



Precision Oncology.
See it. Treat it.

Telix Pharmaceuticals Limited

Half-Year Shareholder Update

Dr. Christian Behrenbruch
Managing Director and CEO

21st August 2020

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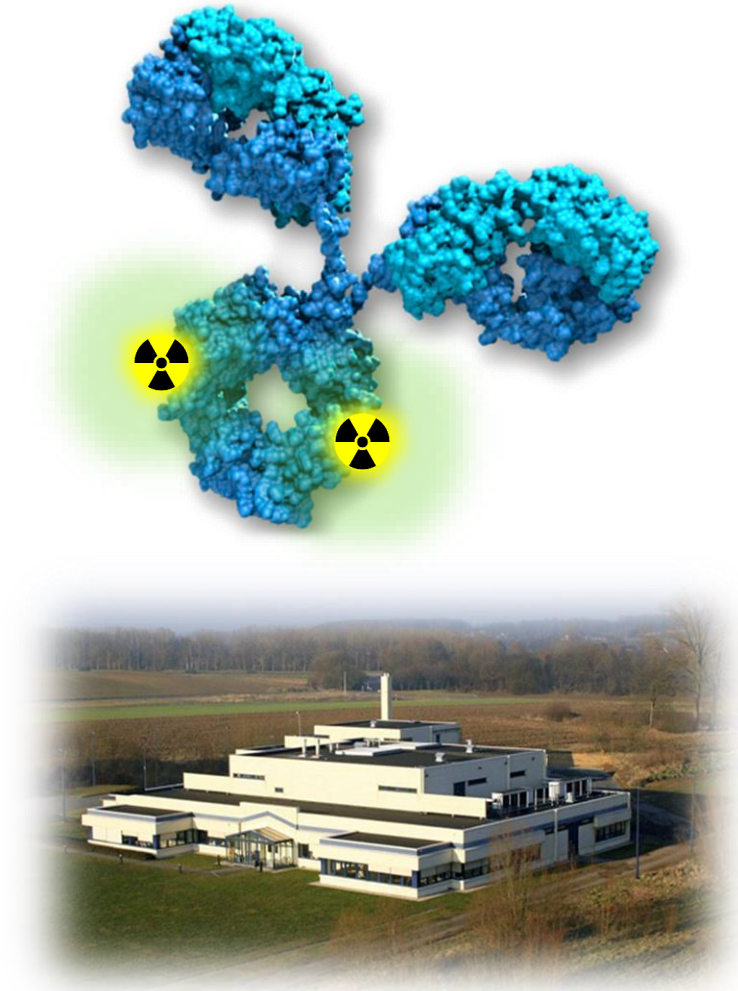
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Company Snapshot

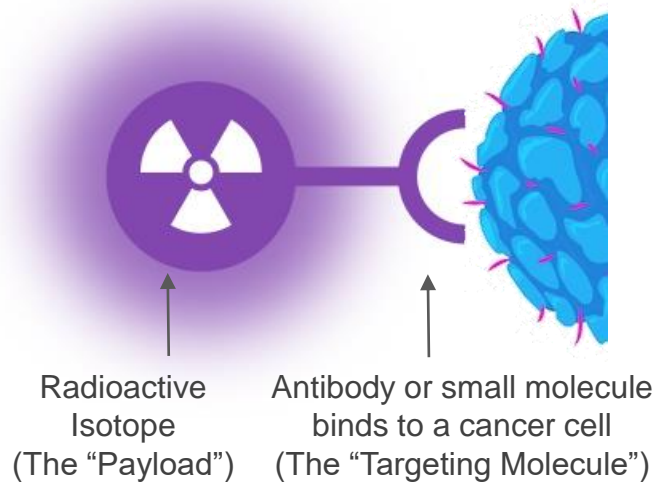


- Late-stage portfolio of **Molecularly Targeted Radiation (MTR)** products :
 - ✓ Prostate cancer, renal cancer, glioblastoma
 - ✓ Significant **total addressable market** value of US\$850M & US\$4B for prostate imaging and therapy, respectively
 - ✓ Clinically active in 25 countries, global reach
- Accomplished major milestones on the path to **commercialisation** of TLX591-CDx (prostate cancer imaging)
 - ✓ European **Marketing Authorization Application** submitted (April)
 - ✓ U.S. FDA **NDA** submission preparation in progress
 - ✓ U.S. commercial distribution agreements with **Cardinal Health** and **Pharmalogic**
- Acquired a **licensed production facility** in Seneffe, Belgium
 - ✓ Vertically integrated drug product manufacturing for the European market
- **Strong financial position**
 - ✓ Cash runway until late 2021, to deliver first 2 commercial products



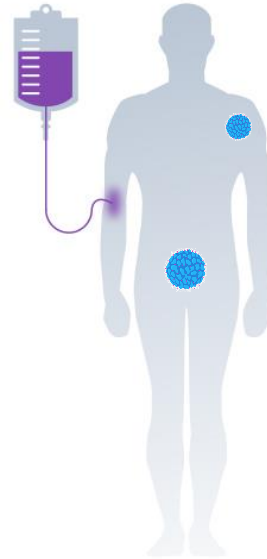
What is MTR? Precise Radiation Delivery

1. Targeted radiation delivery



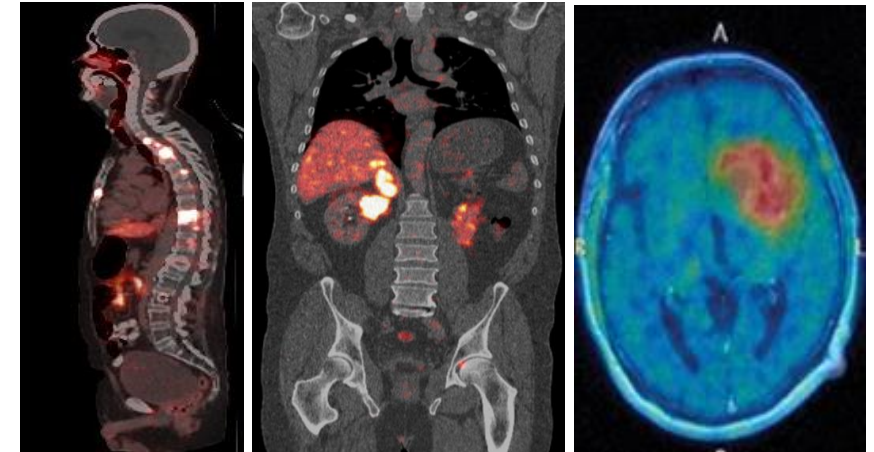
Telex is targeting agent agnostic (antibody or small molecule)

2. Systemic administration



Administered systemically and binds to cancer cells, wherever they are, including small metastases

3. Dual benefit: imaging and therapy



Prostate cancer
TLX591-CDx ⁽¹⁾

Renal cell carcinoma
TLX250-CDx ⁽²⁾

Glioblastoma
TLX101 ⁽³⁾

Cancer-specific Positron Emission Tomography (PET) images of prostate, renal and brain (GBM) cancers for diagnosis, staging and treatment response assessment

Notes: (1) Courtesy of Ammar Chaudhry MD, City of Hope, Duarte CA, USA
(2) Courtesy of Radboud University Medical Centre, Netherlands
(3) Courtesy of Zentralklinik Bad Berka, Germany

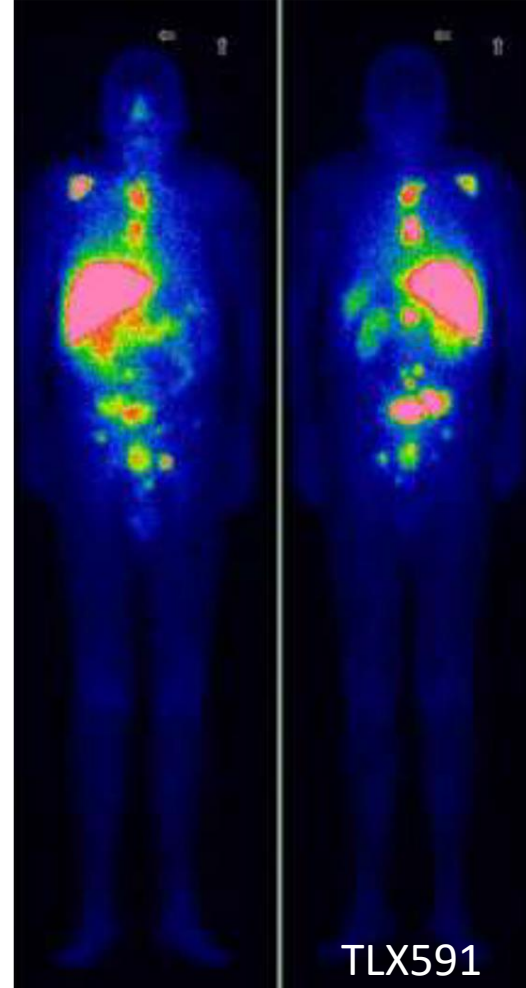
'See It. Treat It'



See...



