



Q4 2022 Quarterly Business Update

Telix Pharmaceuticals (ASX:TLX)

18 January 2023



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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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Today's presenters



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**GROUP CHIEF
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Q4 2022 Highlights



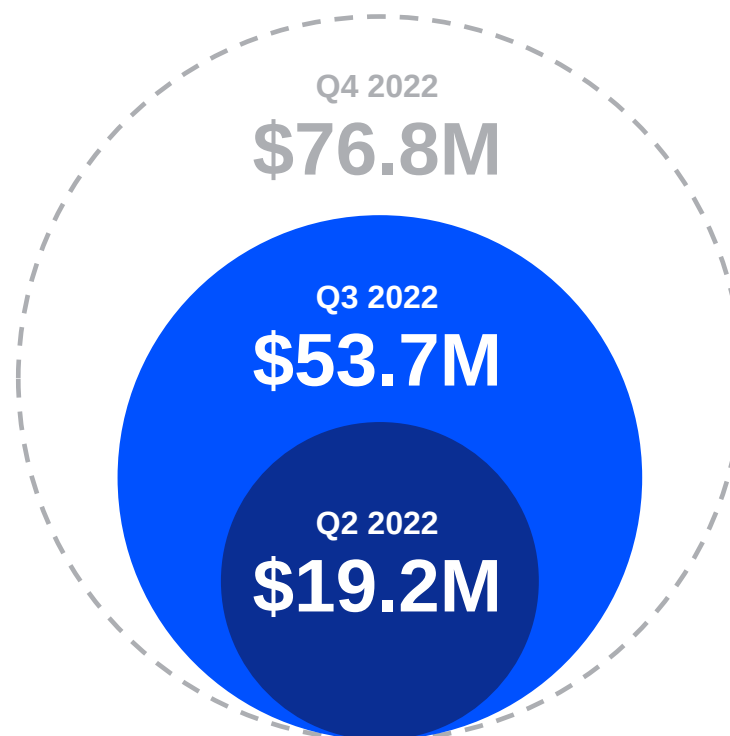
Building on a transformative year

Major milestones delivered, value creating catalysts ahead

Key milestones in Q4 2022¹

- Achieved **positive cash flow** from operating activities, **\$1.6M inflow**
- Revenue from sales of Illuccix in the U.S. **up 43% to \$76.8M** on prior quarter
- U.S. dose demand continues to increase, reflected in **continued month on month growth**
- Highly **positive data** from **ZIRCON** Phase III kidney cancer imaging study (TLX250-CDx)²

Revenue from U.S. Illuccix® sales Q2 to Q4 2022



2023 catalysts

- Illuccix® - **continued revenue growth** and global rollout
- Biologics License Application (BLA) **submission for TLX250-CDx**
- New Drug Application (NDA) for **TLX101-CDx brain (glioma) cancer imaging**
- Prostate cancer therapy program: ProstACT GLOBAL **patient recruitment** and ProstACT SELECT **data readout**

