



1H 2022 Financial Results Presentation

Telix Pharmaceuticals Limited

18 August 2022



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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), and the U.S. Food and Drug Administration (FDA). Telix is also progressing marketing authorisation applications for Illuccix in Europe and Canada.

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

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MEDICAL OFFICER

Agenda

- **1H 2022 milestones**

- **Commercial update**

- **1H 2022 financial results overview**

- **Clinical programs update**

- **Pipeline expansion highlights**

- **Outlook**

Major milestones delivered in 1H 2022

We are delivering to our strategic priorities



Use Illuccix as a commercial launchpad

- U.S. launch off to a strong start, additional global approvals expected
- IND¹ filed for Phase III bridging study in China



Create a high-value diagnostic portfolio

- ZIRCON Phase III trial completed, indication expansion in planning
- Preparing to file NDA² with FDA³ for brain cancer imaging



Advance core therapeutics

- Urology therapies (prostate and renal) enrolling patients
- Follow-on data and further studies advancing for TLX101 and TLX66



Pipeline and manufacturing

- Build-out of manufacturing facility in Brussels South underway
- In-licencing deal with Eli Lilly and Company (Lilly) for olaratumab
- Regulatory filing planned for Telix AI™ platform



Commercially-focused leadership

- Darren Smith appointed as Group CFO
- Kevin Richardson appointed as CEO Americas
- Tiffany Olson appointed to the Board of Directors

Financial dashboard

Key financial metrics underpin commercial transition



1H 2022 Revenue¹

\$24.0M

Up 726% from
\$2.9M in 1H 2021



Cash balance

\$122.6M

Closing cash balance as at 31
December 2021 was \$22.0M



1H 2022 R&D investment

\$24.8M

Up 82% from
\$13.7M in 1H 2021



1H 2022 loss after tax

\$70.9M

Up 118% from
\$32.5M in 1H 2021

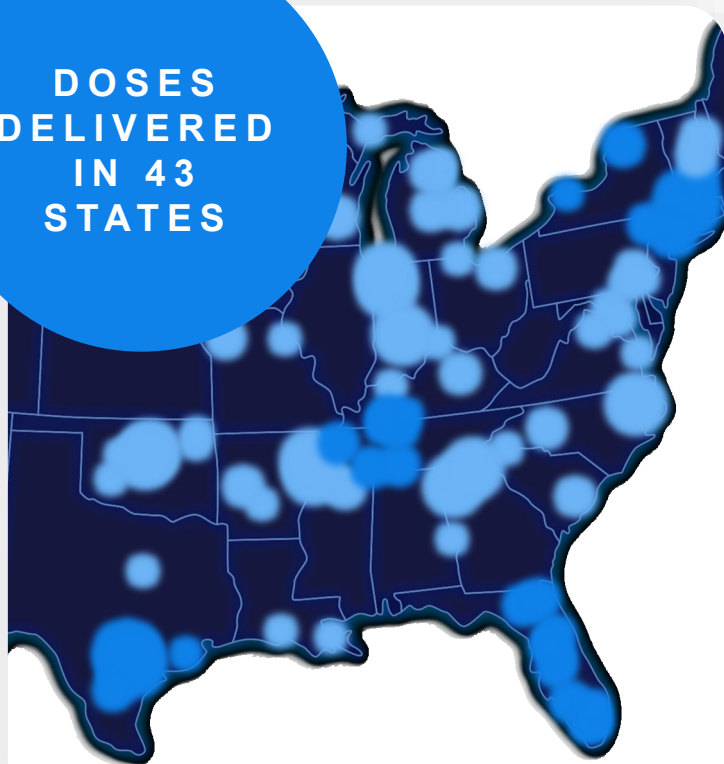
Commercial update



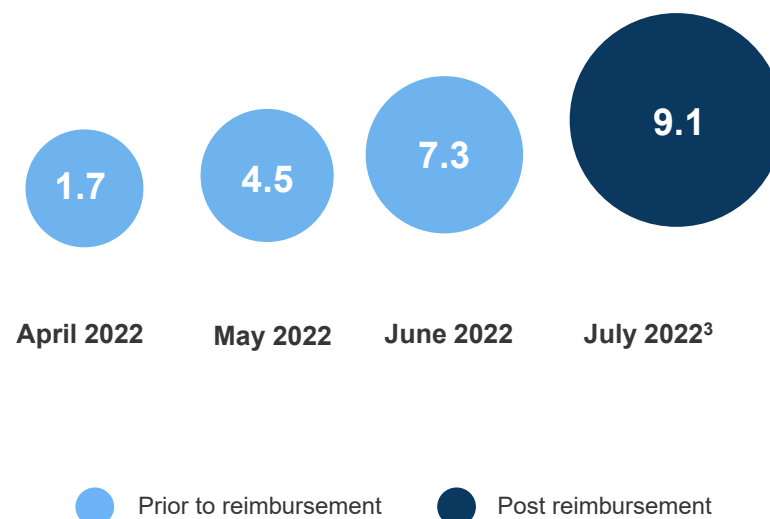
Reimbursement driving sales ramp-up

Growing user base in both major metropolitan and regional markets

DOSES
DELIVERED
IN 43
STATES



U.S. SALES REVENUE ILLUCCIX (US\$M)

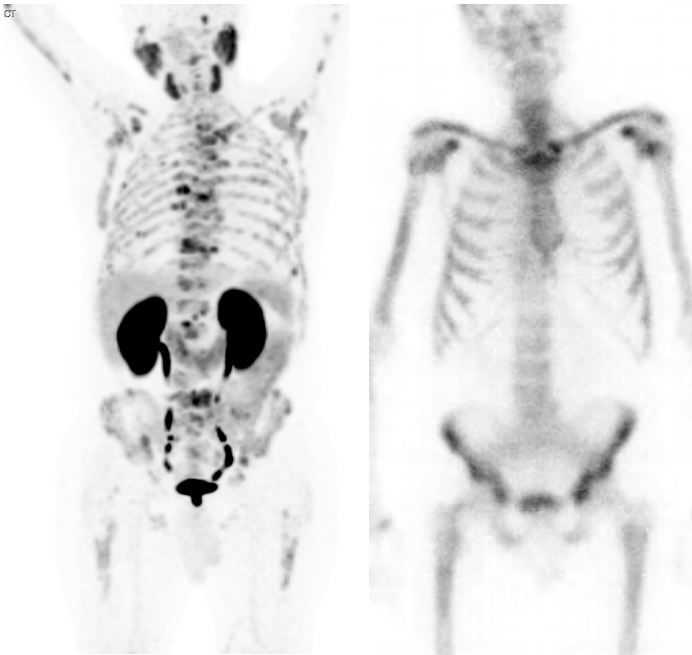


- First commercial dose delivered on 14 April 2022¹
- Reimbursement driving sales growth, up 25% month on month in July²
- Strong sales performance in both major metropolitan markets with existing users and in regions where PSMA-PET has been difficult to access
- Wide geographic coverage via 149 pharmacies
- Able to add new pharmacies to meet metropolitan and regional demand

^{68}Ga -PSMA-11 positron emission tomography (PET)

