TME PHARMA

BUY

TARGET PRICE : 0,62€ +130%

NEWSFLOW

FDA APPROVES IND FOR PHASE II TRIAL IN GBM

Yesterday, TME Pharma announced that the FDA had given its approval for the initiation of a Phase II trial in glioblastoma according to the protocol submitted by the company. The group is now waiting for a decision from the Agency by the end of March concerning fast-track approval for the indication, which should potentially allow accelerated approval if granted and conclusive results are obtained from a randomised, controlled Phase II trial. Based on the Ph I/II results obtained to date, TME Pharma's aim in obtaining an IND for a Ph II trial and a fast-track application for this programme is to offer an attractive package to convince an industrial partner to financially support the project under a licensing agreement. As a reminder, median overall survival in the current Phase I/II trial was 19.9 months versus 10.5 months for standard treatment, with a response rate of 83% versus <10%.

Jamila El Bougrini
+33 1 44 88 88 09
jelbougrini@invest-securities.com

Thibaut Voglimacci-Stephanopoli
+33 1 44 88 77 95
tvoglimacci@invest-securities.com

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First goal obtained, verdict on fast-track approval expected before the end of March

Yesterday, before market opening, the group announced that the FDA had decided to grant approval for the IND relating to the launch of a Phase II trial in glioblastoma (GBM) to assess the benefit of combining NOX-A12 with radiotherapy and bevacizumab. The Phase II protocol envisaged by the company involves around 100 patients with chemotherapy-resistant GBM, newly diagnosed with residual tumour following surgical resection. The trial will be randomised and controlled with five arms of 20 patients each, which could eventually lead to regulatory approval based on the results of the Phase II trial. Indeed, the group has submitted a fast-track application to the FDA, which should issue its opinion in Q1 2024 (end March). The Phase II trial could be launched in 2024, provided that the necessary funds are raised to carry out the trial, or if a partnership is set up. The latter is the preferred option for TME Pharma, which is in the process of identifying a partner to support future developments, in line with previous statements. TME Pharma's short-term objective is to prepare a relatively complete "IND + fast-track" package to make the programme as attractive as possible, with a view to signing a licensing agreement with a potential industrial partner. The group also stated that it has sufficient quantities of product to launch this Phase II trial, which is an additional advantage for initiating the Phase II with the FDA IND now granted, and hence an additional argument for attracting the interest of a potential partner.

The protocol for the Phase II study approved by the FDA will comprise the following five arms:

- Arm 1: NOX-A12 - 200mg/week + radiotherapy and bevacizumab
- Arm 2: NOX-A12 - 400mg/week + radiotherapy and bevacizumab
- Arm 3: NOX-A12 - 600mg/week + radiotherapy and bevacizumab
- Arm 4: NOX-A12 - 600mg/week + radiotherapy
- Arm 5: Monitoring of standard treatment (temozolomide + radiotherapy)

Summary of the main results obtained to date under Ph I/II

The ongoing Phase I/II extension trial showed a mOS (median overall survival) of more than 19.9 months in patients who received the NOX-A12/RT/Beva combination compared with 10.5 months with standard treatment, representing a near doubling of median survival. Median progression-free survival (mPFS) was nine months compared with four

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

in € / share	2023e	2024e	2025e
Adjusted EPS	-0,99	-0,87	-1,06
chg.	*n.s.*	*n.s.*	*n.s.*
estimates chg.	*n.s.*	*n.s.*	*n.s.*

au 31/12	2023e	2024e	2025e
PE	n.s.	n.s.	n.s.
EV/Sales	149,0x	306,7x	495,5x
EV/Adjusted EBITD	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.	370,4%

* After tax op. FCF before WCR

key points	
Closing share price 05/03/2024	0,27
Number of Shares (m)	27,9
Market cap. (€m)	8
Free float (€m)	7
ISIN	NL0015000YE1
Ticker	ALTME-FR
DJ Sector	Health Technology

