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# 2023 Full Year Results

Telix Pharmaceuticals (ASX:TLX)

22 February 2024



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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. SENSEI® - Telix’s miniaturised surgical gamma probe for minimally invasive and robotic-assisted surgery - has attained a marketing authorisation in the U.S., having been registered with the FDA and has attained a Conformité Européenne (CE) Mark for use in the European Economic Area for the intra-operative detection of sentinel lymph nodes (SLNs). With the exception of Illuccix® and SENSEI® as noted above, no Telix product has received a marketing authorisation in any jurisdiction.

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

Unless otherwise stated, all figures are in AU\$. Telix uses various non-IFRS information to reflect its underlying performance. For further information, the reconciliation of non-IFRS financial information to Telix’s statutory measures, reasons for usefulness and calculation methodology, please refer to the Alternative performance measures section in Telix’s Annual Report.

This presentation including earnings guidance has been authorised for release by the Telix Pharmaceuticals Limited Board.

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# Presenters



**Christian Behrenbruch**

Managing Director and  
Group Chief Executive Officer



**Darren Smith**

Group Chief Financial Officer



**David Cade**

Group Chief Medical Officer



**Kyahn Williamson**

SVP Investor Relations and  
Corporate Communications

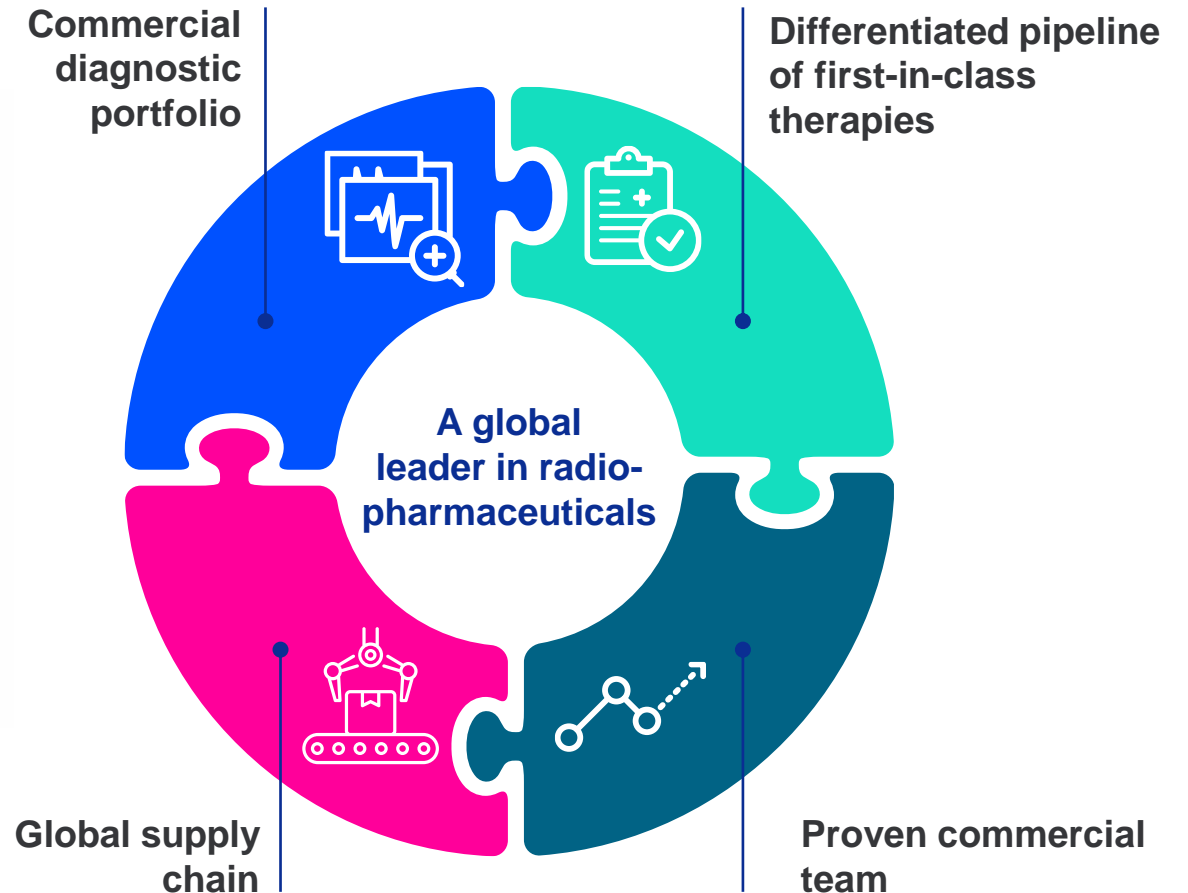
# Agenda

- 01** Operational and financial highlights
- 02** Financial results and commentary
- 03** Clinical programs
- 04** Imaging and technology portfolio
- 05** 2024 guidance

# Operational highlights

## Driving towards our next phase of value creation

- ✓ **Revenue growth** of 214%, demonstrates strong demand for Illuccix® and success of Telix's commercial operations
- ✓ **Phase III ProstACT GLOBAL trial** for TLX591, rADC<sup>1</sup> for prostate cancer therapy dosing patients
- ✓ Preparing to launch **two additional imaging agents** Zircaix™ and Pixclara™<sup>2</sup> in 2024
- ✓ Multiple strategic acquisitions further differentiating our **extensive theranostic pipeline**
- ✓ **Vertical integration** of supply and manufacturing including opening of European production facility



1. Radio-antibody drug conjugate.
2. TLX250-CDx and TLX101-CDx trade name subject to final regulatory approval.

# 2023 Key financial metrics

Strong revenue growth and operating cash flow funding development of late-stage pipeline

Revenue  
growth 214%

**\$502.5M**

(\$160.1M 2022)

Gross margin  
improved

**63%**

(59% 2022)

Profit after tax

**\$5.2M**

(Net loss \$104.1M 2022)

Adjusted EBITDA  
improved \$126.2M

**\$58.4M**

(-\$67.8M 2022)

Operating  
cash inflow <sup>1</sup>

**\$23.9M**

(outflow \$64.0M 2022)

