Stock Data

Share Price:	0.28p
Market Cap.:	£5.92m
Shares in issue:	2,148.96m
52 week high/low:	1.25p/0.20p

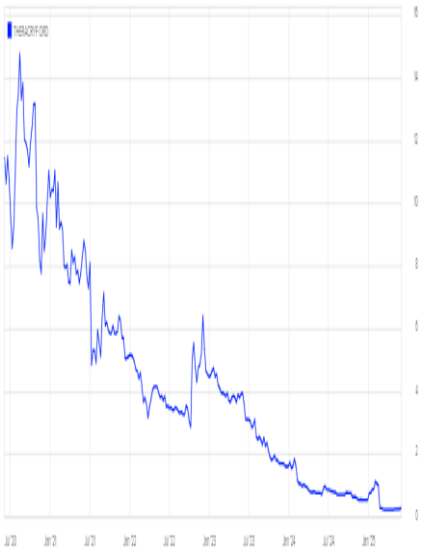
Company Profile

Sector:	Health Care
Ticker:	TCF
Exchange:	AIM

Activities

TheraCryf plc ('TCF', 'TheraCryf' 'the Group') is a clinical stage therapeutics company developing a new generation of innovative therapeutics in oncology and behavioural brain disorders.

5-year share price performance



Source: *LSE*

Past performance is not an indication of future performance.

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TheraCryf plc

TheraCryf has released Final Results for its 12 months to 31 March 2025. These confirm the enlarged Group continues to deliver on operational/financial expectations as it enters a particularly active phase of works that could see considerable value being added to the business as it brings forward new treatment options in areas of real unmet medical needs. Significantly, the £4.25m (gross) equity raise completed in February 2025 has extended the Group's cash runway out to Q4 2026, by which time it is realistic to expect at least two key milestones/inflection points to have been reached. With the Group's refocussed strategy prioritising research on brain disorders and accelerating advancement of Ox-1, its acquired blocker (antagonist) of the brain orexin-1 receptor, the molecule's regulatory submission (IND/CTA) plus outcome from regulatory interactions (MHRA/FDA etc.) anticipated during H1 2026, should be followed by readiness to submit an application for a Phase 1 study in H2 2026. The Group's grant-funded investigator collaboration with the Rotterdam-based Erasmus Medical Centre ('Erasmus') allows it to maintain optionality on its legacy SFX-01 asset, with pre-clinical preparations (including *in vivo* work now underway), in anticipation of this asset entering a Phase 0 study in patients with glioblastoma ('GBM') early in 2026, with first clinical read-out likely before the end of next year. Against a background of renewed industry interest in neuroscience drug discovery, including Johnson & Johnson's (NYSE: JNJ) April 2025 US$14.6 billion acquisition of neuropsychiatric/neurologic disorder specialist, Intra-Cellular Therapies Inc., TheraCryf's ability to deliver compelling data across multiple indications not only derisks its investment opportunity, but also places it firmly on the radar of larger players seeking development opportunities/partners within this expanding global sector.

Financial highlights for the year to 31 March 2025

- Post tax loss of £1.9m (2024: loss of £3.1m).
- Total £5.15m (gross) proceeds raised during the period.
- Cash outflow from operations of £2.4m (2024: outflow of £3.0m).
- Year-end cash and cash equivalents of £4.1m (31 March 2024: £2.0m).