Q4 2022 key financial metrics

Telix reports first positive cash flow quarter



Total revenue

\$78.2M

Up 41 percent from
\$55.3M in Q3 2022



U.S. sales revenue

\$76.8M

Up 43 percent from
\$53.7M in Q3 2022



Receipts from customers

\$72.2M

Up 62 percent from
\$44.5M in Q3 2022



Cash balance

\$116.3M

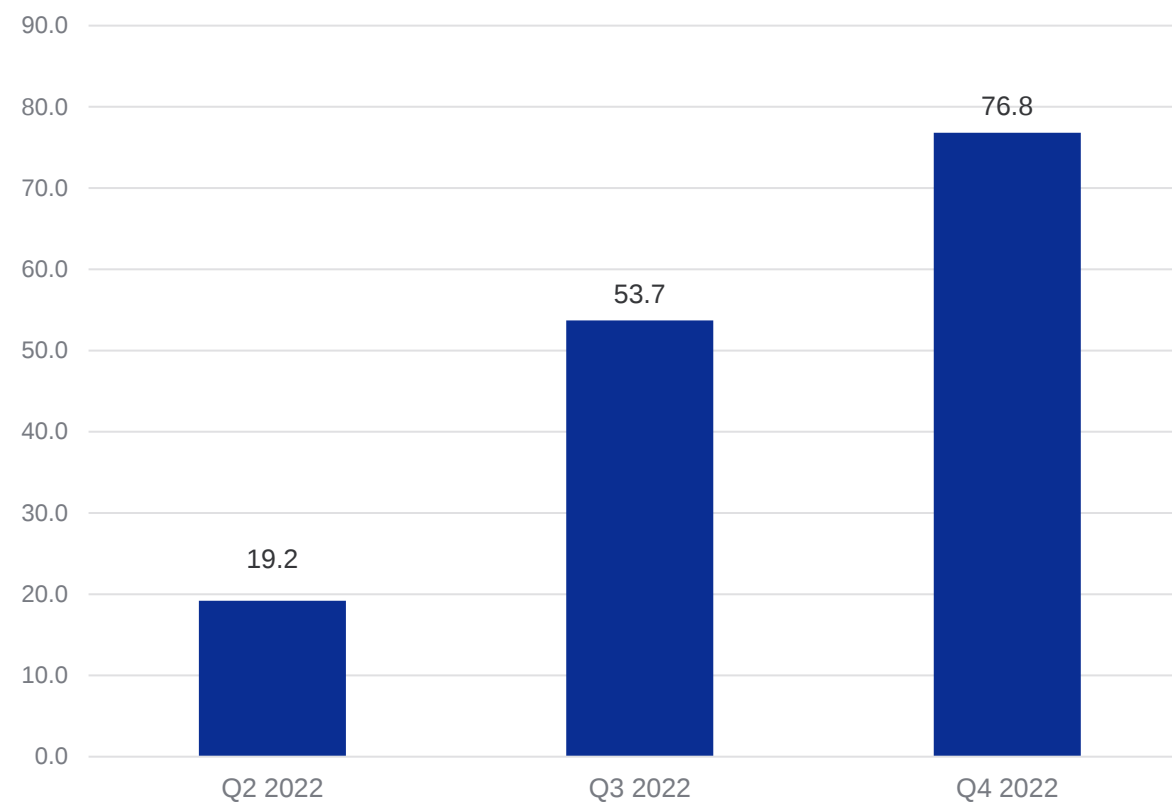
As of 31 Dec 2022
(\$117.1M, 30 Sept 2022)

Illuccix® revenue continues to grow

Q4 performance evidence of strong growth trajectory

- Revenue from U.S. sales of Illuccix up 43% to \$76.8M (US\$50.5M) on the prior quarter
- Reimbursement improving across MACs¹ as Telix specific code is leveraged at an improved rate
- 190 pharmacies routinely dispensing Illuccix across the U.S. and Puerto Rico
- Dose demand driven by new sites added throughout the quarter, combined with repeat orders from existing customers
- Wider adoption of PSMA-PET imaging and evolving patterns of use in routine clinical practice continuing to drive market growth
- Label expansion to include patient selection for therapy: PDUFA² goal date 17 March 2023