Current and potential uses in clinical practice

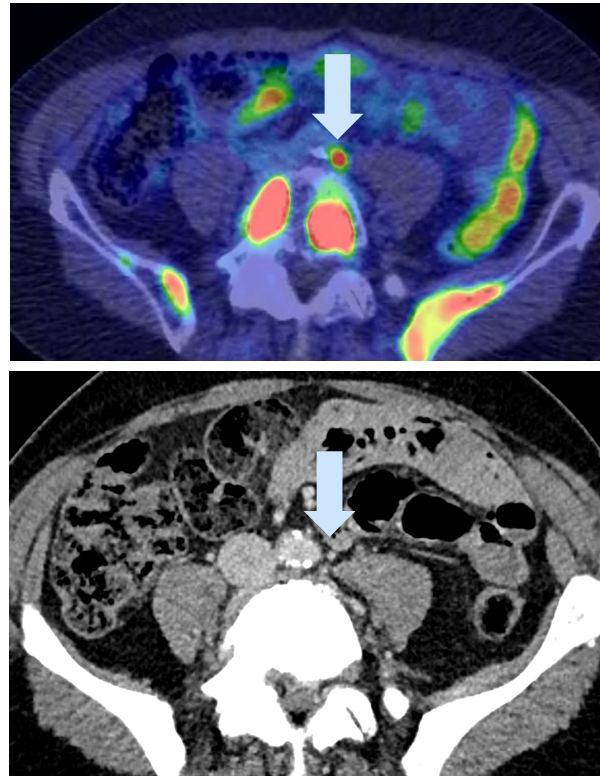
PRIMARY STAGING



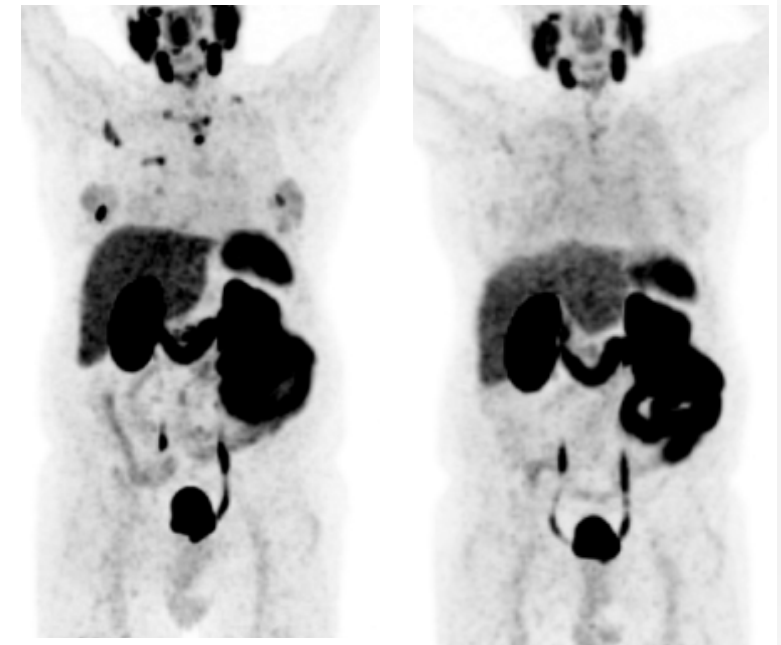
^{68}Ga -PSMA-11

Bone scan

BIOCHEMICAL RECURRENCE



RESPONSE ASSESSMENT¹



Baseline

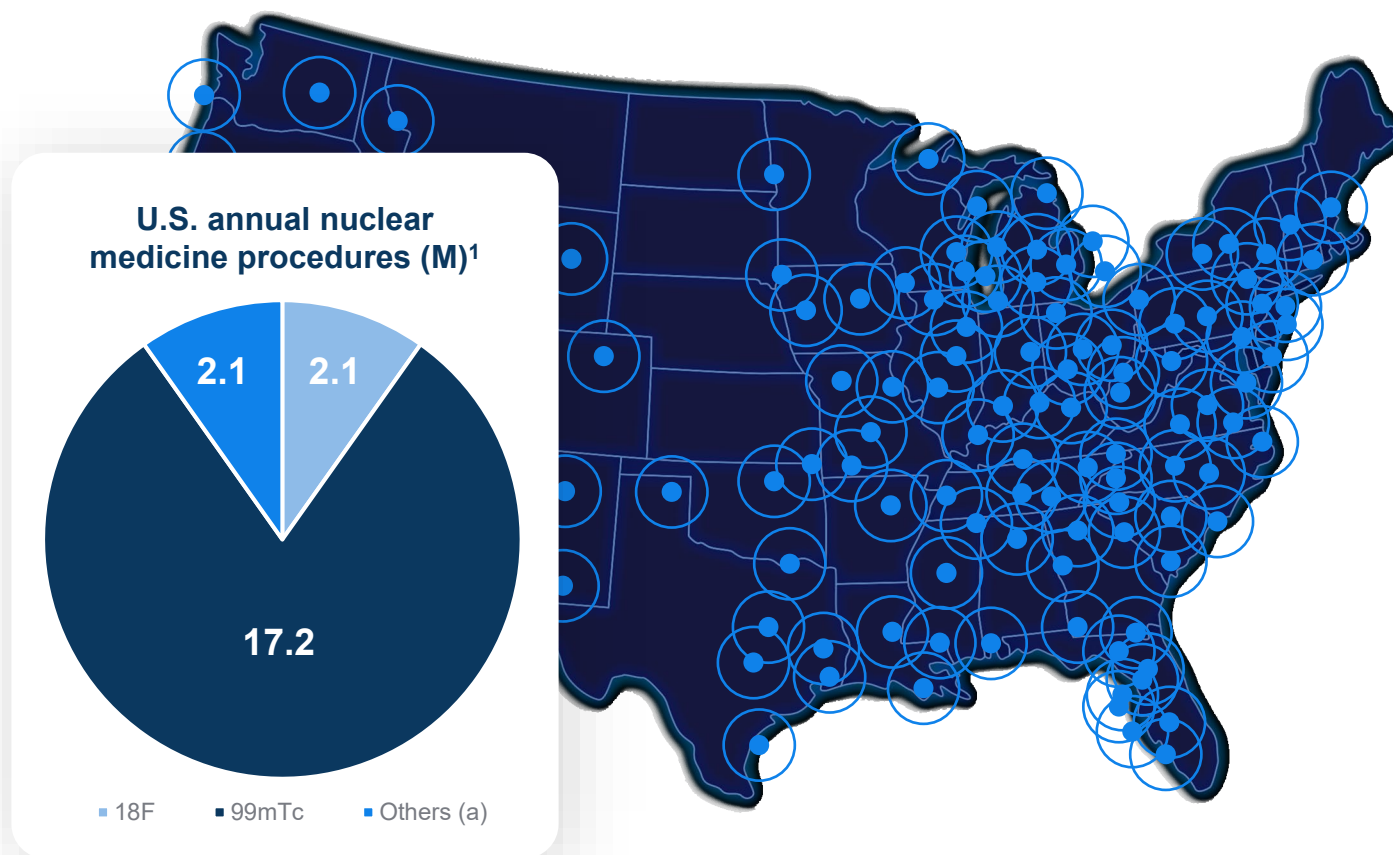
After therapy

Rapidly scalable distribution model

The gallium production method follows the technetium experience

- The gallium generator / radiopharmacy model is rapidly scalable and follows the traditional “nuclear medicine” model used in ^{99m}Tc (technetium) imaging procedures
- ^{99m}Tc is a generator-based production model, primarily dispensed through radiopharmacies
- Of an estimated 46.5 million nuclear medicine procedures performed globally each year, >80% are ^{99m}Tc imaging procedures¹
- The radiopharmaceutical-based generator model enables wide geographic coverage and hyper-localised service delivery to major metropolitan *and* regional markets
- The introduction of 100mCi generators will further increase gallium capacity across the radiopharmacy network

ILLUCCIX NETWORK COVERAGE



The field of PSMA imaging and therapy is evolving

Our ability to deliver globally is a key advantage

PSMA imaging has the potential to shape patient-management strategies:

Defining new disease states

- Existing definitions of disease still rely on conventional imaging

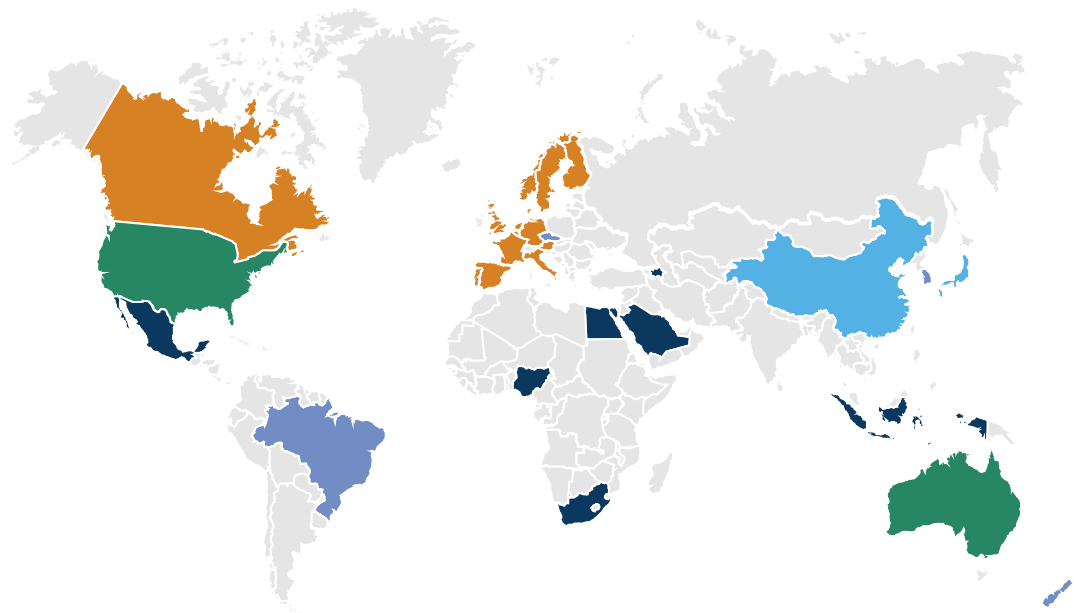
Selection for therapies

- E.g. PSMA targeting agents
- Predicting who will respond
- Adapting therapy strategies

