



2022 Full Year Results

Telix Pharmaceuticals (ASX:TLX)

27 February 2023



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Telix is a recognised leader in radiopharmaceuticals

Industry-leading assets and success in a high-growth sector

Global nuclear medicine market growth forecast: US\$6B in 2021 to \$35B by 2035¹

Telix has demonstrated expertise at every step of the radiopharmaceutical product delivery process



Three pillars of future value creation

-  Multi-product commercial diagnostic portfolio
-  Advanced therapeutic clinical programs
-  Future pipeline: New targets and technologies

Key financial metrics

Telix finishes 2022 in a healthy financial position



Total revenue

\$160.1M

Up 20x
(2021: \$7.6M)



Gross margin

62%

Steady improvement
since commercial
launch



Expenditure
(ex COGS¹)

\$166.3M

104% of revenue in
FY2022
(2021: 1067%)



Cash balance

\$116.3M

As of 31 Dec 2022
(31 Dec 2021: \$22.0M)



Net loss after tax

\$104.1M

Up 29%
(2021: \$80.5M)²



1. Cost of goods sold

2. Prior year included R&D tax incentive income of \$18.6M which was not repeated in 2022.

Note: Conversion to AUD\$ is at the actual exchange rate on transaction date. Average rate realised during the period of AUD\$1 = US\$0.67; AUD\$1 = €0.66. Year end rate of AUD\$1 = US\$0.68; AUD\$1 = €0.64.

Our growth strategy

Creating long term benefit for patients and shareholders



Use Illuccix as a commercial launch pad

- Establish commercial operations and build engagement with the urology customer base



Commercialise the diagnostics portfolio

- Leverage investment in commercial infrastructure and reinforce leadership in the urology field



Unlock the value in the therapeutic pipeline

- Delivery against clinical milestones to build patient impact and value



Strengthen supply chain and manufacturing

- Ensures accessibility and supply to patients globally and strengthens barriers to entry



Expand the pipeline

- Enhances existing pipeline products and build the future pipeline with novel targets and technologies

Our growth strategy

Milestones and achievements in 2022



Use Illuccix as a commercial launch pad

- Successful U.S. launch
- Strong foothold in the growing PSMA-PET imaging market



Commercialise the diagnostics portfolio

- Phase III ZIRCON study delivered highly positive results
- Preparing regulatory filings for two additional products



Unlock the value in the therapeutic pipeline

- Progress across core therapy programs, including patient dosing and manufacturing for prostate cancer therapy program



Strengthen supply chain and manufacturing







- In-house manufacturing and process development strengthened with EU facility buildout and acquisition of Optimal Tracers



Expand the pipeline

- Multiple new partnerships and licensing agreements delivering new IP and future product candidates

Core pipeline: Oncology and rare diseases

	Prostate	PSMA ¹	PHASE 1	PHASE 2	PHASE 3	COMMERCIAL	
	Small molecule	⁶⁸ Ga	TLX591-CDx (⁶⁸ Ga-PSMA-11, Illuccix®)				Imaging
	Antibody	¹⁷⁷ Lu	TLX591 (¹⁷⁷ Lu-rosopatamab)				Therapy
	Kidney	CAIX ²	PHASE 1	PHASE 2	PHASE 3	COMMERCIAL	
	Antibody	⁸⁹ Zr	TLX250-CDx (⁸⁹ Zr-girentuximab)				Imaging
	Antibody	¹⁷⁷ Lu	TLX250 (¹⁷⁷ Lu-girentuximab)				Therapy
	Brain	LAT-1 ³	PHASE 1	PHASE 2	PHASE 3	COMMERCIAL	
	Small molecule	¹⁸ F	TLX101-CDx (¹⁸ F-FET)				Imaging
	Small molecule	¹³¹ I	TLX101 (¹³¹ I-IPA)				Therapy
	BMC/RD ⁴	CD66 ⁵	PHASE 1	PHASE 2	PHASE 3	COMMERCIAL	
	Antibody	^{99m} Tc	TLX66-CDx (⁹⁹ Tc-besilesomab, Scintimun®)				Imaging
	Antibody	⁹⁰ Y	TLX66 (⁹⁰ Y-besilesomab)				Therapy

Strong commercial launch in the U.S.

Sustained month-on-month growth since launch

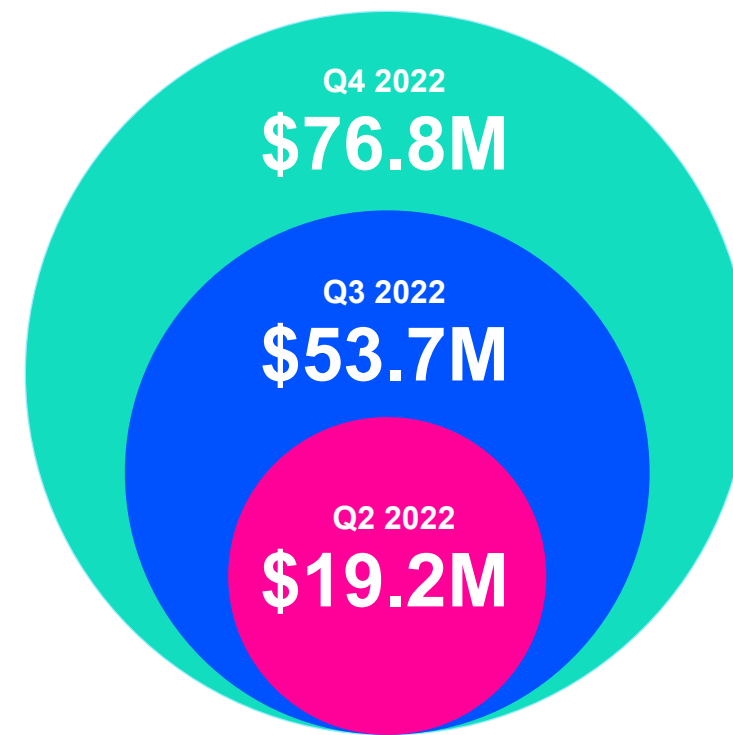


Use Illuccix as a commercial launch pad

Revenue from U.S. sales of Illuccix \$149.7M (US\$100.4M) in first nine months since launch

- In Q4, revenue from U.S. sales of Illuccix up 43% to \$76.8M (US\$50.5M) on the prior quarter
- Fully reimbursed as of 1 July 2022, MACs¹ adoption of Telix specific code progressively improving and driving sales growth
- 193 pharmacies dispensing across the U.S. and Puerto Rico
- Wider adoption of PSMA-PET imaging and evolving patterns of use in routine clinical practice continuing to drive market growth
- Latest update to NCCN Guidelines^{®3} states ⁶⁸Ga PSMA-11 / ¹⁸F PSMA-PET/CT is “preferred” for bone and soft tissue (full body) imaging

Revenue from U.S. Illuccix[®] sales 2022



1. Medicare Administrative Contractor (MAC).
2. Prescription Drug User Fee Act.
3. National Comprehensive Cancer Network Guidelines[®] (NCCN Guidelines) Update, Version 1.2023 – 18/7/2022.