	1m	3m	Ytd
Absolute perf.	+10,2%	+8,0%	+17,4%
Relative perf.	+9,1%	+1,7%	+15,9%

Source : Factset, Invest Securities estimates

73, bd Haussmann - 75008 Paris
T : +33 (0)1 80 97 22 01
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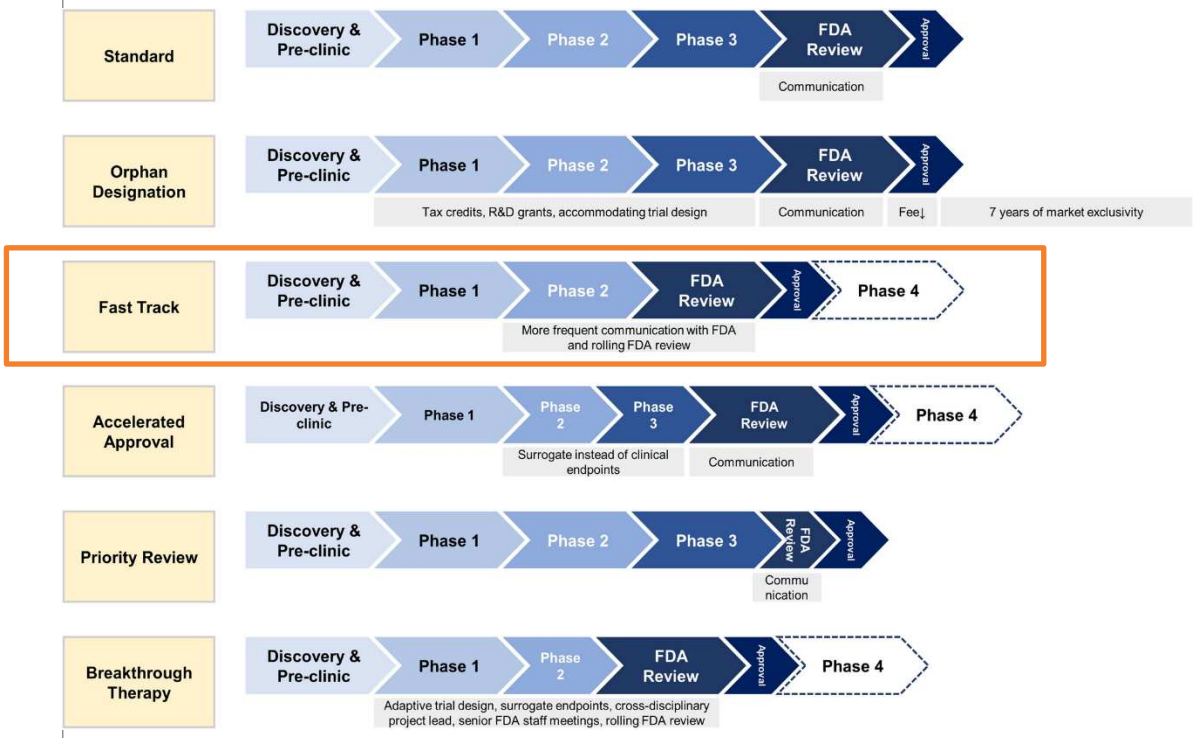
months for the matched group of reference patients, representing an improvement of over 100%. Finally, the cohort of six Ph I/II patients achieved an unprecedented overall response rate (ORR) of 83%, compared with an ORR of less than 10% for all other comparable treatments, with 50% of patients (i.e. three out of six in total) achieving a reduction in the size of the target tumour of more than 99%, which clinically corresponds to a complete or near-complete response.

Balance sheet cleaned up, end to CBs and redemption of associated debt

At the end of 2023, the company set up a sequential refinancing arrangement with the main aim of obtaining the resources and time it needs to identify an industrial partner. In February, TME Pharma carried out a capital increase of almost €1.5m via a private placement, for which the proceeds were primarily used to finance the repurchase of all outstanding ASO (ATLAS) convertible bonds with the aim of definitively ending the convertible bond financing programme. The group also announced the termination of the convertible bond agreement with ASO, except for the CBs already issued on 18 April 2023, having originally entered into the agreement with ASO on 23 April 2020. Thanks to these various capital increases, the company's financial visibility is now secure until July 2024, and potentially beyond. As well as cleaning up convertible bond debt, the funds raised will be used to continue business development in order to identify a partner to support the development of the programme in glioblastoma. The company's objective is to present itself as healthy and attractive as possible to a partner in order to attract M&A interest or simply BD&L (business development & licensing) via a "turnkey" package for the glioblastoma programme: IND for a randomised, controlled Phase II trial whose protocol has been validated by the FDA and which has the potential to be recognised as a pivotal phase (no need to conduct a Phase III trial before registration) + fast-track + sufficient clinical batches of NOX-A12 to conduct a Phase II trial.

