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Telix Pharmaceuticals (TLX)

First Approval Imminent

Speculative
See key risks on Page 4 and Biotechnology Risk Warning on Page 30. Speculative securities may not be suitable for Retail Clients.

Recommendation
Buy (Initiation)
Price
$5.53
Valuation
$8.00 (initiation)
Risk
Speculative

GICS Sector

Healthcare Equipment and Services

Expected Return	
Capital growth	**44.7%**
Dividend yield	**0.0%**
Total expected return	**44.7%**

Company Data & Ratios	
Enterprise value	**$1,557.4m**
Market cap	**$1,508.4m**
Issued capital	**281.6m**
Free float	**82%**
Avg. daily val. (52wk)	**$2.9m**
12 month price range	**$1.31 - $6.65**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	5.54	3.90	1.27
Absolute (%)	-3.97	36.41	320.55
Rel market (%)	-7.78	29.77	295.04

Absolute Price

SOURCE: IRESS

Breaking new ground in Prostate Cancer

Telix Pharmaceuticals is one of Australia's leading pharma groups specialising in the development and commercialisation of radiopharmaceuticals for the imaging and treatment of solid cancers. Its first major product release is on the cusp of approval in several major markets including the US. The pending approval of Illuccix for molecular imaging of metastatic prostate cancer for both initial staging and biochemical recurrence is the first in an extensive product pipeline. The second and related product for renal cancer imaging is due in CY2023.

Molecular imaging is a well established field and the hospital infrastructure to support its ongoing use is a given. Telix's value is contained in its very substantial base of Intellectual Property which it has both acquired in part, and developed internally through research and investment in clinical trials. Telix is at the forefront of the next generation of molecularly targeted radiation products where we believe the collective annual revenue potential runs to billions of dollars such is the unmet need.

In addition to the imaging products, Telix and others have developed the first generation of radiopharmaceuticals intended for therapy. The results from earlier studies in men with metastatic prostate cancer appear highly promising and the company is now enrolling patients in an approval study. In our view the development of radiopharmaceuticals for therapy is in its infancy and Telix is exceptionally well positioned to leverage its technology in the development of new products and applications over many years.

Investment view – Buy (Speculative), Valuation $8.00

We initiate coverage with a Buy (Speculative) rating and valuation of $8.00. The valuation is modest compared to recent transactions in the space. The major short term catalyst for the stock includes FDA approval of Illuccix for various indications related to metastatic prostate cancer. Approval is due in September 2021.

Earnings Forecast

December Year End	FY20	FY21	FY22e	FY23e
Revenues $m	5.2	14.5	93.0	168.6
EBITDA $m	-43.1	-42.3	-11.5	36.4
NPAT (underlying) $m	-44.9	-46.8	-16.0	31.9
NPAT (reported) $m	-44.9	-46.8	-16.0	31.9
EPS underlying (cps)	-17.5	-16.7	-5.7	11.4
EPS growth %	na	na	na	na
PER (x)	nm	nm	nm	48.2
FCF yield (%)	na	na	na	2%
EV/EBITDA (x)	na	na	na	41.1
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0%	0%	0%	0%
ROE %	-28%	-42%	-18%	25%

SOURCE: BELL POTTER SECURITIES ESTIMATES

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Investment Thesis

Overview

Telix Therapeutics Limited (Telix) is a pharmaceutical group specialising in the development and commercialisation of radiopharmaceuticals for the imaging and treatment of certain cancers. Its first major product approval is due in September 2021.

Despite outstanding progress in the development of new treatments for cancers over the last decade including CAR-T therapy and a swathe of new biological products, there remains ample virgin territory for new therapies. Telix is at the forefront of next generation molecularly targeted radiation products where we believe the collective annual revenue potential runs to billions of dollars such is the unmet need.

Radiopharmaceuticals are not new to oncology, however, the field has expanded rapidly over the last decade due to improved funding, which has generated investment in R&D, clinical data resulting in vast expansion of the supply chain. In addition, recent advances in the fields of physics, chemistry, medical imaging and biology have led to the development of new applications for both the imaging and treatment of specific cancers. Telix was established with a view to developing these applications specifically for metastatic castrate resistant prostate cancer, renal cancer and glioblastoma. The company has a large R&D program under way to develop these assets.

The core technology is Molecularly Targeted Radiation (refer Appendix 1) which has attracted major investment by top tier pharmaceutical companies in recent years including US$6bn from Novartis. Several products in this class of drug are now approved in the US and Europe both for imaging and therapy. In our view the progress of these pioneering drugs has considerably de-cluttered the approval pathway for fast followers including Telix.

Other developers including Novartis have competing therapies to those being developed by Telix, however, the Telix products are generally highly differentiated and in our view superior either in efficacy or cost to those currently on market or close to approval.

Telix acquired and in-licensed most of the intellectual property related to its products and is funding the clinical studies which will underpin the approvals. The nearest of these approvals is imminent with the FDA's decision on Illuccix due in September 2021. Illuccix is a new drug designed for the imaging of metastatic castrate resistant prostate cancer. It will be the first prostate cancer imaging agent of its kind designed for commercial application to use the radioisotope ^{68}Ga[1]. Telix is partnered with radiopharmaceutical giant Cardinal Health for the US market. We expect the drug to generate in excess of $90m in its first full year of commercialisation (being CY2022).

We expect the second drug to market will be TLX-250CDx being a new drug for the imaging of renal cancers. There are no radiopharmaceutical competitors in this market and the approval study - ZIRCON is approaching completion by the end of CY21. The drug was awarded Breakthrough Designation by the FDA and we expect an approval in CY23.

As to be expected in a company with a considerable investment in Intellectual Property, the founders have an extensive scientific background in physics and chemistry. The two co-founders Dr Christian Behrenbruch (CEO) and Dr Andreas Kluge (Non Executive Director) retain approximately 24m shares each and both remain instrumental to setting the company's direction and priorities.

We initiate coverage with a Buy (Speculative) rating and valuation of $8.00.

[1] Novartis has 68Ga product approved for imaging of neuroendocrine tumours (NET).

Risk Areas

Key risk areas include but are not limited to the following items:

Telix's ability to achieve profitability is dependent on a number of factors, including its ability to complete successful clinical trials, obtain regulatory approval for its products and successfully commercialise them in key markets. There is no guarantee that the company will achieve these goals.

Telix does not currently generate revenue from approved product sales, however, we do expect revenues in the short term provided there is no delay to the approval of Illuccix in key markets. If there are delays to the expected approval timetable, the company is likely to continue to rely on shareholders to fund the business.

Clinical trial risk

Telix may be unable to secure necessary approvals from regulatory agencies and institutional bodies (clinics and hospitals) to conduct future clinical trials. There is also no assurance that either of the drugs under development will prove to be safe and efficacious in clinical trials, or that the regulatory approval to manufacture and market its products will be received. Clinical trials might also potentially expose the company to product liability claims in the event its products in development have unexpected effects on clinical subjects.

The company is also dependent on commercially attractive markets remaining available to it during the commercialisation phase and there is a risk that, once developed and ready for sale, commercial sales to fund sufficient revenues for continued operations and growth, may not be achieved.

Arrangements with third-party collaborators

Telix's capacity to generate revenues is dependent upon collaborative arrangements with distributors and supply chain partners, academic institutions or other partners to complete the development and commercialisation of its products. There is no assurance that Telix will attract and retain appropriate strategic partners or that any such collaborators will perform and meet commercialisation goals. If Telix is unable to find a partner (which we believe is unlikely), it would be required to develop and commercialise its products at its own expense. This may place significant demands on the Company's internal resources and potentially delay the commercialisation.

Requirement to raise additional funds

Telix is yet to generate a profit or cash inflows from operations. The company may be required to raise additional equity or debt capital in the future. There is no assurance that it will be able to raise that capital when it is required or, even if available, the terms may be unsatisfactory. If the company is unsuccessful in obtaining funds when they are required, it may need to delay or scale down its operations.

Intellectual property

The company's ability to leverage its innovation and expertise depends upon its ability to protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of unauthorised disclosure or be unlawfully infringed, or the company may incur substantial costs in asserting or defending its intellectual property rights.

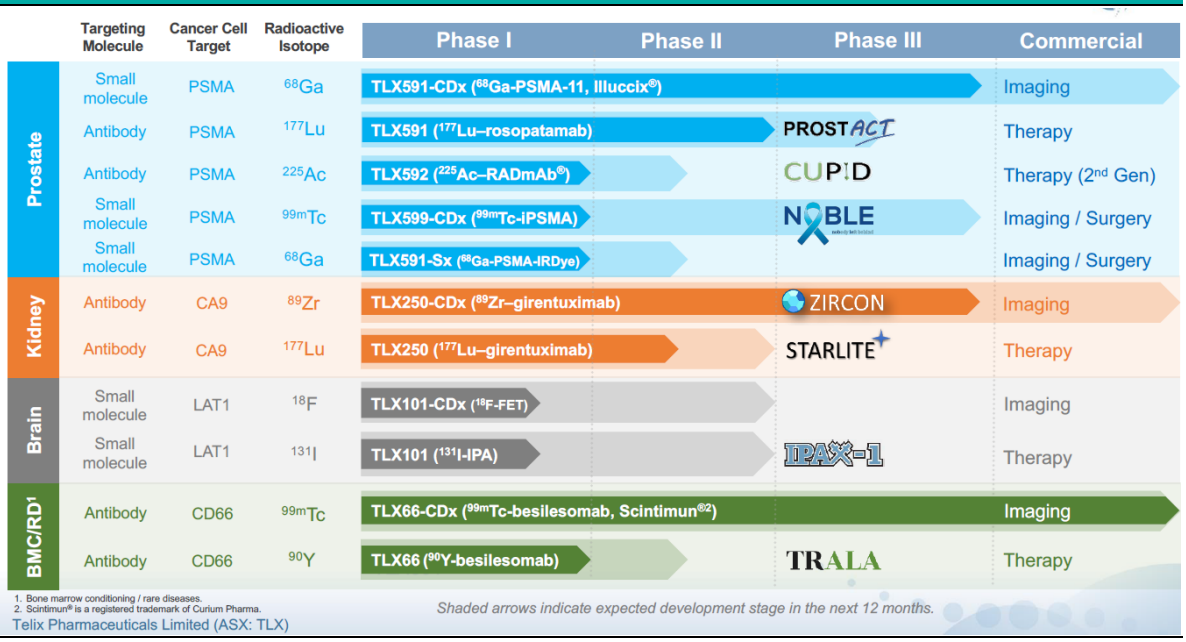
Product Pipeline & Upcoming Approvals

Figure 1 summarises the product pipeline. The most advanced of these are:

- TLX591-CDx for metastatic prostate cancer imaging and TLX250-CDx for renal cancer imaging; and
- The most advanced therapy product is TLX591 for metastatic prostate cancer.