Cash balance  
increased

**\$123.2M**

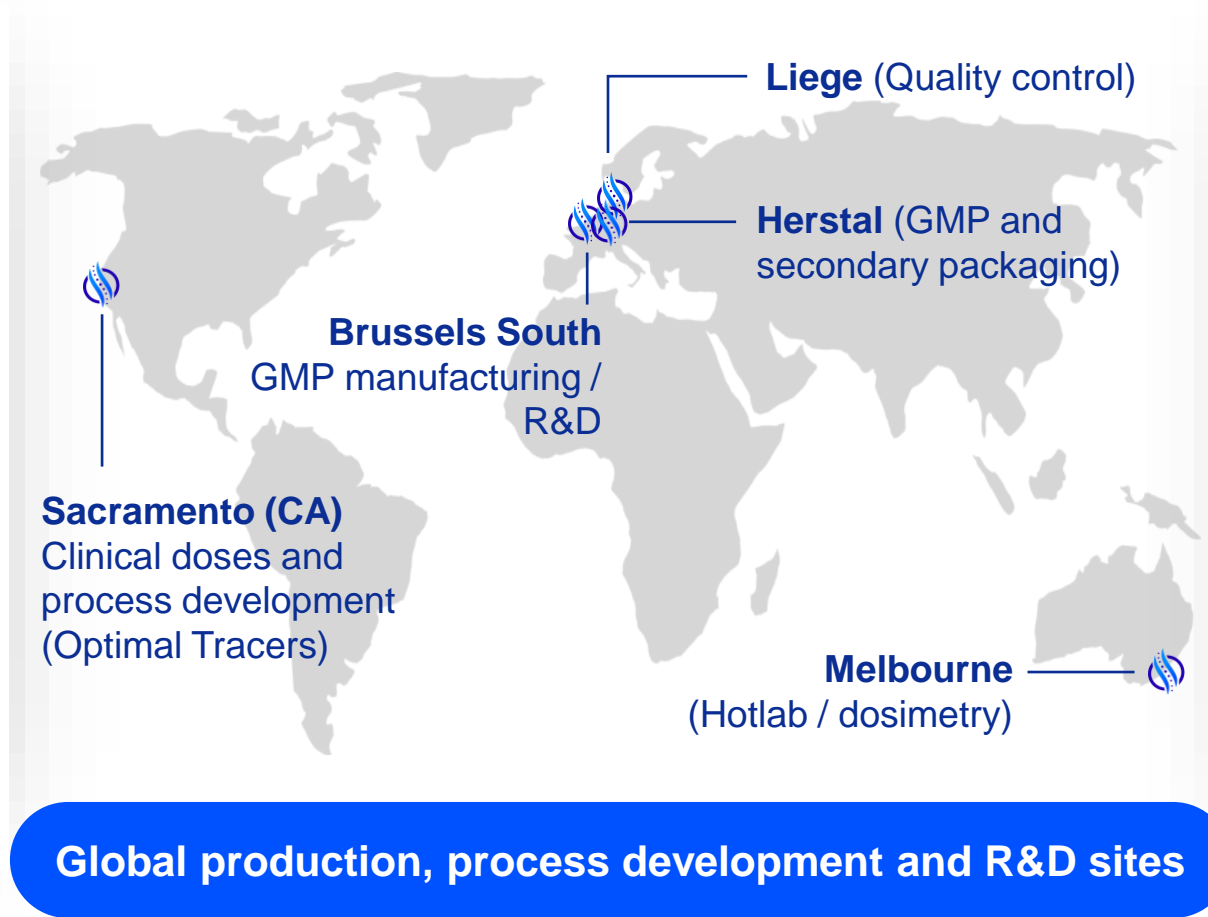
As of 31 Dec. 2023  
vs \$116.3M 31 Dec 2022

# Building a vertically integrated business

## World-class innovation and manufacturing infrastructure

### Equipped to deliver patient doses globally

- Global supply chain
- In-house EU production facility
- “AlphaLab” for specialty R&D
- Radiochemistry and U.S. clinical dose production



### Continuing to invest in in-house development and production capacity

- Isotope production at EU facility
- End-to-end process development and manufacturing technologies

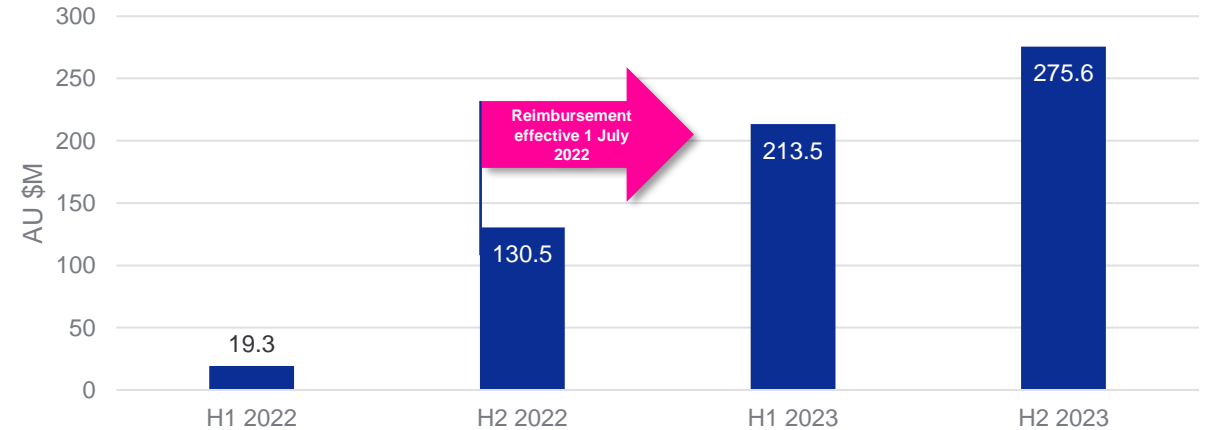
# Illuccix<sup>®</sup>: U.S. market share continues to increase

## Validated ability to commercialise

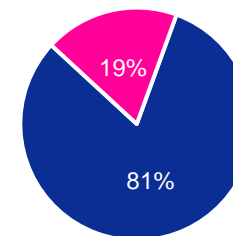
- Average daily dose demand has increased month-on-month throughout 2023
- Overall market continues to grow due to increased clinical utilisation
- New entrants having limited impact
- Deeper penetration in large accounts driving Illuccix<sup>®</sup> volume growth and market share gains
- Customer mix continues to evolve (i.e. Medicare and Medicaid), driven by increased presence in larger hospital accounts
- Key differentiators - image accuracy, end-to-end customer support and reliability with 99% on-time delivery – underpin sticky customer relationships