The Illuccix difference

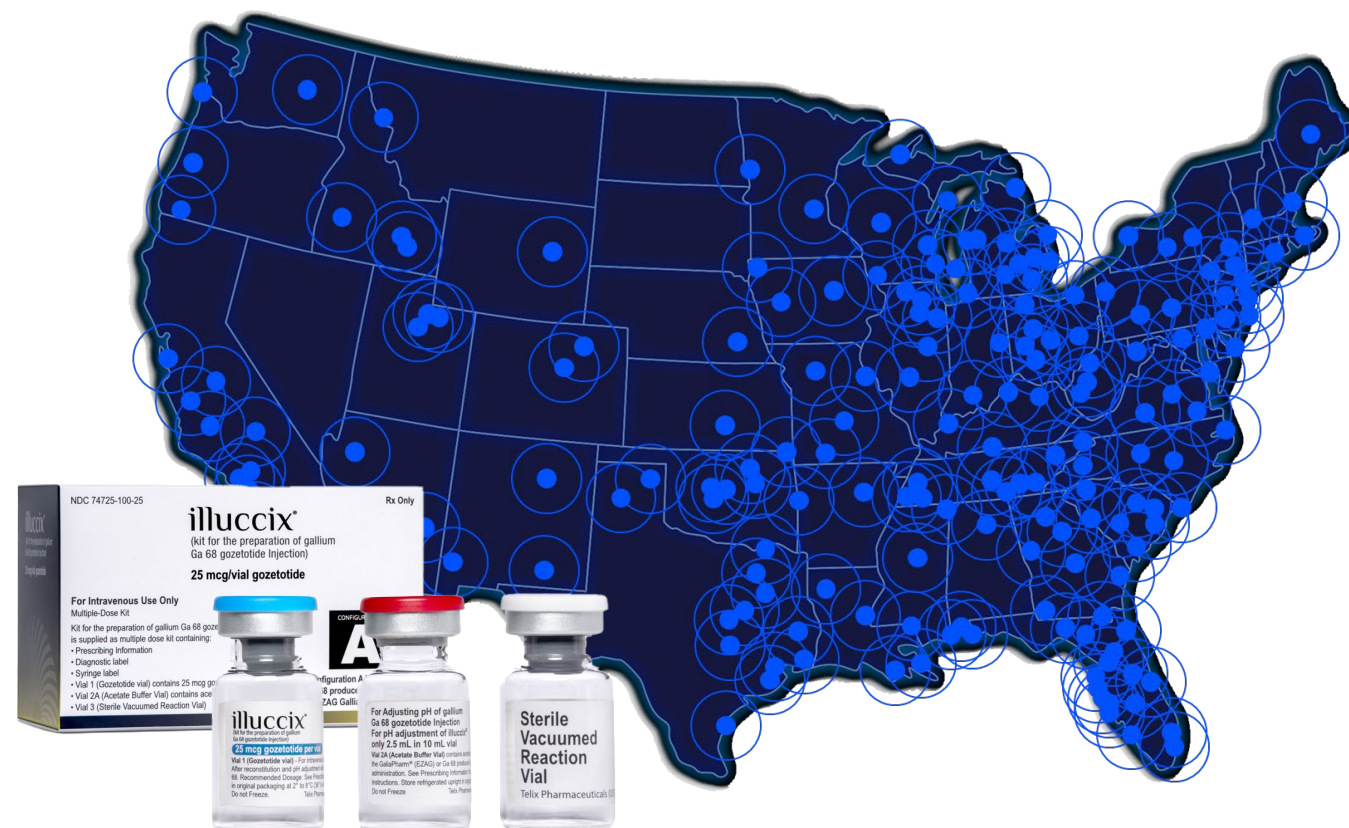
Rapidly scalable model to meet demand in the growing U.S. market



Use Illuccix as a commercial launch pad

- Rapidly scalable model with ability to reach 90% of PET sites across the U.S. and deliver hyper-localised service
- Sites have been progressively added in 2022 to meet customer needs and demand
- Service delivery and scheduling flexibility a key differentiator:
 - Exceptional on-time delivery and immediate confirmation of dose availability
 - ≤ 30 minute scan time and the widest treatment window (range of mCi for accurate images)
 - Mornings, Saturdays, extended-hour and STAT doses available based on location

ILLUCCIX NETWORK EXPANSION



The Illuccix difference

Clinical differentiation + optimum scheduling flexibility



Use Illuccix as a commercial launch pad



Accurate

More sensitive than ^{18}F -based PSMA imaging



Precise

Detects micrometastases before it advances



Easy interpretation

High quality images with minimal radiation dose



Available

The only PSMA radiotracer produced by both cyclotrons and generators

New scientific publications illustrate ^{68}Ga -PSMA-11 PET/CT has the most validated accuracy¹⁻³ compared to other PSMA-imaging agents

- ✓ **High true positive rates** of detection for regional and distant metastases including bone
- ✓ **Unprecedented diagnostic performance** even for micro metastatic disease
- ✓ **Accurate interpretation** with high reproducibility and inter-reader agreement

Case study: Initial staging¹

Critical information for clinical decision making at initial staging



Use Illuccix as a commercial launch pad

In a prospective study of 197 patients evaluated with ⁶⁸Ga-PSMA-11 at initial staging or re-staging after definitive therapy, **69% of patients were restaged and 57% of patients had management plan changes**



Patient case

Before imaging with Illuccix:

- Prostate biopsy
- Gleason score: 0²
- PSA level: 22.9 ng/mL

After imaging with Illuccix:

- ✓ Regional lymph node and bone metastases detected

	Pelvic LNs ³ metastasis ⁴	Femur head Metastasis	Pelvic LNs metastasis
PET ⁵ positive patient			
CT ⁶			
Fused PET/CT			

Note: representative patient response only, may not be representative for all patients.