Overview of FDA review pathways and special designations



Source: Michaeli, D.T., et al. Special FDA designations for drug development: orphan, fast track, accelerated approval, priority review, and breakthrough therapy. Eur J Health Econ (2023). https://doi.org/10.1007/s10198-023-01639-x

73, bd Haussmann - 75008 Paris
T : +33 (0)1 80 97 22 01
invest-securities.com

FINANCIAL DATA

Share information	2017	2018	2019	2020	2021	2022	2023e	2024e	2025e
Published EPS (€)	-2,54	-2,70	-0,08	-0,32	-0,26	-21,88	-0,99	-0,87	-1,06
Adjusted EPS (€)	**-2,54**	**-2,70**	**-0,08**	**-0,32**	**-0,26**	**-21,88**	**-0,99**	**-0,87**	**-1,06**
Diff. I.S. vs Consensus	*n.s.*	*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	1,00	2,00

Valuation ratios	2017	2018	2019	2020	2021	2022	2023e	2024e	2025e
P/E	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
EV/Sales	144,40x	21,14x	27,67x	-14,91x	5,35x	41,09x	149,02x	306,70x	495,46x
EV/Adjusted EBITDA	n.s.	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.	n.s.
Op. FCF bef. WCR yield	n.s.	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.	n.s.
Div. yield (%)	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	370,4%

NB : valuation based on annual average price for past exercise

Entreprise Value (€m)	2017	2018	2019	2020	2021	2022	2023e	2024e	2025e
Share price in €	*15,6*	*0,27*	*0,27*	*0,27*	*0,27*	*0,27*	*0,27*	*0,27*	*0,27*
Market cap.	36	8	8	8	8	8	8	8	8
Net Debt	*1,9*	*0,5*	*0,2*	*-9,7*	*-6,7*	*-1,5*	*14,4*	*35,6*	*61,3*
Minorities	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*1,0*	*2,0*
Provisions/ near-debt	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*
+/- Adjustments	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*0,0*	*1,0*	*2,0*
Entreprise Value (EV)	**38**	**8**	**8**	**-2**	**1**	**6**	**22**	**45**	**73**

Income statement (€m)	2017	2018	2019	2020	2021	2022	2023e	2024e	2025e
Sales	0	0	0	0	0	0	0	0	0
chg.	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*
Adjusted EBITDA	-5	-4	-4	-6	-14	-28	-12	-16	-21
adjusted EBITA	**-5**	**-4**	**-4**	**-6**	**-14**	**-28**	**-12**	**-16**	**-21**
chg.	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***
EBIT	-5	-4	-4	-6	-14	-28	-12	-16	-21
Financial result	-1	-6	3	-5	-5	-5	-5	-5	-5
Corp. tax	0	0	0	0	0	0	0	0	0
Minorities+affiliates	0	0	0	0	0	0	0	1	2
Net attributable profit	-5	-11	-1	-10	-19	-33	-17	-20	-24
Adjusted net att. profit	**-5**	**-11**	**-1**	**-10**	**-19**	**-33**	**-17**	**-20**	**-24**
chg.	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***	***n.s.***

Cash flow statement (€m)	2017	2018	2019	2020	2021	2022	2023e	2024e	2025e
EBITDA	-5	-4	-4	-6	-14	-28	-12	-16	-21
Theoretical Tax / EBITA	0	0	0	0	0	0	0	0	0
Capex	0	0	0	0	0	0	0	0	0
Operating FCF bef. WCR	**-5**	**-4**	**-4**	**-6**	**-14**	**-28**	**-12**	**-16**	**-21**
Change in WCR	0	0	0	0	0	0	0	0	0
Operating FCF	**-5**	**-4**	**-3**	**-6**	**-14**	**-28**	**-12**	**-16**	**-21**
Acquisitions/disposals	0	0	0	0	0	0	0	0	0
Capital increase/decrease	3	8	1	14	16	28	1	0	0
Dividends paid	0	0	0	0	0	0	0	0	0
Other adjustments	-1	-6	3	-5	-5	-5	-5	-5	-5
Published Cash-Flow	**-3**	**-3**	**1**	**3**	**-3**	**-5**	**-16**	**-21**	**-26**