The vast majority of the value in the company is attached to these three products although the entire portfolio is leveraging the technology in these lead products.

Figure 1 - Pipeline Overview



SOURCE: COMPANY DATA

The approval of Illucix for prostate cancer imaging is looming close. The key dates are:

- US - FDA decision due late September 2020;
- Australia – TGA decision likely November/December 2021;
- Europe - Notified Body likely to recommend approval in November 2021; and
- Canada – Awaiting regulatory approval in September 2021.

The company has filed for registration in 17 countries in total with the addressable market value across the US and Europe estimated at US$900m.

The one product currently on market in Europe is Scintimun, indicated for the imaging of areas of inflammation or infection in patients with suspected bone infection (osteomyelitis)[2]. The product was acquired as part of the December 2020 acquisition of TheraPharm in Europe and is currently sold by Curium Pharmaceuticals outside of the US, China and other commercial territories. Revenues are small at this time with the main attraction of Therapharm being the IP in relation to the development ^{90}Y-anti-CD66-MTR for the purpose of bone marrow conditioning (BMC) in patients prior to undergoing hematopoietic stem cell transplant (HSCT) for the treatment of blood cancers (hematologic malignancies) or autoimmune conditions. This is a relatively early stage project having recently reported promising results from a phase I/II study.

[2] Scintimun is a registered trademark of Curium Pharmaceuticals

Prostate Cancer Overview

Prostate cancer is the second most common cancer in men and the fifth leading cause of death worldwide. Whilst early detection and treatment options have improved over recent decades, approximately 375,000 men die from the disease each year.

Prostate cancer screening is via a blood draw to monitor increases in the prostate specific antigen (PSA). Suspected disease is diagnosed via biopsy. Following initial treatment, if PSA levels continue to rise, it is likely the disease has spread beyond the prostate organ and most commonly to bones and lymph nodes. Once disease stops responding to androgen therapy it is classified as metastatic castrate resistant prostate cancer (mCRPC).

Molecular imaging typically involves a PET (positron emission tomography) scan with a radiopharmaceutical to help identify the sites of the cancer spread.

The current 5-year survival rate for men with local or regional prostate cancer is ~95% and ~30% for later stage cancer. The recurrence rate among men who have undergone initial treatment for locally advanced disease is high at ~40%.

The treatment cascade for prostate cancer is displayed in figure 9. Treatment for early stage disease is highly successful in keeping patients alive, albeit removal of the prostate, radiotherapy and or androgen deprivation therapy are not without the possible life long side effects including erectile dysfunction and incontinence, hence the need for improved therapies.

The first radiopharmaceutical to receive approval for the imaging of metastatic prostate cancer was Fluciclovine (^{18}F) in 2016 (brand name Axumin). Axumin opened the door for nuclear medicine and the imaging of mCRPC. Since then one new isotope has been approved – being ^{68}Ga (pronounced Gallium 68) albeit predominantly in a research capacity.

There are several radiopharmaceutical drugs approved for therapy including Xofigo (^{223}Ra) for very late stage prostate cancer, Lutathera (marketed by Novartis) for neuroendocrine tumours, Zavalin and radioactive iodine Treatment (^{131}I) for thyroid cancers.

Unmet need

From an imaging perspective, the unmet need is in detecting the early spread of the cancer in high risk patients and patients with recurrent disease. Conventional imaging is prone to overlook small tumours (i.e. <1cm in size) whether from initial metastatic spread or from disease recurrence. From a therapy perspective, there is an urgent need for new and improved treatments to prolong overall survival and improve quality of life for survivors.

Telix is developing separate radiopharmaceuticals for imaging and therapy of mCRPC. The common thread in these drugs is the targeting of the prostate specific membrane antigen (PSMA). PSMA is highly expressed on 90% of prostate cancers making it an ideal target for systemic drugs.

Several pharma companies are involved in the development of both imaging and therapy agents with the same target (PSMA) using the same radionuclides and we analyse these in the following sections.

TLX's intellectual property for its applications has been licenced in or acquired over numerous deals completed since its IPO in 2017. The use of nuclear imaging (aka molecular imaging) and radiopharmaceuticals for application in prostate cancer remains a relatively new field of medicine with many ongoing research projects.

Prostate Cancer Imaging

TLX is developing TLX591-CDx (brand name Illuccix) as an imaging diagnostic in men with suspected metastatic prostate cancer or suspected biochemical recurrence following initial therapy for local disease. The most common sites for recurrence include pelvic lymph nodes and bones.

The company's entry into this market was via the acquisition of ANMI in 2018 for A$17.2m.

TLX has taken the Illucix from proof of concept to the verge of market approval in approximately 2½ years. The product gained a national use exemption in Czech Republic earlier this year with 17 countries anticipated to approve the product in the second half of CY 2021.

MECHANISM OF ACTION

Illuccix is a form of molecularly targeted radiation (refer appendix 1). The targeting agent is a small molecule (PSMA-11) that is highly selective for PSMA, radiolabelled with ^{68}Ga (Gallium 68). The drug is administered intravenously whereupon it selectively binds to PSMA.

PSMA is over expressed on prostate cancer cells (thousands of times higher) relative to healthy cells. The drug binds preferentially to PSMA compared to normal cells. As ^{68}Ga decays it sheds positrons (aka beta radiation) being low energy sub atomic particles which are detected via a Positron Emission Tomography (PET) scanner[3]. The resultant images from the PET scan show the location of the cancerous cells in very high contrast to normal tissue.

Illuccix comes in a "cold kit" form for the preparation of a ^{68}Ga-PSMA-11 injection. The preparation takes a few minutes and involves combining kit components with ^{68}Ga produced in the hospital radio-pharmacy.

PSMA-11 is a widely used prostate cancer imaging agent. The actual peptide is a public domain asset over which Telix has no IP, however, Telix has other intellectual property embodied in the product which enables it to be classified as a distinct and proprietary drug.

INTELLECTUAL PROPERTY

The key asset in the ANMI acquisition was the cold kit, or more precisely the formulation chemistry which allows the radionuclide to be combined with PSMA-11 to make the drug on demand and patient ready in a few minutes, hence suitable for the hospital pharmacy. The hospital prepared drug is significantly cheaper and more flexible compared to drug made in a GMP facility (i.e. cyclotron) – as is the case for imaging agents using 18F including Axumin.

Illuccix has been validated with the three leading brands of gallium generators. Validation data with IRE, E&Z and ITG generators was provided to the FDA in the Drug Master File (DMF) submission for the product. Currently validated generators reflect a majority of the install base of 68Ga generators in the United States – and globally.

The patents on the cold kit formulation run until at least 2034 in the US and Europe.

[3] ^{68}Gallium is a by product of ^{68}Germanium. Germanium has the atomic number 32 vs gallium 31. The isotope of Germanium decays by shedding positrons in a form a radioactive decay known as beta radiation.

REGULATORY APPROVALS

Telix successfully completed clinical development of Illuccix and expects to launch the imaging agent as its first commercial product in US, EU, Canada and Australia in the second half of CY2021.

Prior to submission the company had conducted a pre NDA meeting with the FDA in July 2019 and received written guidance on key matters regarding the NDA. The NDA is regulated under the 505(b)(2) pathway and was accepted for filing in November 2020. The NDA includes data from supporting literature for 68Ga-PSMA-11 in more than 10,000 patients in published clinical studies from around the world. The written guidance also covered topics including manufacturing, specifications for the cold kit, safety and dosing amongst others.

An EU and UK marketing authorisation application (MAA) was submitted in April 2020 with estimated approval (country-by-country) commencing in Q3CY21.

The Australian TGA submission was accepted in April 2021 with a 150-day dossier review and approval. Canadian approval is anticipated for Q4CY21 with the NDS accepted for review.

The definitive research on 68Ga-PSMA-11 was performed by Hofman et al at Peter MacCallum in Melbourne and was published in 2019[4]. In this randomised study investigators compared PSMA PET to conventional imaging and found the PSMA PET scan was overwhelmingly more accurate with higher sensitivity and specificity. The FDA approval of 68Ga in December 2020 was based on 2 separate studies, the largest of which was conducted at a single arm study at UCLA/UCSF. In this single arm trial investigators found that detection rates for recurrent cancers significantly increased in line with the level of PSA expression.

COMPETITIVE LANDSCAPE

The two isotopes used for prostate imaging are ^{68}Ga and ^{18}F. Figure 2 summarises the competitive landscape in the US. The market is currently dominated by the ^{18}F products where the isotope is produced in the Cyclotron.

