Stock Data

Share Price:	0.20p
Market Cap.:	£4.30m
Shares in issue:	2,148.96m
52 week high/low:	1.25p/0.18p

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.

1-year share price performance

5-year share price performance

Source: *LSE*

Past performance is not an indication of future performance.

Turner Pope contact details

Tel: 0203 657 0050
Email: info@turnerpope.com
Web: www.turnerpope.com

Andrew Thacker
Corporate Broking & Sales

Barry Gibb
Research Analyst

TPI acts as joint broker to TheraCryf plc.

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TheraCryf plc

TheraCryf has released results for its 6 months to end-September 2025 ('the Period'). These deliver on all expectations, with the Group remaining fully funded to continue development of Ox-1, its class-leading addiction programme, in anticipation of targeting regulatory submission (MHRA/FDA, etc.) by Q4 2026 in readiness for first-in-human studies. Inflection points between now and then for this novel blocker (antagonist) of the brain orexin-1 receptor, include completion of all regulatory/large-scale toxicology studies, followed by IND/CTA enabling work. While CT-010018's initial focus on Binge Eating Disorder ('BED') presents a projected peak sales opportunity of almost US$1 billion, the molecule's wider utility across addictive disorders, anxiety, impulse control disorders and PTSD, address total global markets that are forecast to reach as much as US$67.6 billion by 2034. Meanwhile, its grant-funded investigator collaboration with the Rotterdam-based Erasmus Medical Centre ('Erasmus') allows TheraCryf to maintain optionality on its legacy SFX-01 asset, with preclinical preparations (including *in vivo* work) 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 year end. 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., the Group'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 six months to end-September 2025

- Financial performance in line with expectations; post-tax loss of £1.3m (2024: £1.2m)
- Net cash outflow from operating activities of £1.3m (2024: £1.2m)
- Net cash used in operating activities including changes in working capital and tax received £0.7m (2024: £1.4m)
- Cash/cash equivalents/short term investments on 30 September 2025 amount to £3.5m (30 September 2024: £1.2m)
- Continuing low cash burn ensures runway remains unchanged from previous guidance to end of 2026, excluding any potential milestone payments

Operational highlights for the six months to end-Sept. 2025

- Strategic focus on Ox-1, TheraCryf's competitive antagonist (blocker) of the orexin-1 receptor and potential a class-leading addiction-treatment programme made significant further progress
- Programme on track for regulatory submission in Q4 2026, enabling first-in-human studies
- Top-tier global CRO/CDMO, Pharmaron, appointed as development partner for Ox-1 after a rigorous competitive tender process
- Manufacturing scale-up underway and on schedule, including both 0.5kg and 10kg batches required for regulatory submission

Ox-1 expected to achieve clinical readiness by the end of 2026.

TheraCryf's business model is to develop innovative therapeutics in brain disorders to proof-of-concept ('PoC')/early clinical stage. It then expects to use compelling data generated through its research to support out-licensing opportunities with major, sector-focussed Pharma/Biotech companies, therein creating value for shareholders. With neuroscience's share of available venture capital having increased to rank as the second most funded therapeutic area (after oncology) between 2022 and 2024, the Group's timing looks ideal. Potential rewards from any such transaction in terms prospective licensing fees, presumably along with free carry throughout a costly series of human trials (Phases I to IV) followed by collection of ongoing royalties upon commercialisation, could be very significant indeed. Ox-1 achievement of clinical readiness is expected to fire the 'starting gun' for such negotiations to commence. All activities required to reach this point are continuing on, or ahead of, management's schedule (including regulatory submission) for delivery by the end of 2026.

TheraCryf plc – Recent Ox-1 Development News

Highlight	Details
Further Ox-1 Patent Granted	Korea. Only one major territory yet to grant. USA (2039) Greater Europe (2038) already granted
Ox-1 Oral Formulation Selected	Formulation manufactured with enhanced absorption properties
Second Toxicology Species confirmed for Ox-1	Good handling properties seen in a non-rodent second species
First scale up complete	Scale up of 0.5kg completed Late October - *ahead of schedule*
Human Grade Material	Synthesis started late October – *on schedule*

