



TheraCryf plc AIM: TCF.L NOMAD: Cavendish Placing Agent: TPI IR: Vigo, CAG

Dr Huw Jones, CEO

Toni Haenninen, CFO

Dr Helen Kuhlman, CBO

Dr Alastair Smith, Chair



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# TheraCryf

- > TheraCryf is building a drug development powerhouse in profitable segments within oncology and behavioural brain disorders
- Our business model, to deliver value to our shareholders, is to develop compelling preclinical/clinical data sets and monetise these through commercial partnerships
- > TheraCryf has the potential to advance a class leading Orexin-1 blocker\* to clinical readiness in the next 12-18 months
- ➤ Targeting Orexin-1 is relevant in CNS disease areas such as addiction which is a \$40.3bn market\*\* that is attracting significant attention from large pharma and mid-size biotech but with inferior drugs in development
- Project Scarlet
  - ➤ Aiming to achieve a minimum £4m equity raise to fund advancing TheraCryf's Orexin-1 blocker to clinical trial readiness

<sup>\*</sup> Competitive antagonist of the orexin-1 receptor

<sup>\*\*</sup>Substance Use Disorder (addiction) treatment market \$40.3bn 2024 rising to \$67.6bn by 2034 (Future Market Insights SUD Treatment Market Outlook June 2024)

### **TheraCryf Management and Board**



#### **Dr Huw Jones CEO**

Over 30 years' experience of leadership in public and private R&D-based companies within the biotechnology and pharmaceutical sector. Huw is also a non-executive director of biotech industry body OBN. Ashbourne, CVT, Elan, SB (GSK)



#### Dr Alastair Smith Non-Executive Chair\*

20 years' of public company and R&D leadership experience having founded and led Avacta Group plc, from inception.

Alastair is also non-executive director of N4 Pharma plc and Chairperson of SPARTA Biodiscovery Ltd.



#### Toni Haenninen CFO

Over 20 years' experience of financial leadership in public and private companies in the US, APAC and Europe: Danaher Group, Faron Pharmaceuticals



#### **Dr Alan Barge NED**

Former CMO of ASLAN
Pharmaceuticals and former VP
and Head of Oncology and
infection at A7



#### Chronos Nominee NED

Under the agreement Chronos has the right to nominate one NED subject to TheraCryf Board approval.



#### Dr Nicholas Mallard VP - Project Management

Over 30 years' experience in research and early/late phase development spanning large pharma (Takeda, AZ, Scherer DDS), biotech (Oxford Glycosciences, Amarin Neuroscience, Shield Therapeutics) and several CROs.



#### Dr Helen Kuhlman CBO

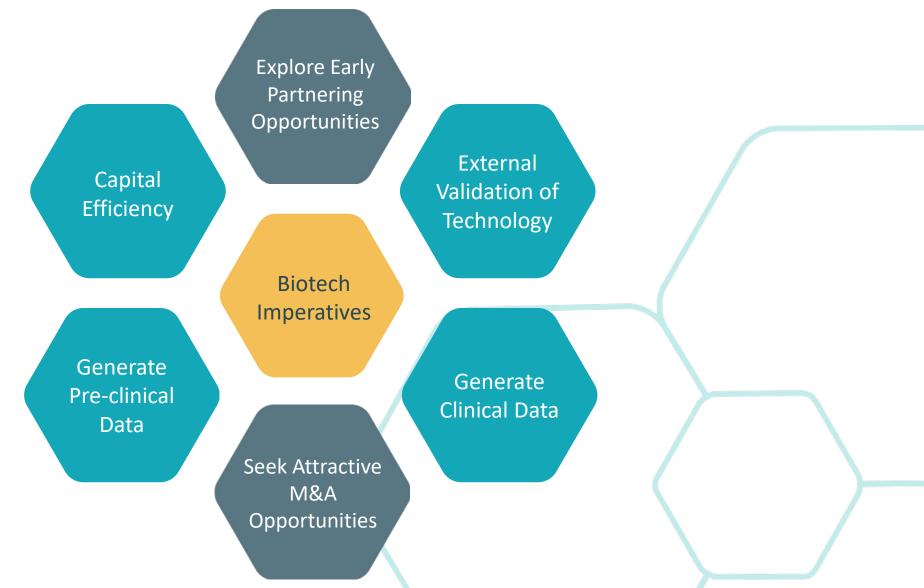
Over 20 years' experience in government funding and equity investment together with scientific and business roles in public and private R&D-based biotechnology companies