The first ^{68}Ga PSMA-11 product was approved by the FDA in December 2020. The NDA was submitted by UCLA Nuclear Medicine and UCSF Nuclear Medicine and this approval is limited to research rather than commercial use. There are several commercialised/ clinical-trial phase PSMA targeting imaging agents.

Figure 2 - Landscape for Prostate Cancer Imaging Agents

Company	Product	Agent	Isotope	Stage	Partner
Blue Earth	Axumin	Amino Acid transporters including LAT-1 and ASCT2	18F	Approved (2016) for US, EU	PETNET
Blue Earth	rhPSMA-7.3	PSMA	18F	Phase 3	PETNET
Lantheus	PYLARIFY	PSMA	18F	Approved (2021) for US	SOFIE/INTERNAL
Novartis	CTT1057	CTT/PSMA	18F	Phase 3	?
UCLA/UCSF	68Ga-PSMA-11	PSMA	68Ga	Approved (2020) for US	NA - Research
Telix	**Illuccix**	**PSMA**	**68Ga**	**Awaiting NDA approval**	**Cardinal Health/Pharmalogic**

SOURCE: BELL POTTER SECURITIES, LABEL INSERT FOR AXUMIN

There is considerable ongoing research in the field of prostate cancer imaging with at least 8 separate investigator led clinical trials, experimenting with ^{68}Ga for the imaging of recurrent prostate cancer. The National Cancer Institute in the US continues to fund numerous trials investigating the use of Fluciclovine (^{18}F) as an imaging agent for metastatic prostate cancer as well as brain cancers, head & neck, and cervical cancers.

[4] Hofman et al, Lancet 2020 Apr 11:395(10231):108-1216

Novartis entered the market for nuclear imaging of mCRPC via the acquisition of Advanced Accelerator Applications. It has several prostate cancer imaging products and therapy drugs under development including ^{18}F-CTT1057.

Blue Earth is the market leader in the US with its Axumin product receiving FDA approval in 2016. Axumin was developed by scientists at Emory University in the US before being licensed to Blue Earth Diagnostics. The drugs package insert describes it as "a synthetic amino acid PET imaging agent labelled with ^{18}F". The drug is taken up by amino acid transporters upregulated in cancer cells.

Axumin has a single indication for suspected biochemical recurrence based on elevated PSA levels following prior treatment.

Blue Earth has a commercial agreement with PETNET solutions (being a Siemens subsidiary) which is the exclusive commercial supplier of Axumin in the United States. PETNET has ~ 45 cyclotron production facilities in the US servicing approximately 90% of the US market. PETNET produces hundreds of thousands of doses of Fludeoxyglucose (FDG) and Axumin (fluciclovine F18) each year for use in hospitals around the country.

Lantheus (LNTHS) had its PYLARIFY drug approved in the US in May 2021. Lantheus is partnered with SOFIE. SOFIE is radio-pharmacy network and contract manufacturer of radiopharmaceuticals for the US. It has 14 cyclotrons servicing the US market with the greatest presence in the north east. It has very limited capacity in southern states and on the western side of the country.

68GA VS 18F

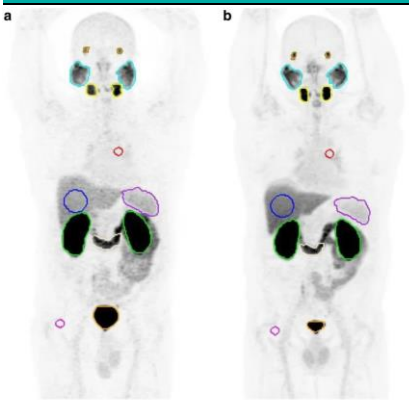
This section reviews the differences in normal-organ bio-distribution and uptake variability between 68Ga-PSMA-11 and 18F-DCFPyL (PYLARIFY). It is relevant because it is important to determine if there are differences in the ability of each tracer to detect PSMA expressing cancers across different organs. The study was conducted at Peter MacCallum Cancer Institute in Melbourne[5].

Figure 3 compares scans of the same patient (we believe it is the same patient) with either isotope. This independently prepared retrospective analysis of 34 patients with low tumour burden showed minor differences in uptake across different organs. Highest uptake for both tracers was found in the kidneys and bladder while lowest organ uptake was found in the liver. The investigators concluded that normal tissue bio-distribution patterns of ^{68}Ga and ^{18}F-DCFPyL (PYLARIFY) were similar.

Based on this analysis we conclude that for hospitals, the choice of which imaging agent to use should come down to other factors including cost, patient safety, ease of handling and flexibility.

[5] Concalo et al, Cancer Imaging19, Article number:23 (2019)

Figure 3 - 68GA v 18 F



Maximum intensity projection images of both scans ([a] 68Ga-PSMA-11; [b] 18F-DCFPyL) with representative VOIs in each of the target organs

SOURCE: BELL POTTER SECURITIES – REFER FOOTNOTE 3

A more recent study conducted by Calais et el found a clear superiority with ^{68}Ga over ^{18}F in the detection of biochemical recurrence in patients following prostate removal[6]. In this head to head study the primary endpoint was the detection rate of biochemical recurrence. The study found:

- Detection rates were significantly lower with 18F PET CT (13/50) than with PSMA (28/50) with an odds ratio of 4.8 and p=0.0026.
- Similar results were found in the sub group analysis of the pelvic node region and in the subgroup analysis of any extra pelvic lesions.
- The investigators concluded PSMA should be the PET tracer of choice.

Figure 4 compares the relative advantages and disadvantages of 18F vs 68Ga. Each produces PET images of similar resolution however, ^{68}Ga is likely to be significantly cheaper and offers great flexibility in patient dosing.

Figure 4 - 18F vs 68Ga for imaging

Criteria	68Ga	18F
Half Life	68 minutes	110 minutes
Radiation	Beta radiation	Beta radiation
Production	Parent isotope ^{68}Ge has a half life of 271 days. Production of ^{68}Ga is highly suited to hospital radiopharmacy. Production is via a standalone ^{68}Ga generator (see figure 5). The isotope is combined with the cold kit to make the drug.	Isotope is produced in an offsite cyclotron facility and transported to the radiopharmacy where it is mixed with the cold kit to form the radiolabelled drug.
Dosing flexibility	Patient dose is produced on demand in 5 minutes	Dose preparation takes at least 70 minutes by which time the isotope is typically already hours old and a fraction of its starting energy level.

SOURCE: BELL POTTER SECURITIES

The major advantage of ^{68}Ga over ^{18}F is that the drug is produced on site under 'Practice of Pharmacy' conditions as compared offsite cyclotron which requires GMP and a host of other logistical challenges to get the isotope safely to the hospital.

The three major US Cyclotron networks (PETNET, SOFIE and Pharmalogic) will continue to have ample demand for their services in the production of other products.

[6] Calais J et al, Lancet, Vol20, issue 9, P1286-1294, September 2019

^{68}GA GENERATORS

In the radio-pharmacy model there are three producers of the benchtop 68Ga Generators. Each brand produces a comparable product. The Telix cold kit has been validated on all three.

Figure 5 - 68Ga generator

SOURCE: IRE-ELITE

This off the shelf unit weighs 16kg and can produce 450 elutions (3 patient doses per elution) over a maximum 1 year time frame. The retail cost of the device is US$70K - $80k. It is designed specifically to serve the molecular imaging market. This particular product is manufactured by IRE.

Figure 6 - Estimated cost per dose

68Ga generator cost	$	75,000
Elutions		450
Patient doses per elution		3
Maximim doses		1,350
Estimated cost per dose	$	56

SOURCE: IRE ELITE

IRE (privately owned) is one of three suppliers of 68Ga generators, the others being Eckert & Ziegler – the German company synonymous with nuclear medicine and ITM being the third manufacturer.

The IRE product as shown above is distributed by Cardinal Health in the US, who are also Telix's distribution partner for the US market. E&Z controls most of the non Cardinal Healthcare market.

Between E&Z and Cardinal/IRE they have the US market for 68Ga generators sewn up. This is not to say a third party could not enter the market, however, it would be difficult to establish a presence given this duopoly.

COMMERCIALISATION

Molecular imaging (aka nuclear imaging) is the standard of care in mCRPC globally. The market leading product in the US and UK is Axumin. In Europe ^{18}F-Fluorocholine is dominant and we understand patent disputes have prevented Axumin from being commercialised in Europe – ironic since the product is owned by an Italian group.

The developer, Blue Earth - was acquired by the privately owned group Bracco Group (Milan, Italy) in 2019. Bracco is a large international group with revenues of €1.5bn, however, there is no publically available data on annual doses for Axumin.

Illuccix is currently awaiting approval in the US (expected September 2021). The potential indications include:

- newly diagnosed high-risk (i.e. high grade cancer) prostate cancer patients;
- patient selection for PSMA targeted therapy;
- biochemical recurrence (BCR) following prostate removal; and
- monitoring of response to systematic therapy.

Figure 7 - Label Indications for metastatic prostate cancer imaging

Indication	Axumin	PYLARIFY	Illucix
Suspected metastasis who are candidates for initial definitive therapy	No	Yes	Prospective
Suspected recurrence based on elevated serum PSA levels	Yes	Yes	Prospective
Patient selection for PSMA targeted therapy	No	No	Prospective
Monitoring of response to systemic therapy	No	No	Prospective

SOURCE: COMPANY DATA, PRESCRIBING INFORMATION FOR AXUMIN, PYLARIFY

MARKET SIZE

There are approximately 250,000 new cases of prostate cancer in the US each year. The majority have localised disease (non metastatic) at diagnosis. Approximately 12% have locally advanced disease at diagnosis.

Biochemical resistance (BCR) following local therapy (prostate removal and or radiotherapy) occurs in up to 70,000 of these men. In total we estimate the addressable market across all three indications at approximately 200,000 doses annually.