### Revenue from U.S. sales of Illuccix<sup>®</sup>

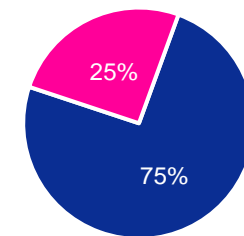


### Customer mix (%) H2 2022



■ Commercial ■ Government

### Customer mix (%) H2 2023



■ Commercial ■ Government

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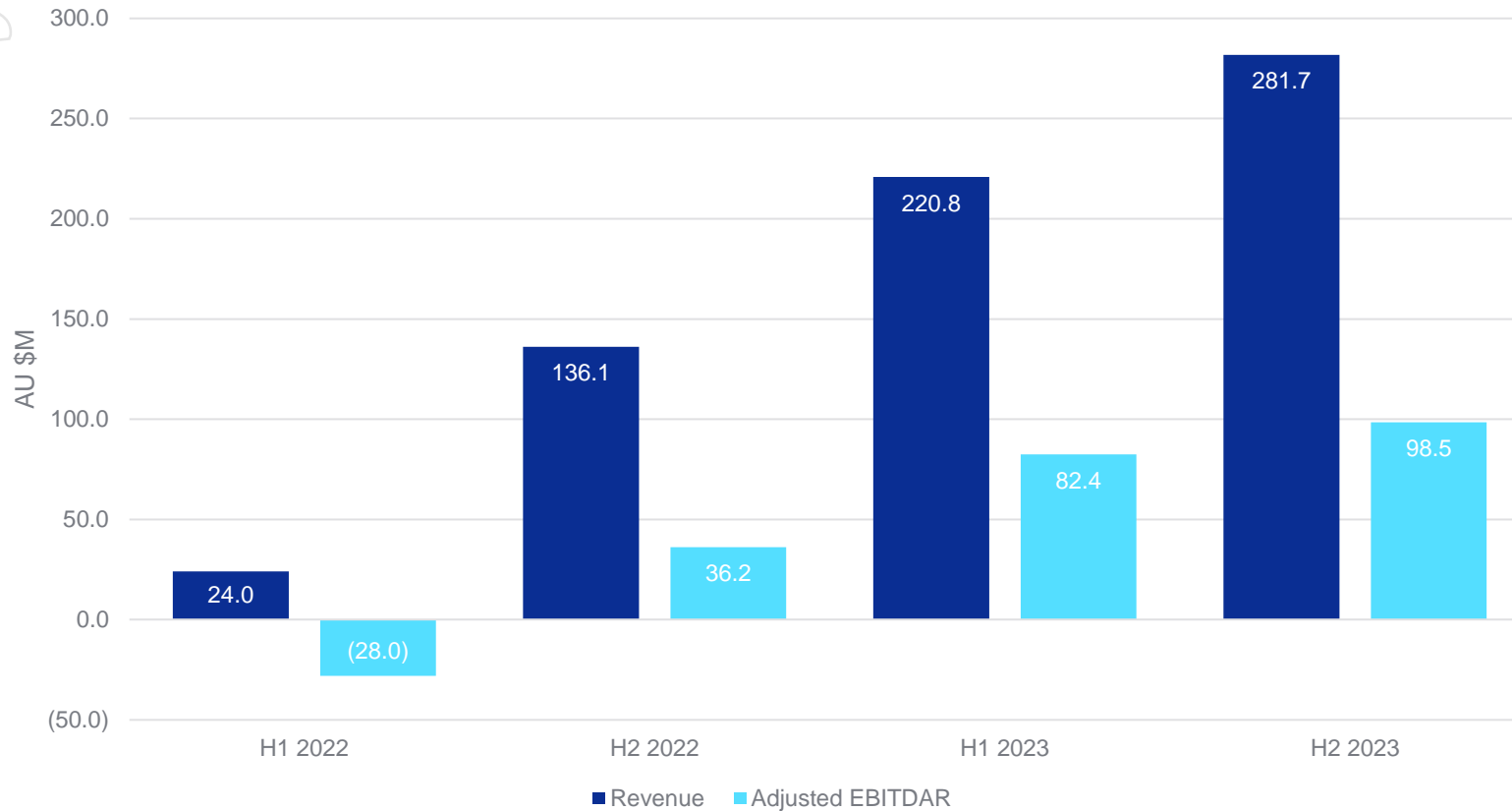
# Financial commentary





# 2023 revenue and adjusted EBITDAR<sup>1</sup>

U.S. sales driving strong, consistent commercial growth



2023 total  
revenue

**\$502.5M**

Up 214% from  
\$160.1M in 2022



1. Earnings before interest, tax, depreciation, amortisation, product development (research and development), other losses (net).

# Group profit and loss statement

## Strong financial stewardship in a period of high growth

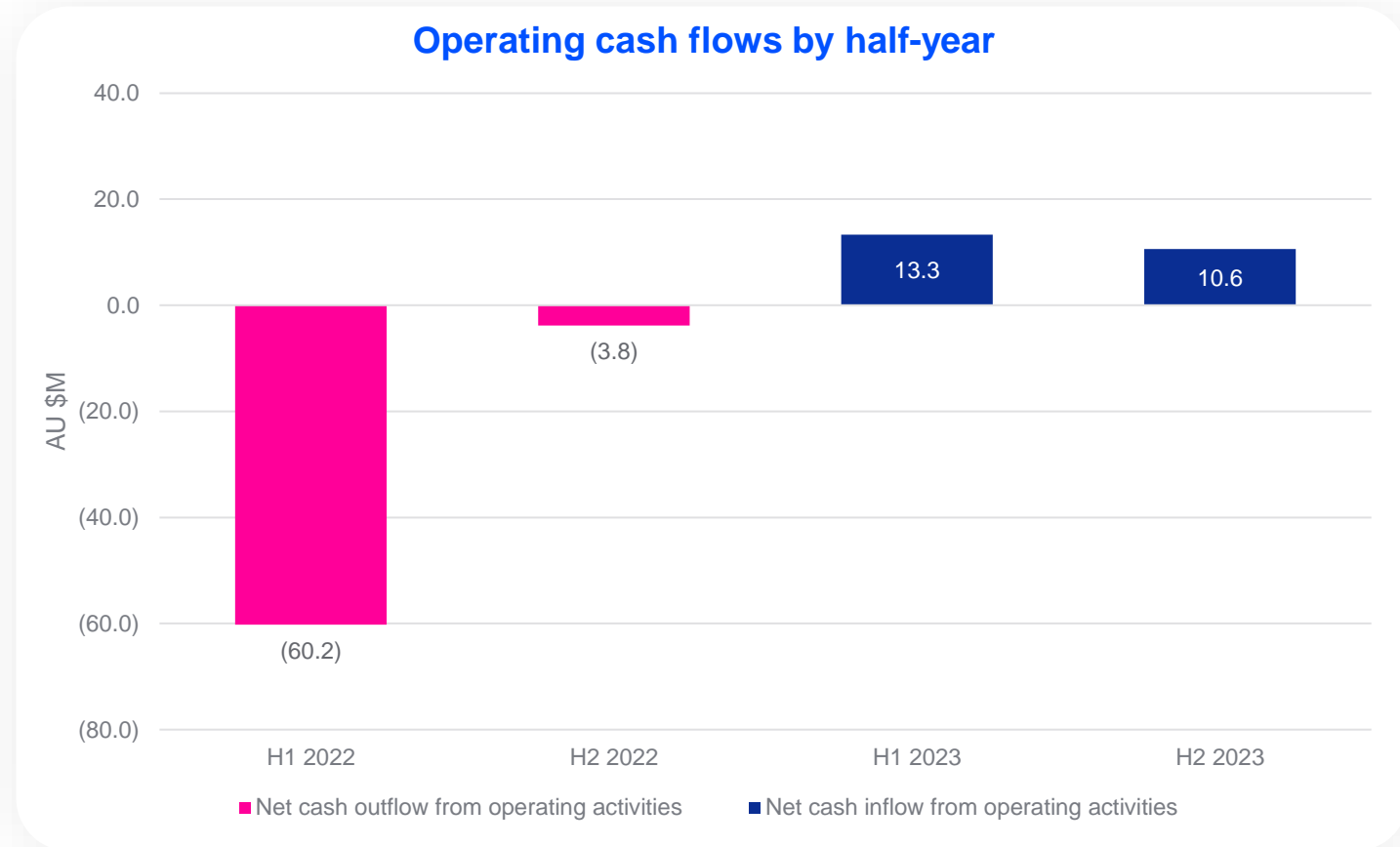
- Gross margin improvement over the full year, reflects optimised distribution and manufacturing costs
- Operating costs have declined as a percentage of sales compared to prior year
- Demonstrates ability to build a sustainable business while investing for growth and pipeline development
- Research and development (R&D) reflects total investment (internal and external expenditure)
- External R&D investment totalled \$86.3M, in line with plan