Low dose / diagnostic radionuclide and a PET scanner images the presence of the cancer target



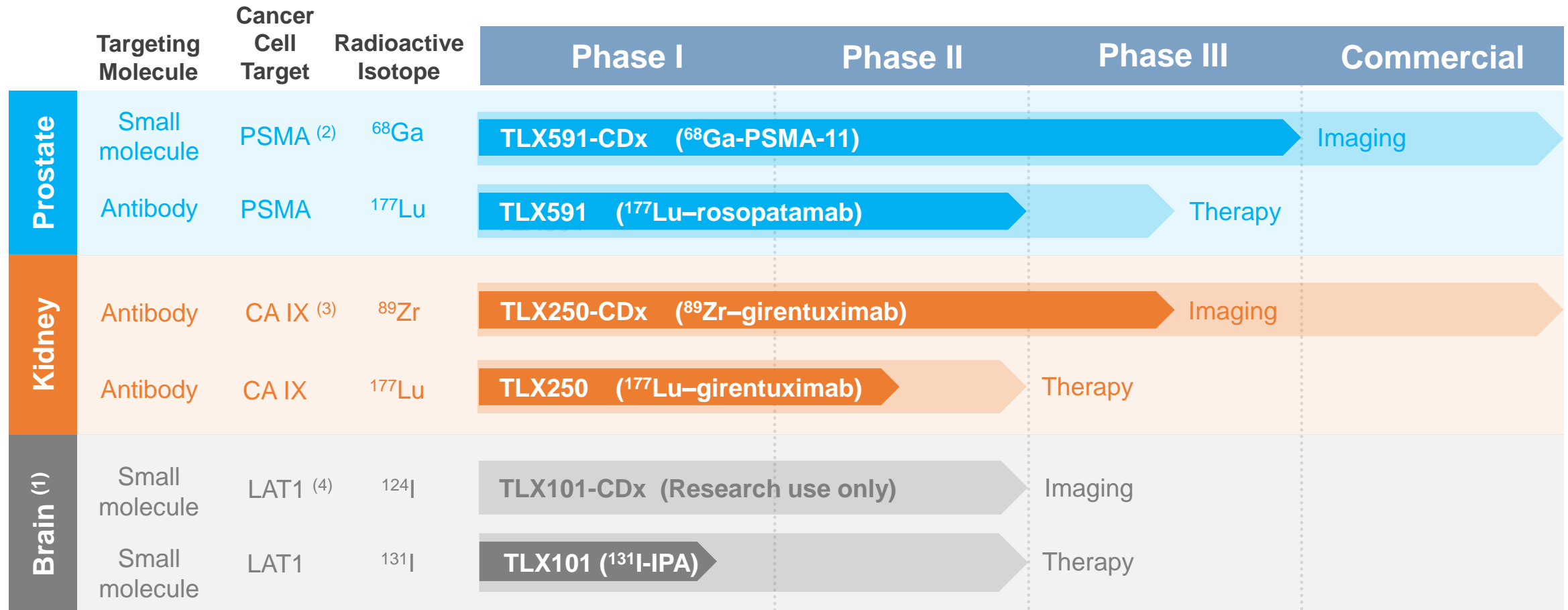
Treat...



High dose / therapeutic radionuclide treats the patient

Dosing and treatment response guided by imaging

Telix's Clinical Pipeline in Prostate, Kidney, Brain Cancer



Shaded arrows indicate completion expectations in the next 12 months

- Notes:
- (1) Glioblastoma multiforme (GBM)
 - (2) PSMA = Prostate-specific membrane antigen 1
 - (3) CA IX = Carbonic anhydrase IX
 - (4) LAT1 = Large amino acid transporter 1

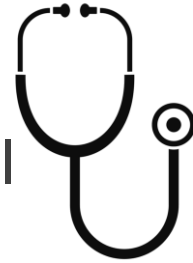
Clinical and Commercial Activity

Activity Focus Areas

Commercialisation
of TLX591-CDx
(prostate imaging)



Clinical
Trials



Pipeline
R&D



Key Accomplishments Year to Date



EU MAA submitted for TLX591-CDx (prostate imaging), NDA preparation



Phase III meeting with the FDA, finalisation of protocol

PROSTACT

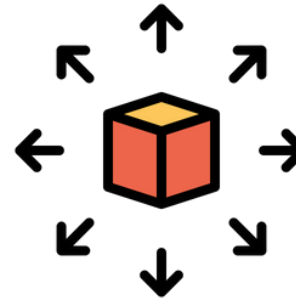
Seneffe (Belgium) site acquisition completed for EU manufacturing



US/EU/AU recruitment, indication expansion, breakthrough designation



Multiple distribution agreements, US and EU



Active R&D including \$500k IMCRC grant for advanced manufacturing

IMCRC

Key hires to build Telix's international bench strength, including US-based CMO



Financial Dashboard

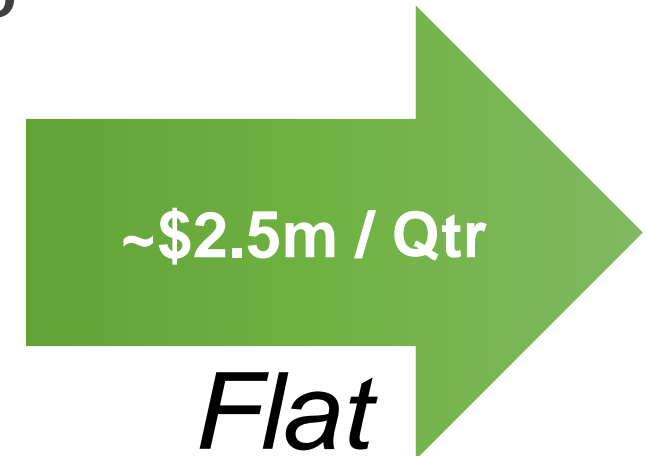
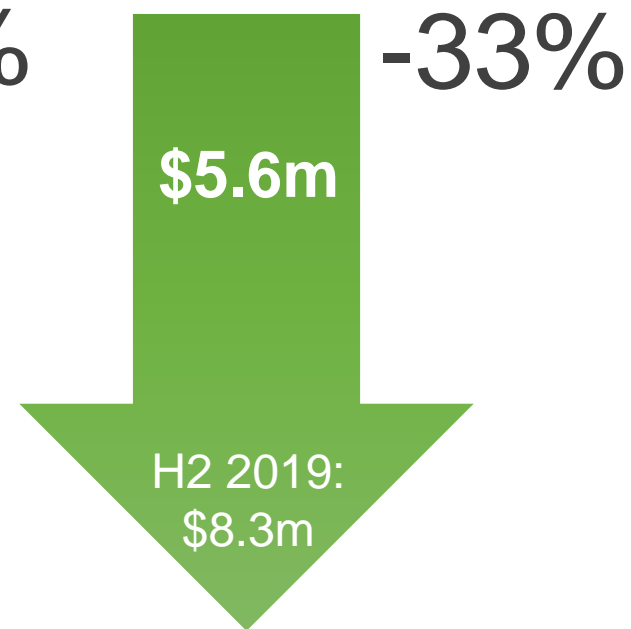
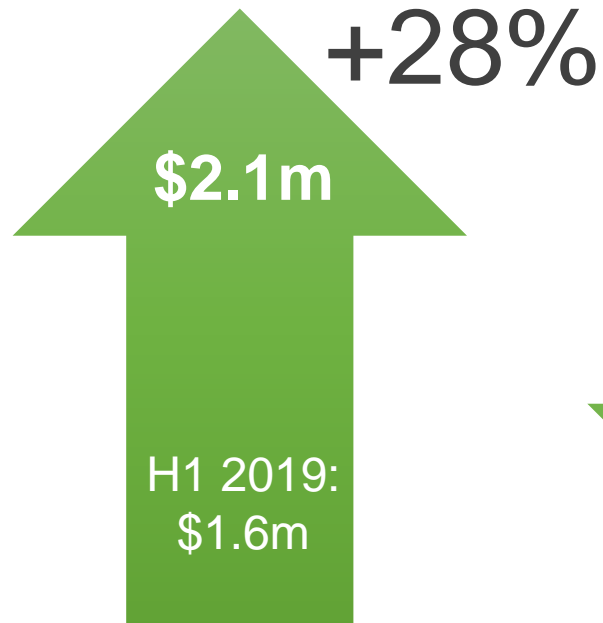
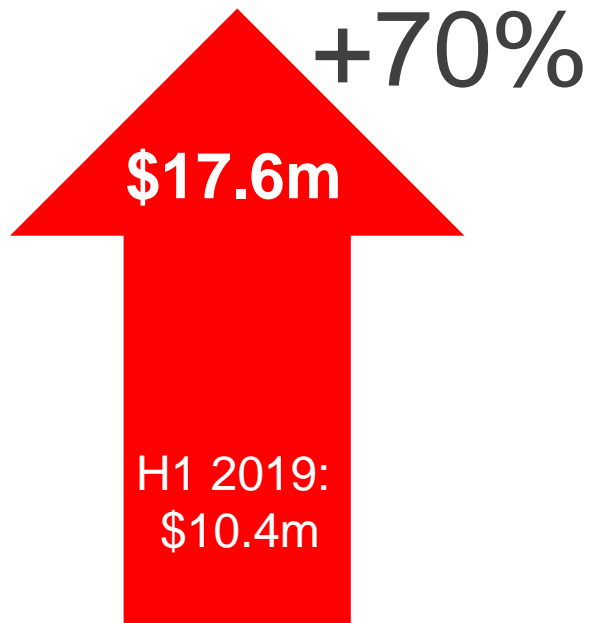


