirmed

The results observed after four years show that the combination of iadademstat and azacitidine seems to be safe and efficient in the treatment of patients suffering from newly diagnosed AML who are inapt for CT treatment. The side effects listed during the trial indicate manageable toxicity levels with no significant non-haematological toxicity observed. Adverse events covered all the AEs signalled, including events emerging during treatment and events unrelated to the treatment. In all, eight deaths were noted due to infections and three due to bleeding. Two other deaths were signalled during the trial following a relapse. Serious adverse reactions related to the treatment were noted in three patients: one case of febrile neutropenia (stage 3), one case of differentiation

Invest Securities and the issuer have signed an analysis services agreement. 1/8

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%	-292,2%	-86,2%
Div. yield (%)	n.s.	n.s.	n.s.

* After tax op. FCF before WCR

key points	
Closing share price 12/12/2022	2,1
Number of Shares (m)	54,7
Market cap. (€m)	115
Free float (€m)	93
ISIN	ES0167733015
Ticker	ORY-ES
DJ Sector	Health Technology

	1m	3m	Ytd
Absolute perf.	-2,8%	-13,6%	-22,2%
Relative perf.	-4,1%	-19,6%	-14,8%

Source : Factset, Invest Securities estimates

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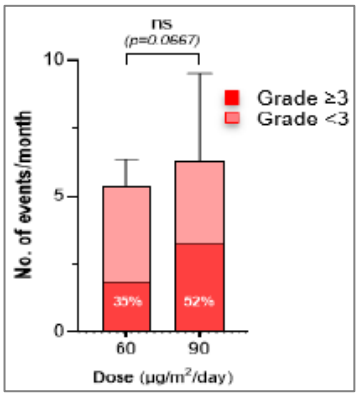


syndrome (stage 3) and one case of intracranial haemorrhage (stage 5).

Safety

Overview of AEs[#]	AEs (n)					
Subjects with	60 µg/m2/d n=17	90 µg/m2/d n=19	Overall n=36	60 µg/m2/d n=17	90 µg/m2/d n=19	Overall n=36
AEs	17 (100.0)	19 (100.0)	36 (100)	16 (94.1)	17 (89.5)	33 (91.7)
SAEs	16 (94.1)	18 (94.7)	34 (94.4)	1 (5.9)	2 (0.5)	**3 (8.3)****
AEs ≥G3	17 (100)	19 (100)	**36 (100)**	15 (88.2)	16 (84.2)	**31 (86.1)**
AEs leading to treatment **reduction**	2 (11.8)	7 (36.8)	9 (25.0)	2 (11.8)	5 (26.3)	**7 (19.4)**
AEs leading to treatment **delay**	10 (58.8)	11 (57.9)	21 (58.3)	7 (41.2)	8 (42.1)	**15 (41.7)**
AEs leading to treatment **hold**	9 (52.9)	13 (68.4)	22 (61.1)	6 (35.3)	4 (21.1)	**10 (27.8)**
AEs leading to treatment discontinuation	5 (29.4)	7 (36.8)	12 (33.3)	0	2 (10.5)	2 (5.6)
Fatal AEs	3 (17.6)	8 (42.1)	**11**(30.6)*	0	1 (5.3)	**1 (2.8)**

AEs include all reported AEs, including both Treatment Emergent and non-Treatment Emergent.
*Deaths due to Infections (8), bleeding (3). Additionally, there were 2 other reported study deaths (PD and death)
**Treatment related SAEs occurred in 3 patients, one with febrile neutropenia (G3) one with differentiation syndrome (G3) and one with intracranial hemorrhage (G5)