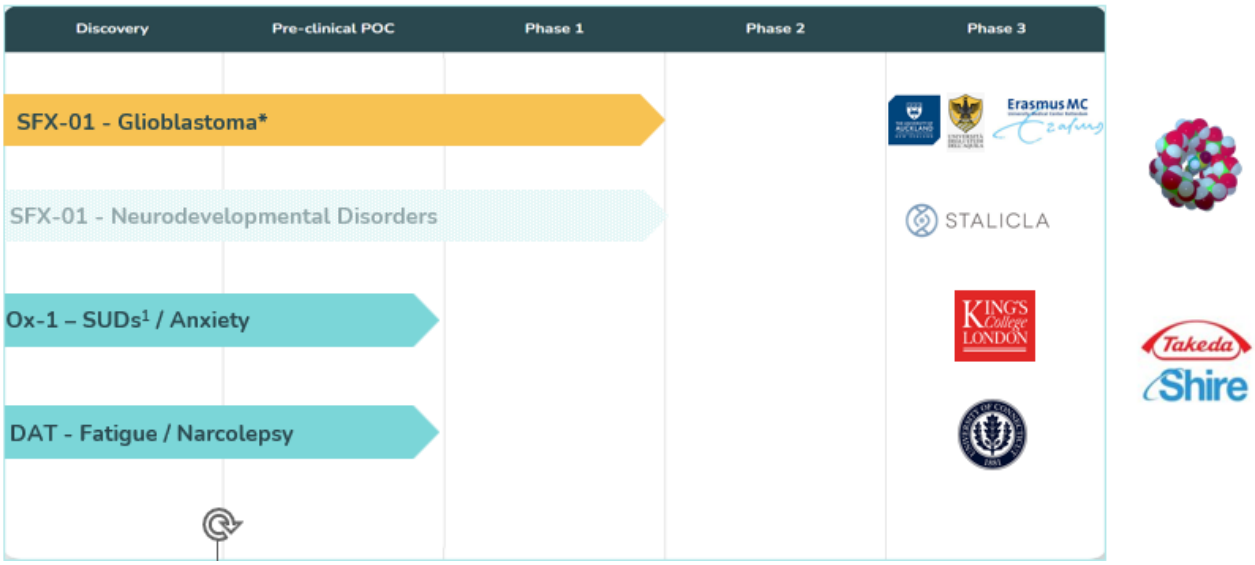
Funded to reach important value inflection points

TheraCryf has a broad clinical and preclinical pipeline in behavioural brain disorders and oncology, although operations are now focused on the orexin-1 antagonist which is the main value driver for the company. Its recently strengthened non-executive team comes with an extensive track record. The executive and non-executive team has over 120 years of combined drug development and commercialisation experience, more than 50 drug development programmes and in excess of 30 in-and-out licensing agreements plus M&A deals, totalling multiple hundreds of US$m in biotech transactions. The Group's business strategy is to deliver value to shareholders based on generation of compelling preclinical/clinical data sets considered sufficiently attractive to be monetised through the partnering and/or licensing of its programmes with mid-size to large pharmaceutical companies.

Year-end cash on hand of £4.1m plus estimated future R&D tax credits of £1.2m (receivable during period 2025-2026) provides a runway into Q4 2026,

of which c.£2.8m has been allocated for pre-clinical development of Ox-1 to clinical Phase 1 readiness, along with supply of SFX-01 tablets for the Erasmus GBM clinical study. Costing of c.£0.6m have also been set aside for Intellectual Property ('IP'), investor relations, legal, listing, financing costs and associated advisors.

TheraCryf – Group Pipeline



[1]*Substance Use Disorders ('SUDs')* **Orphan condition*

Source: TheraCryf, Investor Presentation April 2025, TPI

Orexin role in reward, feeding behaviour/addiction and anxiety, attributed to Ox-1 receptor.

As such is has become a validated drug target and active area of research and development for large pharma and mid-size biotech. It is important to note that while Orexin also has a role in sleep via the Ox-2 receptor, it is essential for any anti-addiction/anxiety drug to only target the Ox-1 receptor. This has presented a significant challenge to date for operators in this area. TheraCryf's priority programme, its Ox-1 antagonist, however, enjoys class-leading specificity for the Ox-1 receptor, while also displaying 'unremarkable preclinical toxicology. Preclinical results demonstrate reduction in bingeing behaviour without affecting normal eating which, assuming it can be replicated in clinic, is the ideal characteristic being sought. Significantly in this respect, patent cover for this lead asset was extended in December 2024 with the grant of a Patent Cooperation Treaty ('PCT') covering the greater UK and European area until 2038. Together with its existing US grant that extends to 2039, the asset enjoys robust exclusivity across the majority of worldwide territories.

The next significant step for Ox-1 is to complete all outstanding preclinical data packages – centred on manufacturing scale up and chronic toxicity studies. These will facilitate TheraCryf's application for clinical trial authorisation (IND/CTA) with potential utility in addiction and anxiety. In support of this, leading CRO/CDMO, Pharmaron UK Ltd., was appointed post-period to carry out a range of activities including all-important manufacturing scale up (to kilograms in weight), along with formulation and clinical drug supply as well as regulatory-standard toxicology studies (each lasting 28 days to confirm the benign toxicology profile already reported from experiments lasting seven days at high doses). This package is expected to permit regulatory submission by H2 2026 with completion toward end-CY2026 and, in turn, lead to MHRA/FDA approval for a Phase 1 study. This can be expected to accelerate Group operational cash outflow somewhat in the coming months.