At any given time in the US, it is estimated that upwards of 3.1m men are being treated for mCRPC[7]. There are few barriers to multiple nuclear medicine exams and it is reasonable to expect oncologists could order multiple exams to monitor progress (1 or 2 a year) on a single patient.

Since Telix acquired ANMI in 2018 it estimates that at least 25,000 doses have been made available either through clinical trials or compassionate use. This includes 9,500 doses in 2020 (as per 2020 annual report) and more than 6,000 doses delivered in 1HCY21.

Also in the 2020 Annual report TLX estimated the addressable market for Illuccix in the US at US$900m. Assuming revenue per dose of US$4,500, this implies 200,000 doses annually and this does not appear unreasonable.

REIMBURSEMENT AND DISTRIBITION

Upon FDA approval, the company expects to apply for a transitional pass through payment (TPT) code. TPTs are specific to patients who receive treatment with certain products in hospital outpatient departments and ambulatory service centres. Medicare makes the additional TPT payment for devices where cost considerations are likely to interfere with patient access. It allows for CMS to collect necessary data and assign appropriate permanent codes and rates, paving the way for routine Medicare reimbursement later. In about three years the treatment and the associated services are bundled into a single payment.

Based on the reimbursement for Axumin, we expect reimbursement from the TPT of ~US$4,500 and this is expected to run for 3 years after which the reimbursement will be part of a bundled payment inclusive of the procedure. The TPT code for Axumin ceased on 31 December 2019. Hospitals now receive a single bundled payment for outpatient

[7] American Cancer Society Cancer Facts and Figures 2021

procedures involving this drug. Our model allows for a 25% price discount at the end of the TPT period.

For information purposes and to demonstrate the value of the IP, reimbursement for a whole of body FDG PET/CT is only US$1,500 with the cost of the radioisotope component less than $100. The cost is low because the radioisotope (FDG) is generic[8].

Newchoicehealth.com estimates the range of prices for an FDG PET/CT across the US from US$3,300 up to US$9,225 for an inpatient service. The outpatient facility average is US$2,550, while the inpatient facility average is $7,275. Depending on insurance coverage the patient meets the difference with an out of pocket payment.

The ^{68}Ga scan has considerable IP attached as does the 18F (Axumin) scan for mCRPC hence the pricing structure is higher.

The supply of radiopharmaceuticals across the US is dominated by the two largest networks being Cardinal Health and PETNET (a Siemens company). PharmaLogic are also a dominant supplier in regional markets. Each of these groups operate cyclotron facilities for the production of radioisotopes for medical applications.

These networks also operate the radio-pharmacy normally located within a very short distance of the hospital. Telix has partnered with Cardial Health which has ~135 nuclear pharmacies across the country, most of which are equipped to make ^{68}Ga.

Telix's second partner is PharmaLogic which services mainly regional areas (mainly in the mid west and north east regionals).

TELIX REVENUE GENERATION

Hospital clients of Cardinal order a patient dose of TLX591-CDx as required. The cold kit is attached the Galium generator to produce the dose.

We estimate each patient dose generates a fee to Telix of US$4,500 of which we estimate ~30% is paid to Cardinal for dispensing and administration fees.

The cold kits are contract manufactured in the US by Grand River Aseptic Manufacturing (GRAM). The cost per kit is negligible. Based on our model assumptions we estimate a GP margin after the cost of the kits and the Cardinal fee of 67%.

In addition, the company has entered into numerous agreements for the related to the supply and distribution of Illuccix in various markets.

Figure 8 - Summary of Illuccix supply chain arrangements

Name	Agreement	Year	Details
Eckert & Ziegler Strahlen und Medizintechnik AG (EZAG)	Co-promotion/ Distribution agreement	2021	Co-promotion of a combination of EZAG's GalliaPharm (gallium-68 generator) and Telix's Illuccix and exclusive commercial distribution agreement with EZAG for Illuccix in the German market.
Grand River Aseptic Manufacturing (GRAM)	Manufacturing agreement	2021	Aseptic fill and finish services of Illuccix cold kits for the US, Canada, EU and Australian markets.
DuChemBio	Commercialisation and partnership agreement	2020	Exclusive rights to commercialise TLX591-CDx in South Korea.
IRE Elit	Distribution agreement	2020	Distribution of TLX591-CDx in France and French overseas territories.
Pharmalogic Holdings	Distribution agreement	2020	Provide nuclear pharmacy and logistics services to support TLX591-CDx and will prepare/ deliver patient specific unit-doses for the US market.
Cardinal Health	Commercial agreement	2020	Provide radio pharmacy and logistics services to support TLX591-CDx in the US market.

SOURCE: COMPANY DATA

[8] CPT code 78813

Prostate Cancer Therapy

TLX591 (177Lu-DOTA-rosopatamab) is a radiopharmaceutical therapy that delivers beta particle radiation to PSMA expressing cells and the surrounding micro environment. Radiopharmaceutical therapies such as lutetium-177 (177Lu)–PSMA-591 can target prostate cancer cells while sparing most normal tissues.

MECHANISM OF ACTION

^{177}Lu is a beta (β−) radiation emitter with a maximum energy of 0.50 MeV with maximum penetration depth of 2 mm and a half-life of 6.7-days. The radiation emitted by ^{177}Lu is significantly higher than ^{68}Ga with broader range (diameter) of affected area around the isotope. The radiation damages the DNA of the cancer cells (and indeed all other cells) causing them to die. ^{177}Lu is produced in a medical research reactor.

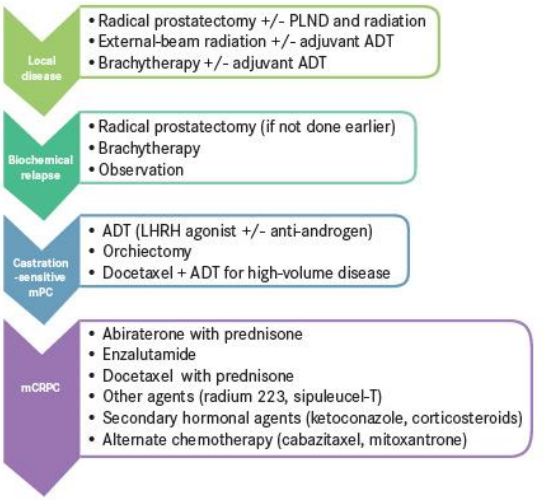
More generally, ^{177}Lu is increasingly used as the radioisotope of choice because it is far easier to handle and transport making it suitable for outpatient use as opposed to in containment facilities. It emits less energy than ^{90}Y (as was used in the Sirtex product) and causes less damage to surrounding tissue.

Approximately 20 – 40% of men who undergo surgery or external beam radiation for the treatment of localised disease end up with recurrent disease. Patients with a short PSA doubling time (e.g. < 6 months) have a poor prognosis and early androgen deprivation therapy (ADT) is normally the treatment of choice. While ADT delays progression, side effects and impairment to QOL are significant.

INTELLECTUAL PROPERTY

TLX591 has been developed over the last 15 years. The targeting molecule is a biosimilar of huJ591, being a widely studied anti PSMA monoclonal antibody.

Figure 9 - Treatment cascade for prostate cancer – initial diagnosis to end stage



ADT indicates androgen-deprivation therapy; LHRH, luteinizing hormone-releasing hormone; mCRPC, metastatic castration-resistant prostate cancer; mPC, metastatic prostate cancer; PLND, pelvic lymph node dissection.

SOURCE: BELL POTTER SECURITIES

Its development dates back to the early 2000's at Weill Cornell Medical Centre in New York. Telix eventually in-licensed the IP via deals with Abzena PLC and a research collaboration with Atlab Pharma SAS (being two companies involved in the early R&D).

Atlab was eventually acquired by Telix in 2018. Telix has exclusive rights for all oncology indications and will pay a royalty to the developers upon commercialisation[9].

Figure 9 outlines the conventional treatment pathway for early stage through to advance metastatic disease. TLX591 is being developed as a second-line drug used in combination with best standard of care for patients with PSMA-expressing metastatic castration resistant prostate cancer (mCRPC)[10].

IN THE CLINIC

TLX591 has been studied in five phase I/II studies across 200 patients. The most important efficacy data is summarised in figure 10.

While the suitability of huJ591 for targeting PSMA was identified early, a great deal more work was devoted to identifying the maximum tolerated dose (MTD). huJ591 is a monoclonal antibody (mAb) and is much larger than a small molecule, consequently the pharmacokinetic profile is far removed from that of a small molecule drug (including PSMA617 in development by Novartis/Endocyte). huJ591 remains in circulation for much longer (than a small molecule) and this has both good and bad consequences:

- The longer circulation time means the drug has a greater opportunity to impact tumours and patients require few doses; however
- The increased exposure time to the drug causes hematologic toxicity (aka myelosuppression) meaning the bone marrow stops producing blood cells required to sustain life. This is a potentially life threatening obstacle.

The use of mAb's for both imaging and therapy applications across all indications is a major point of differentiation between the TLX portfolio and its competitors.

Weill Cornell completed a Phase I/II study of TLX591 in 49 men with the data published in 2019[11]. In figure 9 we line up the data for TLX591 against the Novartis drug (177Lu-PSMA-617) which recently reported data from the phase III Vision.