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



1. Medicare Administrative Contractor (MAC)
2. Prescription Drug User Fee Act

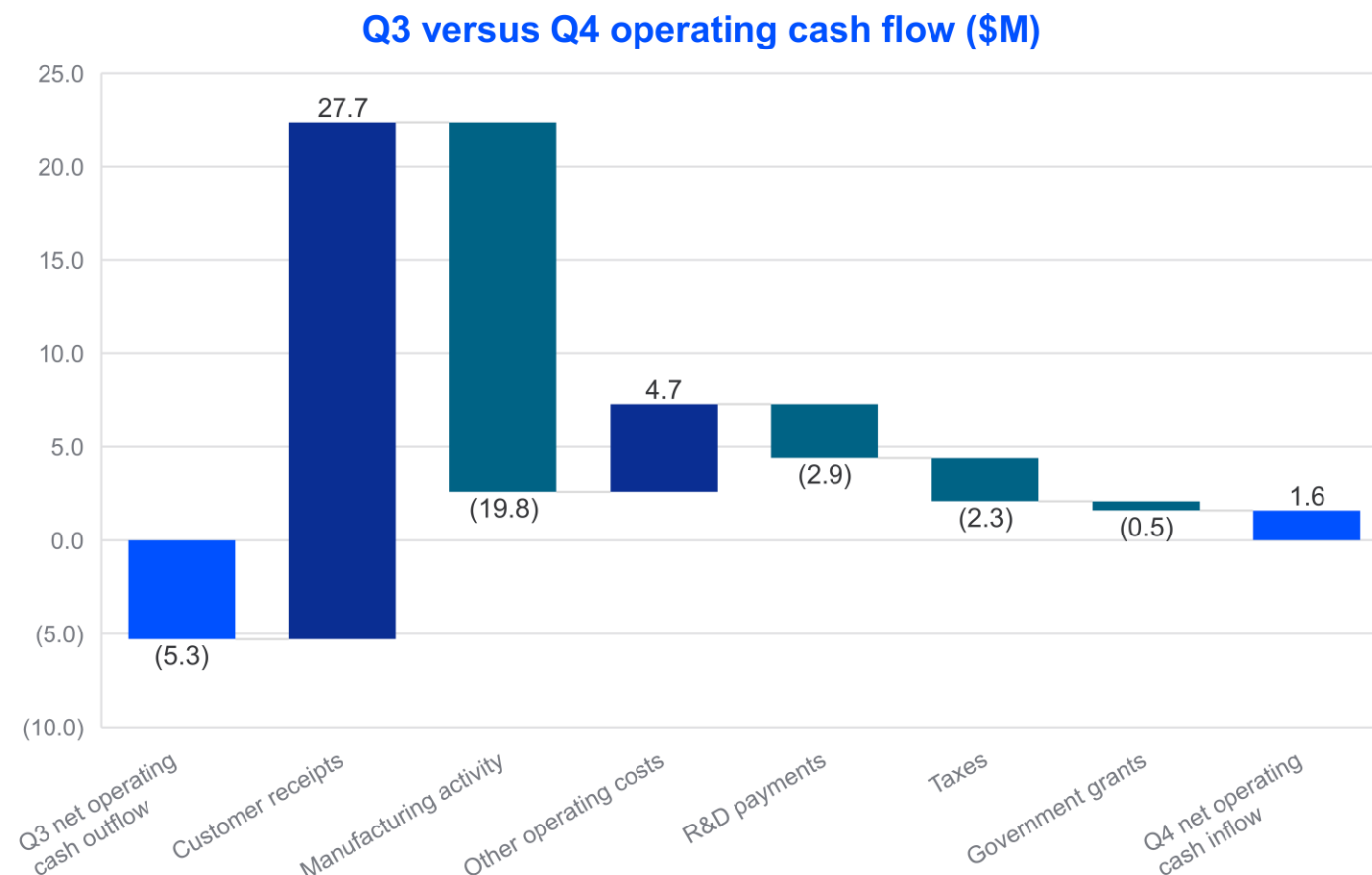
Financial Commentary



Q4 records positive operating cash flow of \$1.6M

First quarter of net cash inflow from operating activities

- Quarterly cash flow improved \$6.9M over prior quarter with a positive \$1.6M inflow
- Customer receipts of \$72.2M, improved 62% over prior quarter, reflecting sales growth and improved collection performance
- Manufacturing and other related costs increased reflecting higher sales volumes and timing of payments
- Other operating cash flow items¹ reduced by \$4.7M compared with prior quarter due to improved working capital management
- Q4 cash outflow includes tax payments in the U.S. and Belgium