1. Staging refers to assessment of the extent of disease, size of tumour and spread

2. Suggestive of a missed biopsy

3. LN, lymph node.

4. Images are from an independent case study from Dr. Thomas Dresser and Dr. Timothy Hoffman at Harry S. Truman Memorial Veterans Hospital, Columbia MO.

5. PET, positron emission tomography.

6. CT, computed tomography.

Case study: Suspected recurrence

Impact of treatment decisions and outcomes for patients with BCR¹



Use Illuccix as a commercial launch pad

In a retrospective follow-up of treatment decisions for BCR patients who received ⁶⁸Ga-PSMA-11 PET/CT (N=203) 60% of patients had a change in management that led to complete responses in 45% of patients



Patient case

Before imaging with Illuccix:

- PSA level at diagnosis: 33ng/mL
- PSA level post-EBRT²: <0.1ng/mL
- Positive body scan with recent PSA level: 5.7 ng/mL

After imaging with Illuccix:

- ✓ Recurrent carcinoma / metastases identified

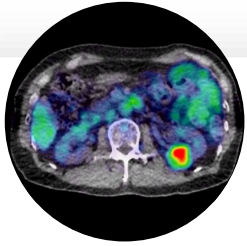
	C7 Vertebral body metastasis ³	Left Iliac metastasis
PET positive patient		
CT		
Fused PET/CT		

Expanding the commercial portfolio

Preparing to launch two additional imaging agents in 2024

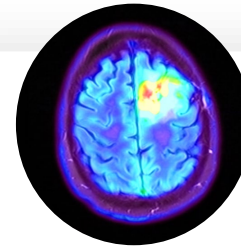


Commercialise the
diagnostics portfolio



TLX250-CDx: Renal cancer imaging

- TLX250-CDx provides a way to non-invasively diagnose and characterise ccRCC – adding confidence in decision making
- **CAIX target is potentially as ground-breaking in ccRCC, as PSMA has been for prostate cancer**
- Potential to change standard of care in the diagnosis and management of renal masses and ccRCC – delivering on a major unmet need
- Preparing FDA regulatory submission, anticipated approval in 2024



TLX101-CDx (^{18}F -FET): Brain cancer imaging

- Estimated 81,900 patients worldwide and 14,700 in North America diagnosed with glioblastoma in 2022¹
- Approximately 30% of treated glioma patients develop treatment-related changes (TRCs) simulating recurrence (pseudo-progression)
- Potential to provide a rapid and conclusive diagnosis of gliomas and improve management of progression/treatment monitoring
- **Identification of pseudoprogression vs tumour progression (TP) a key value driver**

ZIRCON co-primary endpoints

Sensitivity and specificity thresholds exceeded by all three readers¹



Commercialise the
diagnostics portfolio

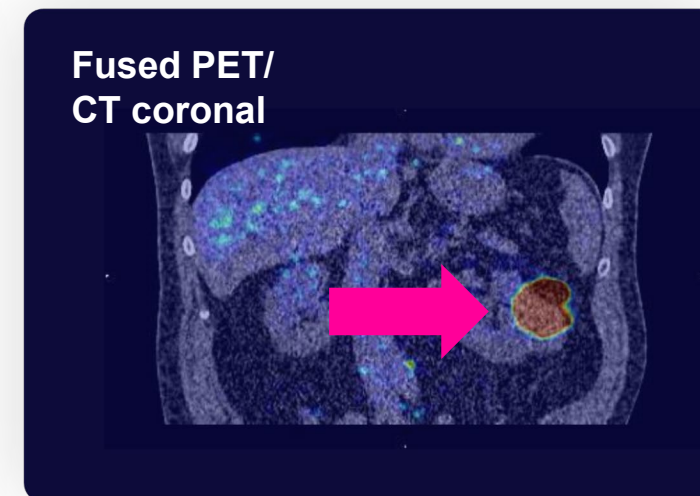
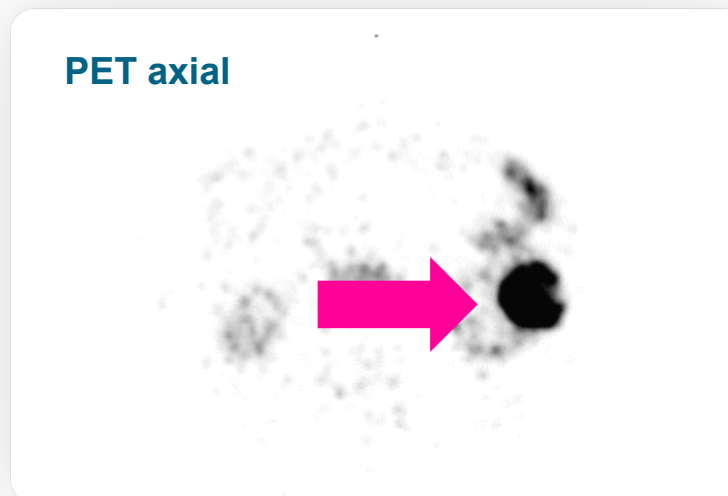
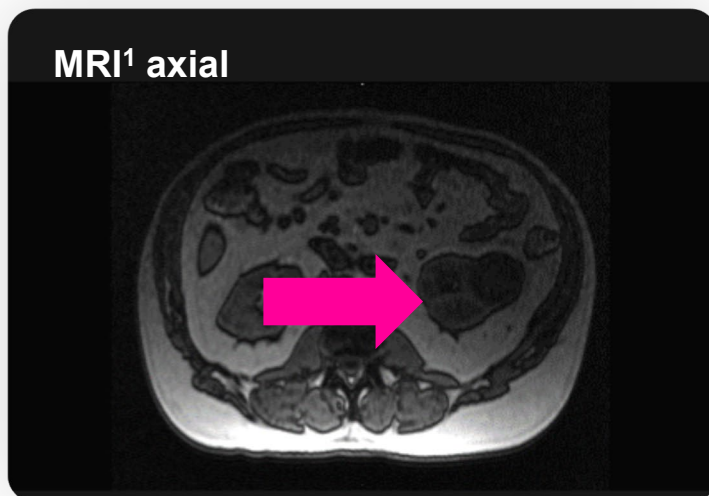
Full analysis set (N=284)	Reader 1	Reader 2	Reader 3	Overall % (95% CI ²)
Sensitivity, %	84.13	85.19	87.30	85.5
Lowest bounds, Wilson 95% CI	78.24	79.42	81.80	(79.8, 89.8)
Specificity, %	88.42	88.42	84.21	87
Lowest bounds, Wilson 95% CI	80.45	80.45	75.57	(78.8, 92.3)
Positive predictive value (PPV)*, %	93.53	93.60	91.67	93
				(88, 96)
Negative predictive value (NPV)*, %	73.68	75.00	76.92	75
				(66, 82)
Accuracy*, %	85.56	86.27	86.27	86
				(81.5, 89.6)