Figure 10 - Summary clinical data

	Weill Cornell	Novartis (Vision Study)
Study design	Phase 2 , single arm, dose escalating in combination with standard of care	Phase 3, randomised trial vs standard of care
Admission criteria	Confirmed mCRPC with any number of previous treatment regimes except for systemic beta emitting therapy. Study did not require confirmed PSMA expression (unlike Vision)	Confirmed mCRPC, progression following adrogen therapy and taxane. No previous treatment with systemic beta emitting therapy
Dosing regime	177Lu-J591 2x Intravenous injections, two weeks apart. Doses ranging from 20 to 45mCi/m^2, plus best SoC.	177Lu-PSMA-617 intravenously every 6 weeks for 4 cycles. Pts showing a response may receive a further 2 cycles
n	49 in total. 17 patients received RP2D	551 in the active arm, 280 in the control group
Radiation dose	~3.5 GBq being recommended phase 2 dose (RP2D)	7.4 GBq (+/- 10%) per cycle
Primary endpoints	Overall survival	Overall survival, progression free survival
Disease stage	Progression following at least one line of ADT. Most patients had received 1 round of taxane chemotherapy	Disease progression following adrogen therapy and several lines of chemotherapy
Efficacy data	**23.6m os for treated population, 42.3m for RP2D**	**mOS 15.3 months vs. 11.3 months. PFS 8.7m vs 3.4m. 38% reduction in the risk of death for patients on 177Lu-PSMA 617 vs control. One sided p value =0.001**
Safety	Myelosuppression, highest in group on the RP2D	Grade 3 or greater 52% v 38%. Most common events were myelosuppression related
Discontinued treatment	not reported	11.9% vs 7.8%

SOURCE: BELL POTTER SECURITIES, OS – OVERALL SURVIVAL, MOS – MEDIAN OVERALL SURVIVAL, RP2D – RECOMMENDED PHASE II DOSE

[9] Further detail on the historical development of huJ591 are included is section 3 of the 2017 prospectus.

[10] Being prostate cancer that has metastasised beyond the prostate gland and hormone therapy is no longer effective.

[11] Tagawa et al, Published on line in Wiley Online Library Month 0, 2019

The solution to the hematologic toxicity problem was to fractionate the dose into two smaller doses delivered two weeks apart. This approach was highly successful in significantly reducing haematological toxicity (including neutropenia and thrombocytopenia in the main).

Drawing definitive conclusion based on the analysis of results across clinical trials is hazardous for the key reason that previous treatments and stage of disease are heterogeneous. Bearing in mind these limitations, some of the key observations are:

Target Population

Participants in both trials had advanced disease (i.e. all had metastatic disease implying some form of previous treatment) and were near to end of life.

- Some (but not all) patients in the Weill Cornell study had received previous therapy including androgen deprivation (ADT) and taxane chemotherapy; and
- In comparison all participants in VISION had received multiple lines of therapy including either one or two lines of ADT and chemotherapy.

Despite these variables, 42 months OS vs 15 months OS is not trivial. This data highlights the key discovery:

- ADT is proven to increase tumour PSMA expression, hence patients are likely to respond better to PSMA targeted radiopharmaceuticals prior to chemotherapy; and
- In the Weill Cornell study patients with high PSMA expression responded the best, conversely, patients with less intense PSMA imaging tended to have a poorer response.

This data has become highly instructive for the design of the Phase 3 ProstACT study. ProstACT is designed to demonstrate the synergistic effect of the radiopharmaceutical PSMA therapy with ADT prior to second line chemo.

Dosing

- **Abbreviated dosing window** – TLX591 requires only two weeks dosing vs up to 6 doses every 6 weeks (over 6 months) for the Novartis therapy. This is particularly important in the US because the Medical Oncologists maintain their patient contact as opposed to giving patients away to the radiation oncology specialists;
- **The cumulative dose** for Telix is far lower than for Novartis i.e. 2 x 3.5 GBq doses vs 4 x 7.5 GBq doses. The Novartis product uses a small molecule targeting agent, the majority of which is cleared through the liver on first pass. Most of the drug ends up excreted in urine before it can affect the target - consequently the dosing has to be higher and this also causes more off target side effects; and
- **TLX591 requires uses fewer patient visits,** therefore lower cost to the hospital and payers.

Toxicity

In the VISION study 52% of patients in the active arm of the trial experience grade 3 or worse adverse events compared to 38% in the control group. In these patients, greater than 90% had metastatic spread to the bones and these cancers are sensitive to radioisotope therapy. The suppression of the cancer in the bone marrow also results predictably in myelosuppression resulting in fewer red blood cells, white blood cells and platelets (responsible for blood clotting). These side effects are predictable and mostly manageable.

PSMA617 uses a small molecule targeting mechanism and consequently the drug is more prone to off target side effects one of which is salivary gland toxicity[12]. The most common side effect was fatigue in 43% of patients in the treatment arm vs 23% in the control arm.

In the Weill Cornell study, Grade 4 thrombocytopenia occurred in 39% of patients. Patients were treated with blood transfusions and the majority recovered within 26 days. Hematologic toxicity was highest amongst the group on recommended phase 2 dose (RP2D). The hematologic toxicity is clearly the dose limiting factor in this class of drug.

The grade 4 side effects didn't cause any deaths and are transient and predictable, In these patients who are near to end of life, the survival benefits would appear to outweigh the risks.

Conclusion

In our view the cumulative impact of these variables amount to a significant differentiation between TLX591 and Novartis's 177Lu-PSMA-617.

The VISION trial produced a survival benefit of 4 months (15.3 months vs 11.3months) in heavily pre-treated patients. Patients on the RP2D in the Telix study achieved median overall survival of 42.3 months.

We acknowledge the limitations on the Weill Cornell data, namely there was no control group and patient numbers were small (only 17 on the final dose), however the difference in survival is years rather than months.

Based on the result from the VISION study we expect Novartis to submit a New Drug Application for the US which is likely to be successful. We theorise 177Lu-PSMA-617 should receive approval in late CY22, being approximately 3 years ahead of the Telix product. The ProstACT study is estimated to take 30 months and commenced in early 2021. Novartis has ongoing clinical trials investigating the use of its products 177Lu-PSMA-617 earlier in the treatment sequence.

ENROLMENT NOW COMMENCED IN ProstACT

Telix commenced recruitment of its Phase III (ProstACT) trial in Australia in May 2021 with additional jurisdictions to follow. The data from this study will support a New Drug Application for the US as well as a European submission.

The data from earlier studies (both Telix sponsored studies and those of peers) has been crucial in determining not only the dosing regime for TLX591 but also, the intended patient population for this trial. The patient group which responded best in the phase II were those with the highest level of PSMA expression as determined by ^{68}Ga-PSMA-11 imaging.

Accordingly, the target population is men with confirmed mCRPC showing progression having received one prior line of taxane chemotherapy (normally docetaxel) AND one regime of a novel androgen axis drugs (in Australia normally abiraterone). In our view this group of patients is less advanced than those in the VISION study, hence we would expect overall survival beyond the 15.3 months recorded in that study and perhaps in line with the 42 months in the Weill Cornell phase II study.

The inclusion criteria includes a requirement that participants undergo a ^{68}Ga-PSMA-11 PET/CT that is PSMA positive. **This companion diagnostic will exclude patients with disease not expressing PSMA**.

This randomised, open label study will compare standard of care therapy alone versus standard of care therapy plus TLX591.

[12] NEJM, Sartor et al, online article 2107322. 38.8% of patients in the treatment arm experienced dry mouth, all grade 1 or 2.

- Primary endpoint - radiographic progression-free survival (rPFS). rPFS is an entirely objective measure not subject to any interpretation by the radiologist. It is a measure of tumour volume based on the RECIST standard;
- Secondary endpoints - overall survival and quality-of-life assessment;
- Patients in the treatment arm of the trial will receive 177Lu-TLX591, 45mCi/m^2 on day 0 and day 14 plus the standard of care (e.g. enzalutamide); and
- Patients in the control group will receive a novel hormone therapy alone (for participants recruited in Australia this would normally be enzalutamide).

The standard of care may vary from institution to institution depending on the country and the hospital.

The final data collection point for the primary outcome is scheduled for June 2024 (36 months after the trial commences).

Data from previous studies indicates a second line Novel Androgen Axis Drug (NAAD) provides approximately 3 to 4 months extension in radiographic progression free survival.

ProstACT will have ~90% power to detect a 3 month increase in rPFS from 3 to 6 months.

The FDA is yet to issue the IND for the US arm of the study. The company intends to make the IND submission before the end of CY2021 so we could expect US enrolment to commence in 1Q CY22.

Our observations on the trial design

- The inclusion criteria for the trial is highly selective which is a major positive. The trial specifically excludes any participants who do not have high PSMA expressing tumours, maximising the likelihood of success by excluding patients who definitely will not respond to treatment.
- The primary endpoint of rPFS is a commonly used proxy for overall survival in this area of oncology. The company's feedback from its pre IND meeting with the FDA (3 Dec 2020) indicates this is an acceptable primary endpoint, however, as far as we are aware, this endpoint was not used in the earlier phase II.

  We expect a very long survival period for participants on this trial (+3yrs) and this justifies the use of a proxy for OS. mCRPC is not considered an aggressive disease where patients die quickly following progressive disease (Glioblastoma is a good example of an aggressive cancer) and it is for this reason that rPFS is a commonly used proxy and definitely not a soft target. In the absence of this endpoint we could be waiting +5yrs for a result.
- The patient group is earlier stage compared to the phase II. Normally this would be a red flag, however, not in this case. The clinical data is strongly suggestive of a synergistic benefit in the combination of NAAD and PSMA therapy and the non trivial nature of the extension in OS warrants targeting of the earlier stage patients. For shareholders this risk will be rewarded in the drug pricing and for participants in the trial, there is potentially years of OS benefit.
- The dosing is the same dose as the recommended phase II dose, hence participants are likely to have a similar toxicity profile.