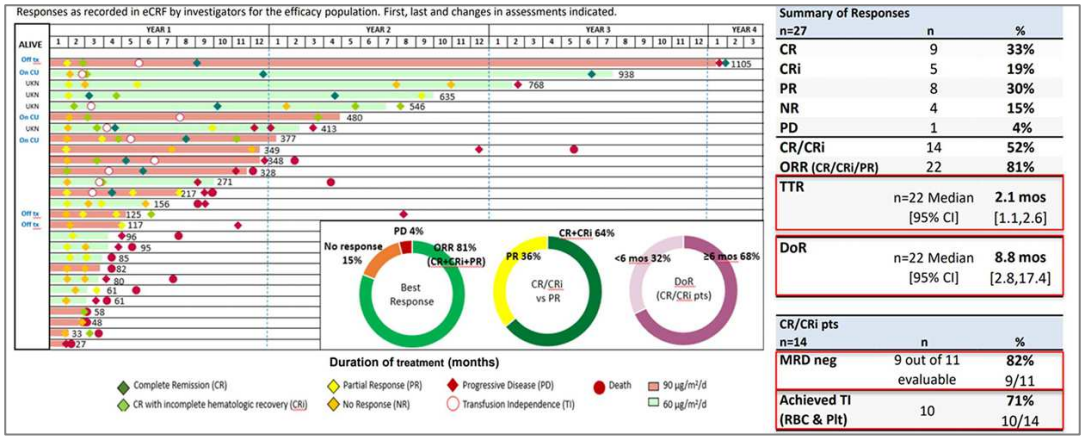
Hb: Haemoglobin; Lympho: Lymphocyte; WBC: White Blood Cell

n=36 Safety Analysis Population		n (%)	
Preferred Term	**SAEs (all)**	**AEs G3-4 (in >2 pt)**	**Related AEs (>10%)**
Investigations			
Platelet ct decreased	0	32 (88.9)	**23 (63.9)**
Neutrophil ct decreased	0	23 (63.9)	**20 (55.6)**
Hb abnormal/decreased	0	5 (13.9)	0
Lympho abnormal/decreased	0	4 (11.2)	0
WBC abnormal/decreased	0	4 (11.2)	0
All Others			
Febrile neutropenia	14 (38.9)	17(47.2)	1 (2.8)
Pneumonia	5 (13.9)	3 (8.3)	0
Pyrexia	4 (11.1)	1 (2.8)	0
Cellulitis	3 (8.3)	4 (11.1)	0
Sepsis	3 (8.3)	3 (8.3)	0
COVID-19 pneumonia	3 (8.3)	0	0
Respiratory tract infection	2 (5.6)	2 (5.6)	0
Skin infection	2 (5.6)	2 (5.6)	0
Urinary tract infection	2 (5.6)	2 (5.6)	0
Septic shock	2 (5.6)	1 (2.8)	0
Haemorrhage intracranial	2 (5.6)	0	1 (2.8)
Constipation	1 (2.8)	3 (8.3)	9 (25.0)
Hypotension	1 (2.8)	3 (8.3)	0
Anaemia	0	24(66.7)	15 (41.7)
Asthenia	0	5 (13.9)	9 (25.0)
Hypokalaemia	0	3 (8.3)	0
Dysgeusia	0	1 (2.8)	15 (41.7)
Nausea	0	0	6 (16.7)
Decreased appetite	0	0	4 (11.1)

The most common adverse events (more than 60% of patients) seen with Vidaza (azacitidine) in patients with myelodysplastic syndromes, CML or AML (with 20-30% abnormal cells) are blood reactions, including thrombocytopenia (low platelet counts), neutropenia (low neutrophil counts), and leukopenia (low white blood cell counts), as well as nausea and vomiting, and injection site reactions. As such, the combination of iadademstat and azacitidine does not seem to worsen the adverse reactions associated with CT, thereby making it a safe and acceptable treatment option for this type of patient suffering from leukaemia.

Promising efficacy ORR of 81% with iada/aza combine vs. 28% with aza alone

Based on results obtained in the two cohorts assessing the 60µg and 90µg doses of iadademstat, the RP2D (recommended Phase II Dose) retained is the 90 µg/m2/d dose of iadademstat in association with azacitidine CT. The overall ORR stood at 81% compared with the historical ORR known in the literature of 28% in the elderly population or inapt for AML treatment with azacitidine. At the RP2D dose, the target LSD1 engagement systematically reached more than 90%, which is correlated with better quality responses without compromising safety. Finally, median overall survival (OS) was more than one year (with 50% of patients surviving for more than 12 months, and 42% more than 18 months).