#### Dr Glen Clack CMO

Over 25 years' experience in oncology drug development with a specialism in translational medicine. AZ, multiple small Biotech Co's





# **TheraCryf Priority Programmes\***

Orexin 1 Blocker\* (Ox-1): Late pre-clinical stage, class leading drug with potential for regulatory submission by mid-2026

- Potential utility in addiction and anxiety
- Substance Use Disorder (addiction) treatment market
   \$40.3bn 2024 rising to \$67.6bn by 2034 (Future Market Insights
   SUD Treatment Market Outlook June 2024)
- Patents granted in major territories including USA, China and Europe. Protections extending to 2038/39
- Next steps manufacturing scale-up, formulation and chronic toxicology to enable first in human trials\*\*
- Entry to Phase 1 clinical studies H2 2026, early clinical POC 2027/8\*\*\*

# SFX-01: Clinical stage and funded by European grant to provide first clinical read-out in Glioblastoma in late 2026

- Extensive IP for lead asset SFX-01 based on highly biologically active "sulforaphane".
- Orphan drug designation in USA for glioblastoma (GBM)
   GBM market \$549.1m 2020 rising to \$868.5m by 2030<sup>+</sup>
- Phase 1b study on commercial grade tablet complete with peer reviewed journal article published in Q4 2024
- Ph0 clinical study (in GBM patients), plus additional preclinical work, to be conducted at the Erasmus Medical Centre, grant funded by the Dutch Cancer Society (KWF)
- Out-license deal with Stalicla SA in neurodevelopmental disorders. \$160.5m milestones, double digit royalty.
   Constructive talks on current dispute. Milestones not included in runway forecast.
- First clinical read out in GBM 2026

<sup>\*</sup>Competitive antagonist of the orexin-1 receptor

<sup>\*\*</sup>Within this £4m fundraise

<sup>\*\*\*</sup> Subject to separate funding

<sup>+ (</sup>Global Data GBM Global Drug Forecast and Market Analysis Dec 2021)

## **CNS Therapeutics Opportunity**

- Current standards of care; limited effectiveness and burdened by side-effects
- Future therapeutic options must be:
  - Effective
  - ✓ Durable
  - ✓ Non-abusable (non-scheduled)
  - ✓ Limited side effects

#### thepharmaletter

US pharma major AbbVie and Hungary's Gedeon Richter have announced a new discovery, co-development and license agreement to advance novel targets for the potential treatment of neuropsychiatric conditions.



As J&J outlines bullish pipeline goals, neuroscience pipeline takes a starring role



Novartis and PTC Therapeutics enter into global license deal to advance Huntington's disease drug candidate PTC518. Novartis will pay \$1 billion upfront and will put up to \$1.9 billion on the line in developmental, regulatory and sales milestones.



Karuna Therapeutics surges 47% after Bristol Myers Squibb announces \$14 billion deal

- Resurgence of interest in CNS indications by Pharma
- Partnering opportunities exist at early clinical stages for differentiated assets

#### **Pharmaceutical**

Technology

Lundbeck has signed an agreement to acquire Longboard Pharmaceuticals for \$2.6bn equity value in a move set to enhance its capabilities within neurorare conditions.



Indivior Enters Into an Exclusive Global License Agreement for C4X Discovery's Orexin-1 (Ox-1) Antagonist Program for \$294m



AbbVie pads neuroscience portfolio with \$8.7B deal to acquire Cerevel



AZ buys into Eolas' antiaddiction programme in \$145m deal

### **Orexin-1: Addiction and Anxiety**

#### **Orexin 1 Blocker (Ox-1)**

- Orexin has a role in reward, feeding behaviour/addiction and anxiety, attributed to the Ox-1 receptor
- A validated drug target and active area of research and development for large pharma and mid-size biotech
- Orexin also has a role in sleep via the Ox-2 receptor: it is essential for any anti-addiction/anxiety drug to only target Ox-1 which has been a challenge to date
- TheraCryf's Ox-1 antagonist:
  - ✓ Class leading specificity for the Ox-1 receptor.
  - Pre-clinical toxicology is "unremarkable"
  - ✓ Proof-of-concept data generated in rodent model
  - √ 12 months plan to regulatory submission
  - Potential for commercial partnership at both preclinical and clinical stage