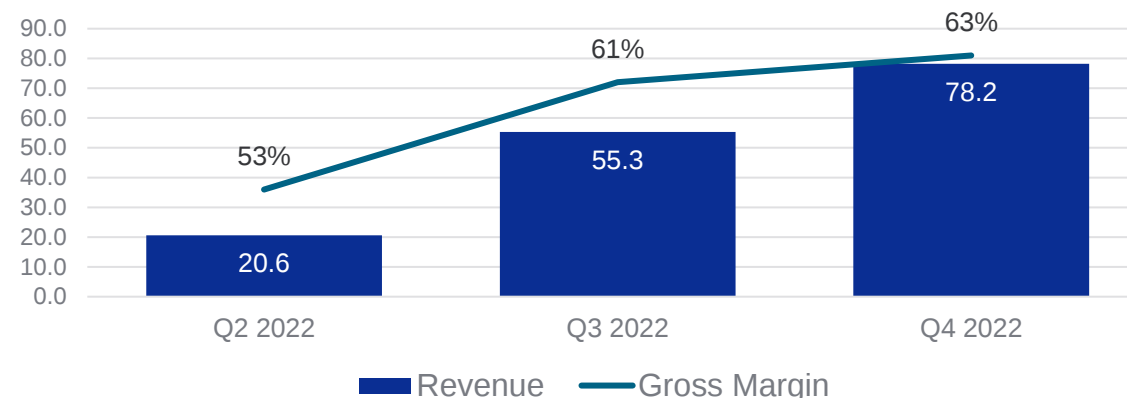
1. Advertising and marketing, staff costs and administration and corporate costs

Sales performance and controlling operating expenditure

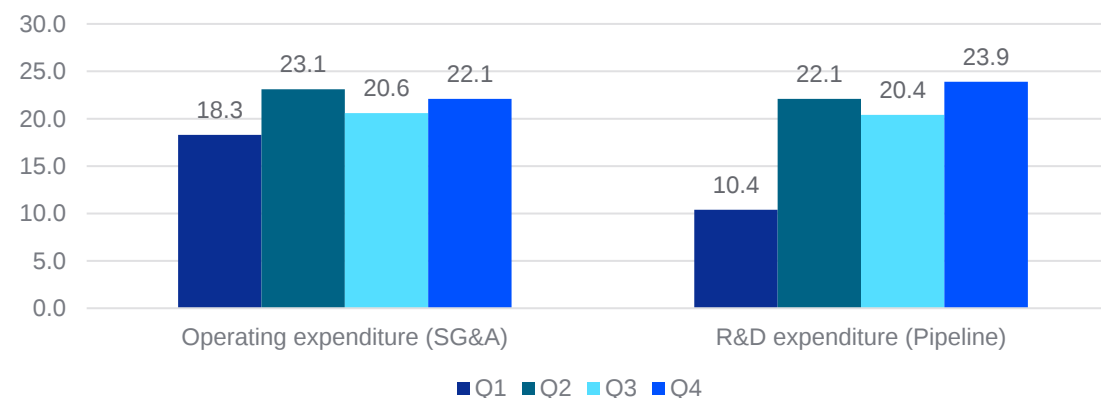
Funding focused investment in priority programs

- Gross margin improvement of 2% from Q3 to Q4 reflects further efficiency gains in manufacturing costs
- Operating expenditure¹ reduced to 28% of sales (37%, Q3 2022) as investment in operational infrastructure stabilises
- R&D investment focused on commercialising late-stage assets and progressing the development of high value assets:
 - TLX250-CDx regulatory filing and manufacturing scale-up
 - ProstACT GLOBAL Phase III manufacturing and international trial commencement
- Continued sales growth and operating expenditure control provides further focused R&D opportunity

Revenue (\$M) and gross margin percentage



Key expenditure (\$M)²



1. Advertising and marketing, staff costs and administration and corporate costs.
2. Q4 2022 operating expenditure excludes a one-off non-cash share based payment charge of \$4.7M.

