



# Q1 2023 Quarterly Business Update

Telix Pharmaceuticals (ASX:TLX)

17 April 2023

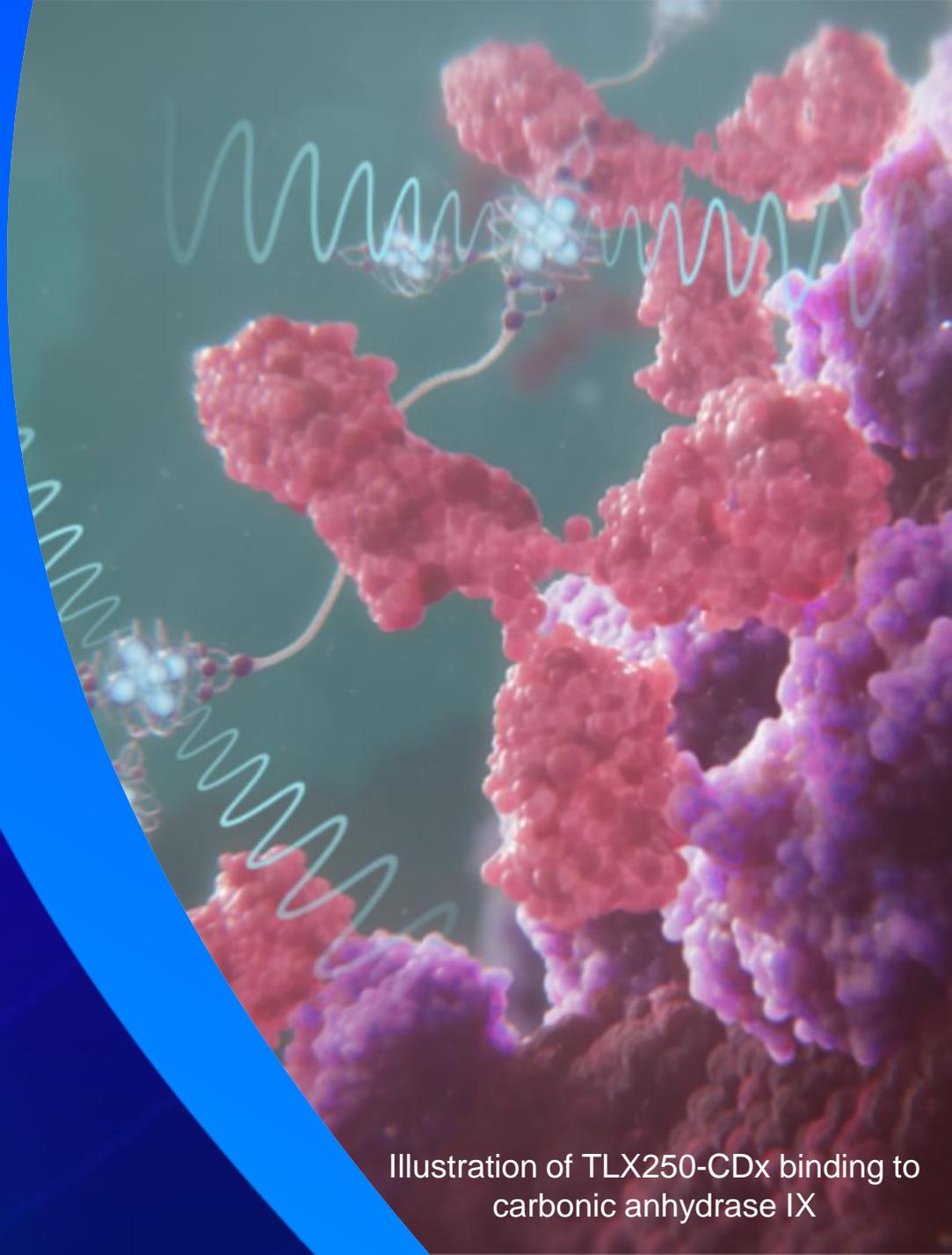


Illustration of TLX250-CDx binding to  
carbonic anhydrase IX

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TLX250-CDx has not received a marketing authorisation in any jurisdiction. Telix’s lead product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been approved by the Australian Therapeutic Goods Administration (TGA), the U.S. Food and Drug Administration (FDA), and Health Canada.

Full United States prescribing information for Illuccix can be found at <http://illuccixhcp.com/s/illuccix-prescribing-information.pdf>

All figures are in AU\$ unless otherwise stated and provided on an unaudited basis.

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# Q1 2023 Highlights

## Advancing our value-creating assets



### Continued growth in prostate cancer imaging (Illuccix®)

- U.S. demand continues to grow; revenue from Illuccix sales up 27%
- Commercial and regulatory progress in key global markets



### Commercialisation plans for two new products on-track

- Positive meeting with FDA for TLX101-CDx NDA<sup>1</sup> filing
- High clinician engagement with TLX250-CDx, BLA<sup>2</sup> progressing



### Continued progress across our deep therapeutic pipeline

- Advancing core therapy programs, including ProstACT GLOBAL Phase III study, data readout for ProstACT SELECT H2 2023



### New theranostic compound progressed to proof of concept

- Olaratumab (TLX300), an antibody in-licensed from Lilly, to progress to human trials following successful pre-clinical program



### Transformation to a cash-generative business

- Second consecutive cash flow positive quarter underpinned by growing commercial revenue and expenditure control