ZIRCON clinical case in a complex cyst

Potential support for clinical decision making



Commercialise the
diagnostics portfolio



Diagnostic challenge:

- 42 yr male
- 3.1 cm (cT1a) left kidney mass
- ⁸⁹Zr-girentuximab PET scan clearly positive → ccRCC highly likely



Clinical management:



- Surgery - radical nephrectomy
- ccRCC confirmed by central pathology
- Low/Focal CAIX expression by IHC²

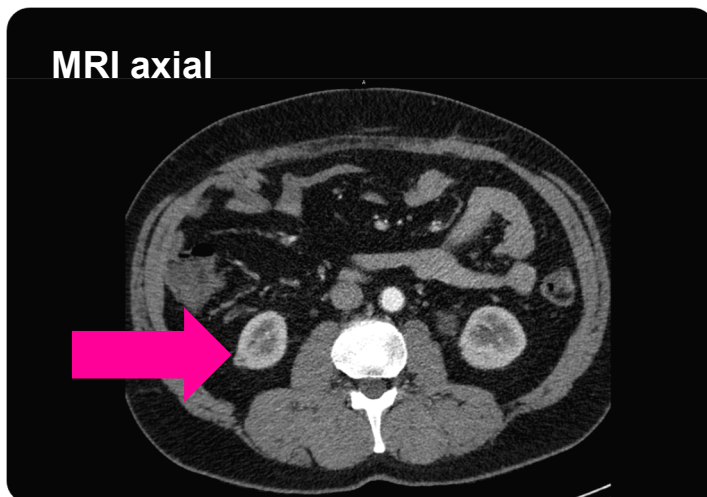
ZIRCON clinical case in a 1 cm mass

Potential support for clinical decision making



Commercialise the
diagnostics portfolio

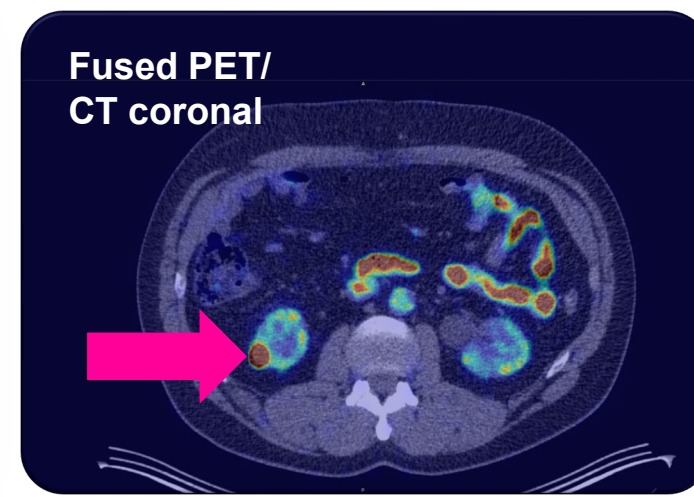
MRI axial



PET axial



Fused PET/
CT coronal



Diagnostic challenge:

- 57 yr male with 1 cm lesion found incidentally in right kidney
- Management dilemma – active surveillance?

- ^{89}Zr -DFO-girentuximab PET clearly positive → ccRCC highly likely



Clinical management:

- Partial nephrectomy
- ccRCC confirmed by central pathology



Note: representative patient response only, may not be representative for all patients.

TLX101-CDx value proposition in glioma

Potential first commercial FET-PET imaging agent for U.S. market



Commercialise the
diagnostics portfolio

1

Provide key information at initial
diagnosis to enable optimal treatment
management

- FET-PET has the potential to provide a rapid and conclusive diagnosis of gliomas, providing an important tool for management of progression or treatment monitoring

2

Identification of
pseudoprogression vs actual
progressive disease (PD)

- Weekly MRIs over 4 – 12 weeks is the current standard of care to identify pseudoprogression v PD or recurrence, compared to FET-PET which has potential to diagnose with a single scan

3

Inform management decisions at first
recurrence and beyond

- When pseudoprogression is **incorrectly** diagnosed as PD, the patient will receive unnecessary EBRT and immunotherapy, which is both costly, and impairs quality of life

New Drug Application preparation underway, pending pre-submission meeting to agree strategy

ProstACT prostate cancer therapy program

A differentiated PSMA-targeting therapy candidate



Unlock the value in the therapeutic pipeline

Lower tumour burden

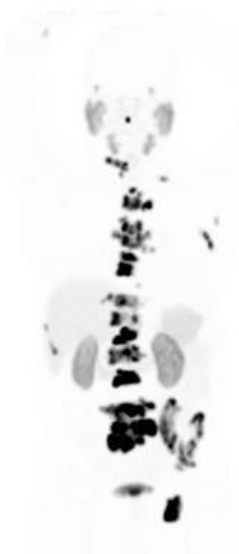


Baseline Illucix
PET scan



TLX591 SPECT
2 weeks post dose

High tumour burden



Baseline Illucix
PET scan



TLX591 SPECT
2 weeks post dose

- SELECT study approaching target enrolment, opportunities for data readouts in H1 2023
- TARGET study dosing patients
- Manufacturing scale-up to support GLOBAL study was a key focus in 2022, preparing to dose patients in AU sites and file IND¹ for U.S. in 2023
- Biodistribution data from SELECT indicates TLX591 antibody is retained in the tumour with high activity remaining at two weeks and beyond
- Longer-term retention of TLX591 in the tumour (and metastases) may maximise the cell-killing effect of the ¹⁷⁷Lu radioisotope at the cancer sites and allow optimised dosing

TLX101: Further studies progressing

Promising data warrants investigation in a front-line setting

- IPAX-1 multi-centre Phase I trial of TLX101 in combination with EBRT in patients with recurrent glioblastoma multiforme (GBM) completed in 2021
- Final data released in 2022 confirmed safety and tolerability profile, encouraging preliminary efficacy for further evaluation, based on 10 patients
- Evidence of potential anti-tumour effect from both imaging and clinical assessment
- Median overall survival (OS) of 13 months from the initiation of treatment in the recurring setting, or 23 months from initial diagnosis

