RNS Number : 2198E
Theracryf PLC
14 May 2026

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TheraCryf plc
("TheraCryf", the "Company" or the "Group")

Positive top line data from first toxicology species in lead Ox-1 addiction programme

Clinical trial enabling work progressing ahead of plan
On track to deliver the major value infection point of all clinical trial application data in 2026
Progress to date is attracting incoming interest from potential partners
Phase 1 clinical stage assets attract up-front payments in the range US 26m-US 49m[1]

TheraCryf plc, the biotech company developing new medicines for addiction and other neuropsychiatric disorders, is pleased to announce that dosing of the first toxicology species in the Ox-1 blocker clinical trial enabling work completed in early May and initial analysis shows that it is well tolerated at very high doses.

TheraCryf's Ox-1 blocker is aimed at treating substance use disorders, a market already valued at over US 70bn[2] per annum. Preclinical data has shown that the Ox-1 blocker has potential class leading performance including proof-of-efficacy in a rodent model of binge eating disorder.

The clinic enabling programme was fully funded in May 2025 to deliver the data to support an application for Phase 1 human clinical trials before the end of 2026. The key outstanding work packages required to make this application were:

1. Drug manufacturing improvements and scale-up
2. Development of the methods of analysis for animal and human clinical samples
3. Toxicology studies in two species

The Company has now successfully scaled-up manufacturing and produced over 2Kg of drug that can be used in human trials. Improvements in the manufacturing process have led to a manufacturing patent application being submitted which, when granted, will provide considerable increased commercial protection until 2046, increasing the value of future licensing deals.

Dosing is now complete in the rodent toxicology study, and using the analysis methods that have been developed, initial analysis shows that the drug is well tolerated at doses up to 100 times the expected requirements for human therapeutic use, which is well in excess of the tenfold safety margin requirements in the FDA guidelines.

All remaining activities are due to complete on schedule by the end Q3 2026 when an application for human phase 1 trials can be submitted - a significant value inflection point for any biotech.

Dr Huw Jones, Chief Executive Officer, commented:

"I am very proud of the team that has delivered this preclinical development programme on budget and ahead of schedule with such outstanding results. Our Ox-1 blocker continues to demonstrate class leading potential and is now clearing the final toxicology hurdles to allow us to apply for a Phase 1 study in healthy human volunteers.

Assets that are at the Phase 1 clinical stage attract up-front payments alone in the range US 26m-US 49m in the neuroscience field which is why reaching clinical stage is such a significant value driver for the Company. We have recently rejected an approach which undervalued the assets in our pipeline and we continue to work proactively with other partners including following up on other incoming approaches with a view to maximising value for shareholders through a licensing deal.

We look forward to continuing to report on strong progress towards clinic readiness over the next few months."

Dr Alastair Smith, Chairman, added:

"TheraCryf is approaching a very exciting inflection point as it moves its lead programme, the Ox-1 blocker, from preclinical development into human trials. Not only does our Ox-1 blocker demonstrate class leading performance, but addiction and the broader neuropsychiatric space is a current focus for large pharma and is generating a lot of commercial activity and M&A, such as the recent acquisition of Centessa by Eli Lily for up to US 7.8bn.

I joined the TheraCryf board last year because it was clear to me that the Company was considerably undervalued given the assets it has in its pipeline, the many recent transactions in the neuroscience space and the obvious near term value inflection points for the Company. I have been impressed by the team's delivery of the final preclinical stages over the past year on schedule and to budget and remain very excited indeed about the potential value uplift for TheraCryf as we head into the clinic."

1. Licensing deals in the therapeutic space (2020-2025) globally, curated to relevant Pre-Clinical and Phase I CNS deals (excluded M&A, platform deals, research projects and deals where public information was unavailable). Most deals also have a royalty component, which is not reflected in the total value. Pre-Clinical: n=17, Phase 1: n=13. Source: Evaluate, Singer Capital Markets, TheraCryf management curation.
2. Substance Use Disorder Treatment Market Size and Share Forecast Outlook 2025 to 2035. Future Market Insights Inc, November 2025: https://www.futuremarketinsights.com/reports/substance-use-disorder-treatment-market

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About TheraCryf

TheraCryf plc is a biotechnology company developing new medicines for addiction and other neuropsychiatric disorders, areas of significant unmet medical need within central nervous system (CNS) disorders.

The Group's lead programme is a novel, best-in-class orexin-1 receptor antagonist being developed as a potential treatment for addiction, including binge eating, alcohol and other substance use disorders.
The programme has already been heavily de-risked for both safety/tolerability and efficacy in previous testing and is fully funded through final pre-clinical trials to clinical readiness, with regulatory submissions for first in man studies targeted for 2026.

TheraCryf also has a dopamine transporter (DAT) modulator programme addressing fatigue of brain origin, including fatigue associated with multiple sclerosis, chemotherapy and narcolepsy. The Group also has a legacy, grant-funded, oncology programme in glioblastoma with SFX-01.

The Group operates a capital-light, virtual development model advancing programmes to early clinical or proof-of-concept stage before partnering with commercially focused pharmaceutical and biotechnology companies.

TheraCryf's headquarters and registered office are at Alderley Park, Cheshire.

For further information, visit: https://theracryf.com

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