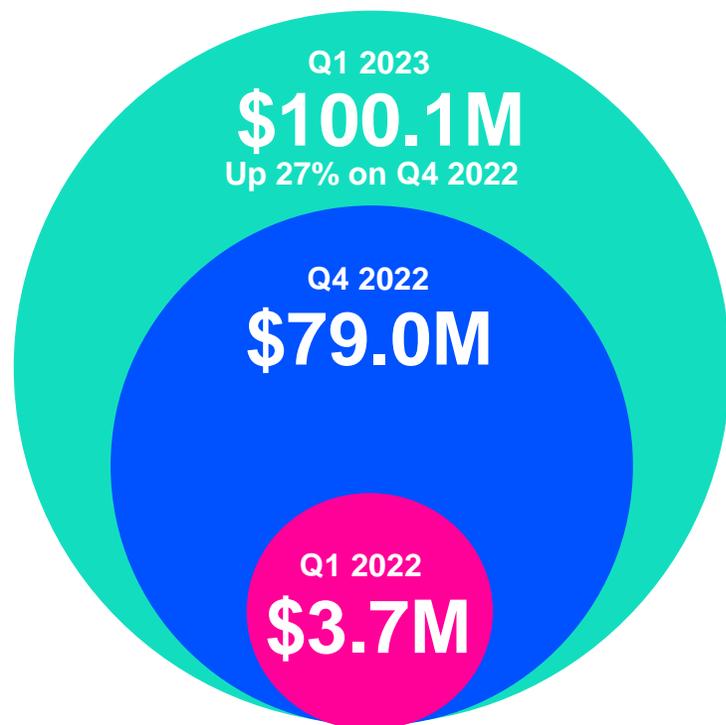


1. New Drug Application.
2. Biologics License Application.

# Q1 2023 Financial metrics

## Rapid revenue growth underpins balance sheet improvement

Total revenue  
comparison to previous periods



Net operating  
cash inflow

**\$2.4M**

Improvement of  
\$0.8M, despite  
impact of annual  
incentive  
payments



Gross  
margin

**63%**

In line with Q4  
2022, reflecting  
period of stable  
manufacturing /  
operating costs



Customer  
receipts

**\$83.2M**

Up 15% from  
\$72.2M in  
Q4 2022



Cash  
balance

**\$121.4M**

As at  
31 March 2023  
(\$116.3M as at  
31 Dec 2022)

# Illuccix® Commercial Update

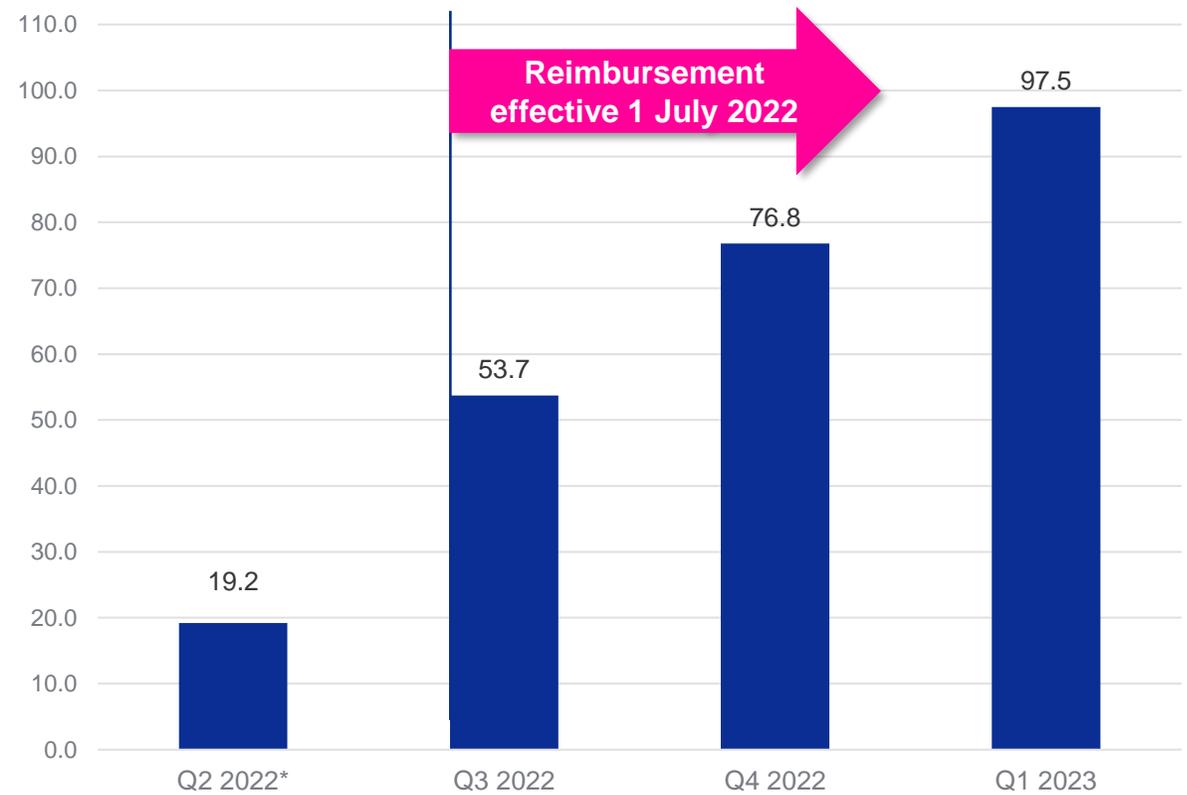


# U.S. market demand for Illuccix continues to grow

## Illuccix performing strongly in the growing PSMA-PET<sup>1</sup> imaging market

- Revenue from U.S. sales of Illuccix up 27% to \$97.5M (US\$66.2M) on the prior quarter, despite a “short” (90 day) quarter
- Average daily dose demand increased steadily throughout the quarter
- Sales growth is being driven by:
  - Expansion into new customer sites
  - Compound growth effect as existing customers increase purchasing – particularly in the hospital segment
- Label now expanded to include patient selection for PSMA-directed radioligand therapy<sup>2</sup>