H1 2020
Comprehensive Loss

H1 2020
Receipts

H1 2020
Program Costs

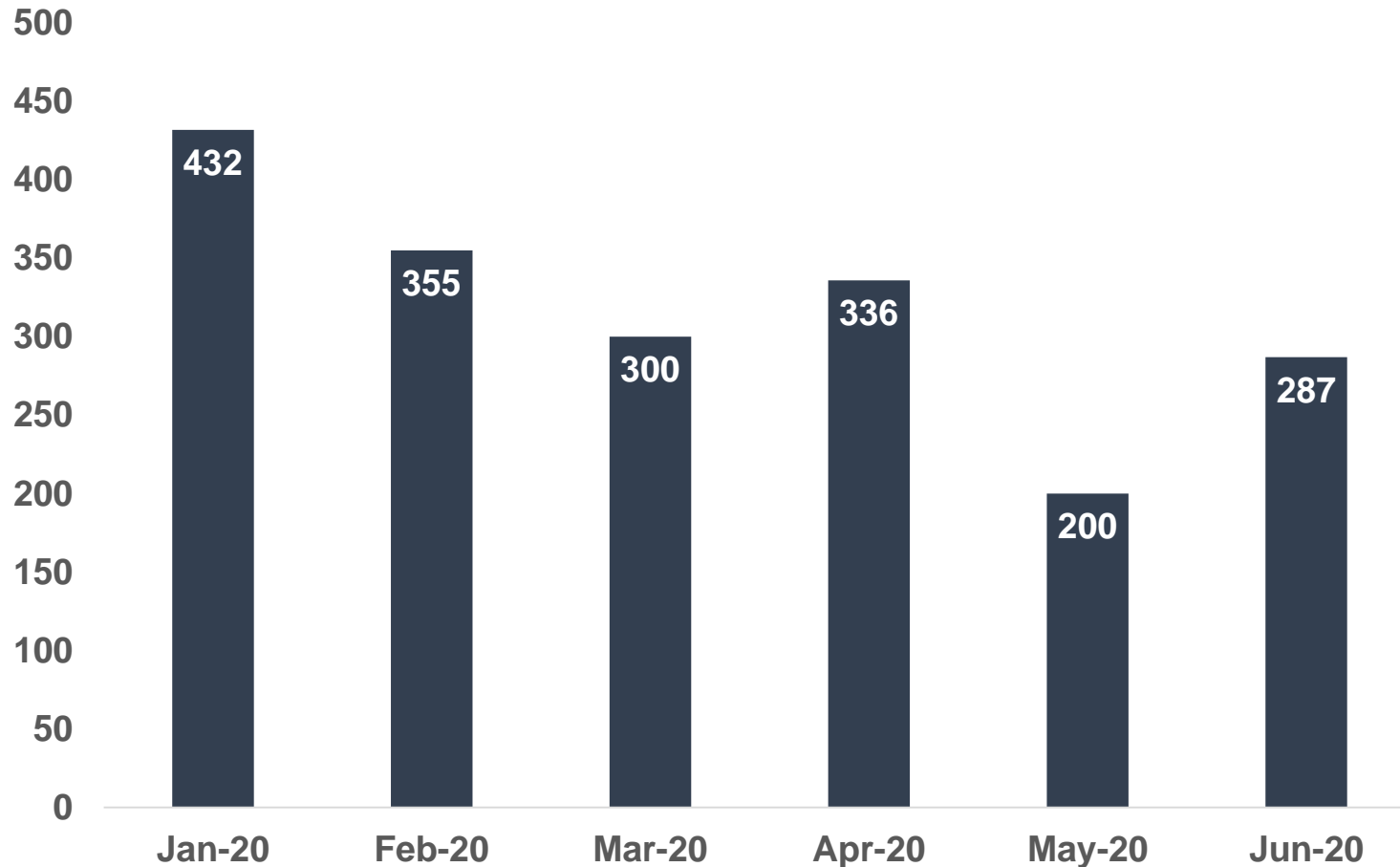
H1 2020
Corporate / Employment Costs



Half Year Sales Review: TLX591-CDx / illumet[®] (prostate imaging)



TLX591-CDx Kit Sales, H1 2020



- Telix delivered approximately 4,600 individual patient doses prepared from over 1,900 TLX591-CDx prostate cancer imaging kits
- Telix received \$2.1m in cash receipts from kit sales for the half, representing a 28% increase over PCP
- Kit pricing remained stable

Current Clinical Activity



PROSTACT

STARLITE★

IPAX-1

ZIRCON

ZIRDAC
Japan

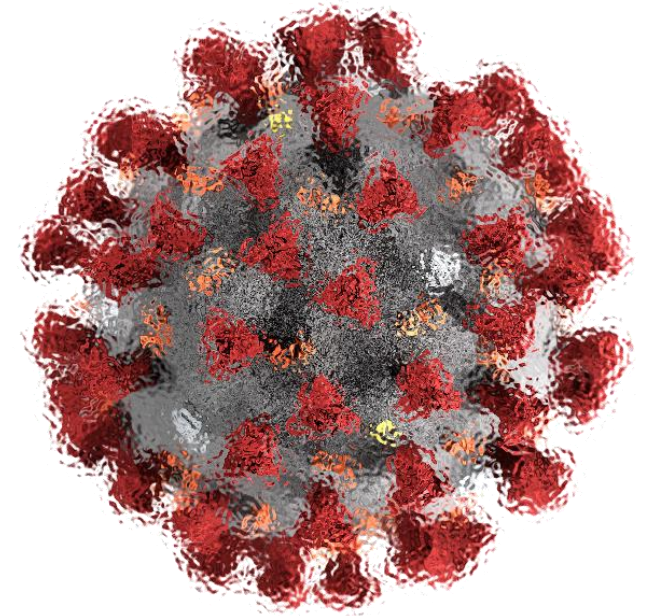
NQBLE

CUPID

Development Stage	Asset	Indication	Status
Phase III (Therapy)	TLX591	Metastatic castrate-resistant prostate cancer (mCRPC)	Ph III IND preparation in progress – Q4 2020 planned start
Phase II (x2) (Therapy)	TLX250	Metastatic clear cell renal cell cancer (ccRCC)	IND(s) in final preparation, manufacturing complete
Phase I/II (Therapy)	TLX101	Recurrent glioblastoma multiform (GBM)	Recruiting
Phase III (Diagnostic Imaging)	TLX250-CDx	Clear cell renal cell cancer (ccRCC) / indeterminate mass	Recruiting
Phase I/II (Diagnostic Imaging)	TLX250-CDx	Clear cell renal cell cancer (ccRCC) / indeterminate mass	Recruiting
Phase II (Registry) (Diagnostic Imaging)	TLX599-CDx	Prostate cancer (registry study)	Recruitment planned to commence Q4 2020
Phase I (Biodistribution)	TLX592	Prostate cancer	Recruitment planned to commence Q4 2020