Balance Sheet (€m)	2017	2018	2019	2020	2021	2022	2023e	2024e	2025e
Assets	0	0	0	0	0	0	0	0	0
Intangible assets/GW	0	0	0	0	0	0	0	0	0
WCR	-2	-2	-2	-2	-2	-2	-2	-2	-2
Group equity capital	-4	-3	-2	8	-6	-11	-27	-48	-74
Minority shareholders	0	0	0	0	0	0	0	1	2
Provisions	0	0	0	0	0	0	0	0	0
Net financial debt	**2**	**0**	**0**	**-10**	**-7**	**-1**	**14**	**36**	**61**

Financial ratios	2017	2018	2019	2020	2021	2022	2023e	2024e	2025e
EBITDA margin	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
EBITA margin	n.s.	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.	n.s.
ROCE	n.s.	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.	n.s.
Gearing	n.s.	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.	n.s.	n.s.	n.s.	n.s.

Source : company, Invest Securities Estimates

73, bd Haussmann - 75008 Paris
T : +33 (0)1 80 97 22 01
invest-securities.com

INVESTMENT CASE

TME PHARMA (ex-NOXXON) is a biotech company with an oncology-focused portfolio. The two products it has developed to date—NOX-A12 (glioblastoma, as well as metastatic pancreatic and colorectal cancer) and NOX-E36 (solid cancers)—are designed to break the tumor protection barrier and block tumor repair by neutralizing chemokines in the tumor microenvironment (TME). Its clinical approach is unique and can be used in combination with other therapeutic approaches, notably radiotherapy and immunotherapy, to weaken tumor defenses against the immune system and enable greater therapeutic impact.

SWOT ANALYSIS

STRENGTHS

- An innovative approach within the IO space
- Partnership with Merck for brain cancer
- Drugs that target indications with little competition

WEAKNESSES

- Relatively early-stage pipeline
- Need for additional financing within a year

OPPORTUNITIES

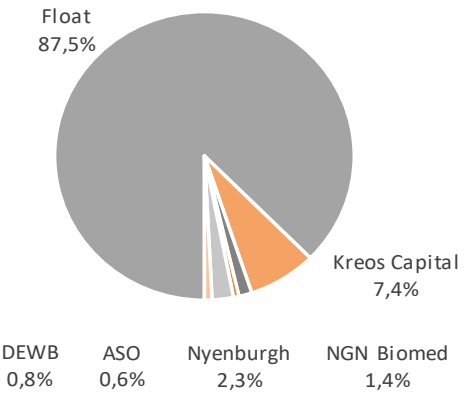
- Combination drug trials
- Possibility of new partnerships
- Significant M&A activity in the field

THREATS

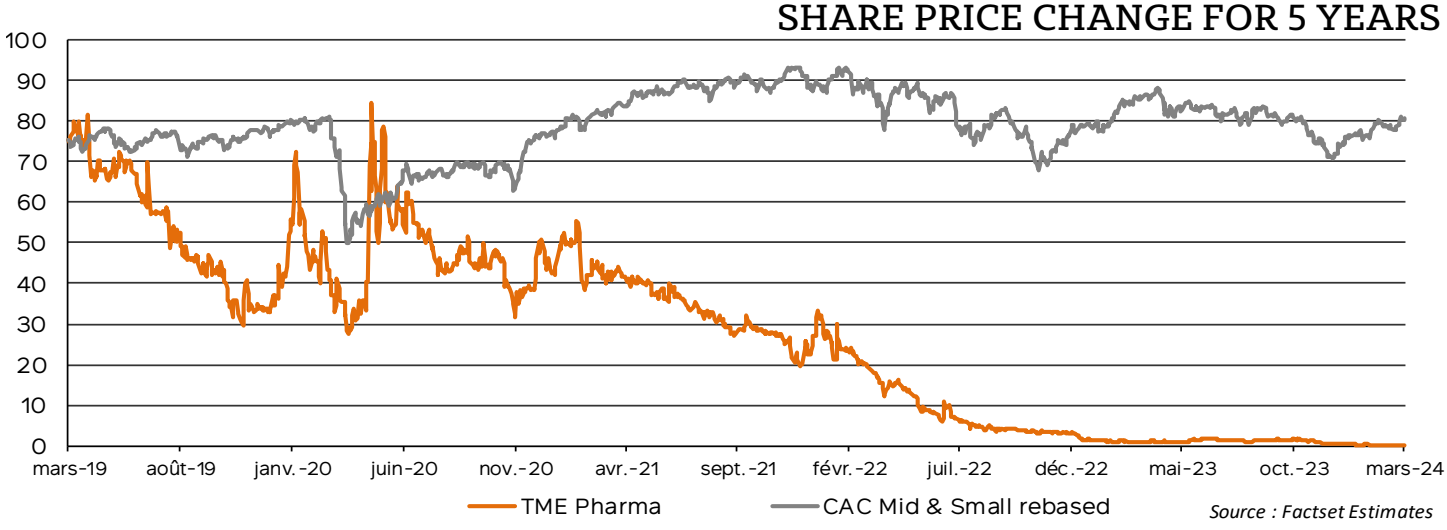
- Regulatory and clinical risks
- Legal risks
- Commercial risks