Monitoring response to therapy

- All prostate cancer therapies

Beyond prostate cancer



TELIX PSMA-PET / SPECT IMAGING GLOBAL ROLLOUT

- Marketing authorisation received in U.S. and Australia
- Sale allowed under special exemption in Brazil, South Korea, New Zealand and Czech Republic
- Marketing authorisation applications under review in 17 countries, including the 14 member countries for the European submission, Canada, Brazil and Korea
- Late-stage clinical programs in China and Japan
- NOBLE registry for PSMA-SPECT (^{99m}Tc -iPSMA) active in 8 countries

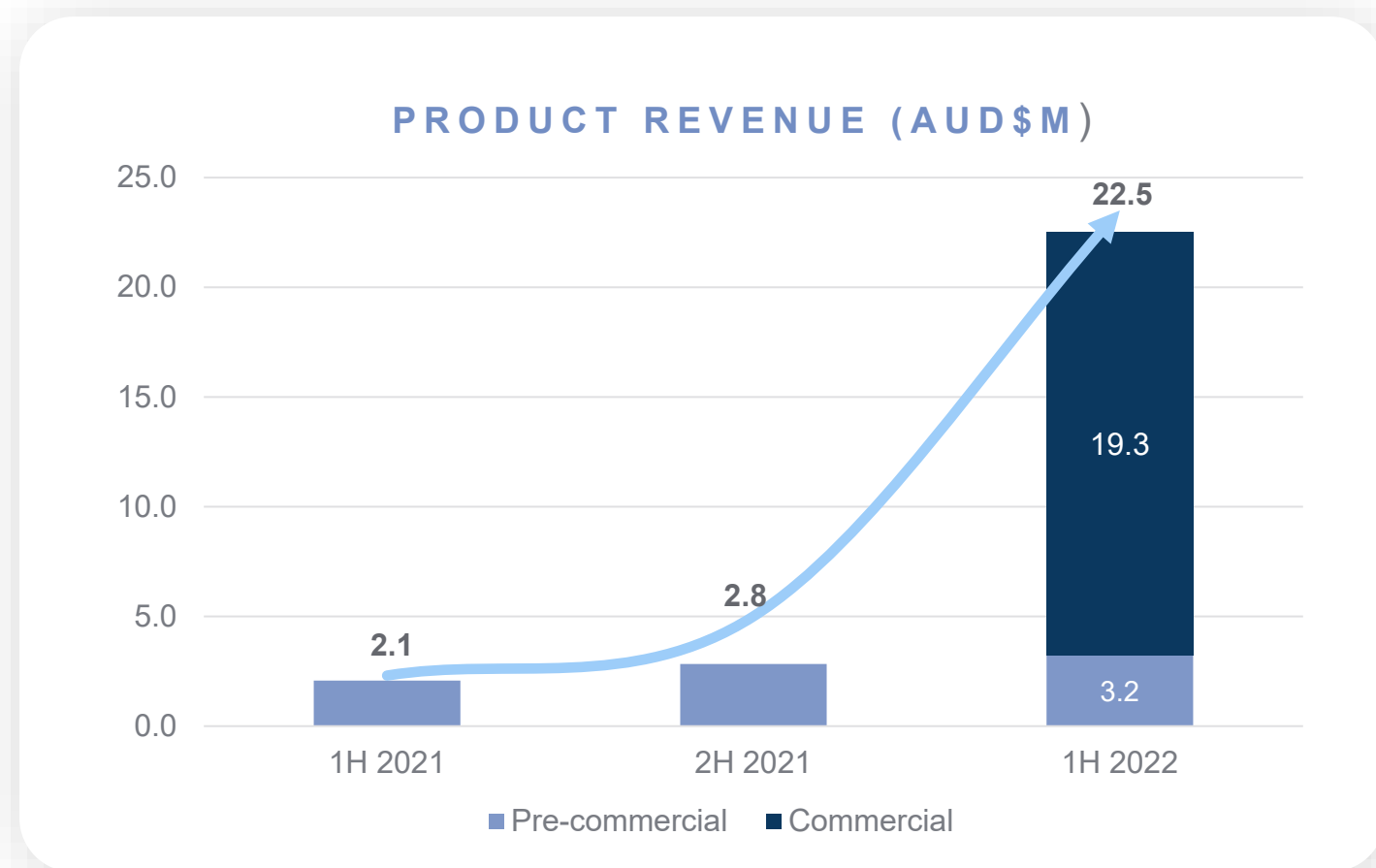
1H 2022 financial results overview



Strong momentum from U.S. commercial launch

Maiden commercial sales drive revenue increase

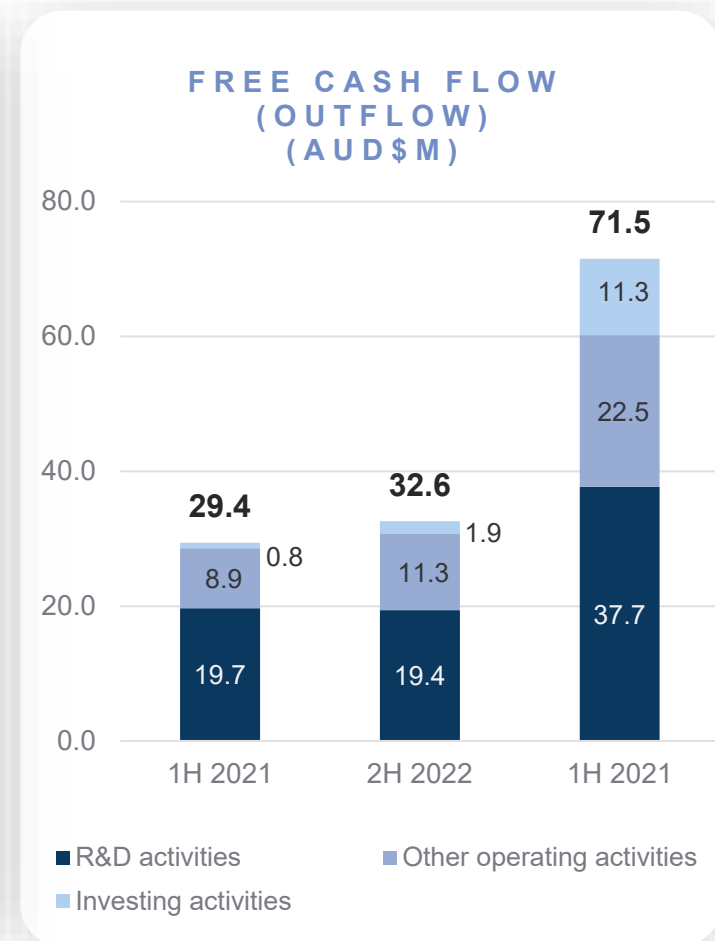
- Worldwide revenue of \$24.0 million, up from \$2.9 million in 1H 2021
- Product revenue \$22.5 million – includes \$19.3 million (US\$13.5 million) of Illuccix U.S. sales
- Research and development services income (revenue recognition of upfront payment from Grand Pharmaceutical Group) of \$1.5 million, up from \$0.8 million in 1H 2021
- Strong performance from pre-commercial sales in Europe, up 52% to \$3.2 million from \$2.1 million in 1H 2021^{1,2}