Source: TheraCryf, Investor Presentation, November 2025

Importantly, on 3 November 2025, the Group confirmed its first 0.5kg scale-up of its selected Ox-1 oral formulation had been delivered ahead of schedule, with no issues and manufacturing execution outperforming expectations. In support of anticipated clinical studies, production of 2.0kg of human-grade material was then initiated. Having formulated to the optimal dosage, the compound will be used in an *in vivo* study to identify the drug's 'therapeutic index' (i.e., the range between which the dose is expected to have a therapeutic effect and the highest dose of compound reached before any harmful effects are observed). Data from this will inform dosing in the key 28-day toxicology studies scheduled to commence in early 2026, being supplied through a 10kg compound scale-up which is also proceeding on plan and schedule.

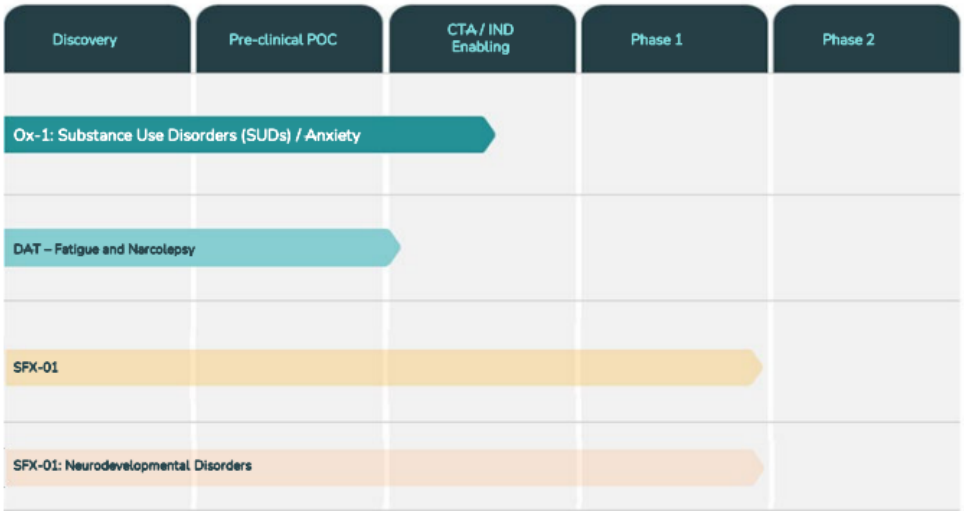
TheraCryf plc – Recent Ox-1 Development News

Highlight	Details
Further Scale up	Completion of large-scale manufacture of 10Kg
Human grade material for trials	Completion of manufacture of 2Kg clinical grade drug
Regulatory toxicology studies	Start/finish of maximum dose toxicology studies
Final Large scale tox studies	Start/finish of full 28-day toxicology studies
Completion of all human enabling work	Completion of all IND/CTA enabling studies
Readiness for human trials	Regulatory submissions for use in man by Q4 2026

Source: TheraCryf, Investor Presentation, November 2025

Ealy in November, work also initiated through TheraCryf's partner, Pharmaron, to manufacture drug product for human use in the Ph1 healthy volunteer study. This process is conducted under special conditions, referred to as GMP (Good Manufacturing Practice), a regulatory standard to ensure safety and quality in order that the product can be given to humans. Data from this activity will form part of the regulatory package required for the clinical trial application.