ADDITIONAL INFORMATION

Shareholders



SHARE PRICE CHANGE FOR 5 YEARS



Source : Factset Estimates

73, bd Haussmann - 75008 Paris
T : +33 (0)1 80 97 22 01
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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

73, bd Haussmann - 75008 Paris
T : +33 (0)1 80 97 22 01
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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	Potential
TME PHARMA	Jamila El Bougrini	13-févr.-24	ACHAT	0,7	+101%
TME PHARMA	Jamila El Bougrini	27-nov.-23	ACHAT	0,4	+36%
TME PHARMA	Jamila El Bougrini	27-mars.-23	ACHAT	4,2	+310%

DETECTION OF CONFLICTS OF INTEREST

	TME PHARMA
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.	Yes
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.

73, bd Haussmann - 75008 Paris
T : +33 (0)1 80 97 22 01
invest-securities.com

MANAGEMENT

Marc-Antoine Guillen
CEO
+33 1 44 88 77 80
maguillen@invest-securities.com

Jean-Emmanuel Vernay
Managing Director
+33 1 44 88 77 82
jevernay@invest-securities.com

Anne Bellavoine
Deputy Managing Director
+33 1 55 35 55 75
abellavoine@invest-securities.com

Pascal Hadjedj
Deputy Managing Director and Head of Primary Market Sales
+33 1 55 35 55 61
phadjedj@invest-securities.com

EQUITY RESEARCH

Maxime Dubreil
Head of Equity Research
+33 1 44 88 77 98
mdubreil@invest-securities.com

Stéphane Afonso
Financial analyst, Real Estate
+33 1 73 73 90 25
safonso@invest-securities.com

Bruno Duclos
Financial analyst, Real Estate
+33 1 73 73 90 25
bduclos@invest-securities.com

Jamila El Bougrini
Financial analyst, Biotech/Healthtech
+33 1 44 88 88 09
jelbougrini@invest-securities.com

Benoît Faure-Jarrosson
Senior Advisor, Real Estate
+33 1 73 73 90 25
bfaure-jarrosson@invest-securities.com

Claire Meilland
Financial analyst, CleanTech
+33 1 73 73 90 34
cmeilland@invest-securities.com

Jean-Louis Sempé
Financial analyst, Automotive
+33 1 73 73 90 35
jlsempe@invest-securities.com

Thibaut Voglimacci-Stephanopoli
Financial analyst, Medtechs / Biotechs
+33 1 44 88 77 95
tvoglimacci@invest-securities.com

TRADING FLOOR

Raphael Jeannet
Institutional Sales
+33 1 55 35 55 62
rjeannet@invest-securities.com

Edouard Lucas
Institutional Sales
+33 1 55 35 55 74
elucas@invest-securities.com

Ralph Olmos
Institutional Sales
+33 1 55 35 55 72
rolmos@invest-securities.com

Kaspar Stuart
Institutional Sales
+33 1 55 35 55 65
kstuart@invest-securities.com

Frédéric Vals
Institutional Sales
+33 1 55 35 55 71
fvals@invest-securities.com

CORPORATE BROKING & ISSUER MARKETING

Thierry Roussilhe
Head of CB & Issuer Marketing
+33 1 55 35 55 66
troussilhe@invest-securities.com

Fabien Huet
Liquidity
+33 1 55 35 55 60
fhuet@invest-securities.com