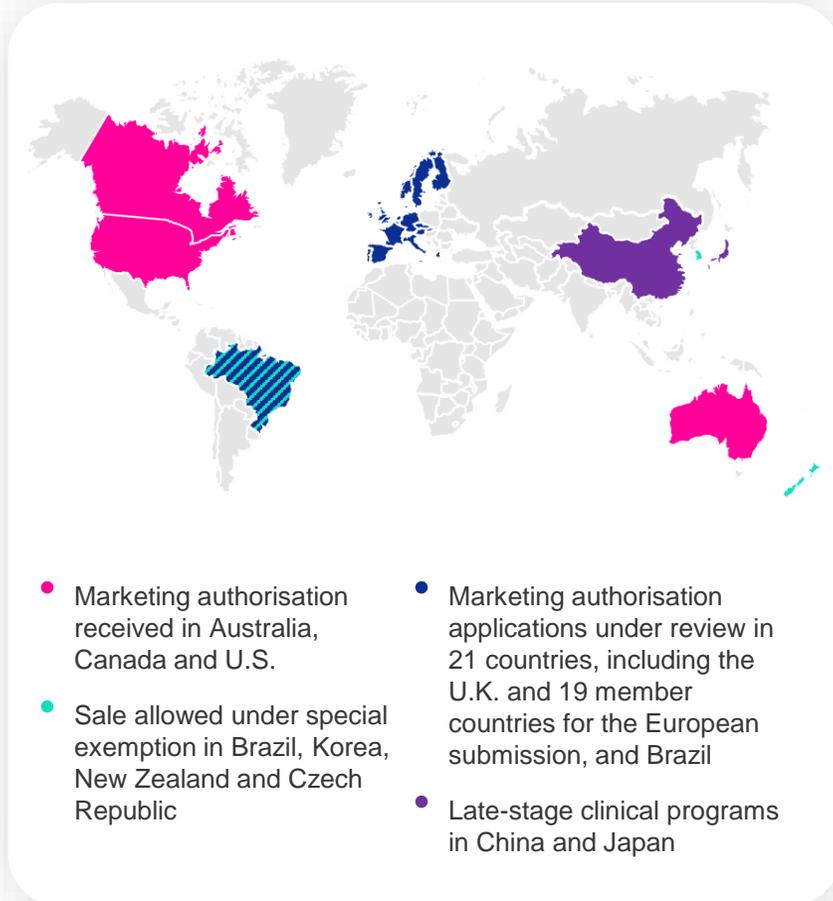
Revenue from U.S. sales of Illuccix (AU\$M)



1. Prostate specific membrane antigen / positron emission tomography.  
2. Telix ASX disclosure 16 March 2023.  
\* Q2 2022 partial quarter of sales (commenced late April 2022), pre-reimbursement.

# Iluccix global rollout

Our ability to deliver globally is a key advantage



**Telix is delivering PSMA-PET imaging on a commercial and pre-commercial<sup>1</sup> basis in major global markets. Recent updates:**

- **Americas:** Commercial launch underway in Canada with partner Isologic<sup>2</sup>
- **EMEA:** Marketing Authorisation Application submitted to UK Medicines and Healthcare products Regulatory Agency<sup>3</sup>; EU filing underway with BfArM Federal Institute for Drugs (Germany) as competent authority
- **Asia Pacific:**
  - Commercial sales underway in Australia / New Zealand
  - Phase III bridging study in China preparing to enrol patients
  - Active engagement with PMDA in Japan on NDA strategy
- **Global collaborations:** Pharmaceutical company collaborations and investigator-led studies underway for collection of longitudinal data to support possible future label expansion



1. Pre-commercial sales are from investigational, clinical trial, magisterial and compassionate use in accordance with local laws and regulations (not as a commercial diagnostic imaging product sold for routine clinical practice).
2. Media release 16 March 2023.
3. Telix ASX disclosure 3 April 2023.