Clinical development focus

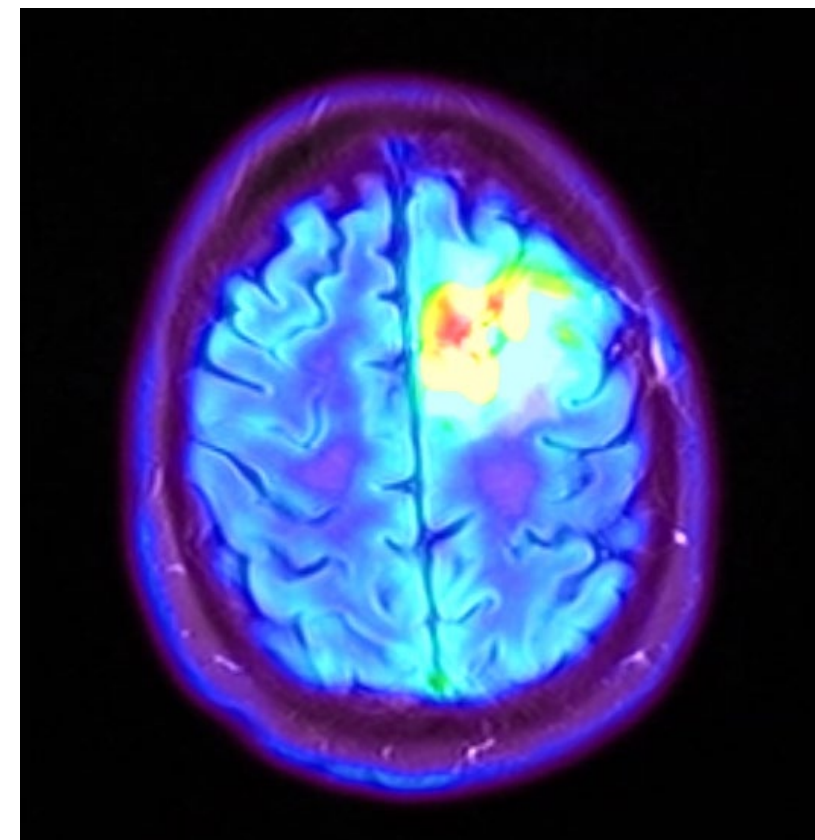
- Sites initiated in IPAX-2 follow on study (Phase I arm) in front line setting (newly diagnosed patients)
- IPAX-Linz (Phase II, IIT¹) treating patients in Linz, Austria, continued access for second-line patients
- IND accepted for review by NMPA² (China) - first therapy trial with Grand Pharma



1. Investigator initiated trial
2. National Medical Products Administration.



Unlock the value in the
therapeutic pipeline



PET/CT scan visualising an area of
post-treatment necrosis

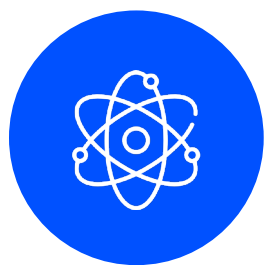
Our approach to supply chain and manufacturing

Extensive network enhanced with added in-house capability



Strengthen supply chain
and manufacturing

Industry-leading supply
chain partners



Clinical and commercial
supply of radioisotopes

SHINE and Eckert &
Ziegler added to ^{177}Lu
clinical supply network

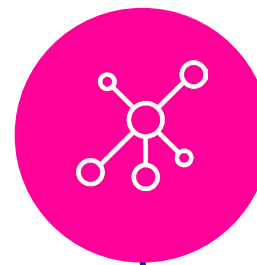
Global manufacturing
and logistics network



Just-in-time manufacturing,
servicing all major markets

Telix + partner network
enables manufacturing and
distribution across major
global markets

Expansive distribution
network



Extension of the
commercial team

U.S. distribution network
expanded to 193
pharmacies, in alignment
with go-to-market strategy

In-house
manufacturing / R&D



Facility in Brussels South
on-track for 2023

Updated licence granted
Acquisition of Optimal Tracers
adds clinical manufacturing
and process development
capability

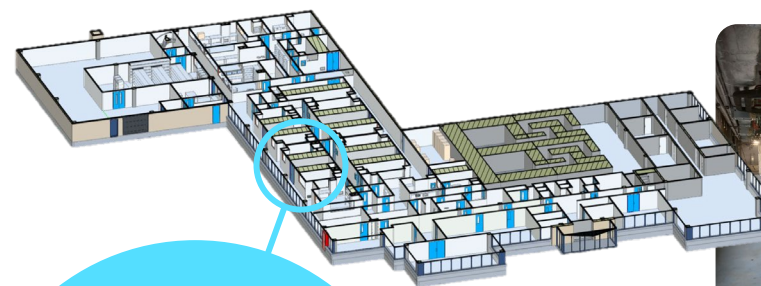
Our European production facility

Brussels South facility expected to be operational in 2023



Strengthen supply chain
and manufacturing

- Brussels South facility will serve as the primary manufacturing site for commercial and clinical supply in Europe
- Integral to R&D, particularly manufacturing scale-up expertise and IP
- Site works have progressed well during 2022:
 - Updated radiation licence granted from the Belgian Federal Agency for Nuclear Control (FANC)
 - R&D hot cells delivered and installed
 - Cleanrooms close to completion
- On-track to complete regulatory inspections and commence operations in 2023



9 x cleanrooms
1 x alpha emitter
translational lab
2 x cyclotrons



Research and innovation: Five areas of focus

Telix has made progress across all focus areas in 2022



Expand
the pipeline



Targeted Radiation (TR) + Immuno-oncology

TR sets the groundwork
for cancer
immuno-therapy in
combination



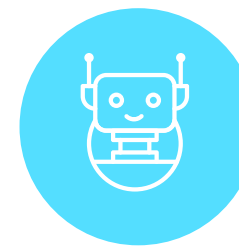
Targeted Alpha therapy

Next generation
therapeutics with
alpha-emitting
radioisotopes



Tumour Microenvironment

Combining TR with
standard of care
treatments for
improved efficacy with
biomarker-driven
patient selection



Artificial intelligence (AI)