COVID-19 has had a significant impact on the operational and expenditure profile of the business

- Clinical activity: most clinical activity paused March – August, some re-start of clinical activity for IPAX-1 and ZIRCON in Europe in July
- Lower program-related (external) costs such as manufacturing, logistics due to reduced clinical activity
- Other than key hires (that had been in long-term recruitment), general hiring freeze to prolong cash runway
- Re-allocation of personnel activities to ‘internal’ (non-clinical tasks such as a regulatory, quality and business systems (QMS, ERP, CRM))
- Severely restricted travel, international team engagement
- Significant service provider delays experienced across all of Telix’s operational activity



EU Marketing Authorisation Status (TLX591-CDx)

Telix has submitted an EU marketing authorisation application (MAA) for TLX591-CDx (prostate cancer imaging)

- Submitted in April 2020, mostly based on pre-COVID-19 effort
- Danish Medicines Agency (DKMA) agreed to serve as reference competent authority (CA)
- 14 countries selected in the first cohort of approval countries, includes EU5 (+UK)
- Submission complete, now in individual CA review
- Expect 'consensus' late-2020 / early 2021
- In discussions with several healthcare authorities for temporary marketing authorisations

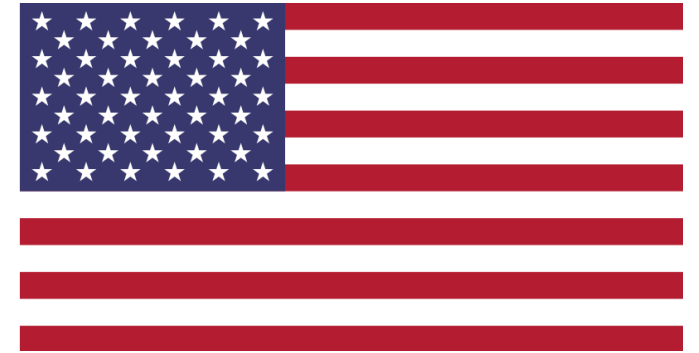


US NDA Submission Status (TLX591-CDx / illumet®)



Telix is in the final stages of preparing a New Drug Application (NDA) to the US FDA

- Will be submitted this quarter (Q3)
- Delays due to both COVID-19 and management decisions around expanding the product label based on FDA consultation and the availability of new clinical data
- All clinical data sources, data quality control and statistical analysis complete. Highly supportive of Telix's submission package
- Currently completing final documentation checks, package QC and preparing for e-publishing
- Close cooperation with US partners (Cardinal Health, Pharmallogic) for market launch
- 30+ IND 'Letters of Authorisation' issued to Telix's Drug Masterfile (DMF) for TLX591-CDx in the H1 of 2020



Other TLX591-CDx Jurisdictions in Progress



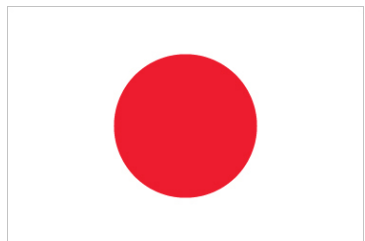
TGA submission preparation in progress, expected to be submitted in Q4 2020. MSAC approval likely mid-2021



Routine provision of compassionate use access under HealthCanada requests. Currently preparing submission package



Swissmedic application in progress. A strategic jurisdiction for many countries that follow EU/Swiss regulatory approvals



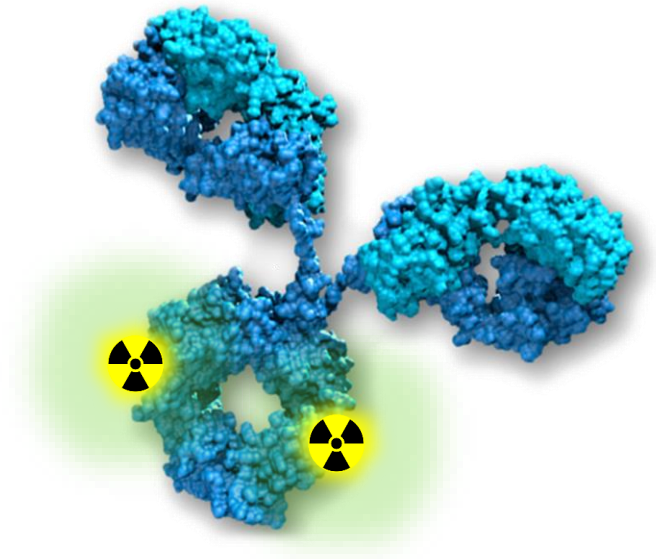
Favourable PMDA and MHLW consultations for establishing 'bridging' clinical activity in Japan to global marketing authorisation packages

ProstACT: Phase III Prostate Cancer Therapy

Valuable pre-Phase III meeting with the FDA completed (Q3)

- Currently refining the clinical protocol based on FDA feedback
- Very useful / positive feedback with respect to the use of imaging (TLX591-CDx) for patient selection and enrichment
- Expect to send a further package to the FDA in the next 3-4 weeks for an additional pre-IND meeting
- Phase III design has focused considerably:
 - ✓ Well defined patient population
 - ✓ Clear proposed end-points
 - ✓ Considerably streamlined patient sample size
- Final protocol expected to be completed in mid-Q4
- Australian arm of ProstACT expect to commence end-2020 with US patients in Q1 2021 (subject to FDA/TGA allowance)

PROSTACT



Summary: Commercial and Clinical

Despite COVID-19, H1 was highly active with significant commercial and program-related progress

- Effective management of Telix's financial resources despite major operational and clinical impact of COVID-19
- EU MAA submitted on time, US NDA delayed but on track for Q3 submission, other commercially useful jurisdictions in progress
- High level of commercial activity, including building global distribution networks for TLX591-CDx and preparation for market launch activities
- Global sales continuing to grow for TLX591-CDx
- H2 2020 will be extremely active for the company on both commercial and clinical fronts



R&D Progress

Telix R&D Strategy








Telix's innovation strategy combines both in-house technology platform development and collaboration with leading academic centres, with several key objectives:

- ✓ Product life cycle management to maintain category leadership
- ✓ Platform development – expanding the capabilities and utility of our core portfolio of molecules (and plenty of new IP creation)
- ✓ New clinical application areas, for example – image-guided surgery
- ✓ Indication expansion for existing products under development



Meet the ‘Extended Family’



Core Technology	R&D Enhancement	Technology Collaborators	Development Status
TLX101 	TLX102 : ²¹¹ At “alpha” variant of TLX101 for multiple myeloma	Osaka University, Japan University of Nantes, France	<ul style="list-style-type: none"> • FDA orphan drug granted • Preparing for first-in-human
TLX591-CDx 	TLX591-Sx⁽¹⁾ : Addition of a fluorescing agent for image-guided surgery	German Cancer Found’n (DKFZ) Univ. of Heidelberg, Germany	<ul style="list-style-type: none"> • IP license option exercised • First investigator-led clinical studies in Q3 2020 (Germany)
TLX591-CDx 	TLX599-CDx : Chemistry for ^{99m} Tc for “rest of world” PSMA imaging where PET is not available	Instituto Nacional de Investigaciones Nucleares, Mexico	<ul style="list-style-type: none"> • Commencing Phase II study in Q3, 2020 (International)
TLX591 	TLX592 : Antibody Pk-engineered to support use with ²²⁵ Ac “alpha” therapy	Abzena Ltd	<ul style="list-style-type: none"> • Commencing first-in-human studies in Australia, Q3 2020 (subject to approvals)
TLX250-CDx 	Exploration of clinical potential to image other cancers, beyond renal cancer	GenesisCare, Australia Radboud Univ., Netherlands ATONCO, France	<ul style="list-style-type: none"> • Investigator-led studies ongoing

Notes: (1) Sx denotes surgical application

TLX102: ^{211}At -Phe

Indication: Multiple Myeloma

Innovation:

- New chemistry to replace ^{131}I in TLX101 with ^{211}At (astatine)
- High-specific activity chemistry, rapid synthesis – new IP portfolio, also benefits commercialisation of TLX101

Rationale:

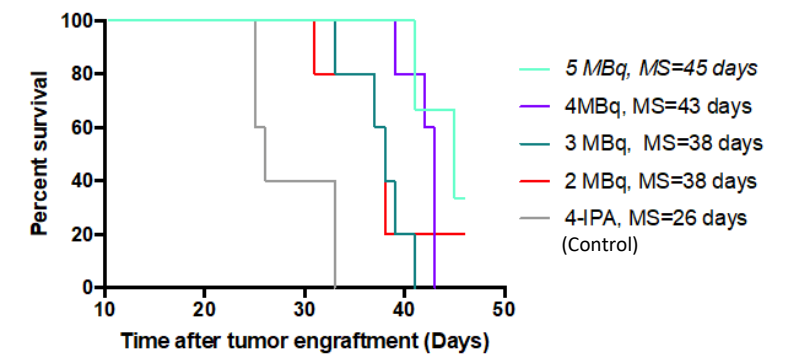
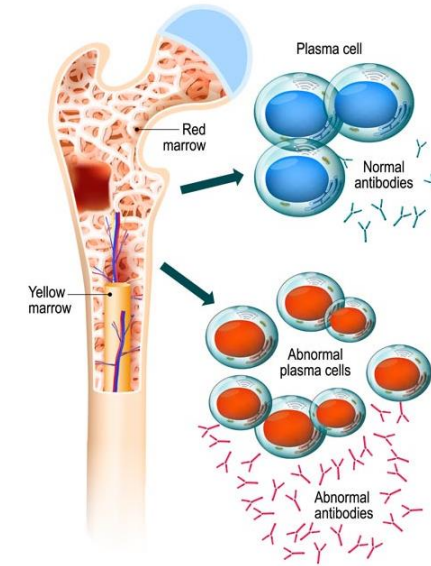
- LAT-1 is highly expressed in multiple myeloma but disseminated nature of the disease means a short irradiation distance isotope is desired
- Example of a ‘Targeted Alpha Therapy’ (TAT) approach to delivering localized radiation

Potential benefit:

- Irradiate abnormal plasma cells with minimal damage to healthy bone marrow

Next steps:

- High promising data in ‘industry standard’ pre-clinical models of MM progression
- Chemistry / planning for clinical evaluation H2, 2021
- Pre-clinical work was completed within 2019/2020 R&D budget with additional funding from the Japanese Science & Technology Agency (JST) OPERA program



Courtesy, University of Nantes

TLX591-Sx: ⁶⁸Ga-DYE-PSMA-11

Indication: Image-guided surgery for prostate cancer



Innovation:

- Extends the TLX591-CDx platform to a dual-modality tracer that combines PET imaging and optical (fluorescence) imaging in the same molecule
- One injection – two images. PET and optical guidance for minimally-invasive / robotic surgery

Rationale:

- Surgical robotics has become a dominant part of the prostate surgery technology landscape. Modern systems include the ability to perform real-time optical imaging to guide surgical resection and margin assessment

Potential benefit:

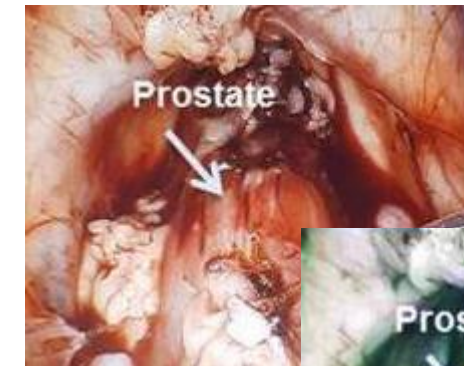
- Provide both a high-quality pre-operative PET image as well as an intra-operative fluorescent image real-time in the operating theatre

Next steps:

- Currently developing a kit for early clinical research adoption (H1 2021)
- Initial clinical evaluation planned for Q3, 2020 under investigator-led study in Germany
- Will assess initial academic clinical experience before planning and commencing TLX-led clinical development



DaVinci® system – Intuitive Surgical



White light



Fluorescence⁽¹⁾

Notes: (1) Baranski et al. J Nucl Med. 2018 Apr;59(4):639-645

TLX599-CDx: ^{99m}Tc -HYNIC-PSMA

Indication: Prostate cancer imaging, globally

Innovation:

- New chemistry to extend the utility of PSMA-11 to ^{99m}Tc to enable imaging of prostate cancer with gamma camera / SPECT imaging

Rationale:

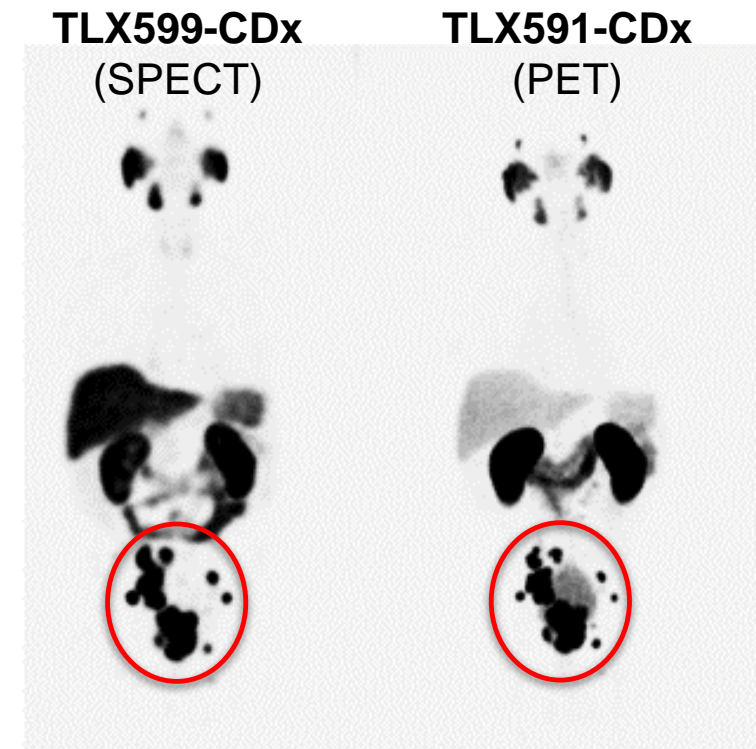
- Outside of developed countries and major cities, PET is less common. However PSMA imaging is needed by millions of men that don't have access to PET
- PSMA therapy adoption, world-wide, will be significantly driven by the availability of ubiquitous imaging

Potential benefit:

- Access to high volume but price-sensitive markets with a cost-effective product
- Significantly increases patient access, ubiquitous supply chain for ^{99m}Tc

Next steps:

- Global Ph2 study – the 'NOBLE' study (Nobody Left Behind) will commence in Mexico, South Africa, Egypt, Australia, UAE, India and Russia (subject to approvals) and will complete before end-2020
- NOBLE study is within planned 2020 R&D expenditure
- Ph III planned for early 2021



(Left) maximum-intensity projection of ^{99m}Tc -HYNIC-PSMA SPECT/CT compared with a maximum-intensity projection of ^{68}Ga -HBED-CC-PSMA PET/CT (right) in the same prostate cancer patient. Courtesy ININ