TheraCryf plc – Group Development Pipeline – Addressing the Opportunity



Source: TheraCryf, Investor Presentation, November 2025

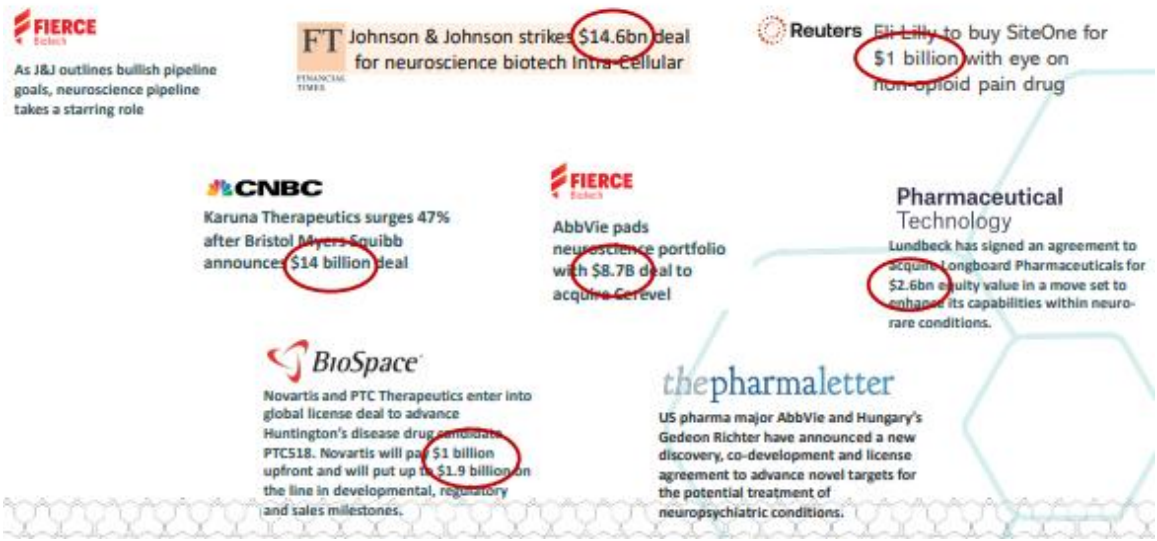
Cash position remains strong – Sufficient to support current level of activity out to end-2026

TheraCryf's total cash position (including cash/cash equivalents and short-term investments) was £3.5m as of 30 September 2025 (30 September 2024: £1.2m). The Board estimates that this will be sufficient to support the current level of activity to the end of 2026. The use of funds during H1 2025/26 predominantly reflected the commencement of the Ox-1 IND/CTA enabling work. Activities on the SFX-01 programme remain mainly grant funded, while integration of Chronos into the Group has already fully completed. Anticipating a slightly reduced working capital movement plus collection of a reasonably sizeable R&D tax credit, the Group is expected to see net cash outflow for the coming 12 months fall slightly from the £1.98m run rate seen in the first half (H1 2024/25: £0.81m).

Resurgence of interest in brain disease by larger pharmaceutical/biotech companies

TheraCryf's assessment of values recently achieved through out-licensing agreements with a large biotech/ pharmaceutical companies for individual therapeutic assets covering different areas of neurodegenerative diseases, suggest successful early-stage developers stand to receive up-front payments in the range of US$26m-US$49m, depending on the stage reached and quality of data generated.

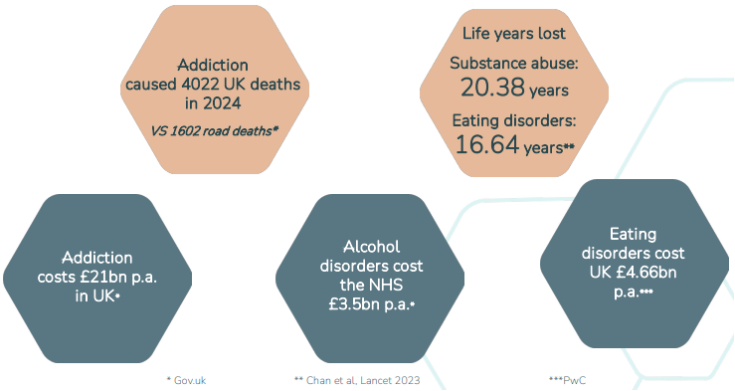
Market Opportunity – Resurgence of Interest in Brain Disease from Larger Sector Players



Source: TheraCryf, Investor Presentation, November 2025

Total milestone payments subsequently accrued as development candidates progress through to full commercialisation amounted to between US$409m and US$570m, while royalties (generally high single digit to low double digits percentages of the wholesale price) also stand to be collected during the life of a transaction (typically until end of patent life). While there cannot be guarantee of what might ultimately be achieved, this at least highlights the substantial financial opportunity available in the area of neuropsychiatric/neurologic disorders. Throughout the development process (for innovative late preclinical/early clinical assets), not only in the far distant future when a drug is approved.