# Financial Commentary



# Positive operating cash flow trend continues

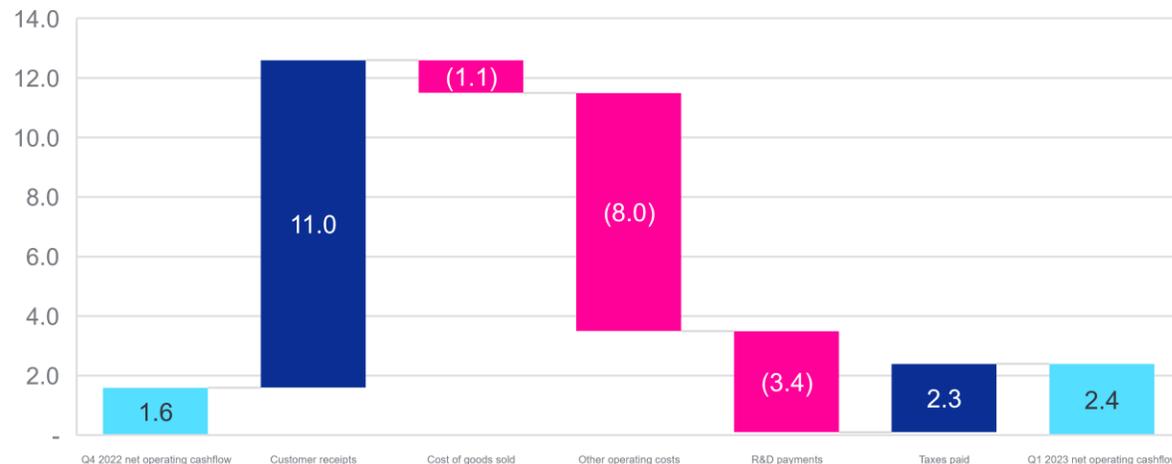
## Second consecutive quarter of net cash inflow from operating activities

- Cash increases to \$121.4M at 31 March 2023 (compared to \$116.3M at 31 December 2022)
- Quarterly operating cash flow improves \$0.8M over prior quarter with a positive \$2.4M inflow
- Revenue growth drives customer receipts 15% higher to \$83.2M, an \$11.0M improvement
- Higher sales volume increases manufacturing and other related payments by \$1.1M
- Further investment building commercial capability to support sales growth plus payment of FY2022 short term incentives (\$4.3M) increases operating cost items<sup>1</sup> by \$8.0M compared with prior quarter

Cash flow from operating activities (\$M)



Q4 2022 versus Q1 2023 (\$M)



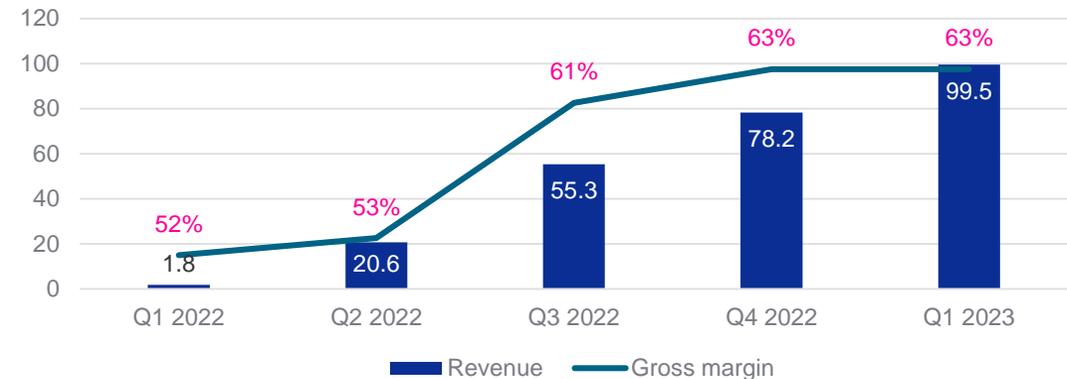
1. Advertising and marketing, staff costs and administration and corporate costs.

# Sales performance and controlling operating expenditure

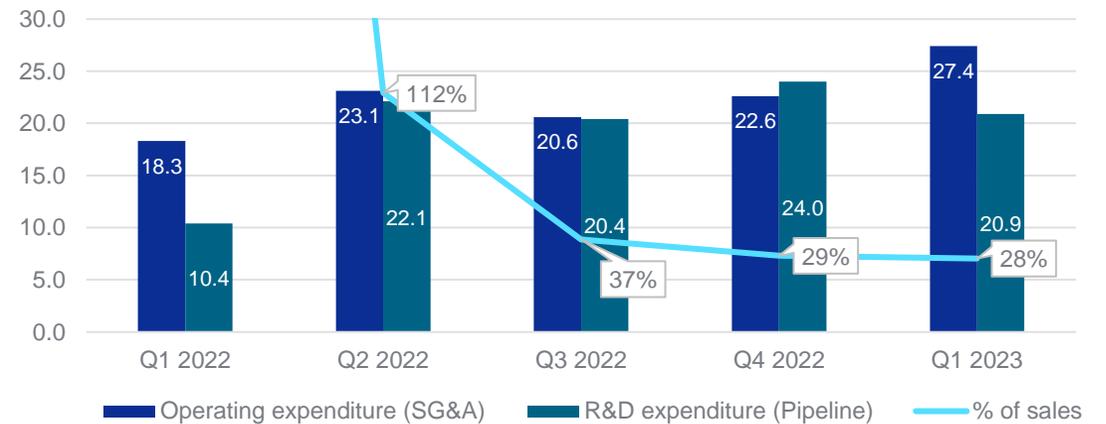
## Funding focused investment in priority programs

- Gross margin has stabilised from Q4 2022 reflecting normalised manufacturing and distribution costs
- Operating expenditure<sup>1</sup> reduces to 28% of revenue (29%, Q4 2022) as investment in commercial infrastructure prepares Telix for future growth in sales
- Investment in research and development (R&D) funded by commercial performance continues to plan and is focused on delivering activities associated with its late-stage, priority development programs
- In Q4 2022 an incremental investment was made in commercial resources to further maximise the Illuccix opportunity, translating to an increase in employment costs in Q1 2023