Global Clinical Leadership



Chair

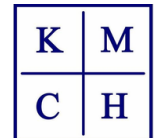
Dr. Batool Albalooshi
Ambassador | UAE



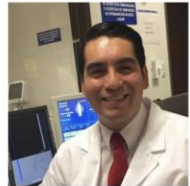
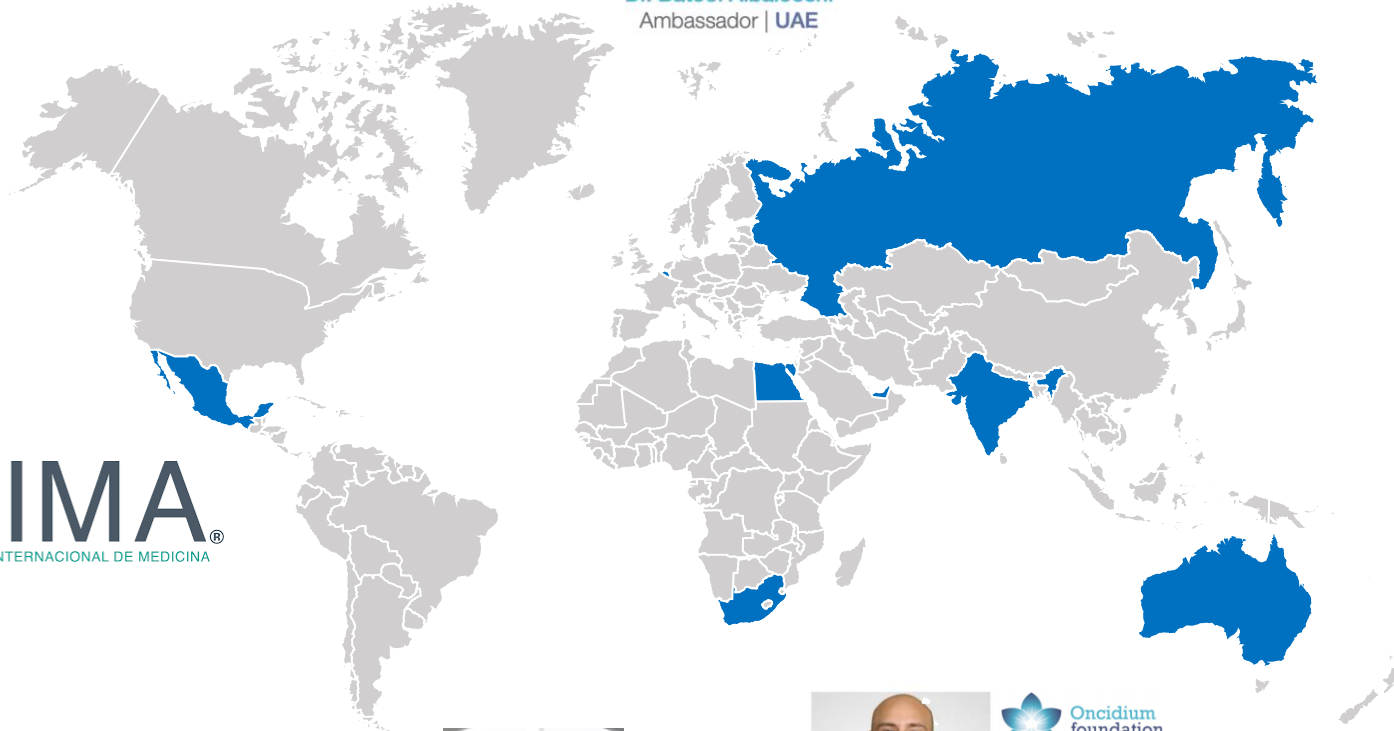
Dr. Pavel Rumiantsev
Russia



Dr. Ajit Shinto
India



Dr. Peter Tually
Australia



Dr. Ivan E. Diaz Meneses
Ambassador | Mexico



Dr. Mike Sathekge
South Africa



Dr. Yehia Omar
Ambassador | Egypt



TLX592: ^{225}Ac -PSMA

Indication: Treatment of ^{177}Lu -PSMA Progressive Patients



Innovation:

- TLX591 antibody re-engineered to clear ~10x faster from the body, while maintaining specificity for tumour-expressed PSMA (liver cleared, no exocrine uptake)
- Harnesses Telix's proprietary RADmAb[®] platform technology

Rationale:

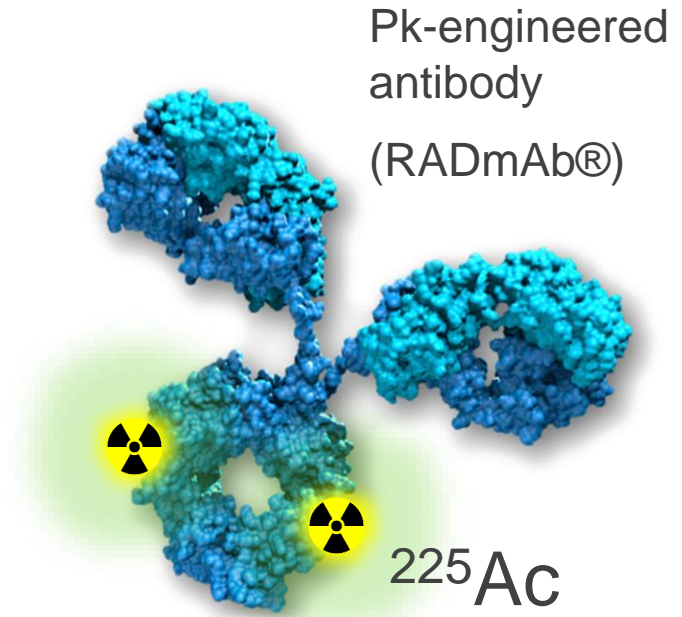
- Targeted Alpha Therapy (TAT) is becoming an important area of PSMA therapy research, particularly in men that are no longer responding to ^{177}Lu
- Existing small molecule approaches do not appear viable due to unacceptable off-target, renal toxicity

Potential benefit:

- Treatment of patients that are progressing off ^{177}Lu -PSMA therapy
- As a potential adjuvant for high-risk patients that may have early metastatic disease

Next steps:

- Commencing initial patient studies in Q3, 2020 (Australia) to assess biodistribution, targeting, Pk modifications
- Preliminary patient studies are within 2020 R&D budget
- Depending on preliminary data, rapid progression to Ph II is possible



TLX250-CDx: ^{89}Zr -girentuximab

Indication: Use in Other (Non-Renal Cancer) Indications

Innovation:

- TLX250-CDx targets Carbonic Anhydrase IX (CA9), a target that is highly expressed in many late-stage cancers

Rationale:

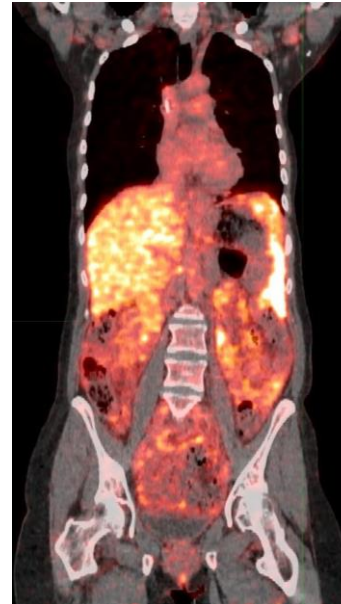
- Explore the utility of TLX250-CDx in other cancers where conventional imaging has limitations

Potential benefit:

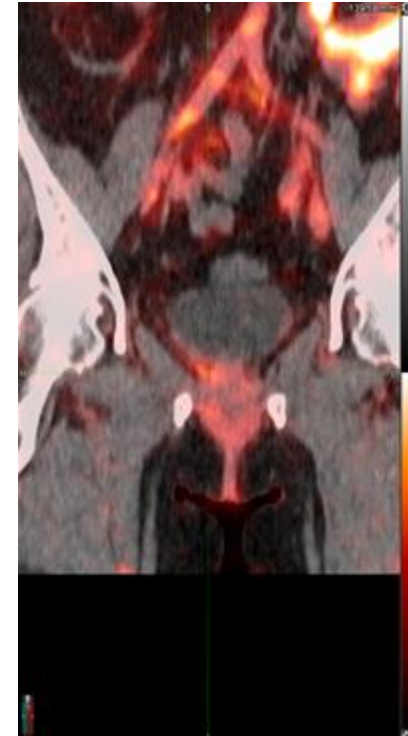
- Improved staging, therapy planning
- CA IX may be particularly important in determining responsiveness to immunotherapy⁽¹⁾

Next steps:

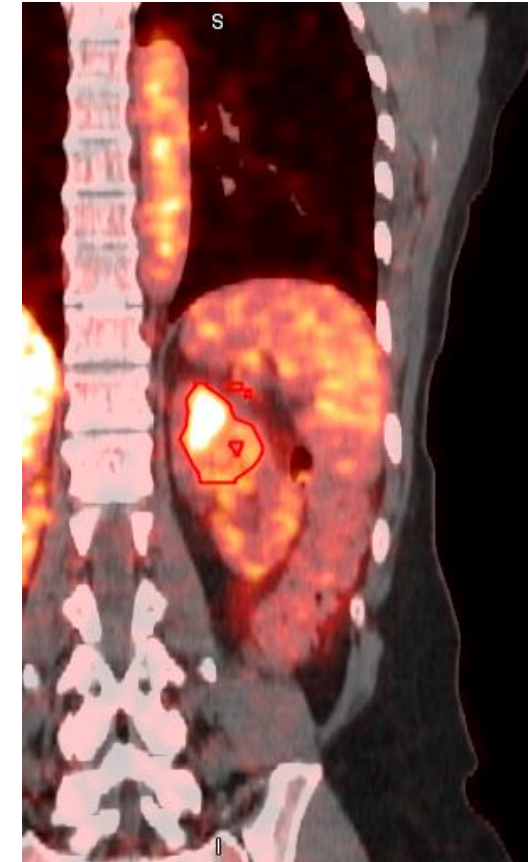
- Multiple investigator-led studies ongoing in ovarian, bladder, urothelial, colorectal, head & neck cancers