Addition and Related Neuropsychological Disorders present Significant Market Opportunity

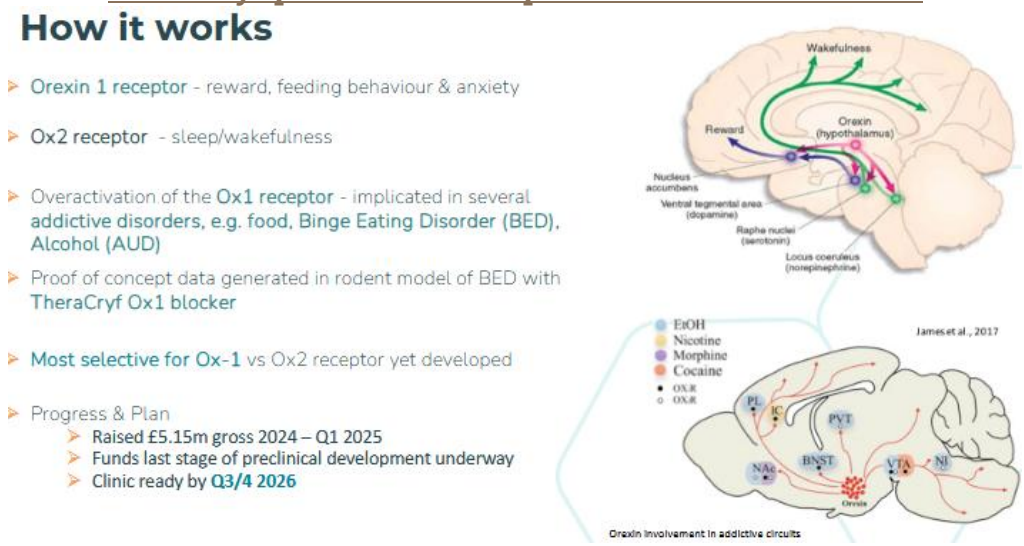


Source: TheraCryf, Investor Presentation, November 2025

TheraCryf's lead programme – Ox-1 in Addiction

Orexin's role in reward, feeding behaviour/addiction and anxiety is attributed to the Ox-1 receptor, enabling it to become a validated drug target and is an active area of research & development for large pharmaceutical and mid-size biotechs. 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 which means there are no preclinical concerns. 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.

TheraCryf plc's - Ox-1 Receptor Mechanism of Action



Source: TheraCryf, Investor Presentation, November 2025

In May 2025, TheraCryf appointed leading CRO/CDMO, Pharmaron, as development partner for its lead Ox-1 addiction programme. Pharmaron is responsible for the manufacture of drug product for human use in the Phase I healthy volunteer study. The second species for toxicology *in vivo* studies and a formulation suitable for administration to preclinical species and to human have been selected. This work remains on track for submission to the relevant regulatory authority in anticipation of achieving clinical readiness before the end of 2026.

Binge Eating Disorder is the most common eating disorder globally

TheraCryf's initial focus is on BED, a condition that affects diverse populations across all ages, genders, ethnicities, and socioeconomic levels. The National Institute of Diabetes and Digestive and Kidney Diseases ('NIH') estimates global prevalence in adults is between 1% and 3%. in the United States, for example, it is said to affect people of all racial and ethnic groups, encompassing about 1.25% of adult women and 0.42% of adult men; roughly 1.6% of teens age 13 to 18 years old are affected. A much larger percentage of teens and adults have episodes of binge eating or loss-of-control eating (i.e., the feeling of being unable to cannot control consumption, regardless of how much food has actually been eaten), but at a rate that is not frequent enough to meet criteria to be formally registered as suffering from BED. The average age at which BED first occurs is 25 years. Nearly two-thirds of people who meet the criteria for BED experience episodes over the span of 1 year or longer.

Lisdexamfetamine dimesylate (brand name: Vyvanse) is currently the only medication specifically approved by the FDA to treat moderate to severe BED in adults. It is a central nervous system stimulant, that is also approved for Attention-Deficit/Hyperactivity Disorder (ADHD). Its MoA is to control the impulsive behaviour that can lead to the condition, although a relatively low level of effectiveness means that other medications are sometime prescribed off-label as alternative solutions; these include Anticonvulsants/Anti-seizure drugs (such as Topiramate and Zonisamide; certain antidepressants, such as Selective Serotonin Reuptake Inhibitors ('SSRIs') like Fluoxetine (Prozac), Sertraline (Zoloft), and Paroxetine (Paxil) and; GLP-1 Receptor Agonists/Anti-Obesity medications such as Semaglutide (Ozempic, Wegovy).