Cash flow

Impact of commercial sales will be evident from 2H 2022

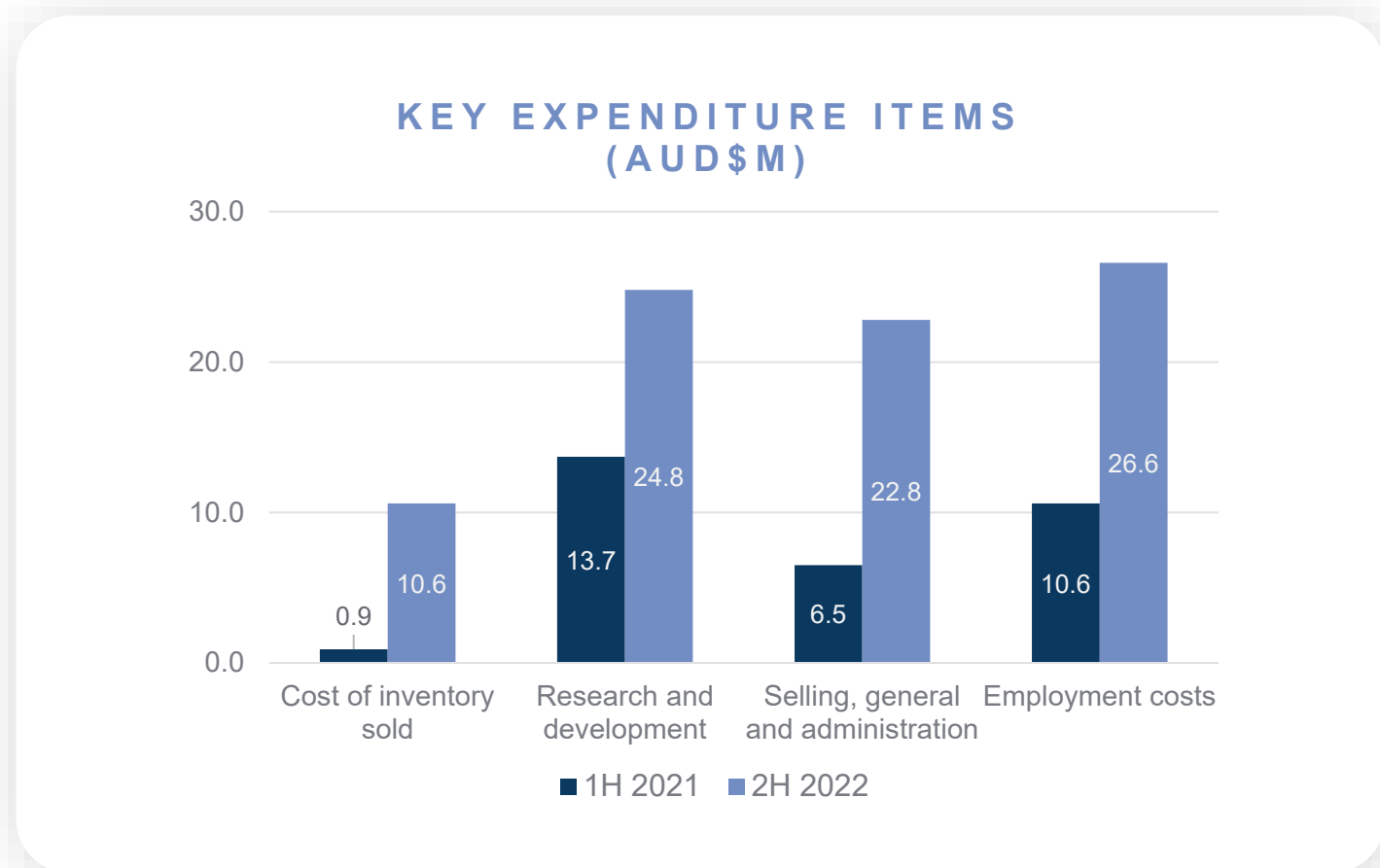
- Cash receipts (from product sales) \$7.3 million (1H 2022) up from \$1.8 million in 1H 2021
- Cash receipts from first quarter of U.S. sales only partially reflected, due to time lag between revenue recognition (at dosing) and payment from customers (average payment 45 days)
- Additional (non-product related) cash inflows include \$18.4 million in government tax incentives for eligible R&D activities undertaken in FY 2021
- Investing activities included:
 - A one-off upfront licence fee payment to Eli Lilly and Company (Lilly) of \$6.8 million (USD\$5 million) and
 - \$4.5 million in decommissioning and build-out costs related to Telix's manufacturing facility in Brussels South (Seneffe)



Key expenditure items

Capital raise proceeds funding R&D for therapeutic program advancement

- Cost of goods sold includes kit manufacturing costs, dispensing fees and once-off production-related costs associated with the U.S. launch
- R&D expenditure primarily directed towards therapeutic programs, with a significant increase in clinical and manufacturing activities compared to 1H 2021
- SG&A includes once-off marketing costs associated with the U.S. launch and increased travel for commercial and operational activities
- Employment costs higher in line with planned build-out of workforce to support clinical and commercial programs



Clinical programs update



Core pipeline: oncology and rare diseases

	Targeting Molecule	Target	Radioactive Isotope	Phase I	Phase II	Phase III	Commercial
Prostate	Small molecule	PSMA ¹	⁶⁸ Ga	TLX591-CDx (⁶⁸ Ga-PSMA-11, Illuccix®)			Imaging
	Antibody	PSMA	¹⁷⁷ Lu	TLX591 (¹⁷⁷ Lu-rosopatamab)			Therapy
	Antibody	PSMA	²²⁵ Ac	TLX592 (²²⁵ Ac-RADmAb®)			Therapy (2 nd Gen)
	Small molecule	PSMA	^{99m} Tc	TLX599-CDx (^{99m} Tc-iPSMA)*			Imaging/Surgery
	Small molecule	PSMA	⁶⁸ Ga	TLX591-Sx (⁶⁸ Ga-PSMA-IRDye)			Imaging/Surgery
Renal	Antibody	CAIX ²	⁸⁹ Zr	TLX250-CDx (⁸⁹ Zr-girentuximab)			Imaging
	Antibody	CAIX	¹⁷⁷ Lu	TLX250 (¹⁷⁷ Lu-girentuximab)			Therapy
Brain	Small molecule	LAT-1 ³	¹⁸ F	TLX101-CDx (¹⁸ F-FET)			Imaging
	Small molecule	LAT-1	¹³¹ I	TLX101 (¹³¹ I-IPA)			Therapy
BMC/RD ⁴	Antibody	CD66 ⁵	^{99m} Tc	TLX66-CDx (^{99m} Tc-besilesomab, Scintimun®) ⁶			Imaging
	Antibody	CD66	⁹⁰ Y	TLX66 (⁹⁰ Y-besilesomab)			Therapy

Shaded arrows indicate completion expectations in the next 12 months

*Registry Study

Clinical development highlights 1H 2022

Phase III imaging trial completes, progress across multiple therapeutic trials



RENAL CANCER IMAGING & THERAPY

- Phase III ZIRCON study completed, readout in 2H 2022
- “Basket study” in set-up, designed to validate new imaging and therapeutic indications together with investigator-led studies
- STARLITE 2 Phase II therapy study enrolling patients, two additional studies to initiate



PROSTATE CANCER THERAPY

- ProstACT SELECT recruiting strongly
- Early insights reinforce need for antibody-based approach to PSMA therapy
- Advancement of ProstACT TARGET and GLOBAL studies



GLIOBLASTOMA IMAGING & THERAPY

- Finalising pathway for NDA submission to US FDA for FET-PET imaging agent
- IPAX-2 study initiated, moving TLX101 into the front-line setting
- One year follow on data from IPAX-1 study



RARE DISEASES PORTFOLIO

- TLX66 granted Orphan Drug Designation for bone-marrow conditioning
- In-license of the antibody olaratumab from Lilly

Carbonic Anhydrase IX (CAIX) program

Phase III imaging study complete, potential to develop as a pan-cancer target

LEAD CANDIDATES

Dx: TLX250-CDx (^{89}Zr -girentuximab)

Tx: TLX250 (^{177}Lu -girentuximab)

TARGETING MOLECULE

Antibody

INDICATION

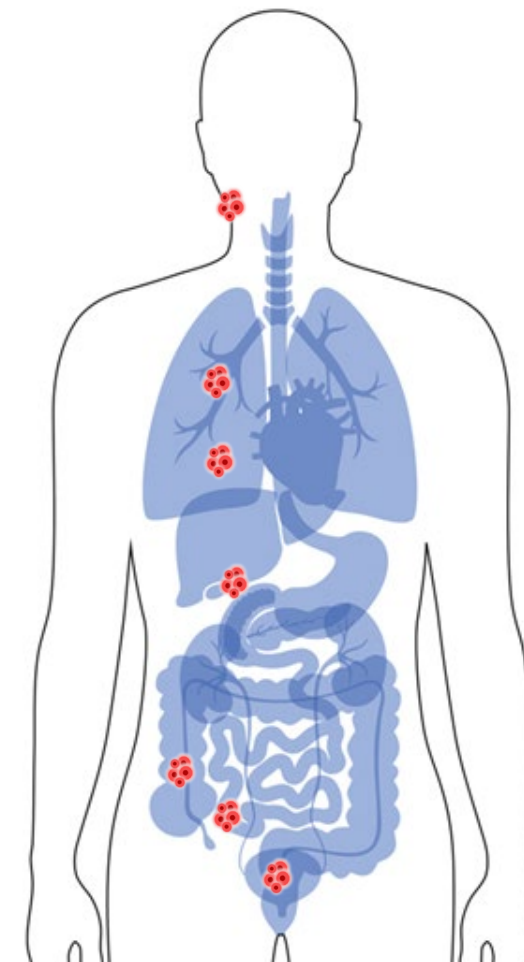
- Clear cell renal carcinoma (ccRCC)
- Further studies in planning to establish CAIX as a pan-cancer target