Product-related revenue (\$M) and gross margin percentage



Key expenditure<sup>2</sup> (\$M) and percentage of sales



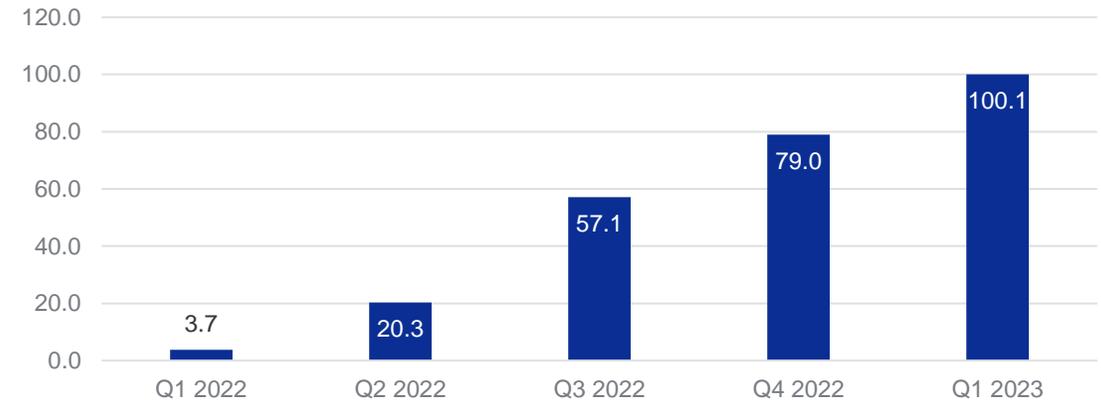
1. Advertising and marketing, staff costs and administration and corporate costs.  
 2. Q4 2022 operating expenditure has been restated to agree to the Group's audited financial report and excludes a one-off non-cash share based payment charge of \$4.7M.

# Continued growth in revenue and adjusted EBITDAR<sup>1</sup>

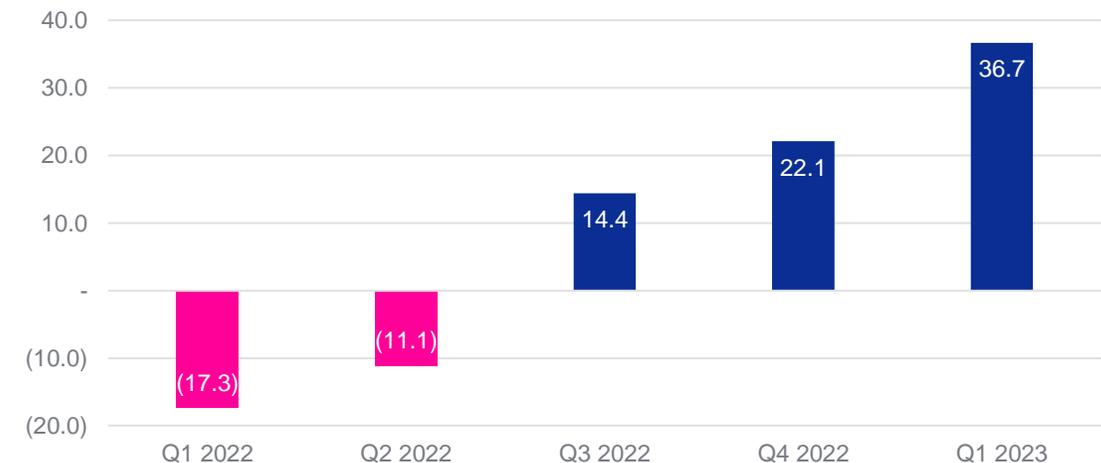
## First quarter of \$100M revenue achieved

- Revenue \$100.1M, up 27% from \$79.0M in the prior quarter
- Total revenue is commercial sales of Illuccix plus all other revenue (eg from pre-commercial sales)
- Telix uses adjusted EBITDAR to assess its commercial performance
- Adjusted EBITDAR improved 66% to \$36.7M, from \$22.1M in the prior quarter, demonstrating improved performance of commercial operations.

Total revenue (\$M)