The trial is likely to be highly instructive for investigators and is based on solid data from earlier studies. In addition, the FDA is already well versed in the risks around the use of radiolabelled molecules for the imaging and treatment of cancers. At the very least we expect the IND will be approved later this year with physicians likely to support this trial as current therapies have harsh quality of life impacts with minimal efficacy.

Renal (Kidney) Cancer Overview

Each year ~400,000 people are diagnosed with kidney cancer worldwide. It is almost twice as common in men than women and majority of patients are between the age of 60-70. Approximately 40% of patients are diagnosed with local tumours with ~30% of these patients developing metastatic disease. The 5-year survival rate for early stage kidney cancer is good. Where tumours are identified early the survival rate is > 90%. Survival decreases rapidly upon the onset of metastatic disease (5 year survival is only 13% with metastatic disease). Most patients are asymptomatic (no symptoms) at diagnosis with tumours often detected while undergoing imaging for other conditions.

The most common type of kidney cancer is clear cell renal cell carcinoma (ccRCC), which accounts for ~90% of all cases.

The standard of care for renal imaging in the US is non contrast CT. Unlike for most other malignancies, application of FDG PET/CT is limited for RCC, mainly because FDG is excreted through the kidneys, thereby decreasing the contrast between renal lesions and normal tissue.

For this reason there is no competing MTR for renal imaging and the only way to confirm a suspected cancerous mass in the kidney is through an ultrasound guided biopsy.

Depending on the extent of the cancer, it is most often treated with either surgery, targeted therapy, immunotherapy, radiation therapy, or a combination of these treatments.

TLX Renal Cancer Program

Telix is developing both a diagnostic (TLX250-CDx) and a therapy (TLX250). Our focus is the imaging program which is currently enrolling a pivotal study.

Figure 11 summarises key data from an earlier study investigating the predictive capability of the assay. The key result is the positive predictive value of 95% and sensitivity of 86%, so the likelihood of a false positive readout is low but not zero. Specificity is also good at 87% so a negative result is a very strong indicator of a true negative.

Figure 11 - Staging renal cell cancer

		Histology (REDECT PhIII with ^{124}I-girentuximab)			
		ccRCC	Non-ccRCC	Total	
PET/CT imaging	ccRCC	123	7	130	PPV = 95%
	Non-ccRCC	20	46	66	NPV = 70%
	Total	143	53	196	
		Sensitivity = 86%	Specificity = 87%		Accuracy = 86%

SOURCE: COMPANY DATA

IMAGING – TLX250-CDX

TLX250-CDx is an imaging radiopharmaceutical designed specifically for the imaging of renal cancers. The targeting agent is the mAB Girentuximab radiolabelled with ^{89}Zr. Girentuximab is targeted to the antigen Carbonic Anhydrase IX (CA IX), that is expressed on the cell surface of ~90% of ccRCC but is absent from normal kidney tissues making it an ideal molecule for targeting of renal cancers and far superior to previous attempts at renal imaging using a radiolabelled small molecule.

Girentuximab was developed over three decades ago and the original chemical composition patents have expired. TLX has developed extensive new IP relating to the use of the drug as a radiopharmaceutical targeting agent.

The investigator led IMPACT study reported in 2019. In this 42 patient study conducted across 4 hospitals in the Netherlands, investigators concluded that the addition of ^{89}Zr-DFO-girentuximab PET/CT significantly improved detection of lesions[13]. The study was a head to head comparison of CT alone vs 18F and 89Zr with either isotope radiolabelled to Girentuximab.

^{89}Zr is a cyclotron produced radioisotope with a long half-life of 89 hours. Trial participants undergo PET/CT imaging within 2 to 5 days following administration of the drug.

There is an abundance of research on ^{89}Zr and its suitability as a radioisotope. In particular for PET imaging the long half-life, moderate energy rating and abundance of the raw material contribute to its appeal. ^{89}Zr remains inside cells for a long period, after having decoupled from the targeting molecule allowing for accumulation and concentration and ultimately in higher resolution images[14].

^{89}Zr is increasingly available from mainstream radio pharmacy suppliers in the US and Europe so supply shouldn't be an issue.

The IP for TLX250-CDx was acquired via the acquisition of Heidelberg Pharma in 2017. Patents extend beyond 2030.

CLINICAL DEVELOPMENT ACTIVITY

ZIRCON[15] is a phase III study (pivotal study) investigating the use of TLX250-CDx for the imaging of ccRCC. It is an international, multi-centre, trial of ~252 patients with an indeterminate renal mass suspected of ccRCC.

- Primary endpoints include sensitivity and specificity of PET/CT imaging with TLX250-CDx to non-invasively detect ccRCC in patients with indeterminate renal masses using histology as a standard of truth;
- The FDA approved Telix's IND in January 2020 to enable ZIRCON to be conducted in the US. Breakthrough designation was subsequently granted in July of 2020; and
- There are 34 sites participating in the trial from Australia, Canada, US and Europe. As at 20 July 2021, recruitment had exceeded 50% with indicative recruitment at 5 to 10 participants per week. As recruitment only commenced in January 2021, this recruitment rate is impressive particularly given the circumstances prevailing across these countries with regard to restricted hospital visitations caused by COVID. Based on this scenario and assuming no further restrictions due to COVID, we anticipate headline results in 1Q CY22.

The fast recruitment is good proxy that the results of the trial will be supportive of a favourable outcome and supportive of registration.

The second ongoing trial is the ZIRDAC-JP Phase I/II bridging trial of TLX250-CDx in Japan. The phase 1 component of the study is now complete with results reported in April 2021. Six patients were enrolled, there were no adverse events. The whole-body and organ-specific radiation dosimetry of TLX250-CDx demonstrated no difference between Japanese and caucasian patient populations. The pharmacology of TLX250-CDx in Japanese patients was comparable to that of previous studies reported in other patient ethnic. The results provide a sound basis for continuation of development of the product for the Japanese market with the aim now to bridge to the ZIRCON data when it becomes available.

Pending the outcome of the trial and subject to no delays with preparation of the Biological Licence Application (BLA), the drug may be on market as soon as early 2023.

[13] Verhoeff et al. Eur J Nucl Med Mol Imaging 2019; 46(9):1931 - 1931

[14] Deri et al, Nucl Med Biol, 2013 Jan 40 (1) 3 - 14

[15] ZIRCON (Zirconium Imaging in Renal Cancer Oncology, NCT03849118)

Breakthrough designation will speed up the FDA's review of the BLA reducing the review time from 10 months down to 6 months.

Upon approval, we expect TLX is likely to partner with Cardinal in the US. The company has not discussed pricing, however, we expect a price at least in line with the prostate imaging drug.

THERAPY – TLX250

TLX250 (^{177}Lu-girentuximab) is a therapeutic radiopharmaceutical that uses the same Girentuximab targeting agent, however, it is combined with Lutetium 177 (^{177}Lu), to deliver a therapeutic dose of targeted radiation to ccRCC. The therapy can be used in combination with other oncology treatments to increase their efficacy.

CLINICAL DEVELOPMENT ACTIVITY

Finalisation is underway for the design of the STARLITE Phase II trial of TLX250 (177Lu-girentuximab) plus nivolumab in 30 patients with progressed ccRCC following immunotherapy. Primary endpoints include determining efficacy of combination therapy with TLX250 as assessed by objective response rate. The program has been significantly affected by COVID-19 with patient recruitment now expected to commence in late 2021/early 2022. The FDA IND filing is in progress.

Business Model

At its core Telix invests to create intellectual property across its drug portfolio. In most cases the nature of its products (being drugs labelled with a radioisotopes for medical application) requires a reasonably complex supply chain of which the Telix product is one part. For these reasons the company relies on a series of distribution arrangements in order to generate revenues.

In addition Telix has in-licenced or acquired certain IP which is common in biotechnology. Figure 12 summarises the acquisitions completed since the 2017 IPO along with the relevant intellectual property rights.

Figure 12 - Acquisition Summary 2017 - July 2021

Name	Transaction	Year	Consideration (AUD)	IP/ Asset	Patent Expiry
TheraPharm GmbH (Switzerland-based Biotechnology Company)	Acquisition	Dec-20	$16.65m	Diagnostic product Scintimun approved in Europe for imaging of suspected bone infection (osteomyelitis). Clinical-stage therapeutic 90Y-anti-CD66-MTR, targeting CD66 expressed on white blood cells. This has been granted orphan drug designation status in Europe for Bone Marrow Conditioning for Hematopoietic Stem Cell Transplantation. Key clinical trial 'TRALA' data package relating to 90Y-besilesomab.	Not disclosed
Advanced Nuclear Medicine Ingredients (ANMI) (Belgian clinical-stage biopharmaceutical company)	Acquisition	Dec-18	$17.2m	Formulation chemistry for 68Ga-PSMA kit (illuccix) allowing the on demand, room temperature creation of the drug without the need for the cyclotron created radioisotope	2034
Atlab Pharma SAS (French Biotech company)	Acquisition	Sep-18	$12.8m	Atlab/BZL patent portfolio supports potential indication expansion for **TLX-591.** Atlab possesses rights to a clinical data set that is informative to the development of TLX591 and materials to develop huJ591 (most clinically-studied anti-PSMA antibody).	The core Atlab patent family for huJ591 is protected until 2022 and various complementary patents and patent applications extend the timing of this protection out until beyond 2030 in most relevant jurisdictions. The patents provide coverage in major jurisdictions such as US, EU, Japan and Australia.
Therapeia GmbH (German pharmaceutical company)	Acquisition	Oct-17	Assumed debt owed by Therapeia to ABX CRO for €701,615.	All IP rights, including exclusive rights to develop and commercialise **TLX-101** through IP owned and in-licensed by Therapeia.	The Therapeia patent family is protected out until 2026 (with patent term extensions available upon regulatory approval) and has coverage across major jurisdictions such as US, Europe, Japan and Australia.
Abzena PLC (UK-based biopharmaceutical service provider of antibody and protein engineering)	Partnership	Jul-17		Abzena IP including IP in relation to antibody technology in anti-PSMA applications.Telix expects to manufacture new GMP antibody material based on the IP for use in development and commercialisation of **TLX-591.**	The Abzena patent family is protected until 2037. The patents in this family are at an early stage in their life cycle and so have not been filed worldwide as yet.
Heidelberg Pharma AG (previously Wilex AG) (German biotechnology company)	Partnership	Jan-17		Heidelberg developed the underlying antibody technology for the **TLX-250** program. In 2017 Heidelberg signed antibody license agreement with Telix giving them the exclusive worldwide rights for the development and commercialisation of diagnostic agent REDECTANE (INN: 124I-Girentuximab).	Various patents have been in-licensed on an exclusive basis from Heidelberg. The core patent family is protected out to 2022, and various complementary patents and patent applications extend this timing out until beyond 2030. The patents provide coverage in major jurisdictions such as US, EU, Japan, Australia and China.

