

NEWS

2ND TARGET REACHED: FAST-TRACK GRANTED BY THE FDA

The FDA's long-awaited decision was announced yesterday, and the company has indeed obtained fast-track designation! TME Pharma has therefore reached the two targets it set itself for the start of the year: (i) obtaining an IND to initiate a randomised, controlled (potentially pivotal) Phase II trial, and (ii) obtaining fast-track designation (saving several months in the regulatory procedure). The challenge now is to resume discussions with pharmaceutical and financial partners in order to present the GBM programme on the strength of these latest achievements: a Ph II protocol validated by the FDA, IND granted, fast-track designation obtained, and extremely promising Ph I/II clinical results. At a time when M&A in the sector is picking up strongly, particularly in oncology, TME Pharma has solid assets to demonstrate the potential of its combination of treatments for patients with "resistant" and residual GBM.

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FDA grants fast track designation for NOX-A12 in GBM

Expected at the end of Q1 2024, the FDA's decision on fast-track designation was announced yesterday after the markets close. The Agency has indeed decided to grant "fast-track" status to applications for marketing approval in the US on the basis of the clinical results obtained in the pivotal phase (Phase II or Phase III, depending on the quality of the data and the medical need). Thanks to this designation, and given the clinical protocol adopted for Phase II (randomised controlled trial), a registration procedure could be initiated as soon as Phase II is completed if the results are positive and superior to reference treatments.

The company has now reached its two targets on the regulatory front: (i) validation of the clinical protocol and obtaining the IND for Phase II, and (ii) obtaining fast-track status. The next step will be to continue discussions with potential partners with a view to concluding a collaboration agreement with one of them. The amounts raised recently (and in the future) will be used primarily for this business development objective. The company's aim is to present itself with the most healthy and attractive profile possible in order to generate interest from a potential partner:

- end to debt and convertible bonds financing programme,
- IND obtained for a randomised, controlled Phase II trial (protocol validated by the FDA),
- fast-track designation obtained and the possibility of submitting an application for marketing approval as soon as the Phase II is completed,
- availability of sufficient clinical batches of NOX-A12 to conduct Phase II.

Financing, the main short-term challenge

At present, the company's financial visibility is secured out to July 2024. If all the outstanding Z warrants are exercised, TME Pharma could raise a total of €951,432 (of which €120k has already been raised), thereby extending its financial horizon to the end of Q3 2024. This would give the company around six months to identify a partner to co-develop the GBM programme.

With the IND and fast track status granted by the FDA, and on the basis of clinical data obtained in Ph I/II trials, TME Pharma has solid arguments to convince an industrial and/or financial partner to support the company. At the same time as these discussions,

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	153,6x	311,3x	500,0x
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.	347,2%

* After tax op. FCF before WCR

key points			
Closing share price	02/04/2024	0,29	
Number of Shares (m)		28,5	
Market cap. (€m)		8	
Free float (€m)		7	
ISIN		NL0015000YE1	
Ticker		ALTME-FR	
DJ Sector		Health Technology	
	1m	3m	
Absolute perf.	-17,7%	+20,5%	+25,2%
Relative perf.	-20,9%	+14,1%	+18,7%

Source : Factset, Invest Securities estimates

the company is studying other non-dilutive sources of financial leverage to pursue the development of its programme. In addition, TME Pharma is considering public subsidies and is studying the eligibility of NOX-A12 in GBM as a compassionate treatment. However, for this prospect, the company would have to demonstrate robust clinical data with satisfactory clinical efficacy AND safety of treatment before considering filing an application and obtaining the green light from the health agencies. In view of the procedure, this is unlikely to happen for several years, and the revenues generated will not be able to contribute to TME Pharma's immediate financing needs.

Initiation of Phase II is subject to sufficient and significant funding, which we estimate at around €50m based on the study design proposed by TME Pharma. The protocol for the FDA-approved Phase II study will comprise the following five arms, each of which will enrol around 20 patients:

- 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: Control of standard treatment (temozolomide + radiotherapy)

The excellent Ph I/II data have demonstrated a mOS (median overall survival) of almost 20 months, so we consider that one of the main criteria will be survival at 24 months. Taking into account the size of the study and the speed of recruitment, we estimate that a first readout at 24 months of treatment will be possible between 3.5 and four years after the start of the Phase II study.

In Ph I/II (cohort of six patients), the mOS was 19.9 months with the NOX-A12/radiotherapy/bevacizumab combination compared with 10.5 months with standard treatment, and the mPFS (median progression-free survival) was nine months compared with four months, with an ORR (overall response rate) of 83% compared with <10% with other comparable treatments. If these results are confirmed in Phase II with a sufficient number of patients to achieve statistical power, and in the context of a randomised controlled trial, the NOX-A12/RT/beva combo could become the new standard of care for patients with newly diagnosed glioblastoma treated by surgery but with residual tumour resistant to chemotherapy.