Tools to
maximise clinical
insights gained from
imaging and link to
therapeutic outcomes



Radio-guided surgery

Bringing molecular
imaging into the
operating room

Research pipeline: Novel targets and technologies

	ASSET	TARGET	ISOTOPE	DESCRIPTION	STATUS
	Immuno-oncology				
	TLX250 Combo	CAIX	¹⁷⁷ Lu	TLX250 + Merck KGaA DNA Damage Response Inhibitor (DDRi) candidate in patients with CAIX-expressing solid tumours	Phase Ib study (STARSTRUCK) to commence H1 2023
	Targeted alpha therapy				
	α-TLX250	CAIX	²¹¹ At	Exploring TLX250 as an alpha therapy, in non-muscle invasive bladder cancer (in partnership with ATONCO). First-in-human study in planning	Phase I proof of concept study (PERTINENCE) completed
	TLX592	PSMA	²²⁵ Ac	Utilises Telix proprietary engineered antibody TLX592 (⁶⁴ Cu/ ²²⁵ Ac-RADmAb®) in prostate cancer, as an alpha therapy candidate	Phase I study (CUPID) in progress
	Tumour microenvironment				
	TLR300	PDGFRα ¹	Undisclosed	Exploring the development of radiolabelled forms of Olaratumab for the diagnosis and treatment of human cancers, in-licensed from Eli Lilly	IND enabling studies planned for 2023
	TLR400	La/SSB ²	⁸⁹ Zr	Novel antibody targeting La/SSB protein in lung and ovarian cancer, in partnership with AusHealth	Phase I study in progress
	Radio-guided surgery				
	TLX591-Sx	PSMA	⁶⁸ Ga/IRDye	Dual-labelled PSMA-targeting molecule that comprises both a radioactive isotope (⁶⁸ Ga) and a fluorescent dye	Phase 0 (biodistribution) clinical studies in progress
	Ilucix life cycle management				
	TLX599-CDx	PSMA	^{99m} Tc	NOBLE Registry in partnership with Oncidium Foundation exploring use of ^{99m} Tc-iPSMA for imaging of prostate cancer where SPECT is the predominant modality	Actively recruiting at eight sites globally



1. Platelet derived growth factor receptor alpha.
2. Small RNA binding exonuclease protection factor La.

Note: TLR designates a research asset that has not yet achieved product candidate status.

Collaboration with Merck KGaA

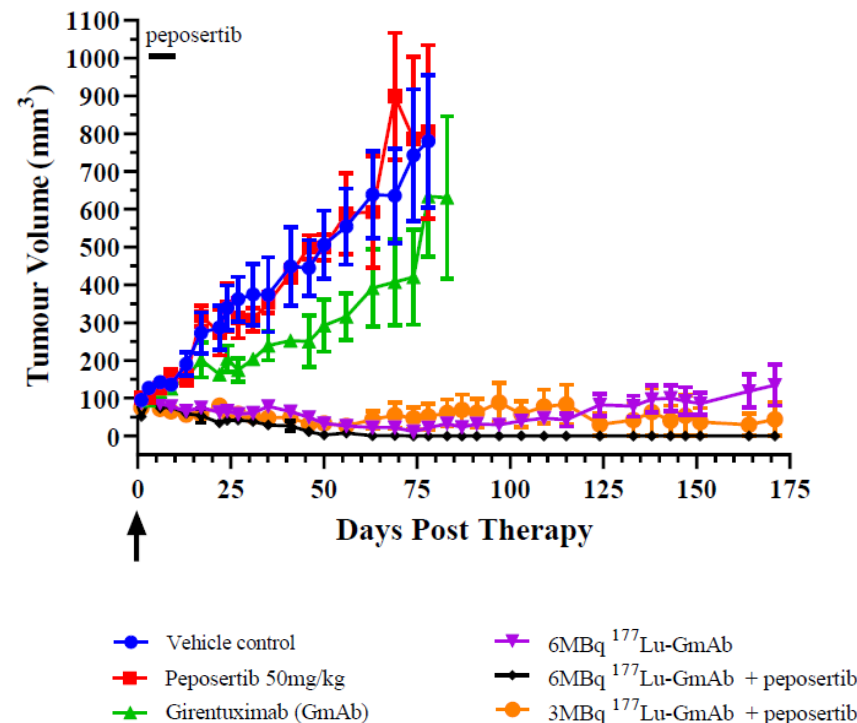


Expand
the pipeline

TLX250 Combo: TLX250 + DNA Damage Response Inhibitor (DDRi)

- Pre-clinical results show TLX250 in combination with DDRi enhances the potency of treatment at a lower dose (TLX250 Combo)
- Targeted radiation effectively induces DNA damage in target cells, while the DDRi prevents the cell from repairing the damage from radiation treatment
- Based on excellent pre-clinical results, program will move into clinical trials commencing H1 2023
- STARSTRUCK: Phase Ib, open label, single-arm, multicentre dose escalation and dose expansion study enrolling up to 80 patients with CAIX-expressing solid tumours

Summary of pre-clinical results in Xenograft mice



- TLX250 Combo shows highly additive effect on tumour reduction in pre-clinical models
- DDRi effect is dependent on radiation damage, with limited effect on tumours alone
- TLX250 Combo demonstrated enhanced effect compared to targeted radiation alone at this dose
- Pre-clinical research has demonstrated proof of concept in two cell lines