SCIENTIFIC RATIONALE

- CAIX is a tumour-associated antigen expressed in up to 95% of ccRCC cases and many hypoxic solid tumors, with low expression in most normal tissue
- Tumour hypoxia correlates with progression and resistance to therapy
- Half-life of ^{89}Zr is optimal for detection of small tumour lesions

DEVELOPMENT PATHWAY

- Phase III renal cancer imaging study readout in 2H 2022, basket study to evaluate new indications in planning
- Phase II therapy study in renal cancer in combination with immunotherapy underway, further combination studies in planning



TLX250-CDx: follow-on to Iluuccix

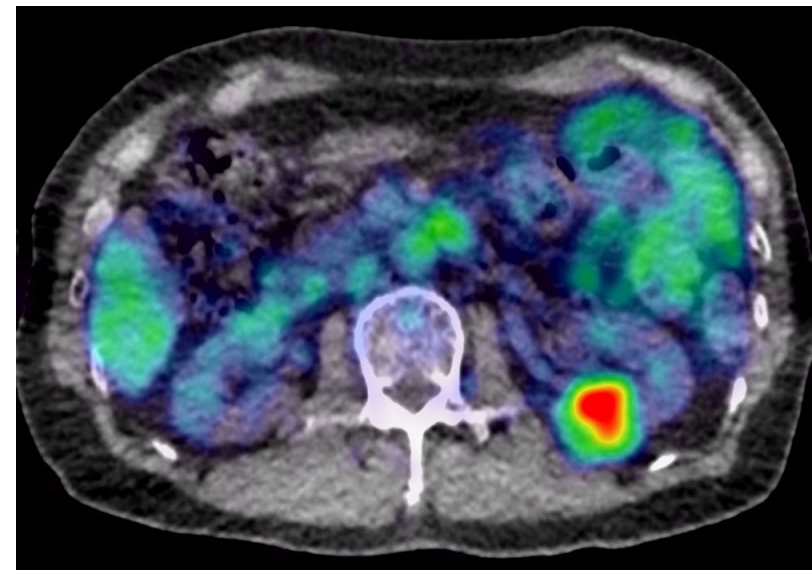
“Breakthrough” designation in an area of growing need

Renal cancer rates have doubled in the last 50 years, to 400,000 cases worldwide in 2020¹ and the incidental detection of small renal masses is increasing

- Current imaging cannot reliably distinguish whether these renal masses are benign lesions or renal cell carcinoma²
- Tumour biopsies are often unnecessary, invasive and limited by the tissue sampled and can lead to complications: ~84,000 biopsies or surgeries are performed each in the U.S.³
- U.S. market opportunity estimated at >100,000 cases per year³

TLX250-CDx has a high binding specificity to CAIX and offers potential benefits to patients

- May be able to determine if “indeterminate renal masses” are ccRCC malignancies and offer a non-invasive method of diagnosis
- Could potentially offer improved surgical staging
- Clinical leadership opportunity, given limited options for patients and limited competitor focus



TLX250 therapy in renal cancer and other indications

Combination therapy strategy could expedite the commercial opportunity

STARLITE PHASE II STUDIES IN COMBINATION WITH IMMUNOTHERAPY

- CAIX upregulated in many hypoxic solid tumours, correlating with progression and resistance to therapy
- Targeted radiation may act as an “immune system primer”
- STARLITE studies investigating TLX250 with tyrosine kinase inhibitors (TKIs) and checkpoint inhibitors
- STARLITE 2 – TLX250 plus nivolumab in patients with ccRCC who have progressed following prior immunotherapy – now dosing patients
- The immunotherapy market is forecast to grow to US\$100B by 2027

COLLABORATION WITH MERCK KGaA DNA DAMAGE REPAIR INHIBITOR

- Phase I dose escalation study combining TLX250 with peposertib (a DNA damage repair inhibitor)
- In patients with CAIX-expressing solid tumours that have progressed on or after receiving standard of care (SOC) and are not eligible for surgery or SOC therapy
- Patient selection to be guided by TLX250-CDx imaging where patients must demonstrate CAIX expression before entering therapy
- Target enrolment 15-20 patients in dose escalation part 1, and 40-60 patients in part 2
- Expected to commence dosing in Q4 2022

Prostate-specific membrane antigen (PSMA) program

A differentiated approach in the emerging field of PSMA therapy

LEAD CANDIDATES

TLX591 (^{177}Lu -rosopatamab)

TLX592 (^{225}Ac -RADmAb®)

TARGETING MOLECULE

Antibody

INDICATION

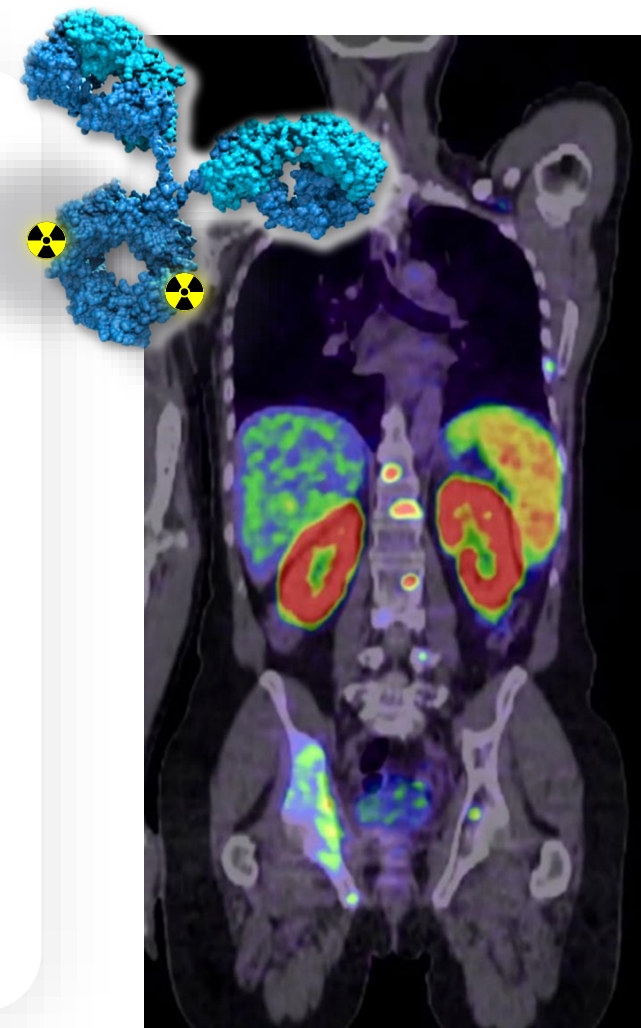
Prostate cancer: studies underway in patient populations ranging from early biochemical recurrence to late-stage metastatic patients

SCIENTIFIC RATIONALE

- Antibodies are functionally specific for tumour-expressed PSMA and do not “hit” most endogenous PSMA expression unlike small molecule radioligands
- Antibodies have a slower turnover rate, so require less radioactivity to exert a therapeutic effect – may deliver superior efficacy and side-effect profile compared to small molecule
- At two doses, TLX591 is a more “patient-friendly” option than small-molecule