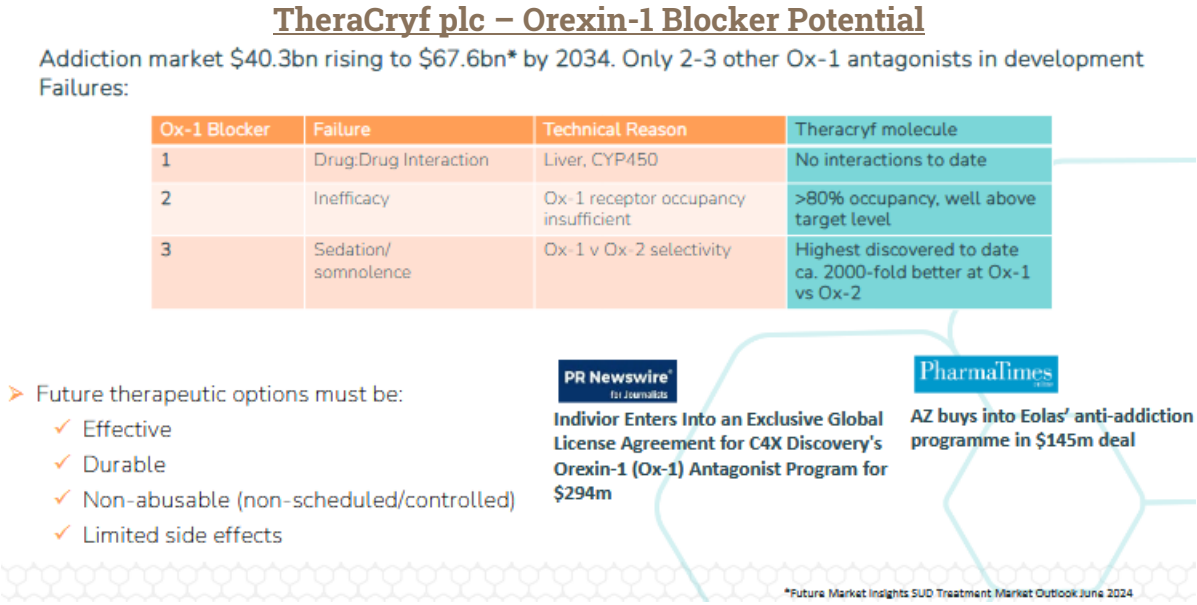
Binge Eating Disorder – Global Market Opportunity

- BED estimated to affect 1.4% of population (WHO survey)
  - >4 million US
  - >7 million EU
  - >1.7 million Japan
- NCS-R study showed that ~25% of individuals with BED received medical treatment specific for BED in a 12 month period. Likely to increase with better awareness of BED
- Current SOC is Vyvanse, an amphetamine prodrug, USA only
  - Scheduled drug: some US states and many insurance carriers limit the quantity of controlled substance dispensed to a 30-day supply
  - Side-effects: Most common side-effects experienced by patients are anxiety, agitation, insomnia
  - Cardiovascular profile – can increase pulse and increase blood pressure. Individual may require ECG to confirm suitability
  - Stimulant MOA – some BED patients prefer not to take this type of medication
  - Unsuitable for use ipatients with co-morbid substance abuse due to its abuse liability [Black box warning]. ~25% of BED patients have risk of abusing other substances
- External market research for TheraCryf by Apex Consulting shows CT-010018 has a peak sales projection of >$1Bn
- *CT-010018 has wider utility in addictive disorders, anxiety, impulse control disorders & PTSD*

Source: TheraCryf, Investor Presentation, November 2025

Three other orexin-1 antagonists have been seen to fail in recent years following active clinical development (Phase II and earlier) for neuropsychiatric conditions. These include Nivasorexant (ACT-539313) which completed a Phase II PoC clinical trial for BED in 2022; Tebideutorexant (JNJ-6139321); and the unnamed JNJ-54717793. The failure of competing molecules that attempt to utilise the same metabolic pathway appears to be down to 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 unlikely. Once the final stage of pre-clinical development is complete in 2026, the Group will consider early partnering/funding opportunities with larger sector players, in the absence of which it will likely proceed into clinical development independently.