Four major focus areas in 2023

Value creating catalysts across the imaging and therapeutic pipeline

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

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

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

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

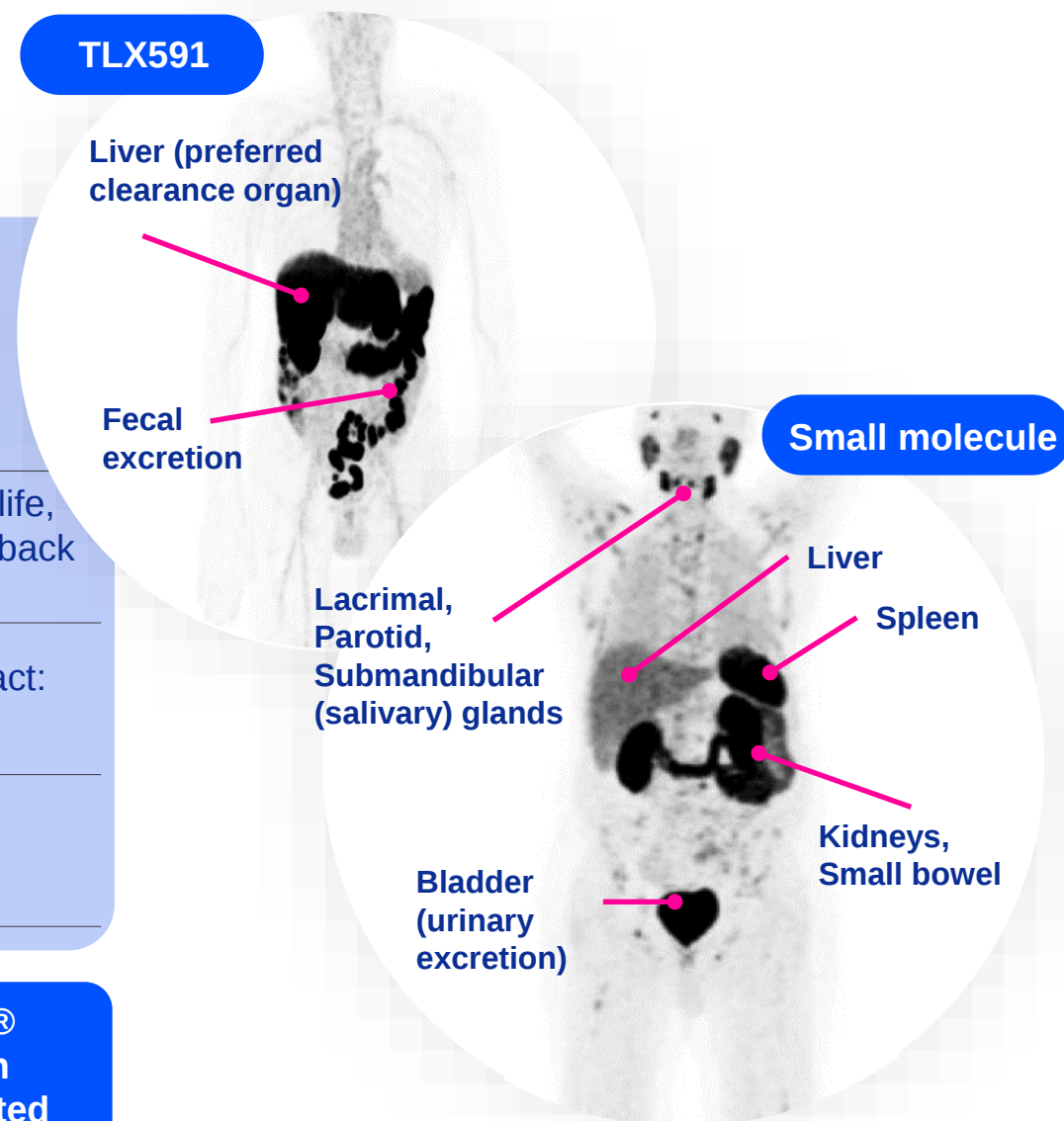
PSMA competitive landscape

Telix approach is highly differentiated

ANTIBODY (TLX591)	SMALL MOLECULES
Functionally specific for tumour-expressed PSMA, does not “hit” most endogenous PSMA	Taken up by endogenous PSMA
Reduced off-target radiation, reduced potential for undesirable side-effects ¹	Off-target effects impact quality of life, including dry eye, xerostomia and back pain from ganglia irradiation
Longer circulation time and tumour retention, cleared in the liver and excreted, allowing for fewer doses ²	Rapidly excreted via the urinary tract: approx. 70% activity lost by 12 hrs
Shortest dosing regimen of all PSMA therapies, two x 76 mCi doses, 14 days apart	Dosing regimens range up to 36 weeks, at up to 200 mCi per dose