SOURCE: COMPANY DATA

Figure 13 provides snapshot of a sample of the numerous collaborations the company has entered into over the last 2 years. This list is not intended to be comprehensive. There are numerous other agreements in place for the supply of MTR products across Europe as well as distribution, manufacturing and supply agreements.

Figure 13 - Key collaborations and partnerships

Name	Date	IP/ Asset
Varian Medical Systems (US-based cancer therapy company)	**Sep-20**	Strategic collaboration evaluating the use of advanced prostate cancer imaging in Varian's radiation treatment planning program. They will utilise Telix's PSMA PET imaging data to develop new image-guided treatment planning functions, automated analysis and AI capabilities within Varian's radiation treatment planning platforms.
RefleXion Medical (US-based radiation oncology company)	**Jul-20**	Strategic collaboration evaluating Telix's PET imaging tracers to guide biology-guided radiotherapy for treatment of prostate and kidney cancers.
Mauna Kea Technologies (French medical device company)	**Dec-20**	Scientific and clinical research alliance with the aim to develop capabilities for pre-operative planning, guidance, surgical margin assessment/ parameters in prostate and kidney cancer initially. They will combine Telix's PET- optical imaging tracers with Mauna Kea product 'Cellvizio' (confocal laser endomicroscopy cellular imaging platform).
China Grand Pharmaceutical and Healthcare Holdings	**Nov-20**	Commercial partnership granting exclusive rights to Telix's current clinical stage diagnostic and therapeutic MTR product portfolio for Greater China. Central to Telix's objective of building significant Asian commercial presence, the partnership represents ~$400m in value. This includes an immediate cash injection of $69.2m from the up-front, non-refundable prepayment of $33.8 million for future regulatory and commercial milestones and equity investment of $35.4 million in Telix.

SOURCE: BELL POTTER SECURITIES

In the short term, the key revenue opportunity is from the sale of TLX591-CDx for prostate imaging. In the US the key distribution partners are Cardinal Health and Pharmalogic. In Europe Eckert & Zeigler are the distributor for Germany with IRE appointed for the French market.

Moving forward, it is not unreasonable to expect that Cardinal may also become a key distributor for pipeline products including for TLX-591 (therapy for CRPC) and TLX250-CDx for renal imaging although the company has not yet entered into such agreements.

As for the other assets in the pipeline, these are too early in the development process to speculate around the commercialisation pathways.

The company may also consider the sale of certain assets as they pass development milestones. The various applications are relatively separate and identifiable hence suitable for sale. TLX has a long pipeline of products or new indications for existing technology many of which will take years to come to market. It is not uncommon for large pharma companies to divest certain pipeline assets to smaller developers because limited capacity. The valuations attached to these early stage assets are modest in the early stages. For example, listed Australian biotech Kazia Therapeutics in-licenced paxalisib (being a small molecule PI3K inhibitor drug) from Genentech or US$5m plus royalties in 2017.

This research excludes detailed analysis of certain pipeline products in early stage clinical development for the key reason that in our opinion most of the value in the company is in the late stage assets.

Financials

Cash position at 30 June was $49m with a burn rate of $17m for the March quarter and $12m in the June quarter. We expect the cash balance will decline to be in the range of $34m - $38m by the time the FDA is due to approve Illuccix in September 2021.

The cash burn at Telix is primarily driven by the company's +A$40m annual investment in R&D mainly in the funding of its clinical trial program. This spend is committed in the short term and we believe will continue at the same level for several years as new products come into development. Assuming the run rate for overheads continues at the same rate as seen in the March quarter we estimate the cash flow break even point is ~ 4,250 units (based on a contribution of A$4K, US$3K per dose).

The forecast assumes Illuccix is approved in September 2021 and we assume 2,000 doses are sold in the December quarter. In the interim period until the TPT is issued we expect the company will rely on patient self-pay hence only 2,000 dose sales in the December quarter.

The timing of the TPT is important not only for uptake but also for the company's cash position. Certainly by 31 December TLX will require additional funding if cash flow from dose sales is insufficient to cover costs. A small capital raise may be required if revenues from sales are slower than expected.

The forecast revenue profile from the sale of Illuccix kits is as follows.

Figure 14 - Illuccix - forecast revenue profile

Year ended 31 December	2021	2022	2023	2024
Doses	2,000	16,600	26,200	31,250
Revenues A$m	12.0	93.0	143.1	166.4
COGS A$m	-2.8	-23.7	-36.9	-44.1
Royalty A$m	0.0	-2.8	-4.3	-5.0
Gross profit	**9.2**	**66.5**	**101.9**	**117.4**
Gross profit margin	*76%*	*72%*	*71%*	*71%*

SOURCE: BELL POTTER SECURITIES

Dose sales represent the US and ROW markets combined. In relative terms, the last published data from Axumin indicates revenues were US$140m in 2019 representing ~31,000 doses at US$4,500 per dose. Axumin has the narrower indication of biochemical recurrence only, hence its addressable market is smaller than Illuccix, although we suspect significant off label use for both initial diagnosis in high risk men as well as for ongoing monitoring of treatment. Based on this data it does appear that the market remains vastly under penetrated relative to the estimated addressable markets of 146,000 and 240,000 doses annually in the US and Europe respectively.

First revenues from renal imaging are expected in FY23.

Figure 15 - History of capital raisings

Fiscal Year	$m	Issue Price $
Nov-17	58.6	0.65
Jul-19	42.3	1.30
Nov-20	35.1	1.69
	136.0	

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

The capital raised in figure 15 is net of fees. TLX raised approximately $50m in the 2017 IPO. There was also a pre-IPO round in 2017 for $8.5m.

Valuation

There have been numerous acquisition transactions in the molecular imaging space in recent years. The key items are as follows:

Figure 16 - Recent transaction in molecular imaging and therapy

Year	Target	Buyer	US$
2014	Algeta	Bayer	$2.9bn
2018	Endocyte	Novartis	$2.1bn
2018	AAA	Novartis	$2.9bn
2019	Blue Earth	Bracco Group	$450m
2020	Progenics	Lantheus	$641m
2021	Noria	Bayer	Not disclosed

SOURCE: BELL POTTER SECURITIES

Novartis acquired Endocyte in October 2018 for US$2.1bn. At the time Endocyte had data from its phase II trial in prostate cancer therapy and was enrolling the VISION clinical trial. Also in this field Novartis acquired **Advanced Accelerator Applications (AAA) for US$2.9bn** in 2018 with its key asset being lutetium 177Lu dotatate (Lutathera) – the first ever approved Peptide Receptor radionuclide therapy for the treatment of somatostatin receptor positive gastroenterpancreatic neuroendocrine tumours. The deal was completed only days before the drug received FDA approval. Lutathera is on track to generate US$500m in revenues in 2021[16].

Not surprisingly the radiopharmaceutical platform at Novartis is the cornerstone of growth in the company's Oncology business along with its investment in CAR-T therapy.

Blue Earth Diagnostics was acquired by Bracco Group in 2019 for US$450m. The vendor was the listed Life Science investor Synconca. At the time of the sale Axumin was approved for prostate cancer imaging in both the US and Europe. According to Bracco's press statement, Blue Earth was expected to generate revenues in 2019 of $140m predominantly in the US.

I**n 2020 Lantheus merged with Progenics in an all scrip deal valued at US$641m**. We understand the deal value includes the contingent value right (CVR) payable in two separate cash payments if PYLARIFY revenues exceed US$100m in 2022 and $150m in 2023. PYLARIFY (18F imaging agent for mCRPC) received FDA approval in May 2021 and is only now beginning to realise revenues, nevertheless the benchmarks are instructive for what to expect from first year revenues from Illucix.

More recently, last month (June 2021) Bayer acquired the privately owned Noria Therapeutics for an undisclosed sum. The Noria/PSMA deal provides Bayer with a preclinical-stage alpha radionuclide compound based on actinium-225 and a small molecule directed towards prostate-specific membrane antigen. The technology behind the drug was licensed from Weill Cornell Medicine and Johns Hopkins University in the US.

The Noria acquisition makes Bayer a competitor to Telix's pipeline drug TLX-592 currently being studied in the CUPID trial. CUPID is a phase I study investigating the use of ^{225}Ac in the treatment of early stage disease i.e. early stage biochemic recurrence, prior to androgen therapy. TLX announced first patient recruited to this trial in August 2021.

The acquisition broadens Bayer's existing oncology portfolio of targeted alpha therapies (TAT), which currently includes Xofigo™ (radium-223 dichloride). Xofigo is approved for the treatment of late stage CRPC in patients with bone metastasis only. It is used in palliative care and is not a competitor to TLX250. Xofigo currently generates revenues of

[16] Estimate based on Novartis 1Q21 revenues from Lutathera of $122m.