During this coming 18 months or so, profile raising efforts to attract mid-size biotechs to large pharma partners seeking to bolster inferior drug candidates in their own pipelines, with a view to securing funding necessary for larger trials/commercialisation based on compelling data sets to preclinical and/or clinical proof of concept, could well bear fruit. Given that its presently strong balance sheet positions TheraCryf amongst the top-20% of European listed peers in terms of forward runway, the Board will have sufficient time to shape/negotiate any such opportunity(s) for the maximum benefit of shareholders.

The Substance Use Disorder (addiction) treatment market was values at US$40.3bn 2024, rising to US$67.6bn by 2034 according to research and consulting group, Future Market Insights (SUD Treatment Market Outlook, June 2024). Current therapies include naltrexone/buprenorphine, along with only one FDA-approved option, lisdexamphetamine (Vyvanse/Elvanse), for its Binge Eating sub-sector which has already identified a multibillion-dollar market. These substance use disorder markets are considered to be readily addressable by an effective, non-sedating, non-scheduled (non-controlled) orexin-1 blocker drug, given that the mechanism is thought to reduce impulsive behaviours regardless of the food or substance being abused.

Alongside this, the global Generalized Anxiety Disorder ('GAD') treatment market was valued at US$2.1 Billion in 2025, according to market forecaster, Future Market Insights, Inc. It is expected to expand at a CAGR of 9% and reach US$5.1 Billion by 2035. The global GAD treatment market is being led by increasing awareness of mental illness and the expanding range of available treatments. The US, which presently accounts for over half of the global market opportunity, mainly consisted of standard treatments like SSRIs/SNRIs, Benzodiazepines, Tricyclic Antidepressants/Azapirone (Buspirone), and others (Antiepileptics, antipsychotics, etc.), which were said to have generated revenues of just over US$1bn in 2023. The low general efficacy of these and their potential for dependence highlights a continuing unmet need.

There are two orexin-1 antagonists currently in active clinical development for neuropsychiatric conditions. The failure of competing molecules that attempt to utilise the same metabolic pathway appears to be down various side effects, such as somnolence or sedation, or otherwise interactions with other medicines in circulation as well as, in one case, relative inefficacy. TheraCryf's Ox-1 has been designed to overcome such shortcomings and the extensive preclinical data set thus far indicates the greatest selectivity, making somnolence extremely unlikely; it also shows high potency and receptor occupancy making inefficacy considerably less likely. Once the final stage of pre-clinical development is complete in 2026, the Group we will consider early partnering/funding opportunities with larger sector players, in the absence of which it will proceed into clinical development independently.

SFX-01 – Ph. 1 clinical study indicated molecule well tolerated with no serious adverse events

Sulforaphanes have shown potential benefits in neurodevelopmental disorders, oncology and inflammatory conditions. TheraCryf's clinical asset, SFX-01, is the only stabilised sulforaphane suitable for clinical research and eventual approval as a medicine. TheraCryf's core technology is Sulforadex®, a method for synthesising and stabilising sulforaphane and novel proprietary analogues based on sulforaphane. Its Phase 1b healthy volunteer clinical study on SFX-01 that reported in August 2023 was subsequently published in a peer-reviewed journal, Advances in Therapy, in July 2024. This showed the molecule to be very well tolerated with no serious adverse events. Sulforaphane and active metabolites from the Group's patented formulation were delivered at levels that, in the laboratory, produce striking pharmacological effects.

The Group will focus its internal resources and recent capital raised on the orexin-1 programme but maintains the optionality of the SFX-01 asset through a grant funded collaboration with the Erasmus Medical Centre in Rotterdam. The Group originally received notification of a €1.1 million grant from the KWF Dutch Cancer Society in June 2023, which took the form of non-dilutive funding to support work performed by TheraCryf's academic partner, Erasmus. Continuing during FY2024/25, *in vitro* experiments in human tumour tissue with meaningful responses to SFX-01 were completed and significantly confirmed findings from previous research collaborations. *In vivo* pre-clinical experiments have since started at Rotterdam and will form a key part of the data package to support further grant funded administration of SFX-01 to patients with the fatal brain cancer glioblastoma, in the form of a Phase 0 study commencing at the same medical centre early in 2026, with release of first clinical data in H2 2026.