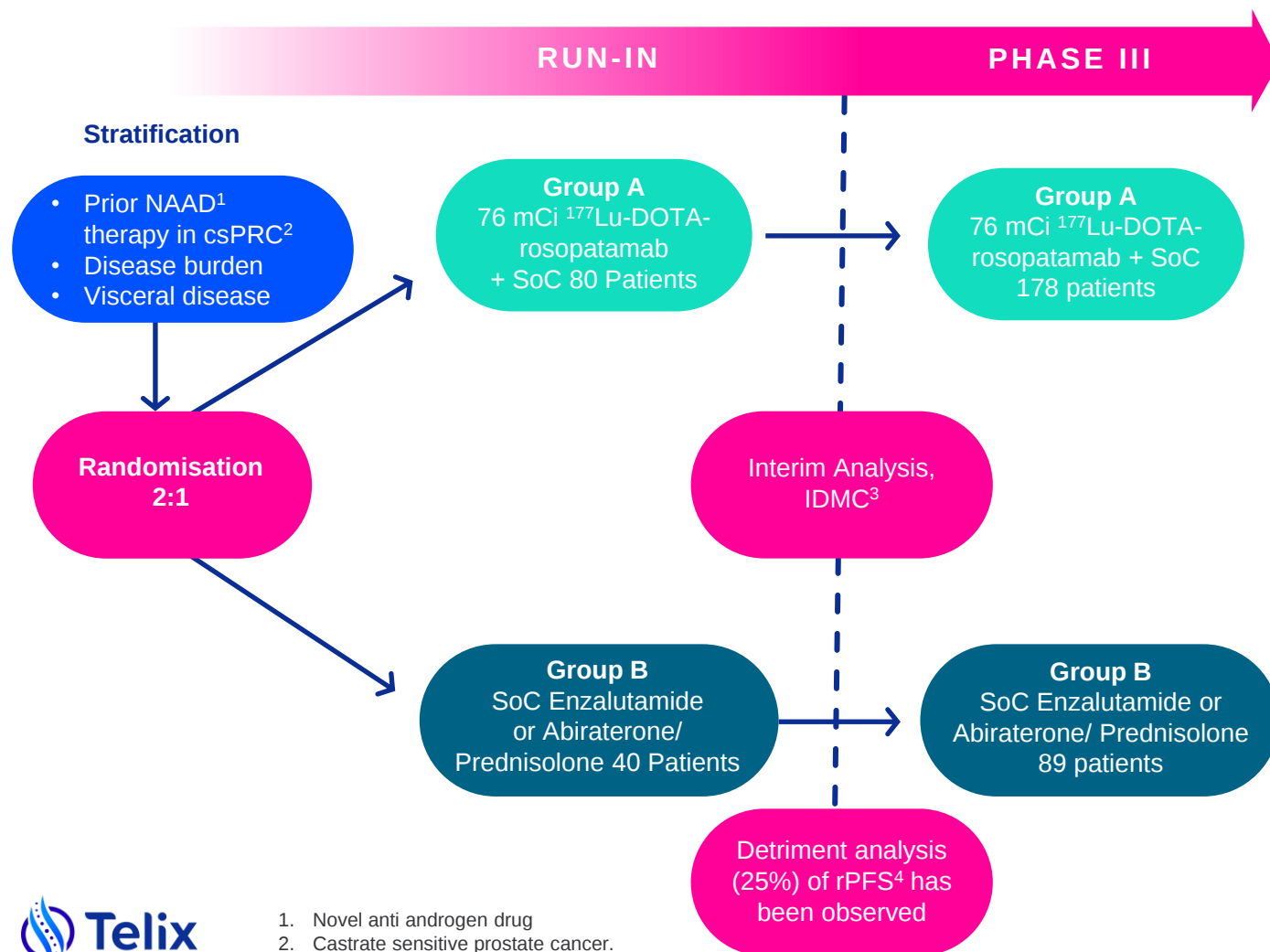
TLX591 is the most clinically advanced antibody-based PSMA therapy in development