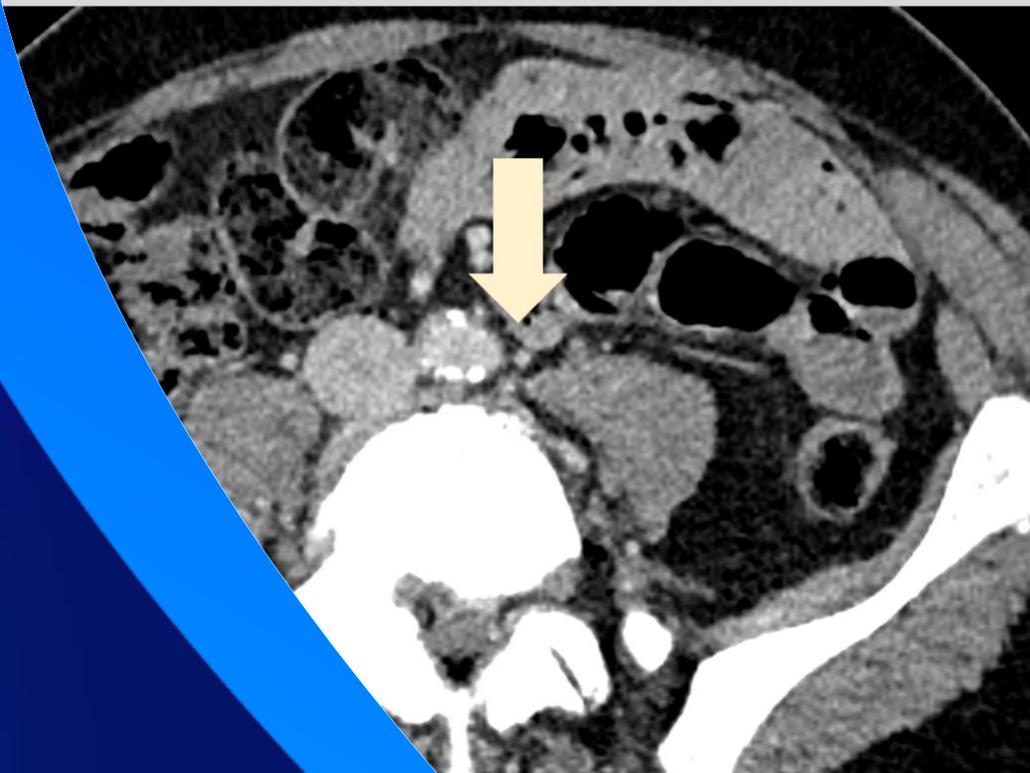
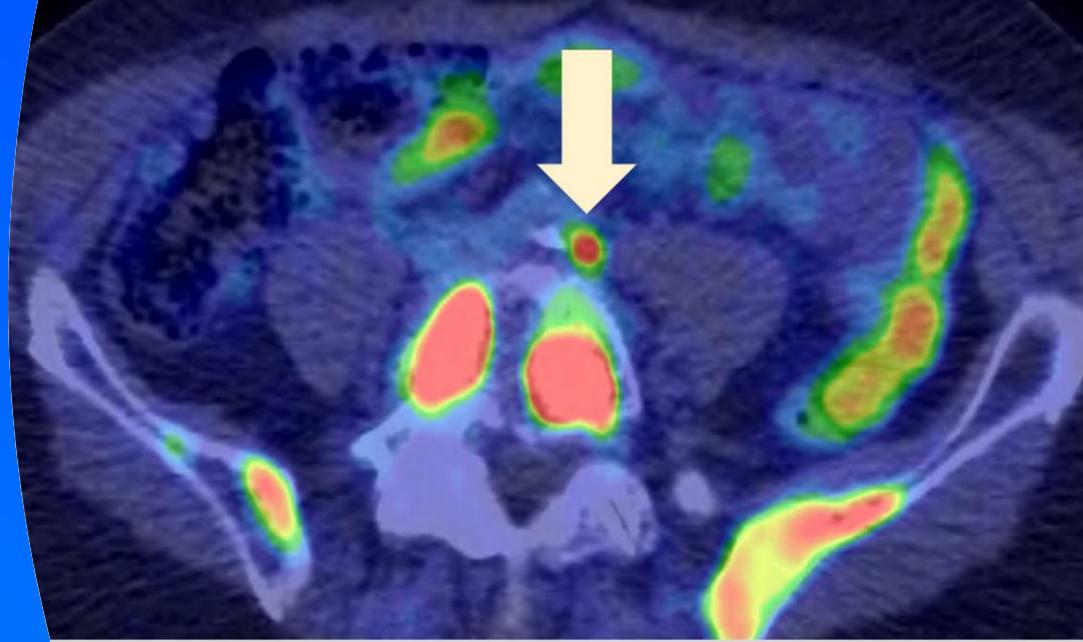


Adjusted EBITDAR (\$M)



1. Adjusted EBITDAR is an alternative performance measure (APM) defined as adjusted earnings before interest, tax, depreciation and amortisation and research and development costs. Refer to note 4 of the 2022 financial report for a reconciliation of adjusted EBITDAR.

# Clinical Programs



# Core pipeline: Oncology and rare diseases



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



1. Prostate-specific membrane antigen.
2. Carbonic anhydrase IX.
3. Large amino acid transporter 1.

4. Bone marrow conditioning/rare diseases.
5. Cluster of differentiation 66.

Note: Shaded sections indicate expected development stage in the next 12 months.

# Research pipeline: novel targets and technologies



ASSET	TARGET	ISOTOPE	DESCRIPTION	STATUS
<b>Immuno-oncology</b>				
TLX250 Combo	<b>CAIX</b>	<sup>177</sup> Lu	TLX250 + Merck KGaA DNA Damage Response Inhibitor (DDRi) candidate in patients with CAIX-expressing solid tumors	Phase Ib study (STARSTRUCK) to commence 1H 2023
<b>Targeted alpha therapy</b>				
α-TLX250	<b>CAIX</b>	<sup>211</sup> 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	<b>PSMA</b>	<sup>225</sup> Ac	Utilizes Telix proprietary engineered antibody TLX592 ( <sup>64</sup> Cu/ <sup>225</sup> Ac-RADmAb®) in prostate cancer, as an alpha therapy candidate	Phase I study (CUPID) in progress
<b>Tumour microenvironment</b>				
TLX300	<b>PDGFRα<sup>1</sup></b>	Undisclosed	Exploring the development of radiolabeled forms of olaratumab for the diagnosis and treatment of human cancers, in-licensed from Lilly	IND enabling studies planned for 2023
TLR400	<b>La/SSB<sup>2</sup></b>	<sup>89</sup> Zr	Novel antibody targeting La/SSB protein in lung and ovarian cancer, in partnership with AusHealth	Phase I study in progress
<b>Radio-guided surgery</b>				
TLX591-Sx	<b>PSMA</b>	<sup>68</sup> Ga/IRDye	Dual-labelled PSMA-targeting molecule that comprises both a radioactive isotope ( <sup>68</sup> Ga) and a fluorescent dye	Phase 0 (biodistribution) clinical studies in progress
<b>Illuccix life cycle management</b>				
TLX599-CDx	<b>PSMA</b>	<sup>99m</sup> Tc	NOBLE Registry in partnership with Oncidium Foundation exploring use of <sup>99m</sup> 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.