Metastatic ovarian cancer ⁽²⁾



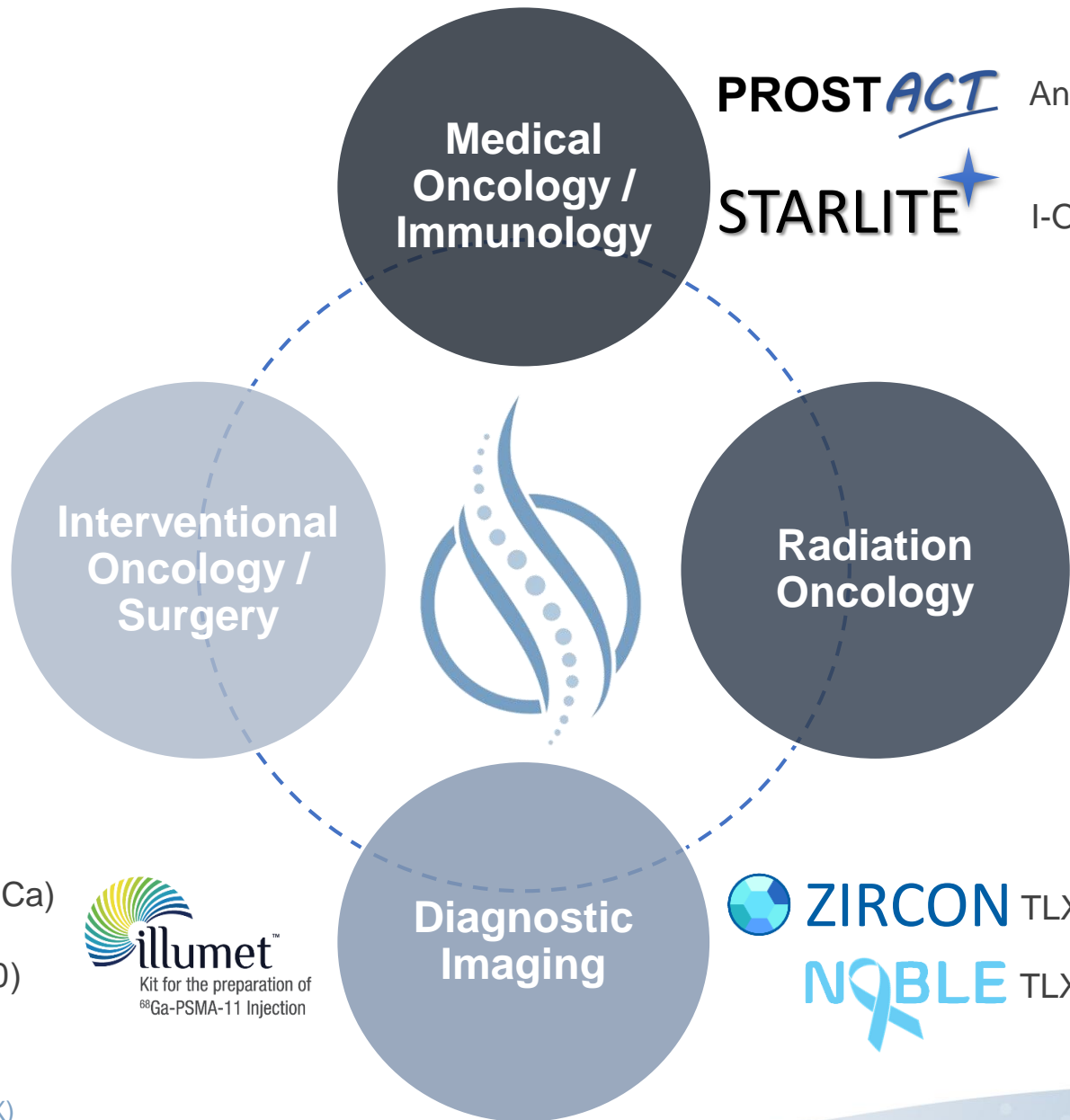
Infiltrating bladder cancer ⁽²⁾



Metastatic urothelial cancer (Transition cell) ⁽²⁾

Notes: (1) Giatromanolaki A et al. British Journal of Cancer (2020) 122:1205–1210
(2) Non-ccRCC TLX250-CDx Images courtesy of Dr Nat Lenzo, GenesisCare

R&D Vision: Telix will Integrate Oncology



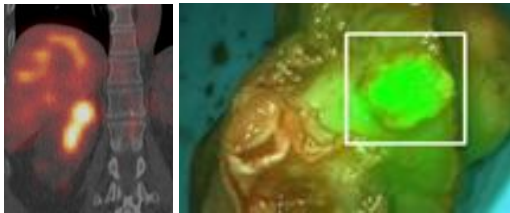
Medical
Oncology /
Immunology

PROSTACT

Androgen + TLX591 (PCa) – Ph III

STARLITE

I-O + TLX250 (RCC) – Ph II (x2)



TLX591-OR (PCa/GBM) – Ph I

dkfz.

German Cancer Consortium

Radiation
Oncology

IPAX-1

XRT + TLX101
(GBM) – Ph I / II



XRT + TLX591-CDx
(PCa) – Ph II

reflexion

Biology-guided
radiation therapy

Diagnostic
Imaging

TLX591-CDx (PCa)
EU MAA (Filed)
US NDA (Q3 '20)

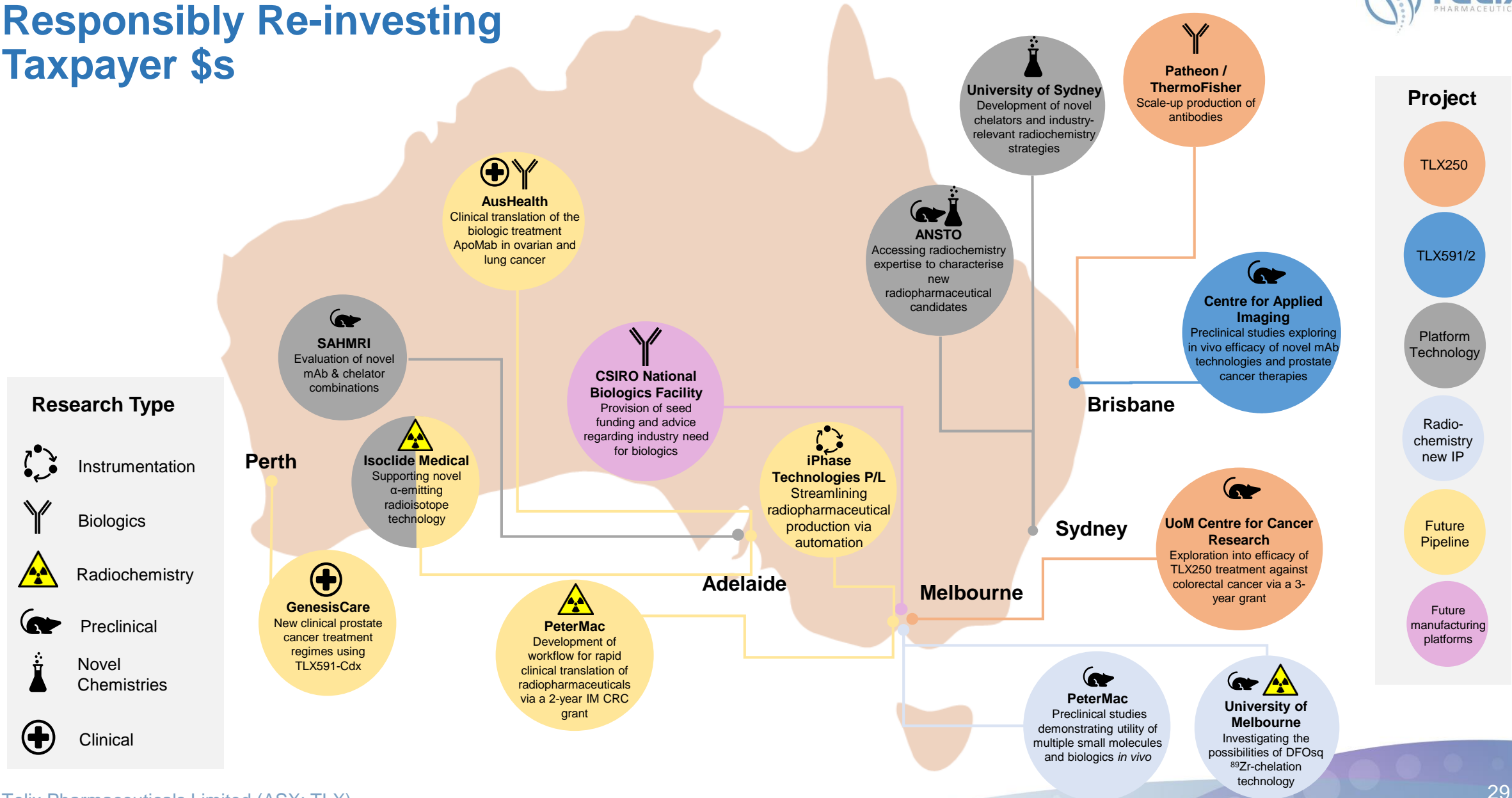


TLX250-CDx (RCC) – Ph III (breakthrough)