|                                       | FINANCIAL YEAR |            |                |            | HALF-YEAR    |            |               |            |
|---------------------------------------|----------------|------------|----------------|------------|--------------|------------|---------------|------------|
|                                       | 2023           | % of sales | 2022           | % of sales | H2 2023      | % of sales | H1 2023       | % of sales |
|                                       | \$M            | %          | \$M            | %          | \$M          | %          | \$M           | %          |
| Revenue                               | 502.5          |            | 160.1          |            | 281.7        |            | 220.8         |            |
| Cost of sales                         | (188.2)        |            | (65.2)         |            | (106.5)      |            | (81.7)        |            |
| <b>Gross profit</b>                   | <b>314.3</b>   | <b>63%</b> | <b>94.9</b>    | <b>59%</b> | <b>175.2</b> | <b>62%</b> | <b>139.1</b>  | <b>63%</b> |
| Research and development              | (128.8)        | 26%        | (81.0)         | 51%        | (79.9)       | 28%        | (48.9)        | 22%        |
| Selling and marketing                 | (54.9)         | 11%        | (38.0)         | 24%        | (28.6)       | 10%        | (26.3)        | 12%        |
| General and administration            | (79.0)         | 16%        | (49.1)         | 31%        | (46.6)       | 17%        | (32.4)        | 15%        |
| Other losses (net)                    | (35.9)         | 7%         | (18.8)         | 12%        | 2.3          | 1%         | (38.2)        | 17%        |
| <b>Operating profit (loss)</b>        | <b>15.7</b>    | <b>3%</b>  | <b>(92.0)</b>  | <b>-</b>   | <b>22.4</b>  | <b>8%</b>  | <b>(6.7)</b>  | <b>-</b>   |
| <b>Profit / (loss) before tax</b>     | <b>3.1</b>     |            | <b>(98.6)</b>  |            | <b>15.4</b>  |            | <b>(12.3)</b> |            |
| <b>Profit / (loss) after tax</b>      | <b>5.2</b>     |            | <b>(104.1)</b> |            | <b>19.5</b>  |            | <b>(14.3)</b> |            |
| <b>Adjusted EBITDA</b>                | <b>58.4</b>    |            | <b>(67.8)</b>  |            | <b>23.7</b>  |            | <b>34.7</b>   |            |
| <b>Cash from operating activities</b> | <b>23.9</b>    |            | <b>(64.0)</b>  |            | <b>10.6</b>  |            | <b>13.3</b>   |            |

# Improving operating cash flow

## 2023 delivers first year of net cash inflow from operating activities

- Improved customer receipts reflect sales growth and sound debtor management
- Sound management of working capital
- Operating cash inflow reflects adjusted EBITDA performance and achieving net profit after tax
- Commercial revenue is being deployed to fund investment in core pipeline development, including late-stage programs
- H2 2023 net operating cash inflow includes outflows for Zircaix™ and Pixclara™<sup>1</sup> manufacturing process qualification and validation. Additionally, \$22.2M for ANMI contingent consideration (\$16.3M) and BLA filing fees (\$5.9M)



# Profit contribution from commercial operations

## Validated commercial model

- Revenue increased by 218%, reflecting a full year of commercial sales of Illuccix<sup>®</sup> and continued growth in sales and market share gains
- Selling and marketing expenses reflect increased investment in promotional marketing programs and salesforce operations, effectively deployed to drive higher sales volumes
- General and administration includes investment in infrastructure to support the expansion of services assisting commercial operations in each region

|   | 2023         |              | 2022        |              |
|---|--------------|--------------|-------------|--------------|
|   | AU\$M        | % of revenue | AU\$M       | % of revenue |
| Revenue (product)                         | 497.1        |              | 156.4       |              |
| Cost of sales                             | (188.2)      |              | (65.2)      |              |
| <b>Gross profit</b>                       | <b>308.9</b> |              | <b>91.2</b> |              |
| Selling and marketing                     | (54.4)       | (11%)        | (37.8)      | (24%)        |
| General and administration                | (36.1)       | (7%)         | (17.7)      | (11%)        |
| Other items                               | (1.2)        | (0%)         | (1.5)       | (1%)         |
| <b>Operating profit</b>                   | <b>217.2</b> |              | <b>34.2</b> |              |
|   |              |              |             |              |
| <b>Group adjusted EBITDAR<sup>1</sup></b> | <b>180.9</b> |              | <b>8.2</b>  |              |



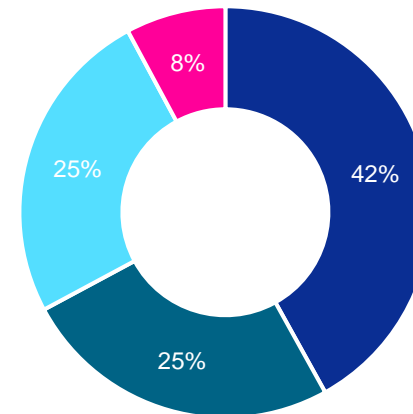
1. Earnings before interest, tax, depreciation, amortisation, product development (research and development), other losses (net).