The global glioblastoma multiforme ('GBM') treatment market was valued at US$2.78bn in 2024 and is projected to reach around US$5.68bn by 2033, growing at a compound annual growth rate (CAGR) of 8.23%, according to a report by market researcher, GlobeNewswire. This growth is said to be driven by factors including rising geriatric

population, increasing incidence of GBM, and a developing pipeline of new treatments. In past years, the size of the underlying opportunity has been limited by a lack of availability of drug interventions/marketing. Should SFX-01 provide meaningful clinical efficacy for patients, a substantial market expansion might be expected.

TheraCryf – Projected News Flow out to end-2026

Q3 2025	• Ox-1 bulk manufacturing complete • Ox-1 formulation for toxicology studies complete
Q4 2025	• Ox-1 chronic toxicology studies commence • SFX-01 GBM clinical trial preparations commence
H1 2026	• SFX-01 1st GBM patients dosed in Ph0 study • Ox-1 enabling studies, for first in man clinical trials, complete • **Ox-1 regulatory submission (IND/CTA) outcome of regulatory interactions (MHRA/FDA etc)**
H2 2026	• SFX-01 GBM clinical data flow • **Ox- 1 MHRA/FDA approval for Phase 1 study** • [Ox-1 Phase 1 study start]* • [Ox-1 Phase 1 study complete]*

*Forecast, subject to technical success and related risks *Subject to further funding/partnering*
Source: TheraCryf, Extract from Investor Presentation February 2025, TPI

Out-Licensing - Constructive discussions continuing towards resolution with STALICLA SA

In late 2022 the Group concluded a transaction worth up US$160.5m in milestones, for the global rights for lead asset SFX-01 in neurodevelopmental disorders and schizophrenia to STALICLA SA, a private Swiss biotech company specialising in the identification of specific phenotypes of Autism Spectrum Disorder ('ASD') using its proprietary precision medicine platform. TheraCryf retain the global rights for all other indications.

Considering it had met the terms required to satisfy the first milestone, in accordance with the License Agreement, STALICLA was notified that payment had become due. Having failed to service its obligation, a formal notice of dispute was issued in February 2024. Discussions have continued constructively throughout the ensuing period while seeking resolution, which the Board expects to be able to confirm within the coming financial year. At this time, however, no such an outcome has been factored into any of the Group's forecasts.

Pre-clinical collaborations

University of Michigan

A collaboration with the University of Michigan to investigate the potential anti-tumour effects of SFX-01 in colorectal cancer has demonstrated biological activity of SFX-01 in models of this common condition. Further data supporting this opportunity is expected to be released in the coming financial year.

Sapienza University of Rome

The collaboration with Sapienza University of Rome resulted in work investigating the radio-sensitising effects of SFX-01 in Rhabdomyosarcoma, the most frequent soft tissue sarcoma in childhood. This followed publication in the peer reviewed journal, BMC Cancer. The research carried out by Prof. Francesco Marampon of the Department of Radiotherapy and Dr Simona Camero of Prof. Francesca Megiorni's research group at the Department of Experimental Medicine continues.

Dopamine reuptake inhibitor – Potential to target fatigue associated with Multiple Sclerosis

As resources permit, TheraCryf looks to unlock remaining latent value presented in the pipeline acquired from Chronos, in the form of an atypical dopamine reuptake inhibitor that can be used to target fatigue/narcolepsy.

DAT (originally coded as 'CT-005404') is a dopamine transporter inhibitor with a non-stimulant profile. The dopamine transporter is a brain protein that moves dopamine into and out of neurons; it is a key part of regulating dopamine neurotransmission, which in turn affect movement, motivation and learning. Multiple Sclerosis ('MS') is a chronic, autoimmune disease that damages (attacks) healthy cells in the brain and spinal cord. Up to 80% of MS patients suffer from moderate to severe fatigue (depending on type of disease), roughly half of which depend on drugs to control (but not cure) the condition. There are currently no approved fatigue-based drug treatments with a label in MS.

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