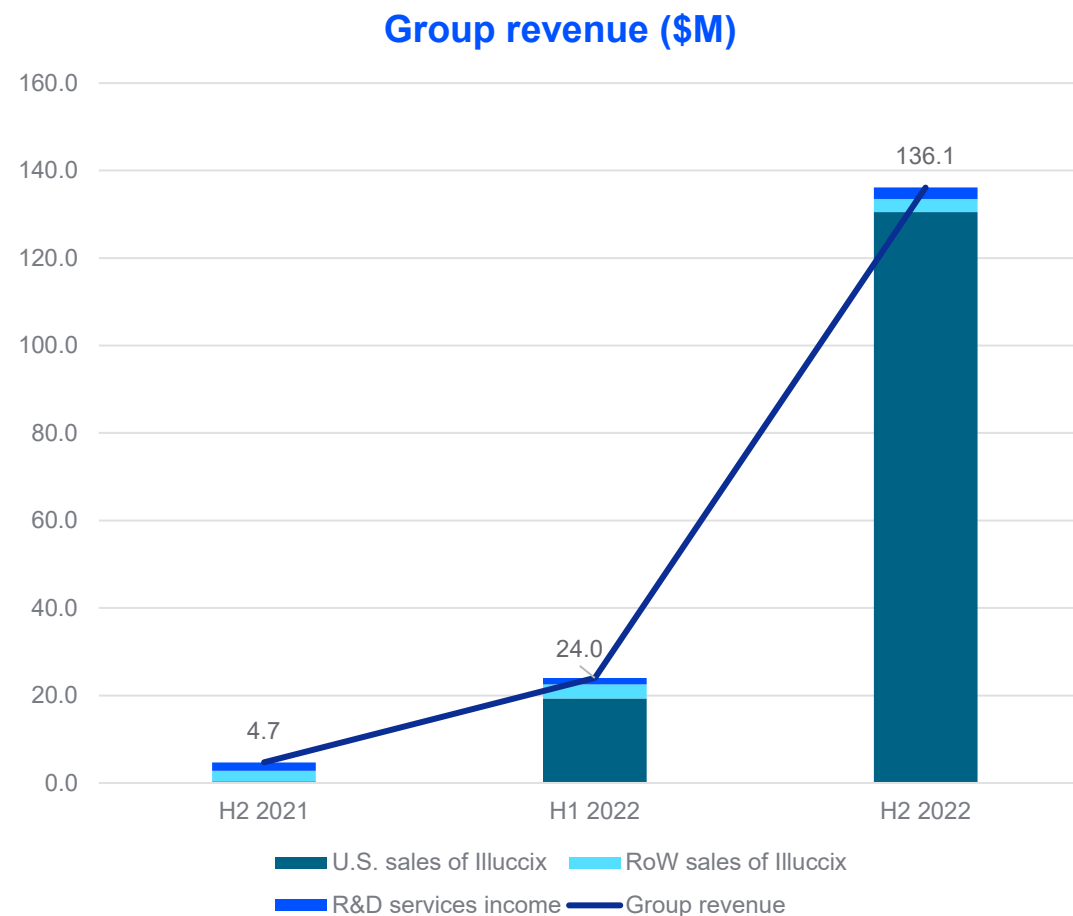
Financial Commentary



Commercial launch drives 20x increase in revenue

U.S. Illuccix sales delivers growth throughout the year

- Group revenue up 20x to \$160.1M (2021: \$7.6M)
- U.S. revenue from Illuccix the main driver with \$149.7M (\$US100.4M) recorded since commercial launch in April 2022
- Rest of world revenue increased by 44% to \$6.2M (2021: \$4.3M)
- Recognition of \$3.4M (2021: \$2.7M) of revenue from Grand Pharmaceutical Group's upfront payment for development services ¹

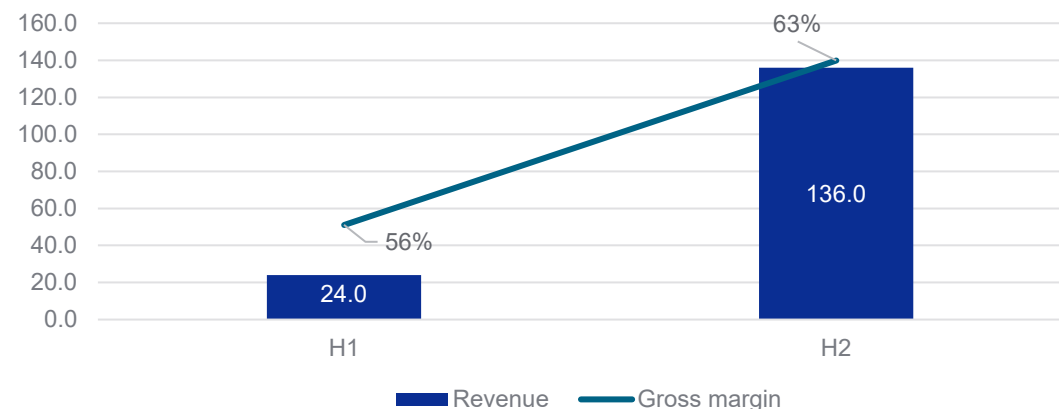


Growing revenue building a sustainable business

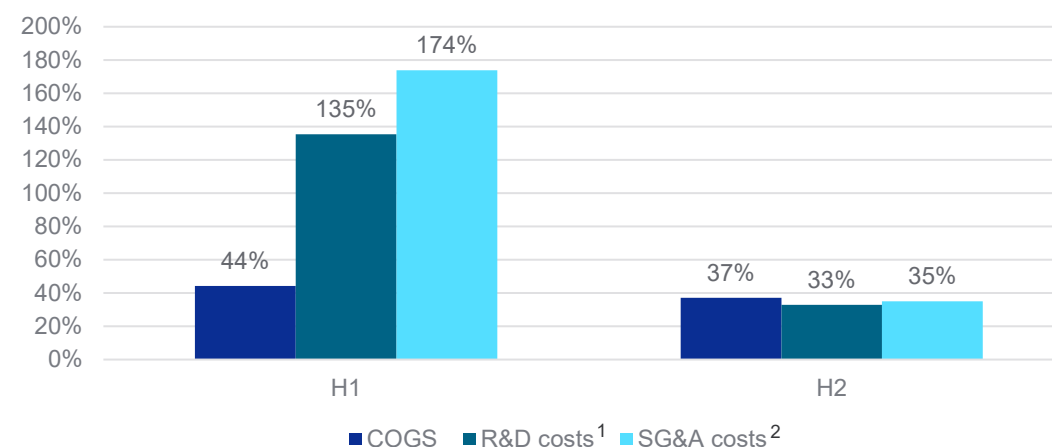
Key expenditure has reduced as a percentage of sales

- Gross margin of 62% for FY2022
- Improvement of 7 basis points from H1 (56%) to H2 (63%) due to manufacturing efficiencies and scale, with operations now at normalised levels
- Significant reduction in selling, general and administration costs (SG&A) as a % of revenue in H2 with revenue growth far exceeding cost base growth
- Commercial business now generating sufficient cash to fund research and development (R&D) pipeline

Revenue (\$M) and gross margin percentage (%)



Key expenditure items compared to revenue (%)



Income statement summary

Investing for future growth, while delivering an improvement in profit/(loss)