DEVELOPMENT PATHWAY

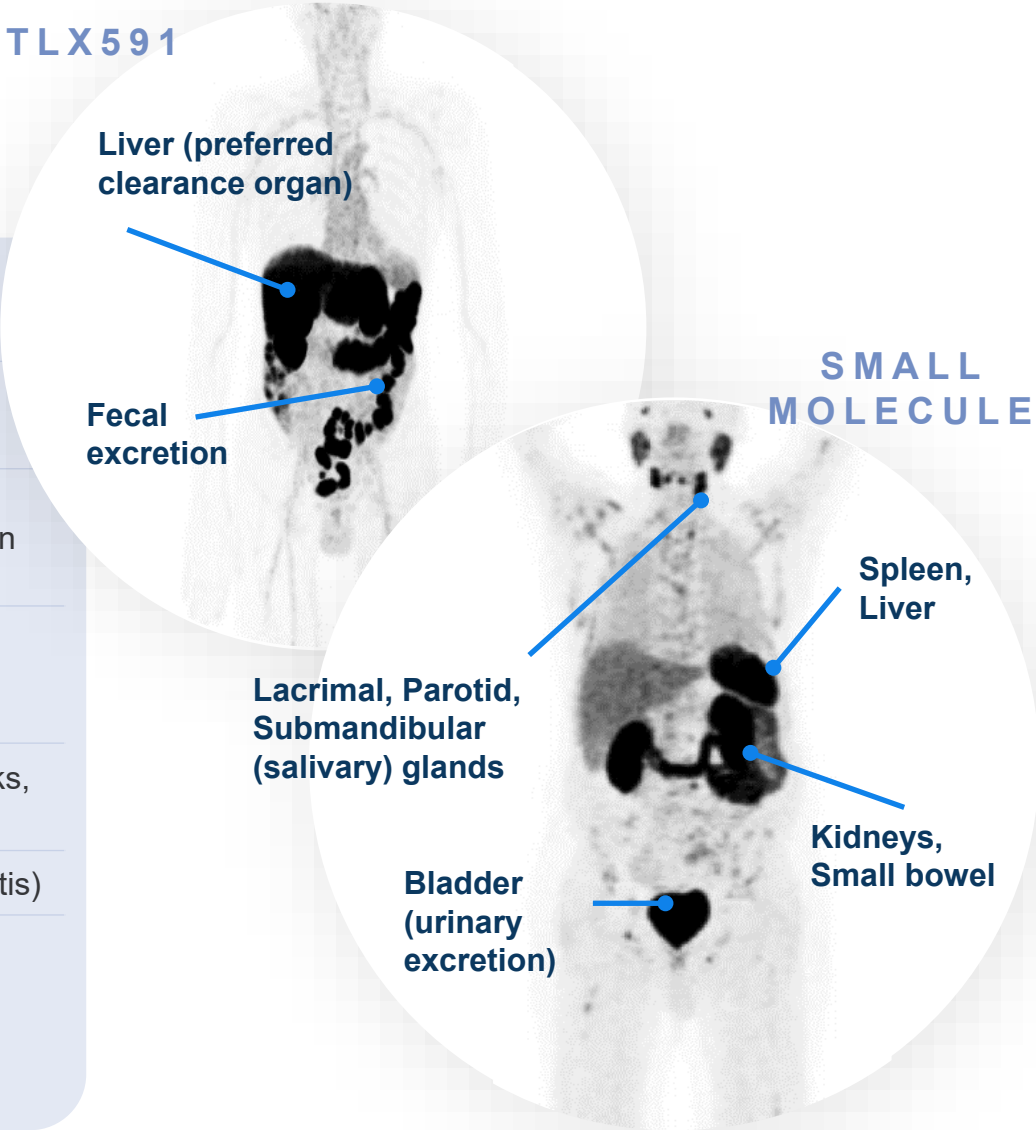
- Multiple studies underway assessing TLX591
- TLX592 (alpha therapy) a potential adjuvant for high-risk patients that may have early metastatic disease or progressing from conventional ^{177}Lu -PSMA Tx



PSMA competitive landscape

Potential advantages of the antibody approach

ANTIBODY (TLX591)	SMALL MOLECULE
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
Shortest dosing regimen of all PSMA therapies, two x 76mci doses, 14 days apart	Dosing regimens range from 24 to 36 weeks, at up to 200mci per dose
Approved products: N/A	Approved products: PLUVICTO® (Novartis)
Products in development: TLX591	Products in development: ¹⁷⁷Lu-PNT-2002 (Point Biopharma) ¹⁷⁷Lu-PSMA-I&T (Curium)



ProstACT program overview

Multiple opportunities to deliver insights into TLX591, across multiple patient segments



Radiogenomics study (Phase I)

Treat the scan

Aims to demonstrate correlation between imaging and therapy to optimise patient selection. Supports indication expansion based on a “theranostic” approach

Trial top line data expected 1H 2023



Combination with EBRT¹ in oligometastatic early recurrence (Phase II)

Early data in front line care

Efficacy data in patients in their first recurrence. Uniquely positions Telix as the leading radiopharmaceutical company combining external beam radiation and a PSMA-targeting therapy

In partnership with GenesisCare – patient screening underway



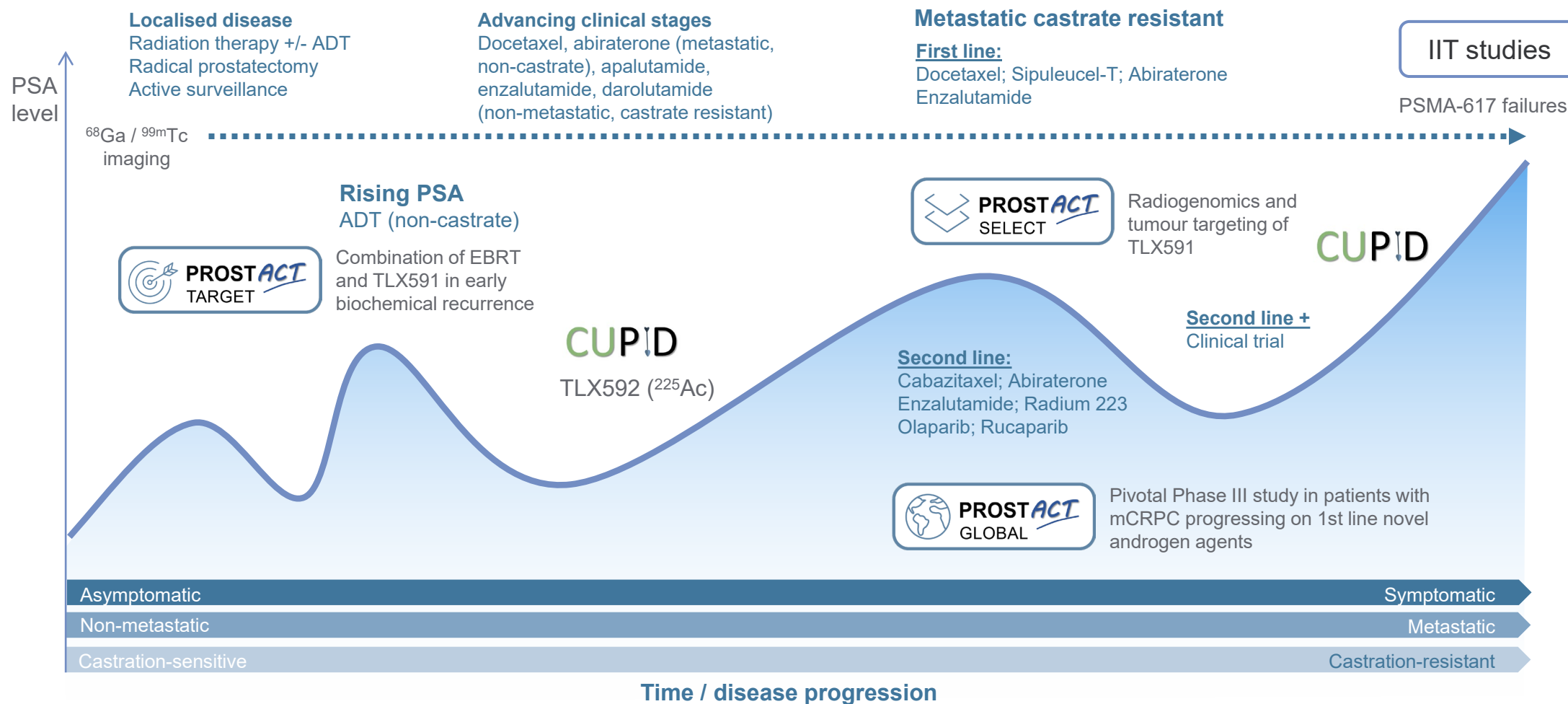
Pivotal Phase III study in patients with mCRPC² progressing on 1st line novel androgen agents