Source: TheraCryf, Investor Presentation, November 2025

Claight Corporation (Expert Market Research) has assessed the expanding global market opportunity for BED, which is being driven by increasing awareness, advancements in treatment options and rising prevalence of the disorder across the 8 major markets, valuing it at US$0.81 billion in 2024. This it projects to grow at a CAGR of 6.00% over a forecast period 2025-2034 before ultimately attaining a market value of US$1.45 billion by 2034. While this might be considered relatively small for a major sector play interested in expanding its opportunity in neurodegenerative diseases, Ox-1's wider potential utility across addictive disorders, anxiety, impulse control disorders and PTSD, prospectively makes it a much high value opportunity. The total global market across all these conditions has been forecast to reach as much as US$67.6 billion by 2034 by research consultants, Future Market Insights in its SUD Treatment Market Outlook (June 2024).

TheraCryf's legacy programme – SFX-01 in Glioblastoma ('GBM')

Glioblastoma is the most aggressive and common type of malignant primary brain tumour in adults. General frequency of occurrence is relatively low in the overall population, with the annual age-adjusted incidence rate in the United States, for example, approximately 3.2 to 4.0 per 100,000 persons; global rates are similar, typically estimated at 3–5 cases per 100,000 population. The condition accounts for about 14.2% of all primary brain and CNS tumours, comprising approximately half of all malignancies. Their exact cause is unknown, with the only established non-genetic risk factor being exposure to high-dose ionizing radiation, while certain rare inherited genetic syndromes, such as Li-Fraumeni syndrome and Neurofibromatosis type 1, can also increase the occurrence. Prognosis with severe form is poor, indicating median survival of just c.14 months and a 5-year rate of only c.5% for diagnosed patients.

Treatment options are presently limited to surgery followed by radiotherapy, along with few drugs (of limited efficacy) that have been approved for the condition. This suggests a high need for new novel treatments. The choice of existing treatments, which vary according to whether the condition is newly diagnosed or recurrent, include Temozolomide, the standard chemotherapy drug, usually given alongside radiation therapy, to slow tumour cell growth; Dexamethasone, a corticosteroid that is used to reduce swelling around the tumour; Bevacizumab (Avastin), a monoclonal antibody approved for recurrent glioblastoma, which works by reducing the tumour's blood supply; Carmustine wafers, which are biodegradable implants that deliver chemotherapy directly into the site post and Anticonvulsants, that are used to manage seizures caused by the tumour.

Sulforaphanes have shown potential benefits in neurodevelopmental disorders, oncology and inflammatory conditions. TheraCryf's technology, Sulforadex®, utilises a method for synthesising and stabilising the plant-based isothiocyanate compound and novel proprietary analogues on which it is based. As such, SFX-01 is the only stabilised sulforaphane suitable for clinical research and eventual approval as a medicine. Its Phase I clinical study indicated the molecule to be well tolerated with no serious adverse events. Its Phase Ib healthy volunteer clinical study that reported in August 2023 was subsequently published in a peer-reviewed journal, Advances in Therapy, in July 2024. Sulforaphane and active metabolites from the Group's patented formulation were delivered at levels that, in the laboratory, produce striking pharmacological effects. SFX-01 has already been awarded orphan drug status in this indication by the USA FDA, while regulatory scientific advice received subsequently from the Dutch Medicines Evaluation Board confirmed there are no specific concerns regarding its clinical safety profile.

The next steps in this programme will be to administer SFX-01 to preclinical models of GBM and, if successful, to then apply for permission to conduct a clinical trial in GBM patients. Past development of SFX-01 has, however, proven challenging and, given the relatively limited resources available, the Board has decided TheraCryf's primary focus should remain on its Ox-1 programme at this time, due to its lower risk profile and significantly greater market opportunity.

Out-Licensing - Constructive discussions continuing towards resolution with S 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. TheraCryf's Board believes that the terms contained in its License Agreement with Stalicla, require a US$0.5m milestone payment to be serviced immediately following completion of SFX-01's Phase I clinical study. Although it continues to work on routes to resolve this ongoing dispute, TheraCryf has not included any milestone payments from Stalicla in its financial forecasting.

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