# 2023 R&D investment breakdown

## Investing in product development to create future value

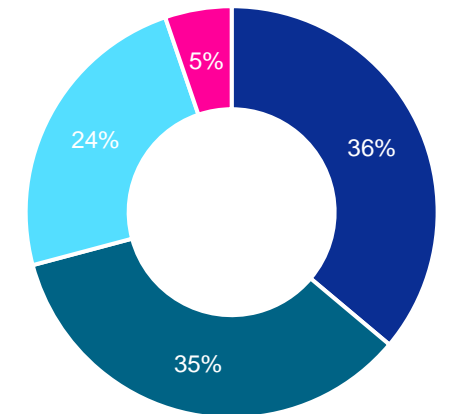
- Growing revenue base deployed to accelerate the development of pipeline assets
- Investment focused on preparation for commercial launch of late-stage diagnostic assets (Zircaix™ and Pixclara™<sup>1</sup>) including:
  - Commercial manufacturing process qualification and validation
  - Preparation of U.S. Food and Drug Administration (FDA) filings
  - Commercial launch plans and early access programs
- Late-stage therapeutic asset spend directed towards clinical manufacturing and progressing ProstACT GLOBAL
- Employment costs and general and administration reflect increased activity in our late-stage assets

2023 R&D costs



- Late-stage diagnostics
- Therapeutics and other assets
- Employment costs

2022 R&D costs



- Therapeutics and other assets
- General and administration costs

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# Clinical programs

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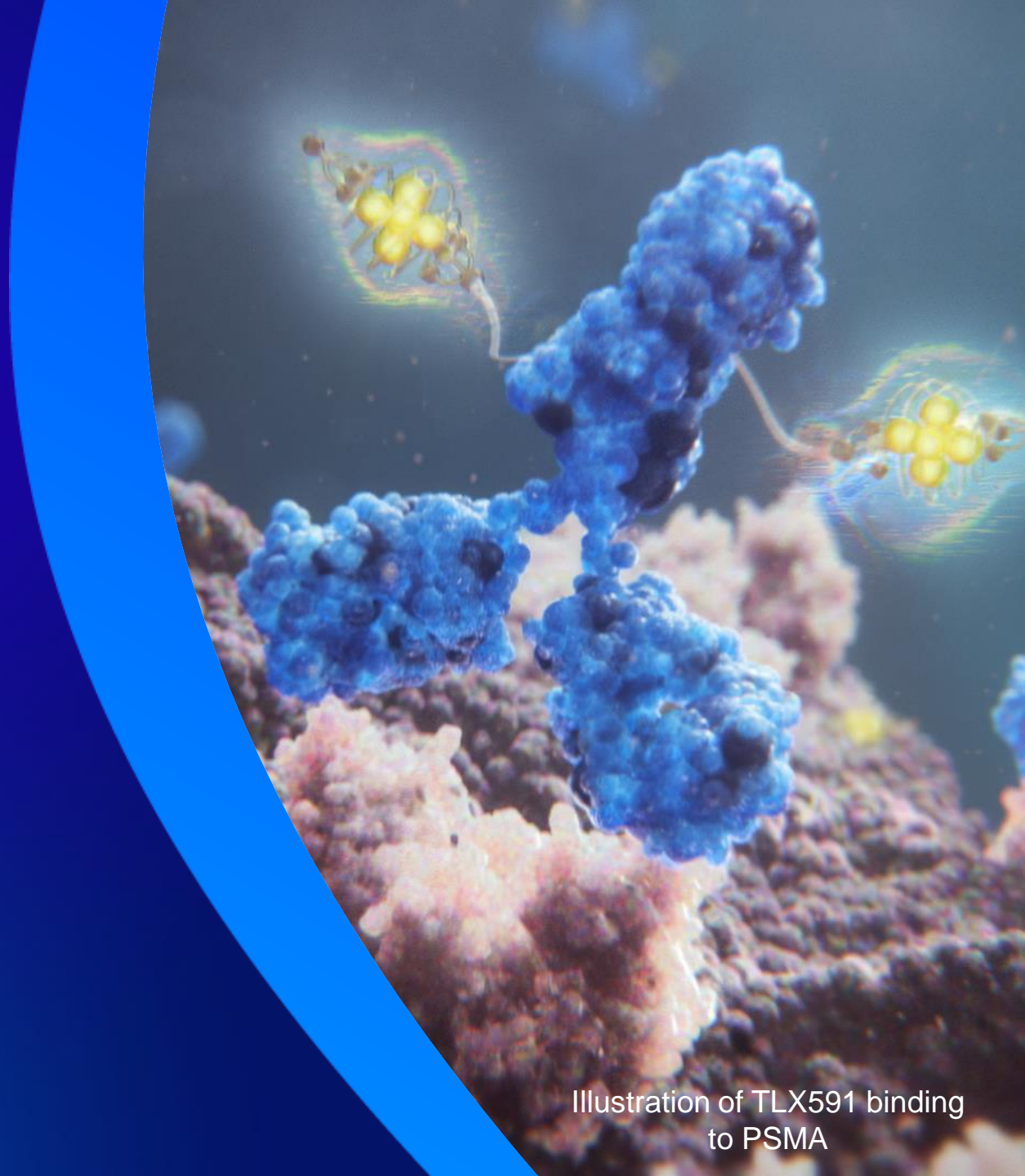