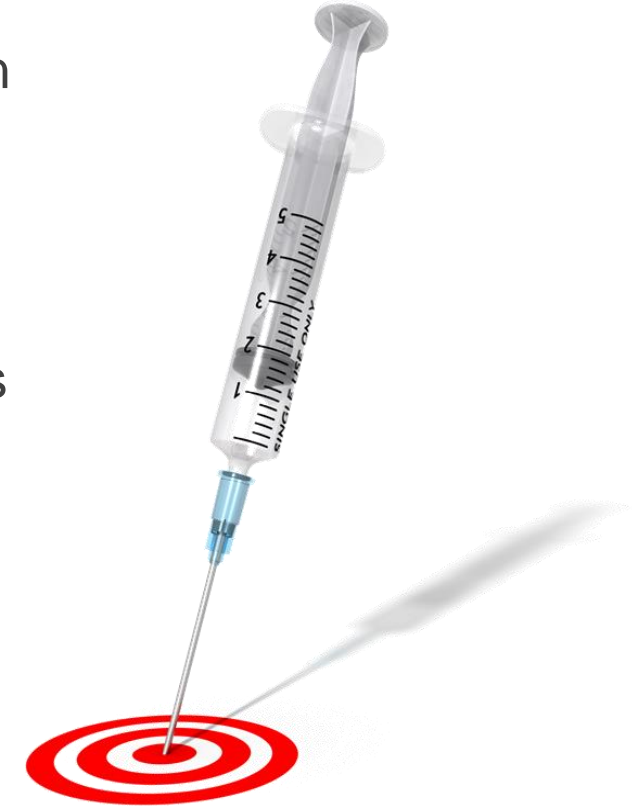
TLX599-CDx (PCa) – Ph II

Closer to Home: Telix is Responsibly Re-investing Taxpayer \$



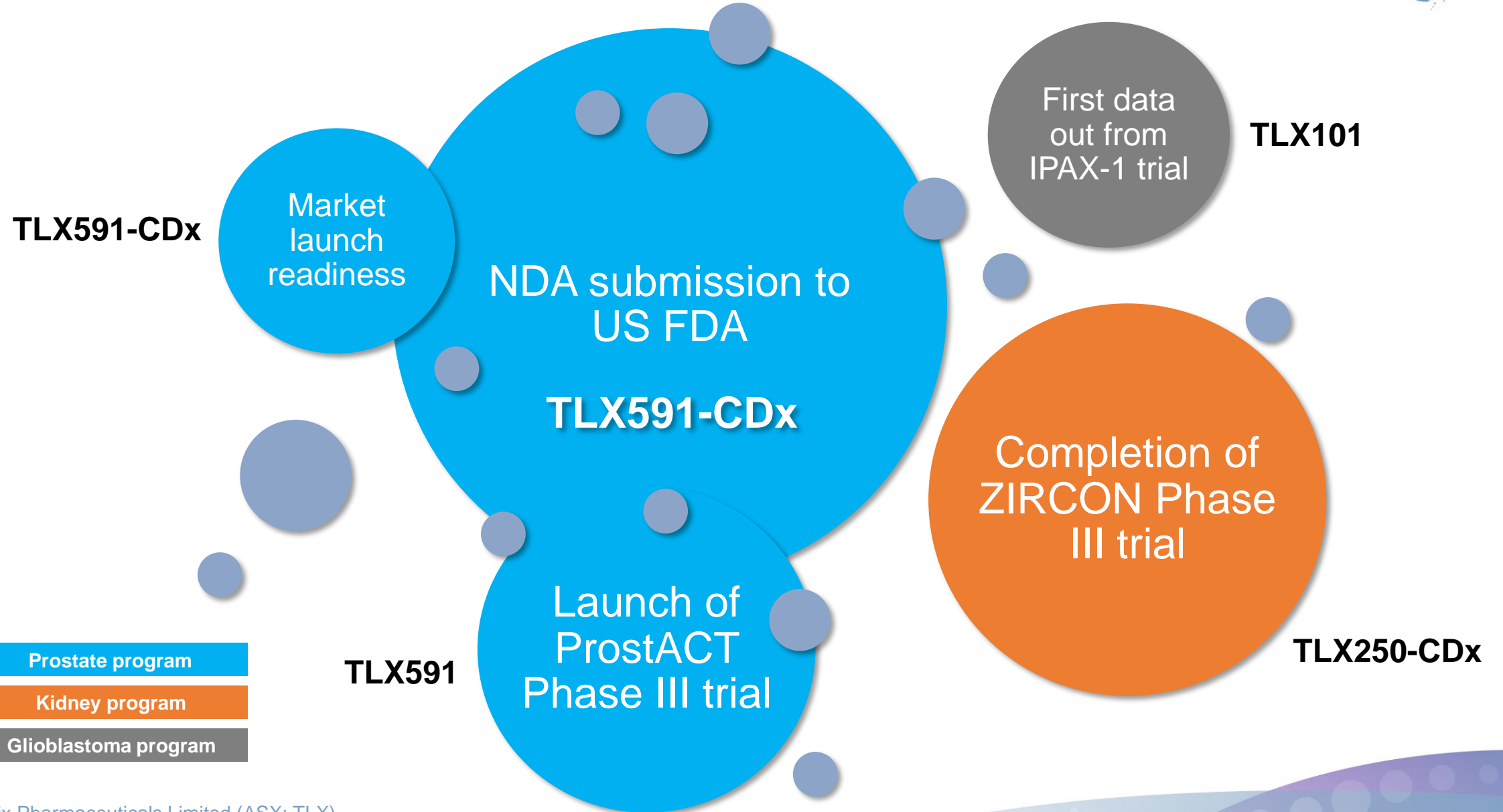
Summary: R&D Impact

- Telix's R&D activities are high-impact and cost-effective, harness third party funding and high-quality collaborations
- Leverage both internal development capabilities and academic key opinion leaders
- Pipeline / indication expansion rationally builds on existing pipeline of molecules and platform technologies
- Significant potential upside in terms of access and new patient populations
- Supports Telix's objective of category leadership in urologic oncology
- Australia is a strategic R&D asset for Telix, alongside extensive global collaborations. Taxpayer R&D funds are being re-invested
- Positions Telix as a leading player in the field of Targeted Alpha Therapy (TAT), with two clinic-ready programs



Second Half 2020...

Five Big Events will Define the Next Six Months



Summary of 2020 Inflection Points



April – June 2020

Prostate cancer imaging (TLX591-CDx)

- ✓ European MAA submitted (April)



July – September 2020

Prostate cancer imaging (TLX591-CDx)

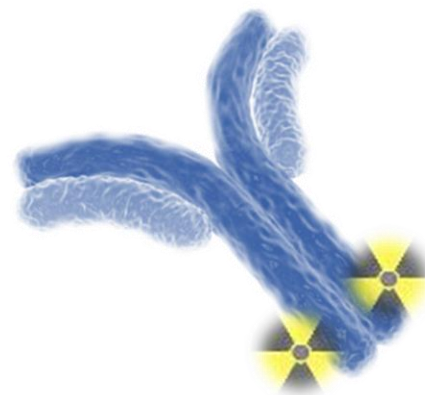
- ✓ US NDA submission imminent

Prostate cancer therapy (TLX591)

- ✓ US FDA pre-IND meeting for PROSTACT Phase III RCT (July)

Kidney cancer therapy (TLX250)

- ✓ IND submitted to US FDA for STARLITE Phase II trial



October – December 2020

Prostate cancer imaging (TLX591-CDx)

- ✓ Commercial launch readiness for early 2021

Prostate cancer therapy (TLX591)

- ✓ PROSTACT Phase III RCT initiated

Kidney cancer imaging (TLX250-CDx)

- ✓ ZIRCON Phase III patient recruitment completed

Kidney cancer therapy (TLX250)

- ✓ STARLITE Phase II trial open

Glioblastoma therapy (TLX101)

- ✓ Preliminary safety and efficacy data available



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