#### **Market Opportunity**

- Addiction, (Substance abuse, BED): Market \$40.3bn 2024 rising to \$67.6bn by 2034\*\*
  - Current therapies: naltrexone/buprenorphine, lisdexamphetamine (Vyvanse/Elvanse)
  - Unmet needs: non-controlled/scheduled drugs, non-amphetamine/opioid derived
- Anxiety (GAD): 16m patients, 52% in USA, \$1bn market, 2022\*
  - Current therapies: older drugs, SSRI/SNRI, treatment resistance common (ca.50%)
  - Unmet needs: efficacy, low dependence potential

<sup>\*</sup>DelveInsight GAD Market Report Oct 2023

<sup>\*\*</sup> Future Market Insights SUD Treatment Market Outlook June 2024

## **Ox-1 Competitive Landscape**

Company	Stage	Status	Deal Size	Indication
Indivior (C4X)	Ph2	First patient dosed in Ph2 opioid use disorder trial in June 2024, trial ongoing	\$294m deal 2018 incl. \$10m upfront. £15.95m Aug 2023 (bought from C4X)	Opioid use disorder
Cerevance (Takeda)	End Ph1	Completed Ph1, planning to initiate Ph2 in Schiz and BED patients, current timings not disclosed	N/A	Schizophrenia, BED
AZ (Eolas)	Ph1/2	Discontinued after dosing in opioid users taking additional medications highlighted a DDI (announced Nov 2024)	>\$145m plus royalties (licensed from Eolas)	Smoking cessation, opioid use disorder
JnJ	Ph1/2	Unknown, not currently reported in pipeline, possibly shelved due to somnolence observed in clinic due to inadequate selectivity for Ox-1 over Ox-2	N/A	Panic/anxiety, depression
Idorsia (Actelion)	Ph2	2022 missed Ph2a endpoint in BED (query receptor occupancy), shelved	N/A	BED, anxiety

#### **Project Scarlet**

£4m gross placing to advance Ox-1 antagonist to regulatory submission and provide cash runway into Q4 2026

£2.8m	Pre-clinical development of Ox-1 (addiction/anxiety) to clinical Phase 1 readiness Includes supply of SFX-01 tablets for Erasmus GBM clinical study		
£0.6m	Development staff, consultants		
£0.6m	Intellectual Property, investor relations, legal, listing and financing costs and associated advisors		
£4.0m*	Total		

- Issue will be split into firm placing using existing authorisation and conditional placing, subject to GM
- Up to £4.3m VCT/EIS available advance assurance from HRMC dated October 2024
- Appointment of Turner Pope as joint broker following admission

<sup>\*</sup>Cash on hand of £1.2m at Sept 30<sup>th</sup> 2024 and estimated future R&D tax credits of £1.2m, during period 2025-2026, offset total expenditure. Non-dilutive funding will be sought to support DAT inhibitor (fatigue) programme.

#### **Project Scarlet**

Delivering significant value inflection points across both programmes during 2025/6

Q1 2025	<ul> <li>Neuropsychiatry programme restarts</li> <li>Ox-1 manufacturing optimisation commences</li> <li>New board appointment/s</li> </ul>
Q2 2025	<ul> <li>Further SFX-01 in vivo data from Erasmus GBM collaboration expected</li> <li>Ox-1 bulk manufacturing commences</li> </ul>
Q3 2025	<ul> <li>Ox-1 bulk manufacturing complete</li> <li>Ox-1 formulation for toxicology studies complete</li> </ul>
Q4 2025	<ul> <li>Ox-1 chronic toxicology studies commence</li> <li>SFX-01 GBM clinical trial preparations commence</li> </ul>
H1 2026	<ul> <li>SFX-01 1<sup>st</sup> GBM patients dosed in Ph0 study</li> <li>Ox-1 enabling studies, for first in man clinical trials, complete</li> <li>Ox-1 regulatory submission (IND/CTA) outcome of regulatory interactions (MHRA/FDA etc)</li> </ul>
H2 2026	<ul> <li>SFX-01 GBM clinical data flow</li> <li>Ox- 1 MHRA/FDA approval for Phase 1 study</li> <li>[Ox-1 Phase 1 study start]*</li> <li>[Ox-1 Phase 1 study complete]*</li> </ul>