Approved product: Pluvicto® (Novartis). Other products in development are undifferentiated



TLX591: ProstACT GLOBAL study overview

U.S. and EU patient enrolment commencing in 2023



Summary

- Total patients: ~392
- “Run-in” to accommodate new scale-up manufacturing method
- Interim analysis expected after the first 120 patients
- Enables for early readout, discussion opportunities, allows earlier assessment of study
- *PSMAfore* study reinforces potential for PSMA targeted radioligand therapy throughout prostate cancer journey
- TLX591 is the most advanced PSMA antibody therapy in development – investigator interest in U.S. and ROW is high

TLX101-CDx: value proposition for glioma imaging

Potential to lead with first commercial FET-PET solution for U.S. market

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/treatment monitoring

2

Identification of pseudoprogression vs actual progressive disease (PD)

- Weekly MRIs over 4 – 12 weeks is 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

505(b)2 NDA preparation underway, pre-submission meeting in planning to finalise submission strategy

TLX250-CDx: imaging agent with high commercial potential

Strong results support potential for TLX250-CDx to change standard of care

Top-line data reported in November 2022¹

- **93% positive predictive value (PPV)**
- **Primary endpoint met:** Sensitivity of $\geq 84\%$ and specificity of $\geq 84\%$ in all three readers (86% / 87% overall)
- Considerably exceeds confirmatory trial sensitivity and specificity success target of 70%
- **Key secondary endpoints met**, namely sensitivity and specificity targets in small renal masses (less than 4cm)
- Clinical data presentation at ASCO-GU February 2023²

Planning for FDA regulatory approval in 2024

- Phase III data demonstrates TLX250-CDx provides a way to non-invasively diagnose and characterise clear cell renal cell carcinoma (ccRCC) – delivering on a major unmet medical need
- Data strongly validates that the CAIX target is potentially as ground-breaking in ccRCC, as prostate-specific membrane antigen (PSMA) has been for prostate cancer
- Potential to change standard of care in the diagnosis and management of renal masses and ccRCC
- An effective non-invasive tool for more confident decision making



TLX250-CDx: U.S. market opportunity

Identification and characterisation of ccRCC

FUTURE

New incidental renal mass

- Estimated 73,994 incidental findings
- Over 1/3 of IDRM are non-ccRCC¹
- >45% of small renal masses <1cm are benign²

Renal cancer diagnosis

- 79,000 patients will be diagnosed with RCC in 2022 in the U.S.³
- 80% of patients with RCC are clear cell⁴
- Over 60% of ccRCC is found incidentally⁵

Of total patient population ~ 110,000 expected to be suitable for imaging with TLX250-CDx

Initial addressable market

>US\$500M
in the U.S.

Active surveillance for known renal mass

- Prevalence unknown
- Active surveillance is recommended for patients with select renal masses (e.g. older patients, <2cm)
- A 6-monthly, then annual, CT/MRI scan is currently recommended in the NCCN Guidelines® kidney cancer v3.2023

Previously treated ccRCC high risk

- 599,000 patients living with kidney cancer in the U.S.³ in 2019



1. Telix: Data on file from ZIRCON study (patients with IDRM diagnosed every year).
2. Johnson et al., 2015.
3. SEER. (2022). Cancer Stat Facts: Kidney and Renal Pelvis Cancer: <https://seer.cancer.gov/statfacts/html/kidrp.html>.
4. STATPEARLS Rahul D. Arora 2020;11(3):79-87.
5. Vasudev et al. BMJ 2020.

Note: TLX250-CDx pricing estimate based on Illuccix.

Upcoming catalysts

Four key catalysts

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 data readout
ProstACT SELECT**

EXPECTED MILESTONES 2023

Additional milestones

Illuccix® label expansion

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

Illuccix EU resubmission

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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