Illustration of TLX591 binding to PSMA

# Pipeline snapshot: oncology and rare diseases

|   | TARGETING AGENT | ISOTOPE           | Dx/<br>Tx | PHASE I  | PHASE II | PHASE III | COMMERCIAL | UPCOMING MILESTONES   |
|---|-----------------|-------------------|-----------|--|----------|-----------|------------|---|
| Prostate<br>PSMA <sup>1</sup>           | Antibody        | <sup>177</sup> Lu | Tx        | TLX591 ( <sup>177</sup> Lu rosopatamab tetraxetan)                   |          |           |            | ProstACT GLOBAL interim readout: Q1 2025  |
|   | Antibody        | α (alpha)         | Tx        | TLX592 (alpha-RADmAb <sup>®</sup> )                                  |          |           |            | Phase I CUPID trial results: H1 2024  |
|   | Small molecule  | <sup>68</sup> Ga  | Dx        | TLX591-CDx ( <sup>68</sup> Ga-PSMA-11, Illuccix <sup>®</sup> )       |          |           |            | EU approval decision: H1 2024<br>Phase III China bridging study complete: H2 2024 |
| Kidney<br>CAIX <sup>2</sup>             | Antibody        | <sup>177</sup> Lu | Tx        | TLX250 ( <sup>177</sup> Lu-girentuximab)                             |          |           |            | Phase II trial data readouts: H2 2024   |
|   | Antibody        | <sup>89</sup> Zr  | Dx        | TLX250-CDx ( <sup>89</sup> Zr-girentuximab, Zircaix <sup>™*</sup> )  |          |           |            | FDA approval decision: H2 2024  |
| Brain<br>LAT1 <sup>3</sup>              | Small molecule  | <sup>131</sup> I  | Tx        | TLX101 ( <sup>131</sup> I-IPA)                                       |          |           |            | Phase I IPAX-2 trial data readout: H1 2025  |
|   | Small molecule  | <sup>18</sup> F   | Dx        | TLX101-CDx ( <sup>18</sup> F-floretyrosine)                          |          |           |            | FDA approval decision: H2 2024  |
| STS <sup>4</sup><br>PDGFRα <sup>5</sup> | Antibody        | Undisclosed       | Tx        | TLX300 (-olaratumab)   |          |           |            | Phase I trial commencement: H1 2024   |
|   | Antibody        | <sup>89</sup> Zr  | Dx        | TLX300-CDx ( <sup>89</sup> Zr-olaratumab)                            |          |           |            |   |
| BMC <sup>6</sup><br>CD66 <sup>7</sup>   | Antibody        | <sup>90</sup> Y   | Tx        | TLX66 ( <sup>90</sup> Y-besilesomab)                                 |          |           |            | Phase II trial commencement: H1 2024  |
|   | Antibody        | <sup>99m</sup> Tc | Dx        | TLX66-CDx ( <sup>99m</sup> Tc-besilesomab, Scintimun <sup>®8</sup> ) |          |           |            |   |



\*Note: Nominated trade name subject to final regulatory approval.

1. Prostate-specific membrane antigen.
2. Carbonic anhydrase IX.

3. L-type amino acid transporter 1.

4. Soft tissue sarcoma.
5. Platelet derived growth factor receptor alpha.

6. Bone marrow conditioning.

7. Cluster of differentiation 66.
8. Marketed under license by Curium Pharma.

# Core pipeline: 2023 achievements and near-term milestones



## PROSTATE CANCER THERAPY



### 2023 achievements

- ProstACT SELECT positive interim data
- ProstACT GLOBAL dosing patients in APAC



### Upcoming milestones 2024

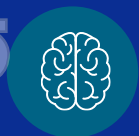
- ProstACT GLOBAL to open in U.S.
- Data from SELECT and CUPID (592) trials
- ProstACT GLOBAL interim readout (2025)



## CAIX PROGRAM (INCLUDING RENAL CANCER)

- TLX250-CDx (Zircaix™<sup>1</sup>) BLA submitted
- Four clinical trials dosing patients
- OPALESCENCE positive data in TNBC<sup>2</sup>

- Zircaix™<sup>1</sup> U.S. launch on FDA approval
- Initial data from STARLITE-2 trial
- Continuation of global EAP<sup>3</sup>



## GLIOMA IMAGING AND THERAPY

- IPAX-2 second patient cohort enrolled
- IPAX-Linz exceeds 70% recruitment

- NDA submission for TLX101-CDx
- Completion of IPAX-2 and IPAX-Linz trials
- Initiation of global label-indicating study



## RARE DISEASES PROGRAM<sup>4</sup>

- Pre-clinical proof of concept for radiolabelled olaratumab (TLX300)
- Ethics application submitted for TLX300-CDx trial in soft tissue sarcoma

- TLX66: Commencement of Phase II trial
- Commencement of biodistribution and safety study of TLX300-CDx



1. Trade name subject to final regulatory approval.
2. Triple-negative breast cancer.
3. Expanded access program.
4. Rare disease program includes programs for bone marrow conditioning and soft tissue sarcoma.



# ProstACT GLOBAL trial design

Recruiting patients, designed to integrate with real-world standard of care



ProstACT  
GLOBAL

Phase III trial in patients with mCRPC<sup>1</sup> progressing on 1<sup>st</sup> line androgen agents or docetaxel

TLX591 + Standard of Care (SoC) vs. SoC alone

Product designed to be “patient-centric”, only requires two treatments with TLX591 compared with up to six treatments with competitor products. Potential for less off-target toxicity.

Global study enrolling ~400 patients  
Interim readout planned for Q1 2025

N = ~400 patients

Randomisation stratification 2:1

- SoC – ARPI<sup>2</sup> or docetaxel
- Disease burden
- Visceral disease

Patients progressing on minimum of 12 weeks ARPI



PSMA-positive disease

Endpoints

Primary: rPFS<sup>3</sup>

Secondary: OS,<sup>4</sup> PFS,<sup>5</sup> SSE,<sup>6</sup> PSA50,<sup>7</sup> quality of life and safety and tolerability

Group A  
2 x 76mCi  
TLX591 +  
SoC

Group B  
SoC

SoC, either:

- ARPI alone
- Taxane alone



1. Metastatic castrate-resistant prostate cancer.
2. Androgen receptor pathway inhibitor.
3. Radiographic progression-free survival
4. Overall survival
5. Progression-free survival.

6. Symptomatic skeletal event.
7. Prostate-specific antigen decline of >50%.

# Strategic acquisition: QSAM Biosciences, Inc

## Highly complementary addition to Telix's therapeutic pipeline

### About the company

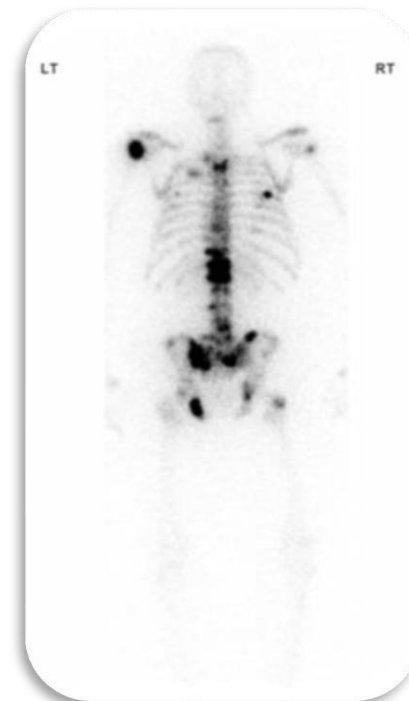
- Austin, TX-based company
- Launched in 2019, U.S. OTC-listed
- Founded by a scientific leadership team with extensive radiopharmaceutical experience