#### **Project Scarlet Summary**

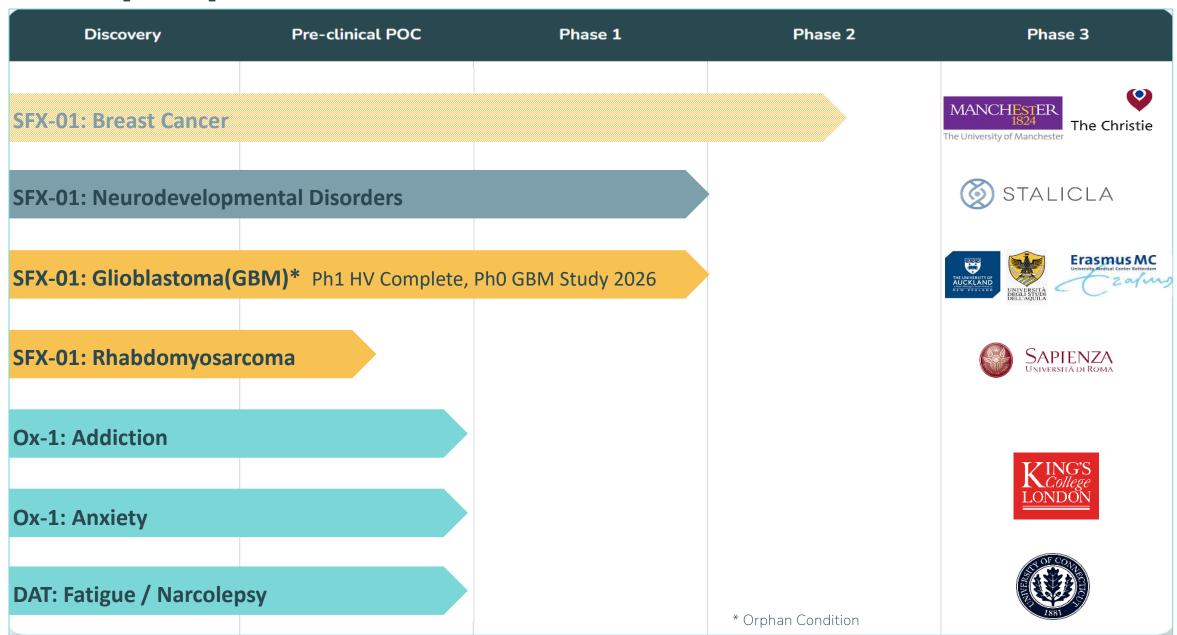
- ➤ TheraCryf has the potential to deliver a significant shareholder return in the next 12-24 months by advancing a class leading Ox-1 antagonist drug molecule to the stage of clinical readiness alongside it's grant –funded clinical programme for SFX-01 in glioblastoma
- Ox-1 is a compelling drug target in CNS disease areas (addiction and other neuropsychiatric disorders) that is attracting significant attention from large pharma but with inferior drug candidates in their own pipelines
- Successful submission of a regulatory filing to advance TheraCryf's Ox-1 antagonist into Phase 1 studies should attract significant commercial interest
- > Project Scarlet aims to achieve a £4m equity raise to advance TheraCryf's Orexin-1 blocker through to clinical trial readiness and unlock commercial opportunities