Summary of Responses		
n=27	**n**	**%**
CR	9	**33%**
CRi	5	**19%**
PR	8	**30%**
NR	4	**15%**
PD	1	**4%**
CR/CRi	14	**52%**
ORR (CR/CRi/PR)	22	**81%**
TTR	n=22 Median [95% CI]	**2.1 mos [1.1,2.6]**
DoR	n=22 Median [95% CI]	**8.8 mos [2.8,17.4]**

CR/CRi pts		
n=14	**n**	**%**
MRD neg	9 out of 11 evaluable	**82% 9/11**
Achieved TI (RBC & Plt)	10	**71% 10/14**

CU: Compassionate use; tx: treatment; UKN: Unknown; eCRF: electronic clinical record file; CR: Complete Remission; CRi: Complete Remission with incomplete hematologic recovery; PR: Partial Response; NR: No response; PD: Progressive Disease; ORR: Overall Response Rate; MRD: Measurable Residual Disease; TTR: Time To Response; DoR: Duration of Response; TI: Transfusion Independence; RBC: Red blood cells; Plt: Platelets

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Although an indirect comparison is not accurate on a scientific level since the conditions of the trial and the patient profiles are not similar, trials carried out previously by other teams in patients suffering from AML (including bone marrow containing more than 30% of abnormal cells), have shown that treatment with Vidaza prompted an improvement in the average survival duration to reach 10.4 months with aza vs. 6.5 months for patients receiving classic treatments. Median survival with the iada/aza combo was more than one year, and the duration of responses presented in the previous illustration show overall median survival of 9.6 months in vulnerable and fragile target patients.

Strengthened by this first data, Oryzon intends to expand the scope of exploration to study more in detail the activity of iadademstat in second line treatment of AML. In the near future, the company intends to launch the Phase Ib trial FRIDA, a new clinical trial with iadademstat in association with gilteritinib in FLT3 mutation refractory/relapsed AML. Approval to launch this trial has been granted (ClinicalTrials.gov Identifier: NCT05546580), and the first patient should be recruited and treated in coming weeks.

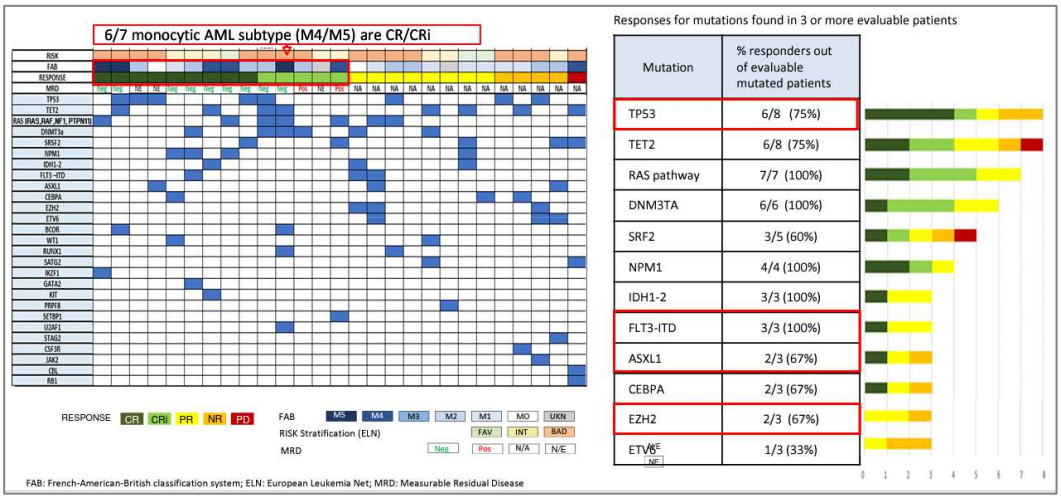
ClinicalTrials.gov Identifier: NCT05546580

Recruitment Status : Not yet recruiting
First Posted : September 21, 2022
Last Update Posted : September 21, 2022

See Contacts and Locations

ALICE revealed preferential mutational sub-groups to treat with the combo

Under the framework of this Phase II a trial, sub-analyses of patterns enabled the group to highlight better responses observed in patients presenting a wide range of AML mutations, including the FLT3 and TP53 mutations, and with monocytic AML sub-types, nevertheless known to provide a poor prognosis for current standards of care. Note that the different responses were observed in patients presenting a different mutational profile, thereby suggesting a wide range of application for iadademstat in AML. Indeed, all FLT3+ patients included in ALICE (100%; n=3) and a high share of TP53+ patients (75%; n=8) responded favourably to the iada/aza combo. Patients suffering from the monocytic AML sub-types (M4/M5) also demonstrated high response rates (86%; n=7).