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
<i>Diff. I.S. vs Consensus</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>
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	22,92x	30,09x	-10,33x	9,94x	45,67x	153,61x	311,28x	500,05x
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.	347,2%

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	0,29	0,29	0,29	0,29	0,29	0,29	0,29	0,29
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	9	8	-2	1	7	23	46	74

Income statement (€m)	2017	2018	2019	2020	2021	2022	2023e	2024e	2025e
Sales	0	0	0	0	0	0	0	0	0
<i>chg.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>
Adjusted EBITDA	-5	-4	-4	-6	-14	-28	-12	-16	-21
adjusted EBITA	-5	-4	-4	-6	-14	-28	-12	-16	-21
<i>chg.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>
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
<i>chg.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>	<i>n.s.</i>

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

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
- ❑ Promising Ph I/II results in GBM
- ❑ Drugs that target indications with little competition

WEAKNESSES

- ❑ Relatively early-stage pipeline
- ❑ Need for additional financing

OPPORTUNITIES

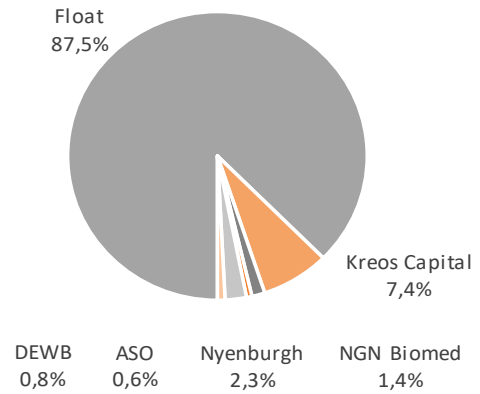
- ❑ Combination drug trials
- ❑ Possibility of new partnerships
- ❑ Significant M&A activity in the field

THREATS

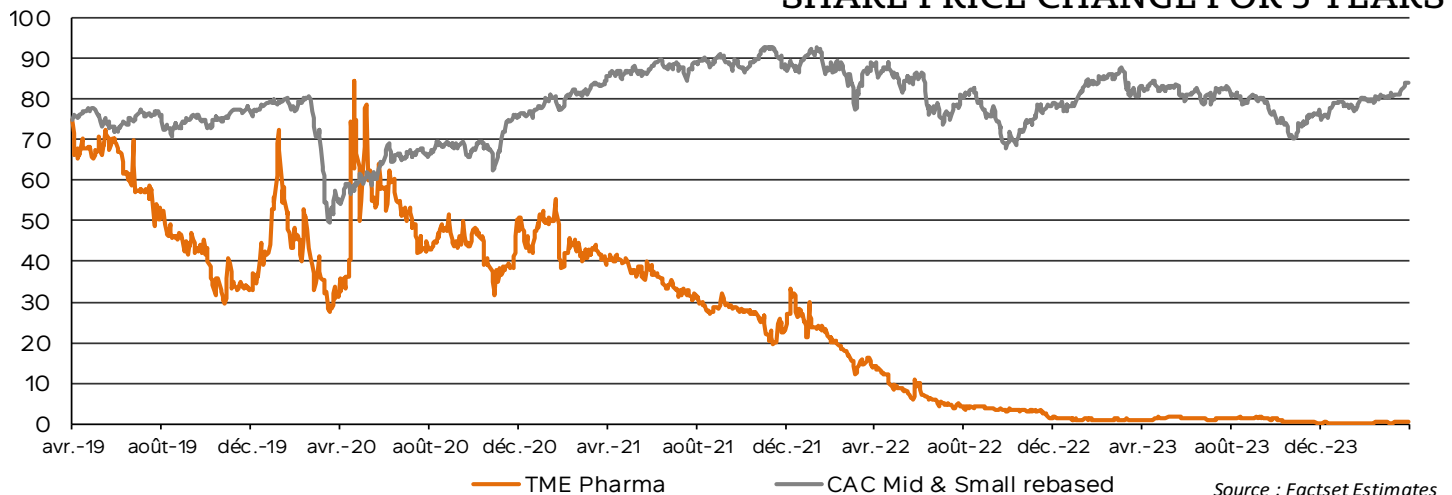
- ❑ Regulatory and clinical risks
- ❑ Legal risks
- ❑ Commercial risks

ADDITIONAL INFORMATION

Shareholders



SHARE PRICE CHANGE FOR 5 YEARS



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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.)
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- 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

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	02-avr.-24	ACHAT	0,61	+94%
TME PHARMA	Jamila El Bougrini	26-févr.-24	ACHAT	0,62	+130%
TME PHARMA	Jamila El Bougrini	13-févr.-24	ACHAT	0,67	+101%
TME PHARMA	Jamila El Bougrini	27-nov.-23	ACHAT	0,4	+36%

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 Compliance 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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