### Transaction details

- Upfront: US\$33.1M (AU\$50.8M)<sup>1</sup> payable in ordinary shares at closing, subject to certain adjustments
- Contingent Value Rights: Entitling holders to receive up to US\$90M (AU\$138M)<sup>1</sup> payable in cash and/or equity, subject to achievement of agreed clinical and commercial milestones

### About the technology

- “Next generation” bone seeking targeted radiopharmaceuticals
- Proven isotope platform for this application: <sup>153</sup>Sm (samarium) combined with “next generation” chelator technology
- Two major potential applications in bone cancer: Pain management of osteoblastic bone metastases and osteosarcoma
- Kit-based, leverages Telix's integrated supply and distribution expertise

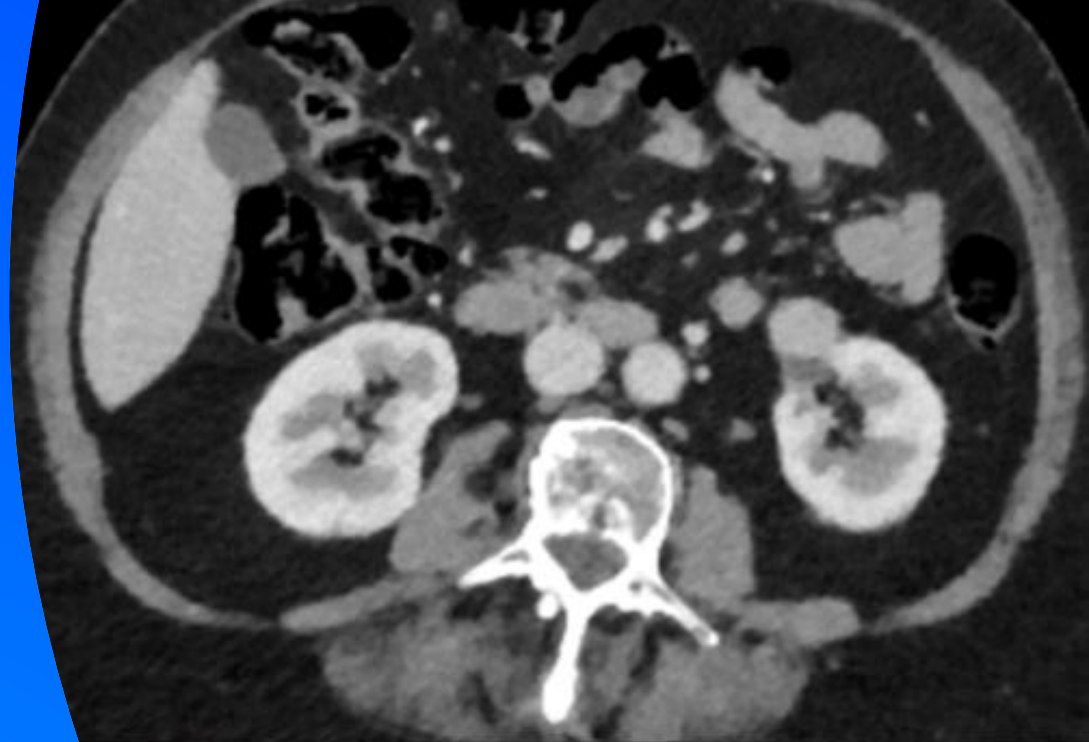


Whole body SPECT/CT<sup>2</sup> scan of metastatic prostate cancer patient showing bone tumour uptake and continued concentration of <sup>153</sup>Sm-DOTMP at bone lesions (brighter areas seen at 48 h). Patient representative scan - individual results may vary.

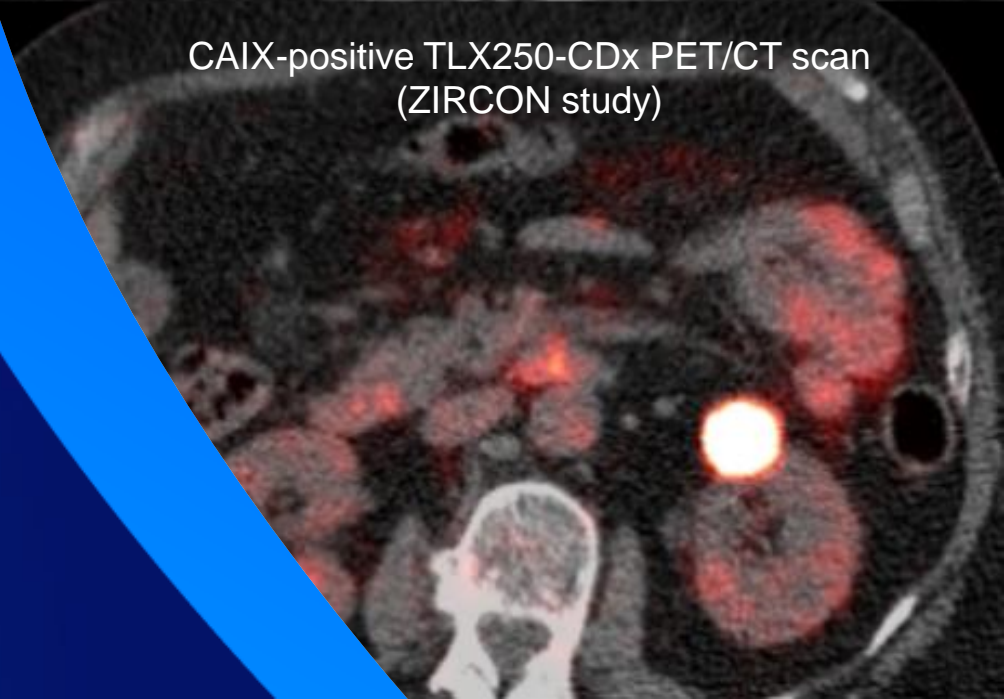
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# Imaging portfolio

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CAIX-positive TLX250-CDx PET/CT scan  
(ZIRCON study)



# Update: TLX250-CDx (Zircaix™<sup>1</sup>) in kidney cancer imaging

## \$500M+ initial U.S. opportunity, further expansion potential in staging and recurrence

### Annual potential scans estimate

#### Potential clinical utilisation:

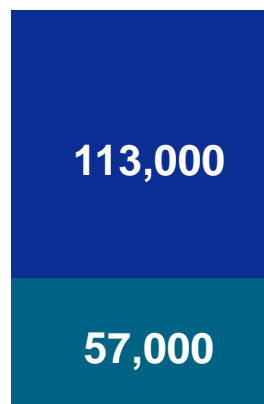
1. Characterisation of renal masses as ccRCC
2. Staging of ccRCC, detection of recurrence