# Clinical development highlights

## Progress across multiple therapeutic trials



### Renal cancer imaging and therapy

- TLX250-CDx BLA and pre-commercialisation activity in “high gear”
- IND approved for STARBURST study for indication expansion, preparing to recruit patients
- STARLITE-2 study dosing patients



### Prostate cancer therapy

- ProstACT GLOBAL: Preparation for U.S. patient recruitment continues<sup>1</sup>
- ProstACT SELECT completion of initial cohorts, data readout expected H2 2023
- ProstACT TARGET continues to enrol patients



### Glioma imaging and therapy

- Positive consultation with FDA for FET-PET imaging agent
- IPAX-2 study screening patients, moving TLX101 into the front-line setting (newly diagnosed patients)
- Approval to commence Phase I therapy study in China



### Rare diseases portfolio

- Olaratumab (in-licensed from Lilly) has demonstrated proof of concept as a radiopharmaceutical
- TLX66 manufacturing scale-up to support clinical trial underway

# TLX250-CDx: Featured at major medical congresses

## ZIRCON results presented to the medical community for the first time

- Detailed analyses presented at prestigious international medical congresses ASCO-GU<sup>1</sup> and EAU<sup>2</sup>
- Data points support accuracy of the imaging agent
- Key opinion leaders support case for clinical utility – namely the ability to confirm presence of ccRCC and show precise location (for surgical planning and potential staging) assists in the diagnosis and characterisation of renal masses
- BLA submission progressing, formal meeting with the FDA expected in May 2023
- Expanded access program currently being rolled out in the U.S. initially, then into other global markets



**Dr Jeremie Calais, MD**  
Director, Clinical Research  
Program, Ahmanson  
Translational Theranostics  
Division, UCLA

**“Often, these masses are being detected incidentally and then they can get further characterisation with MRI or CT.**

**The tracer is excellent. You have an excellent tumour to background ratio, so these are very easy to read. We were able to see very intense uptake – very rapidly – in the suspected lesions. Here PET can really help to characterise these masses and give a better localisation of the lesions within the kidney.”**



1. American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium.  
2. European Association of Urology.  
3. Telix media release 20 February 2023.

# TLX101-CDx for imaging of glioma

Positive feedback on U.S. regulatory strategy, intention to file NDA in 2023 confirmed

Clear value proposition for imaging of glioma

- TLX-101CDx has the potential to provide a rapid and conclusive diagnosis of recurrent gliomas, providing an important tool for management of progression/treatment monitoring

Initial indication in line with orphan drug designation

- Telix will pursue the initial indication of diagnostic for the characterisation of recurrent glioma or treatment related change
- High unmet need due to severity of disease

38,800 patients diagnosed with gliomas in the U.S. each year<sup>1</sup>

- Following treatment, MRI is used to identify recurrence - it is estimated that in ~30% of cases MRI is inconclusive

Market opportunity in first indication ~US\$90M<sup>2</sup> with potential to expand

- Market estimate assumes 1-2 scans per patient as a baseline
- Potential for future expansion to larger indications, eg brain metastases, over 100,000 cases diagnosed in U.S. each year<sup>3</sup>



1. Pharma Intelligence 2023 / SEER 2019.
2. Dollar (\$) value is management estimate based on US reported incidence.
3. Pharma Intelligence 2023.

# Radiolabelled olaratumab (TLX300) advancing to clinical trials

## Strong scientific, clinical and commercial rationale for development

### Olaratumab (Lartruvo®) was commercialised by Lilly as a “naked” antibody<sup>1</sup>

- In-licensed from Lilly in April 2022 with exclusive rights to develop as a radiopharmaceutical<sup>2</sup>
- It has an established clinical safety profile, favourable toxicology dataset and advanced manufacturing
- Lartruvo® was granted an accelerated approval for the treatment of soft-tissue sarcoma (STS) based on Phase II data, but was subsequently withdrawn voluntarily from market

### High unmet medical need for treatment of STS

- Poor prognosis (12-18 months in advanced metastatic cases) and few treatment options
- While STS is generally responsive to radiation, external beam radiation can be difficult to administer in patients with advanced disease
- A rare disease, meets eligibility criteria for orphan designation<sup>3</sup>
- Annual incidence rates:<sup>4</sup> U.S. - 13,040 and Europe – 23,600 patients

### Olaratumab targets PDGFR $\alpha$ <sup>5</sup> – a promising target

- Expressed in the STS tumour microenvironment as well as in several other carcinomas including gliomas and non-small cell lung cancers
- Also expressed on tumour-associated fibroblasts – similar to FAPI<sup>6</sup> – which is generating high interest in nuclear medicine due to pan-cancer utility



PDGFR $\alpha$  (platelet-derived growth factor receptor alpha)