# Appendix



## **Group Pipeline**



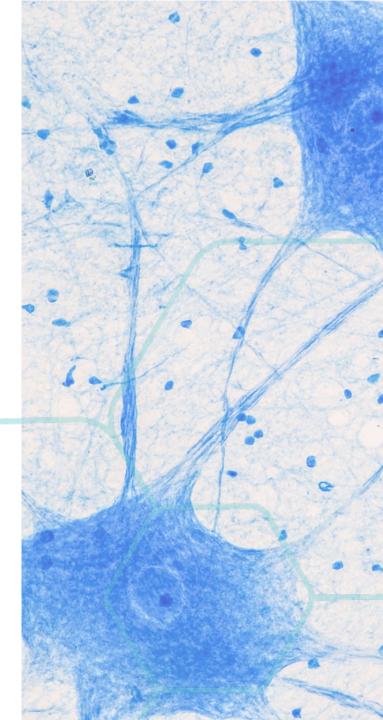


April 2024, Evgen Pharma plc acquired Chronos Therapeutics Ltd in an all-share transaction\* and rebranded to TheraCryf plc



Neuropsychiatry portfolio, attractive targets, resurgent area for big pharma

- More than **tripled the size of the Evgen portfolio** and newsflow
- Capitalises on **renewed interest** and deal activity in Neuroscience
- Chronos neuropsychiatry assets are complementary to Evgen's neurodevelopmental disorders and brain cancer asset
- Group has the expertise to develop and commercialise the combined portfolio
- Multiple potential inflection points within 2 years
- High quality investor base in Chronos



# **Chronos Acquisition: Transaction Details**

Low upfront, de-risked and back-weighted

- Acquisition of entire issued share capital of Chronos Therapeutics
  - Single share class, no warrants, no debt, on a cash and debt free basis
- £0.9m in Evgen shares upfront to Chronos shareholders\*
  - Includes Vulpes, Odey, Oxford University, WA Capital, Takeda, HNWs
  - Chronos shareholders locked in for 18 months
- £1m in shares or loan at TheraCryf's discretion on start of first Phase 1 clinical trial
- £1.5m in shares or loan at TheraCryf's discretion on end of first successful Phase 1 clinical trial
- 10% of first three milestones of any out-licensing transaction involving of a former Chronos asset, capped at total consideration of £10m
  - o Payment in shares or loan notes at TheraCryf's discretion