**U.S. BLA filing commenced on a rolling review. Commercial launch H2 2024<sup>1</sup>**

**U.S. TAM**  
170,000+ scans



**Upside to TAM from multiple scans per patient, active surveillance**



**Initial opportunity: USD \$500M+**

- 63k ccRCC patients per year<sup>2-3</sup>
- 50k other renal masses per year<sup>4-11</sup>

**Expansion potential in new indications<sup>12-13</sup>**

**U.S. total addressable market (TAM) USD \$750M+**

1. Trade name subject to regulatory approval
2. SEER. (2022). Cancer Stat Facts: Kidney and Renal Pelvis Cancer: <https://seer.cancer.gov/statfacts/html/kidrp.html>.
3. STATPEARLS Rahul D. Arora 2020;11(3):79-87.
4. Sigmon et al. 2022, StatPearls Renal cyst article
5. Garfield et al. 2022, StatPearls Simple Renal Cyst Article; Tay et al. 2018 JGIM
6. Cancer.Org, Kidney Cancer Key Statistics
7. Escudier et al. 2019, Annals of Onc; ESMO guidelines RCC
8. Mittal et al. 2016, Ind J Rad Img

9. Metin et al. 2022, Medicina (Kaunas)
10. Tshering Vogel et al. 2021, Urology; Di Vece et al. 2016, Ultrasound
11. Vasudev et al. 2020, BMJ
12. Pharmintelligence RCC – Accessed January 2024
13. Hollenbeak et al. 2019, BMC Urology

# Update: TLX101-CDx (Pixclara™<sup>1</sup>) in brain cancer imaging

\$100M-140M initial U.S. opportunity, upside to \$475M-665M from indication expansion

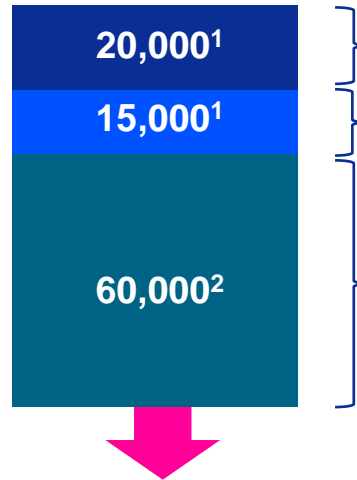
## Annual potential scans estimate

### Potential clinical utilisation:

- 1. Glioma:**  
Characterisation of recurrence
- 2. Glioma:**  
Radiation treatment planning
- 3. Brain metastases:**  
Characterisation of recurrence

**U.S. NDA submission  
Q1 2024**

**U.S. TAM  
95,000+ scans**



**Initial opportunity: USD \$100-140M  
Exploring through ongoing clinical  
studies**

**Further potential in brain metastases**

**U.S. total addressable market (TAM) value USD \$475M-\$665M**

1. Trade name subject to regulatory approval.

2. Ostrom 2022, CBTRUS (Central Brain Tumour Registry of the United States) Statistical Report; Dressler Neuro-Oncology Practice, 2019. Annavarapu 2021, CNS Oncol.

3. Amsbaugh 2023, StatPearls.

Note: Dollar (\$) values are management estimates based on ACS (US)

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# Outlook



# Guidance

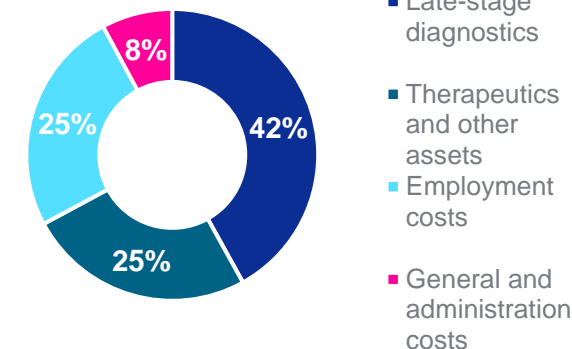
## 2024 financial performance

- Full year revenue expected range of US\$445M to US\$465M (\$675M to \$705M at current exchange rates), representing a ~35-40% increase on 2023
- Revenue guidance is based on worldwide sales of Illuccix<sup>®</sup>, with potential upside from Zircaix<sup>™1</sup> (kidney cancer imaging) and Pixclara<sup>™1</sup> (glioma imaging), subject to product regulatory approvals. Guidance will be updated as appropriate to reflect product approvals
- Expected additional investment 40-50% in R&D (compared with 2023), including both external and internal costs funded by operating cash flow and broadly in line with revenue growth
- 2024 R&D investment activity is expected to include:
  - Validation of commercial manufacturing and market launch activities in preparation of approval of Zircaix<sup>™1</sup> and Pixclara<sup>™1</sup>
  - Fully operationalised ProstACT GLOBAL therapy trial in prostate cancer and initiation of additional therapeutic clinical trials, including manufacturing activity, across the broader pipeline
  - Indication expansion and life-cycle management of Illuccix<sup>®</sup>

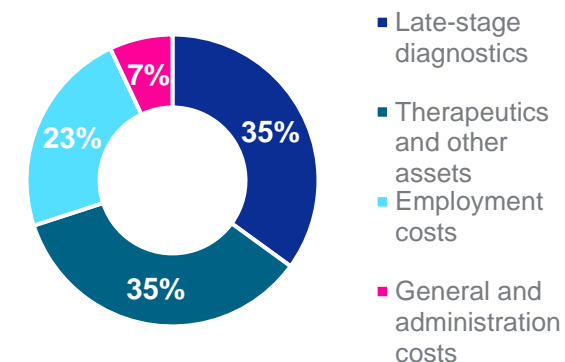


1. Trade name subject to final regulatory approval.

### Total R&D investment allocation 2023



### Planned total R&D investment allocation 2024



# A strong foundation for growth

## R&D program to drive value creation

### Progress late-stage therapeutics

- Phase 3 ProstACT GLOBAL trial for prostate cancer therapy (TLX591)
- Phase 2 STARLITE trials and Phase 1b STARSTRUCK trial of TLX250
- Phase 2 trials exploring CAIX pan-cancer utility

### Advance next-generation “alpha” radiopharmaceuticals

- Additional trial of alpha therapy candidate for prostate cancer (TLX592)<sup>1</sup>
- Phase 1 trial of TLX300-CDx in soft-tissue sarcoma expected to commence in 2024<sup>1</sup>



### Commercialise diagnostics

- Planned launch of Zircaix™ and Pixclara™<sup>1</sup>
- Geographic expansion of Illuccix®
- Illuccix® life cycle management

### Vertically integrate supply chain

- Continue to expand U.S. manufacturing footprint
- Enhance in-house process development and production capacity



1. Subject to regulatory approval.



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