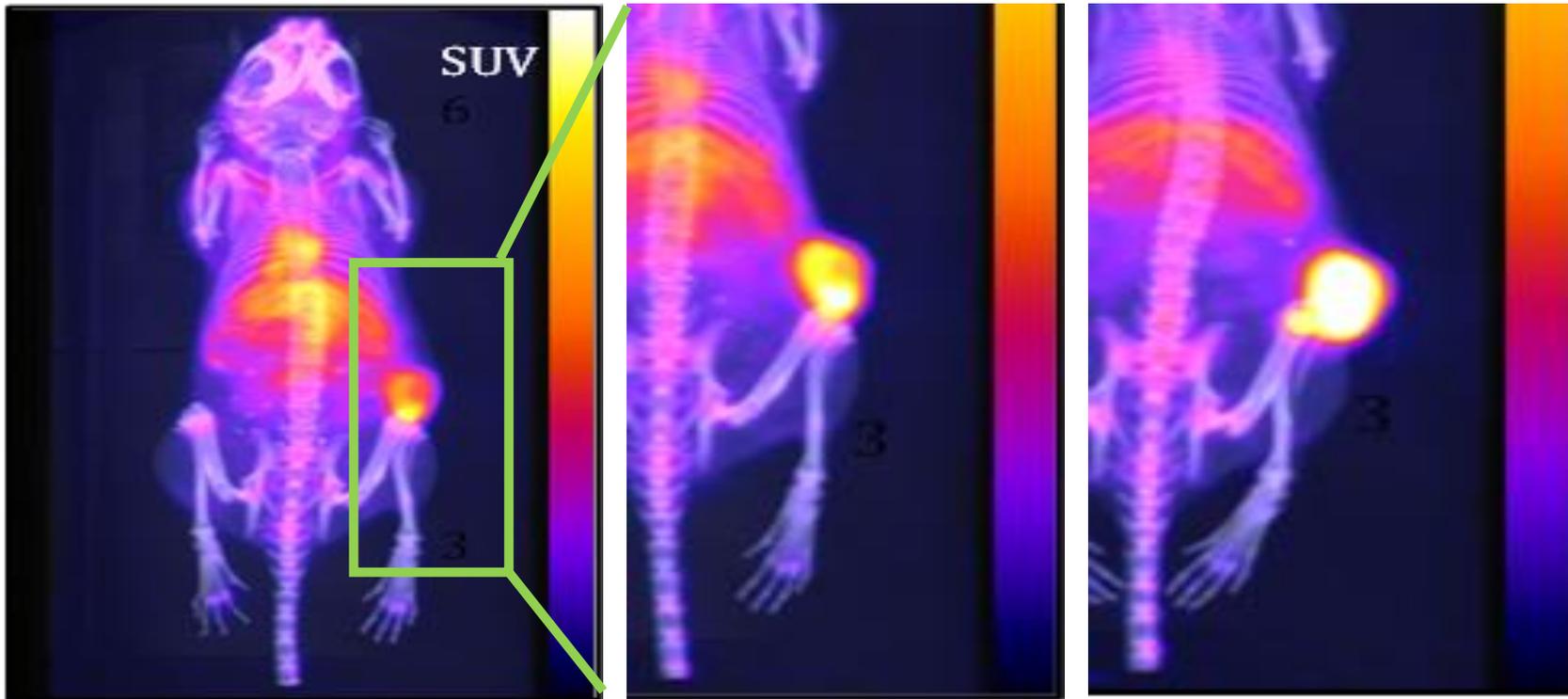


1. On 19 October 2016 the FDA granted accelerated approval for Olaratumab (LARTRUVO, Eli Lilly and Company)
2. Telix ASX disclosure 11 April 2022.
3. Haas et al (2021) Radiation Research.
4. [www.cancer.org](http://www.cancer.org).

5. Platelet-derived growth factor receptor alpha.
6. Fibroblast Activation Protein Inhibitor.

# Pre-clinical images show high uptake and retention in tumours

PET images<sup>1</sup> of a single mouse at 24, 48 and 120 hours after dosing with <sup>89</sup>Zr-TLX300-CDx



**Olaratumab radiolabelled with <sup>89</sup>Zr with imaging and therapeutic radionuclide payloads demonstrate:**

- Tumour targeting
- Tumour retention
- Ability to deliver a therapeutic radionuclide payload / potential therapeutic effectiveness

# Upcoming catalysts

## Four key catalysts

Illuccix® - continued revenue growth and global rollout

ProstACT GLOBAL patient recruitment and data readout  
ProstACT SELECT

BLA submission for TLX250-CDx

NDA for brain cancer imaging (TLX101-CDx)

## EXPECTED MILESTONES 2023

## Additional milestones

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

Illuccix® US label expansion and EU resubmission

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

Prostate and renal imaging bridging studies commence in China

TLX250 therapy + Merck KGaA DDRi combination study launch

Brussels South (Seneffe) manufacturing facility operational

STARBURST study exploring TLX250-CDx in solid tumours launched

Regulatory filing Telix AI™

Olaratumab (TLX300) demonstrates theranostic proof of concept

Illuccix Brazil approval decision

CUPID study of TLX592 fully enrolled

ZiP-UP and OPALESCENCE studies of TLX250-CDx complete

TLX66 study launch in BMT<sup>1</sup>



1. Bone marrow transplantation.

# Thank you & questions

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