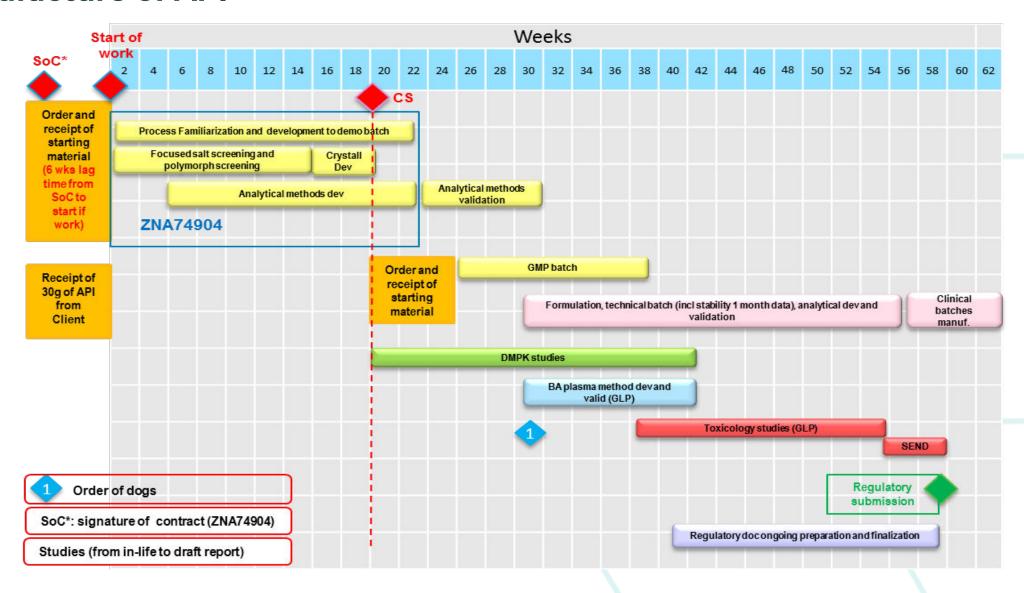




# **Risk and Mitigation**

Risk	Nature	Mitigation
SFX-01 Translation Failure	<b>Standard Biotech.</b> Pre-clinical effects do not translate to patients.	Extensive pre-clinical work, in rodents and human primary (patient derived) cells, conducted by multiple independent laboratories.  Non-dilutive funding secured (NL government).
Ox-1 Technical Issue	Standard Biotech. Hitherto unseen toxicology.	Non-GLP toxicology complete and unremarkable. Ox-1 class has progressed to clinic.
DAT Technical issue	<b>Standard Biotech.</b> Hitherto unseen/severe toxicology.	Non-GLP toxicology consistent with mechanism of action.
Funding shortfall	Financial. Funding below target or delayed.	One programme to be progressed. Alternative non-dilutive funding to be sought.
Programme delays/overrun	<b>CRO capacity.</b> May have to wait to secure manufacturing/study slots due to provider capacity. New findings during process development may extend timelines.	Close management of CROs, intense qualification of providers. Financial incentives and penalties to be incorporated.
Loss of key talent	Resourcing challenges common to small biotech. Small internal team and UK/European talent pool makes talent retention imperative.	Flexible working model for management. Multiple CROs engaged for execution including PM support. Frequent market review of remuneration packages.

# Example workpackages for IND-enabling studies excl. initial manufacture of API



#### Market background ASD & GBM

#### **Autism Spectrum Disorder**

#### Therapeutic Market forecasts

USD 3.78 billion 2021 – 5.15 billion 2028 (CAGR 4.5%), Fortune Business Insights; Autism Spectrum Disorder Therapeutics Market, 2021-2028 (Oct 2021)

Treatment estimate \$15-30k per patient per annum

#### Characteristics

Prevalence rate 1:100 children worldwide (WHO, 2022), 1:36 (US, CDC, 2020) Increasing rates of diagnosis (CDC)

The major drivers of growth in the forecast period across the 8MM are:

- Increasing incidence worldwide
- Diagnosis and prescribing increases enabled by growing acceptance of telehealth during pandemic, and recognition of diagnostic tools such as Cognoa Inc's ASD Diagnosis Aid
- Supportive regulatory environment to fast track therapeutic development programmes, as demonstrated by the achievement by HLR of an advanced therapy title from the FDA for Balovaptan

The major barriers to growth in the forecast period in the 8MM are:

- Competition Phase 2 onwards (Roche, Jazz, Zynerba, Impel)
- Emergence of novel Digital Cognitive Therapies
- Patient heterogeneity (Stalica claim to have a proprietary biomarker/enrichment technique)
- Reluctance to submit paediatric population to long term therapeutic interventions

#### Glioblastoma

#### Therapeutic Market forecasts

USD 549.1 million 2020 – 868.5 million 2030 (CAGR 4.7%), Global Data; GBM Global Drug Forecast and Market Analysis to 2030 (Dec 2021)

Branded standard of care treatment, Temodar approx. \$29k per patient per annum

#### Characteristics

Total 5 year prevalent population: 243,850 Total treated newly diagnosed (in 2020): 33,985 Total treated recurrent diagnosed (in 2020): 13,914

The major drivers of growth in the forecast period across the 8MM are:

- Approvals and launches of high-priced therapeutics, including 2 cancer vaccines, 3 protein kinase inhibitors, and 3 small molecule chemotherapies
- An increasing number of incident cases of GBM, particularly in the US (due to underlying population growth) and China (due to urbanization)
- A high level of unmet need in GBM that warrants faster uptake of the pipeline agents expected to launch during the forecast window, as patients have few other treatment options

The major barriers to growth in the forecast period in the 8MM are:

- The patent expiration of Avastin and subsequent entry of biosimilars may reduce market traction, resulting in higher discounts from upcoming players such as Bio-Thera Solutions' BAT1706 for the biosimilar market
- Increased cost-consciousness will limit reimbursement and the uptake rate of new market entrants, particularly in the 5EU. Moreover, China has made pledges to cut costs, likely to reduce prices further than anticipated in the forecast
- A high failure rate has been historically observed for Phase III GBM trials and may impact the pipeline forecast and impede market growth

#### **Oncology Advisors**



**Dr Mary Stuart Kingston Oncology** 

Pharmaceutical Physician specialising in oncology, with specific expertise in breast cancer and with over two decades of experience in large multinational pharmaceutical companies. She was the clinical lead for the setup of the positive MonarchE adjuvant breast cancer study for Eli Lilly and the successful Falcon, Olympiad and Olympia studies for AstraZeneca , and was the Breast Cancer Disease Area expert for AstraZeneca.