Responses for mutations found in 3 or more evaluable patients

Mutation	% responders out of evaluable mutated patients
TP53	6/8 (75%)
TET2	6/8 (75%)
RAS pathway	7/7 (100%)
DNM3TA	6/6 (100%)
SRF2	3/5 (60%)
NPM1	4/4 (100%)
IDH1-2	3/3 (100%)
FLT3-ITD	3/3 (100%)
ASXL1	2/3 (67%)
CEBPA	2/3 (67%)
EZH2	2/3 (67%)
ETV6	1/3 (33%)

Favourable conclusions for the programme's continuation as part of a Phase IIb

The Phase IIa ALICE trial concerned 36 patients with a median age of 77, of which 27 patients were assessable for measures relative to efficacy. Clinical responses were observed in patients presenting various mutations, which supports the assumption that the combo could present an interest in different patient profiles. Additional research works combining iada with targeted therapies for the treatment of sub-populations of AML could be initiated. Finally, the iada/azacitidine combo proved to be safe and efficient for treatment of elderly/inapt patients with newly diagnosed AML. The safety profile was generally favourable with no significant non-haematological toxicity observed.

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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*	*3,5*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*
Market cap.	156	0	158	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**	**131**	**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

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SWOT ANALYSIS

STRENGTHS

- Epigenetic platform
- Extensive development pipeline
- Differentiating positioning

WEAKNESSES

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

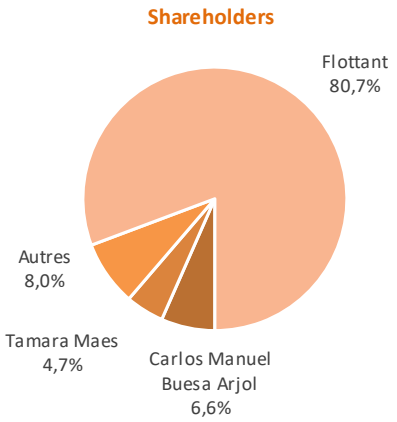
OPPORTUNITIES

- Potential partnership
- Extension of indications

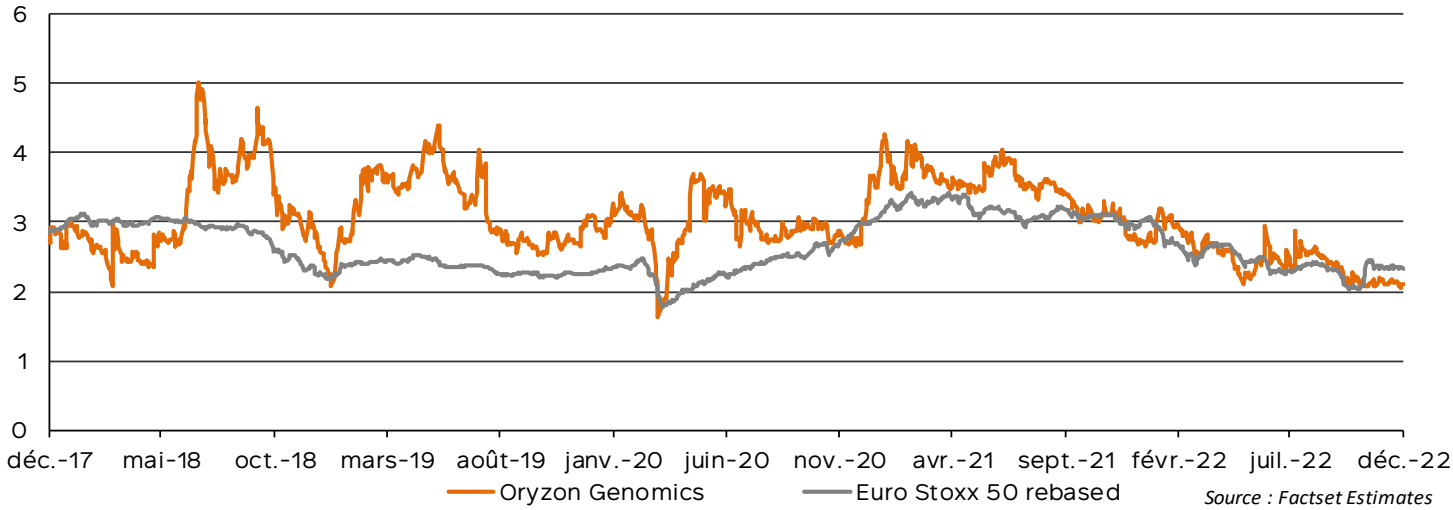
THREATS

- 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.

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-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
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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