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

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

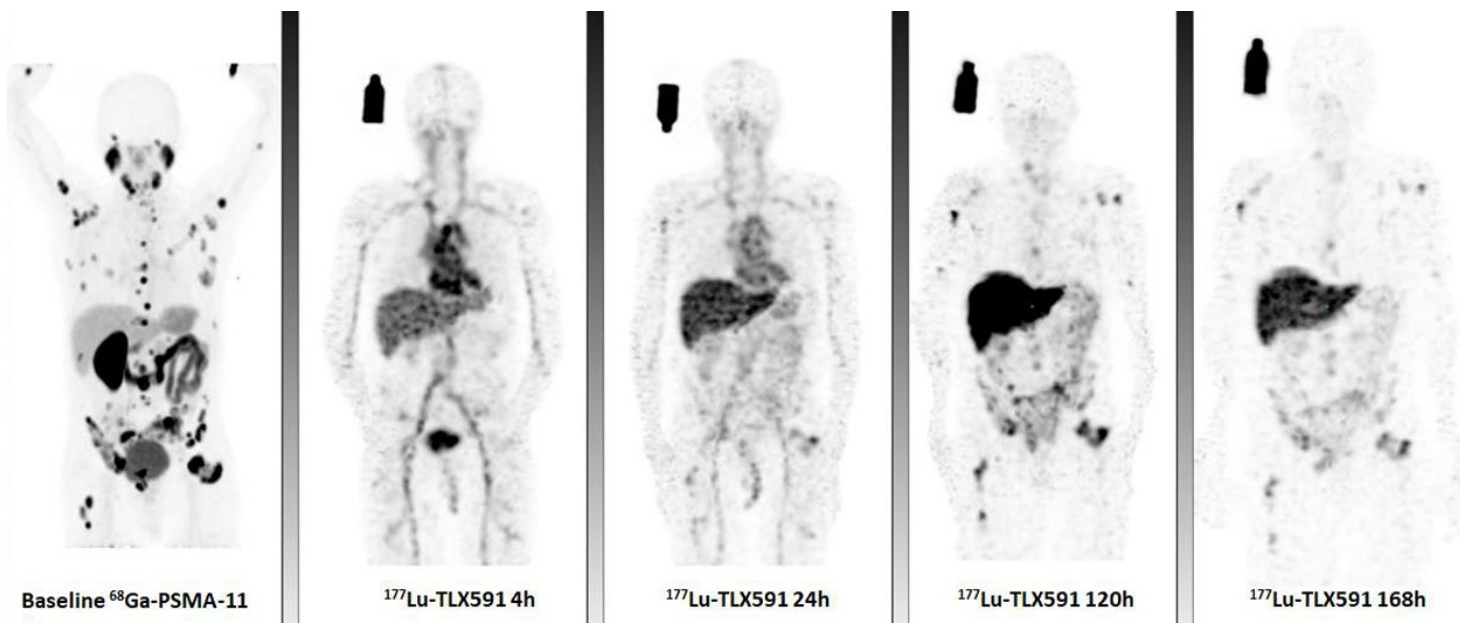
Global study enrolling ~390 patients, patient screening in AU due to commence in 2022

Our clinical mission: support the patient every step of the way



Radiation retention in tumour with antibody therapy

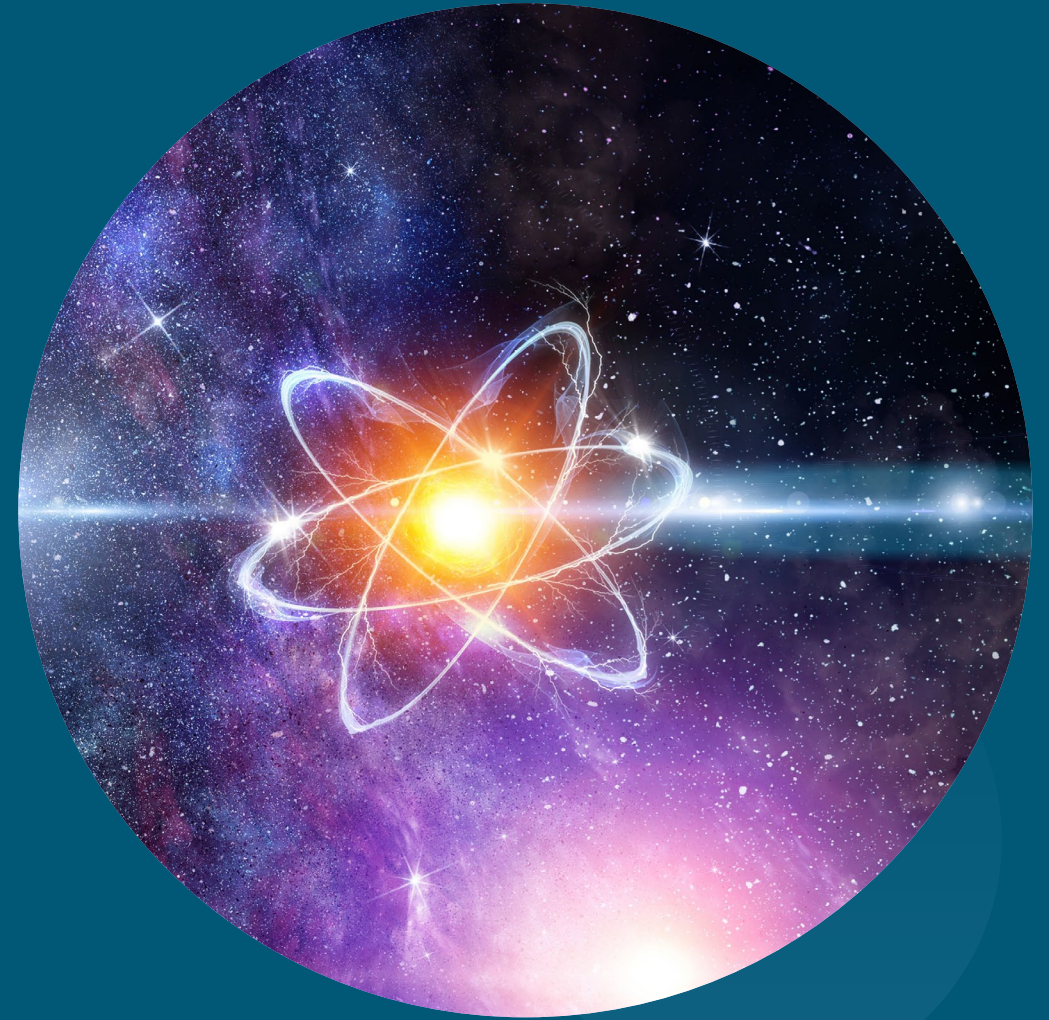
Demonstrates high retention of ^{177}Lu in the tumour



- Biodistribution data indicates TLX591 antibody is retained in the tumour with high activity still at day seven
- Longer-term retention of TLX591 in the tumour (and metastases) may maximise the cell-killing effect of the ^{177}Lu radioisotope at the cancer sites and allow optimised dosing



Pipeline expansion highlights



In-licensing of olaratumab from Eli Lilly and Company

Established safety profile, promising “theranostic” target

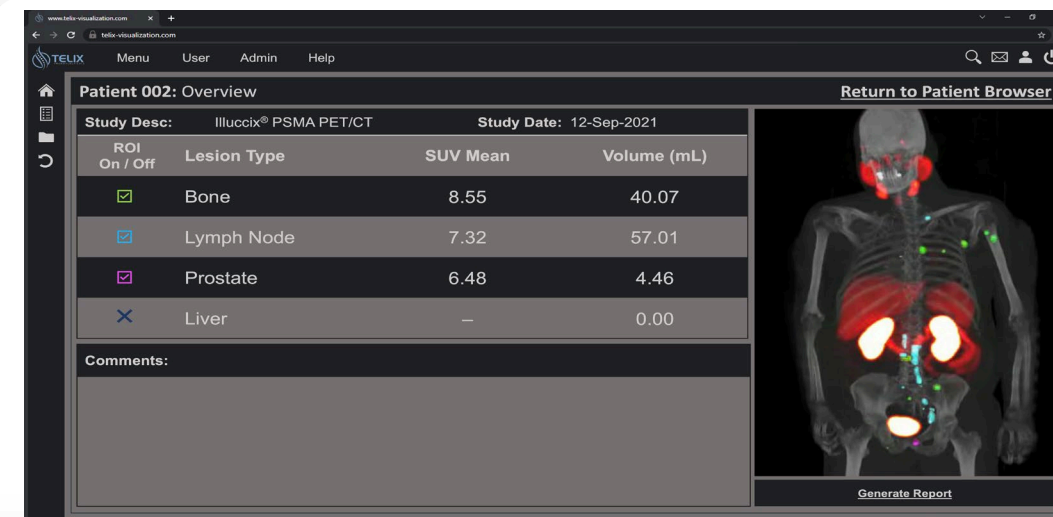
- Olaratumab was originally developed by Lilly as a “naked” (non-radiolabelled) monoclonal antibody
- Soft tissue sarcoma (STS) has a poor prognosis (12-18 months in advanced metastatic patients) and few treatment options¹
- Sales under “accelerated approval” as Latruvo® reached US\$203M in first year, peaked at US\$304M in 2018²
- Voluntarily withdrawn from market after a Phase III pivotal study with expanded inclusion criteria did not significantly improve overall survival (OS), when compared with chemotherapy alone, in patients with advanced or metastatic STS³
- Data generated by Lilly – and the early commercial response – significantly de-risks the program for Telix



Telix AI™ artificial intelligence platform

Potential to enhance efficiency and accuracy of both imaging and therapy

- Telix AI™ artificial intelligence platform being developed in partnership with Invicro LLC
- Seeks to increase efficiency and reproducibility of clinical images
- Automatically separates healthy versus abnormal tracer uptake and then classifies lesions as either visceral (soft tissue) or bone lesions
- Initial focus on prostate cancer, but able to be adapted for use with TLX250-CDx and other products
- Regulatory filing 510(k) planned for 1H 2023 (prostate cancer)



HOW CAN AI ASSIST IN SEGMENTATION AND SCORING?