### Professor Albena Dinkova-Kostova University of Dundee

Professor of Chemical Biology at the Jacqui Wood Cancer Centre, Division of Cellular Medicine, University of Dundee School of Medicine. She has a core research interest in oxidative stress and inflammation and has published over 100 research papers including many on sulforaphane as an activator of the Nrf2 pathway and as a potential therapeutic strategy for protection against chronic degenerative diseases.



Dr Claudio Festuccia L'Aquila University

Researcher at the University of L'Aquila and is an associate professor in pathology and biology. Currently devoted to the study of new therapeutic approaches for glioblastoma.



## Professor Rob Clark University of Manchester

Professor of Breast Biology and Director of the Manchester Breast Centre, based at the Oglesby Cancer Research Building.



### Dr Sacha Howell University of Manchester

Clinical Senior Lecturer in Breast Oncology carrying out translational research into mechanisms of action and resistance of endocrine therapies, both in the treatment and prevention of breast cancer. Treatment of patients with early and advanced breast cancer at The Christie and Manchester University NHS Foundation Trusts.



Dr Marjolein Geurts Erasmus University Medical Centre

Neuro-oncologist at Erasmus University Medical Centre. Studied medicine in Utrecht, combining her training as a neurologist with a PhD programme researching cerebral infarctions. Committed to identifying new treatments that can provide long-term survival and good quality of life for patients with a brain tumour.



#### Prof. Francesco Marampon La Sapienza University, Rome

Researcher at the University of Rome Sapienza and an associate professor of Radiotherapy. He studies the molecular mechanisms responsible for radioresistance, particularly in rhabdomyosarcomas, and is currently dedicated to the study of new radiosensitizing approaches.

#### **Neuropsychiatry Advisors and Consultants**



#### Professor Alan Young KCL

Professor Young is the clinical academic lead in the Psychological Medicine and Integrated Care Clinical Academic Group in the South London and Maudsley NHS Trust where he is also a Consultant Psychiatrist and the head of the National Affective Disorders Tertiary Clinic.

Professor Young is a member of several editorial boards and is a member of numerous professional and scientific societies. He is immediate Past-President of the International Society for Affective Disorders, President of the British Association of Psychopharmacology and the immediate past Chair of the Special Committee for Psychopharmacology of the Royal College of Psychiatrists.



Dr Fraser Murray
Pheno Therapeutics/Advent Life Sciences

Almost 30 years of experience in drug discovery and early development in both pharma and biotech. Currently Head of Scientific Evaluation at Advent Life Sciences and CEO of Advent portfolio company Pheno Therapeutics.

Fraser studied Immunology and Pharmacology at the University of Strathclyde and undertook a PhD in Neuropharmacology at the School of Pharmacy, University of London. He later studied for an executive MBA at Alliance Manchester Business School.



## Dr John Salamone University of Connecticut

Dr Salamone is the Professor and Director of Behavioural Neuroscience at the University of Connecticut.

His primary research interested include psychopharmacology and drug development, neurochemistry, signal transduction, and behaviour, behavioural functions of dopamine, acetylcholine, serotonin, and adenosine and animal models of Parkinson's disease, depression, schizophrenia, fatigue.

He teaches undergraduate courses in general psychology and drugs and behaviour and graduate course in foundations of neuropsychology and neuropsychopharmacology.



### Dr Timothy Schulz-Utermoehl Pheno Therapeutics/DMPK Consulting

Over 20 years of DMPK experience within the academic, pharmaceutical, biotech and CRO sector, spanning early- and latestage discovery research as well as preclinical development.

Timothy received his B.Sc. combined honours degree in Pharmacology & Physiology at the University of Leeds and his M.Sc. degree in Toxicology at the Royal Postgraduate Medical School, University of London. He studied for his PhD in Biochemistry at Imperial College School of Medicine in London.