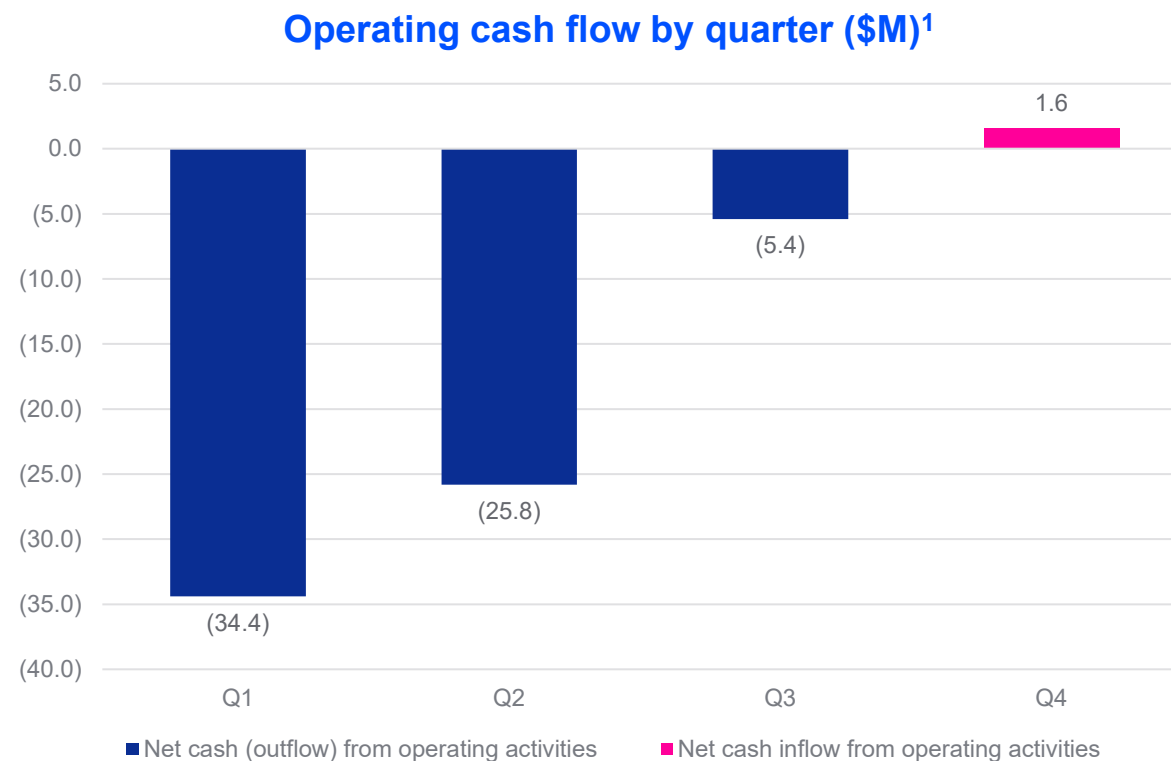
- Gross profit substantially up 1870% YOY
 - H1 includes one-off launch costs, while H2 reflects normalised manufacturing costs and full six months of sales
- Employment costs in H2 reflect increased headcount to support commercial and clinical activities, and include a one-off share-based payment charge of \$4.7M (non-cash)
- SG&A costs stable in H2 reflecting normalised operations and operating expenditure control
- Higher R&D costs in H2 to support commercialisation of late-stage diagnostic assets and progress the development of high value therapeutic assets

	FINANCIAL YEAR				HALF-YEAR			
	2022	2021	Var.	Var.	H2	H1	Var.	Var.
	\$M	\$M	\$M	%	\$M	\$M	\$M	%
Revenue	160.1	7.6	152.5	2,007%	136.1	24.0	112.1	467%
Cost of inventory sold	(61.6)	(2.6)	(59.0)	2,269%	(51.0)	(10.6)	(40.4)	381%
Gross profit	98.5	5.0	93.5	1,870%	85.1	13.4	71.7	535%
Employment costs	(64.5)	(30.1)	(34.4)	114%	(37.8)	(26.6)	(11.2)	42%
SG&A costs	(44.0)	(16.9)	(27.1)	160%	(21.3)	(22.8)	1.5	(7%)
R&D costs	(57.8)	(34.1)	(23.7)	70%	(33.0)	(24.8)	(8.2)	33%
Other costs ¹	(30.8)	(4.4)	(26.4)	600%	(20.9)	(9.9)	(11.0)	111%
Loss before income tax	(98.6)	(80.5)	(18.1)	22%	(27.9)	(70.7)	42.8	(61%)

Improving operating cash flow

Q4 delivers first quarter of net cash inflow from operating activities

- Telix finishes 2022 in a stronger financial position with:
 - Improved balance sheet, with net assets of \$80.0M and cash reserves of \$116.3M
 - Sound management of working capital
- Transition to a sustainable business:
 - Profitability improving with net loss before tax reducing to \$27.9M in H2 (H1: \$70.7M) through revenue growth, improved gross margins and lower operating costs as a percentage of sales
- Commercial business supporting investment in pipeline development, including late-stage programs



Four major focus areas in 2023

Value creating catalysts across the imaging and therapeutic pipeline

**Illuccix® -
continued revenue
growth and global
rollout**

**Biologics License
Application (BLA)
submission for
TLX250-CDx**

**New Drug
Application (NDA)
for brain cancer
imaging
(TLX101-CDx)**

**ProstACT
GLOBAL patient
recruitment and
ProstACT
SELECT/TARGET
data readouts**

Upcoming catalysts

Four key catalysts

Illuccix® - continued revenue growth and global rollout

BLA submission for TLX250-CDx

NDA for brain cancer imaging (TLX101-CDx)

ProstACT GLOBAL patient recruitment and data readout
ProstACT SELECT

EXPECTED MILESTONES 2023

Additional milestones

IPAX-2 (TLX101 GBM therapy) patient dosing, IPAX-L continued enrolment

Illuccix® label expansion

STARLITE-1 (TLX250 therapy) patient dosing and STARLITE-2 continued enrolment

Prostate and renal imaging bridging studies commence in China

Illuccix Brazil approval decision

TLX250 therapy + Merck KGaA DDRi combination study launch

Brussels South (Seneffe) manufacturing facility operational

CUPID study of TLX592 fully enrolled

STARBURST study exploring TLX250-CDx in solid tumours launched

Regulatory filing Telix AI™

ZiP-UP and OPALESCENCE studies of TLX250-CDx complete

TLX66 study launch in AL-Amyloidosis (TRALA-2)

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