Image reconstruction: Lower dosage and faster scan times

Automatic artefact detection and removal: Higher fidelity images

Lesion segmentation and classification: Accurate quantification of disease burden and changes over time

HOW COULD AI ENHANCE TREATMENT PLANNING?

Incorporating imaging and clinical data:

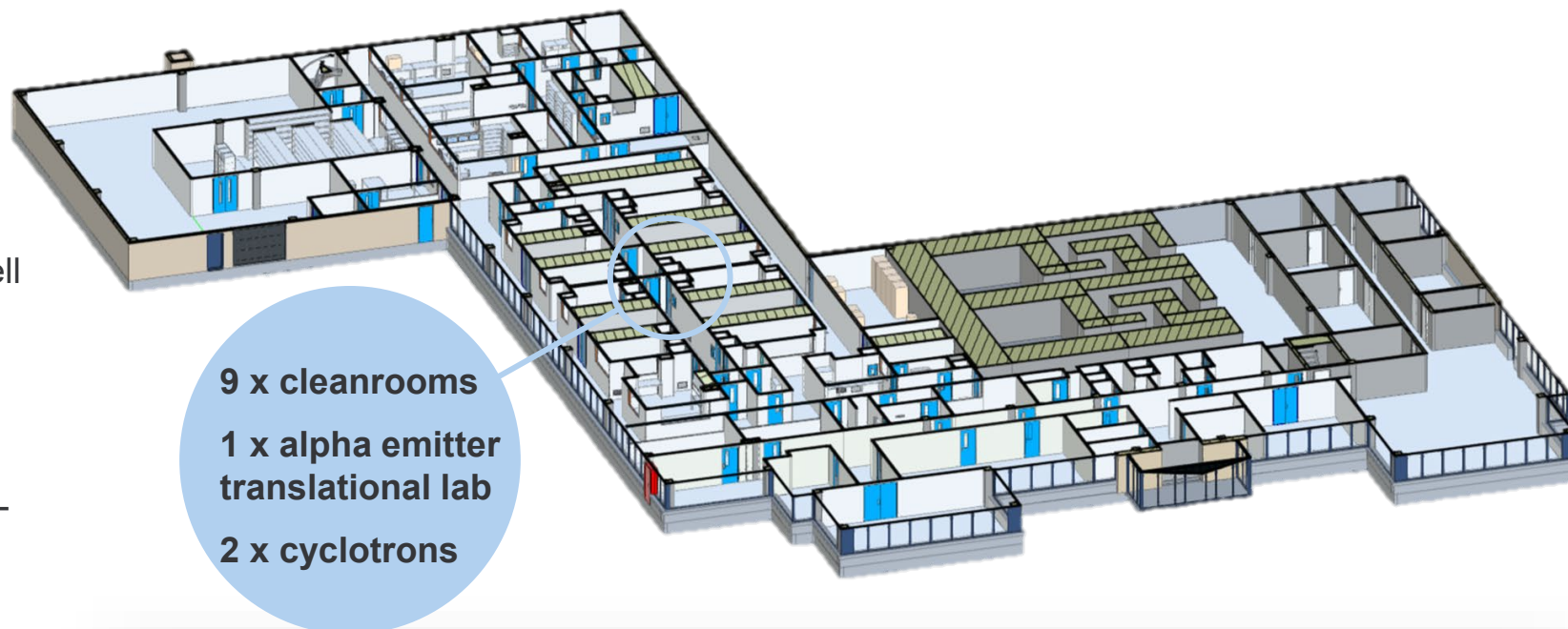
- Disease prognosis prediction
- Optimal dose prediction/treatment response analysis
- Optimal personalised treatment regime

Advanced manufacturing and supply chain

Working with industry leading partners to service patients in all major markets

Build-out of radiopharmaceutical production facility (Brussels South) underway

- Infrastructure works enabling commencement of clean room and hot cell installation for nine GMP manufacturing lines for isotope processing and radiopharmaceutical manufacturing
- On track to complete build-out and commence regulatory inspections by end-2022
- First €2.0 million (~A\$3.0 million) in building costs to be funded by Telix, remainder drawn from project finance and government grants
- Will serve as the primary EU manufacturing site, gives greater control over supply chain and central hub for R&D



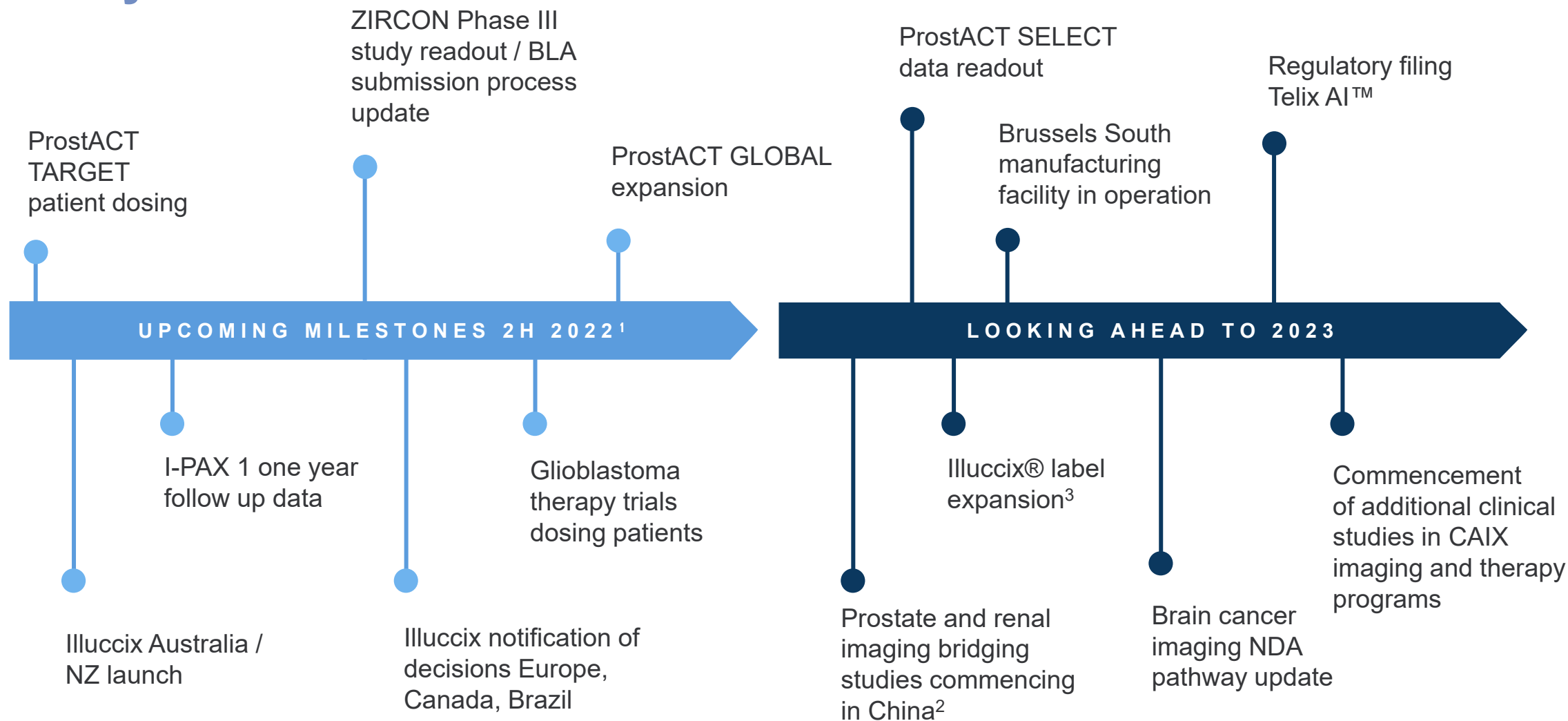
Continued expansion of global supply chain

- Global clinical supply agreements for highly pure no-carrier-added (n.c.a.) lutetium-177 (^{177}Lu) signed with Eckert and Ziegler and SHINE Technologies
- Enhances supply network, ensuring global supply chain with built-in redundancy and ability to obtain highest quality isotopes and service global markets

Outlook



Catalysts





Thank you and questions

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