~US$250m. Peak sales were achieved in 2018 when revenues reach approximately US$500m.

Xofigo was developed by the Norwegian pharma group Algeta. **Bayer paid $2.9bn to acquire Algeta in 2014**. Algeta was attractive to Bayer because of its pipeline of radiation therapy candidates. Algeta specialised in developing anticancer therapeutics based on alpha particle emitting radionuclides. Xofigo received FDA approval in 2015 and remains the only FDA approved alpha emitting radionuclide in the market.

Among this group the very high priced acquisitions by Bayer and Novartis were for the acquisition of platform technologies including therapeutics. There is a very significant difference in the price point of the therapy products relative to the diagnostics. Each dose of Lutathera costs US$47K and the normal course is 4 doses.

KEY ASSUMPTIONS IN THE DCF

Our valuation is influenced by these previous acquisition transactions. The DCF also includes a component of valuation for the pipeline products including TLX250-CDx (renal cancer imaging) and TLX591 for prostate cancer therapy. Both are currently recruiting participants in approval studies and both are likely to receive approval.

There are a further 6 programs in earlier stage development as detailed in figure 1 all of which remain several years from commercialisation. The exception is Scintimun acquired as part of the TheraPharm acquisition in December 2020 where the product is approved and is marketed in Europe by a third party. We understand revenues are not material.

The DCF potentially undervalues the company because it takes into account all the development costs in the form of the ongoing R&D spend but significantly discounts the revenues from mid stage products in development and assumes no revenues from those projects in phase 1 studies.

MAJOR CATALYSTS

- FDA Approval of Illuccix – due September 2021;
- CMS granting the Transitional Pass Through payment – this should not be a major hurdle given that the competitor product Axumin was up until recently reimbursed on the same basis; and
- Opening of the IND in the United States for the ProstACT study investigating the use of TLX591 in mCRPC. This drug has huge potential to vastly change the treatment landscape for men with re-current disease following radical prostatectomy.

LISTED PEERS

There are no listed peers that represent a good comparison valuation of for TLX – certainly none in Australia. Various companies including Clarity Pharmaceuticals (CU6.ASX), Fusion Pharmaceuticals (FUSN.NASDAQ) and Curasight (CURAS.SS) have assets in nuclear medicine, however, all are relatively early stage and accordingly their market capitalisations are a small fraction of TLX. There are various start up companies in the sector with assets in various stages of development.

VALUATION

We commence coverage with a valuation of $8.00/share. The valuation is based on a discounted cash flow which assumes a weighted average cost of capital of 13%. The valuation includes a 20% discount to the cash flows for Illuccix and 40% for TLX-250CDX and 80% for TLX592. The valuation implies an EV of A$2.2bn (US$1.7bn) and a very significant discount to the high price transactions listed above.

Telix Board

Mr H Kevin McCann – Chairman

Mr McCann is a former Partner of Allens Arthur Robinson and now professional Non Executive Director for high profile listed Australian companies. His experience as a director includes as Chairman of Macquarie Group and Macquarie Bank Limited, Chairman of Origin Energy Limited, Healthscope Limited and ING Management Limited. Mr McCann is also Chair of several high profile philanthropic institutions based Australia.

Dr Christian Behrenbruch – Chief Executive Officer and Managing Director

Dr Behrenbruch is the co-founder of the company along with Andreas Kluge. Dr Behrenbruch has extensive Executive and Board experience amongst both privately owned and public corporations, mostly within the healthcare technology industry. This includes CTI Molecular Imaging (now Siemens Healthcare), Factor Therapeutics (FTT), Amplia Therapeutucs (ATX) and ImaginAb, Inc. Dr Behrenbruch holds a PhD in biomedical engineering (Oxford University), MBA (U. New York) and Juris Doctor (Law).

Mr Oliver Buck – Non Executive Director

Mr Buck is a bio-physicist who has spent his professional career in a variety of entrepreneurial and management positions in industrial companies. He is a co-founder of ITM Isotopen Technologien München AG, one of the largest isotope manufacturing and distribution companies in the world, founded with Technical University of Munich.

Dr Andreas Kluge – Non Executive Director

Dr Kluge has over 20 years of clinical research and development experience, including as Founder, General Manager and Medical Director for ABX-CRO, a full service CRO for Phase I-III biological, radiopharmaceutical and anticancer trials based in Germany.

He is also Founder and was founding CEO of ABX GmbH (www.abx.de), one of the leading manufacturers of radiopharmaceutical precursors globally. Dr Kluge has extensive experience in the practice of nuclear medicine and radiochemistry, molecular imaging and the clinical development of novel radionuclide-based products and devices.

Dr Mark Nelson – Non Executive Director

Dr Nelson is Chairman and Co-Founder of the Caledonia Investments Group, and a Director of The Caledonia Foundation. He has extensive experience as an investor in biotechnology both in Australia and the United States.

Ms Jann Skinner– Non Executive Director

Ms Skinner has extensive experience in audit and accounting and in the insurance industry. She was a partner of PricewaterhouseCoopers for 17 years before retiring in 2004.

Figure 17 - Director Shareholdings

	Shareholding (m)	Options (m)
K McCann	160,000	990,000
O Buck	1,552,500	-
A Kluge	24,675,000	-
M Nelson	2,638,750	990,000
J Skinner	100,000	495,000
C Behrenbuch	24,675,000	600,000
	53,801,250	3,075,000
Shares on issue	281,373,408	
Free float	81%	

SOURCE: COMPANY DATA

Appendix 1 - Molecularly Targeted Radiation (MTR)

MTR involves using a molecule as a targeting agent to carry radiation in the form of radioactive isotopes (radionuclides) directly to the tumour in a highly specific and selective way. The combination of these two components comprises the radiopharmaceutical.

The MTR approach ensures that even very small tumours and tumour cells circulating in the blood stream are irradiated, considerably reducing the rate of disease spread and improving patient outcomes as a consequence.

In nuclear medicine, radionuclide therapy uses specific radiopharmaceuticals to treat specific disease. Treatments are delivered using either alpha or beta particles to deliberately cause damage to the cells of the target organ. The radiopharmaceutical remains in the target cell for the duration of its radioactive life or until excreted.

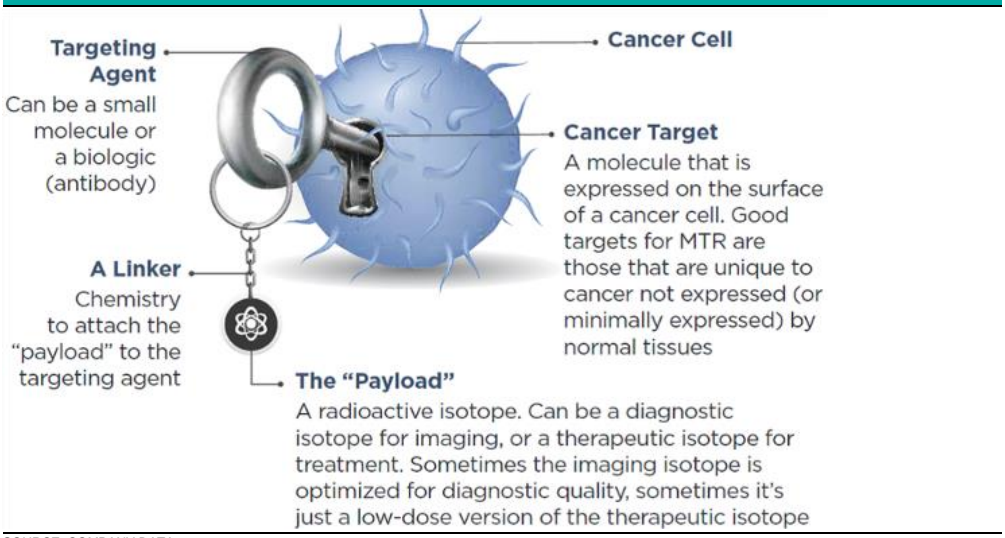
In addition, MTR approaches can deliver *diagnostic* radiation that can be imaged with conventional Positron Emission Tomography (**PET**) or Single Photon Emission Computed Tomography (**SPECT**) systems to allow very accurate detection and staging of cancer patients prior to therapy.

HOW DOES IT WORK?

The primary element of MTR is the radionuclide. These are unstable chemical elements that dissipate excess energy (alpha or beta particles). The radiation damages the DNA of the cancerous cells (and all other cells) leading to their death. The radionuclide is attached to a targeting molecule in a radiolabelling process immediately prior to patient dosing. The radionuclides used in nuclear medicine typically have a short half-life, which means the amount of the energy they emit halves in a known times space – 68 minutes for ^{68}Ga.

Radionuclides are produced are typically produced in a nuclear reactor or Cyclotron device which is more typical for radionuclides used for medical applications).

Figure 18 – Components of MTR



SOURCE: COMPANY DATA

ADVANTAGES OF MTR

Some of the main advantages of MTR include its effectiveness and tolerability as a result of its more personalised nature. MTR offers precise, modern imaging to accurately map a patient's cancer and inform treatment decisions. It is more localised than traditional external radiation oncology and a superior treatment of metastatic disease.

Telix Pharmaceuticals

as at 10 August 2021

Recommendation	Buy, Speculative
Price	$5.53
Valuation	$8.00

Table 1 - Financial summary

A$m	FY19	FY20	FY21e	FY22e	FY23e
Year Ending 31 December					
Total Revenue	**3.5**	**5.2**	**14.5**	**93.0**	**168.6**
COGS	-2.5	-2.0	-3.8	-26.5	-51.4
Gross profit	0.9	3.2	10.7	66.5	117.3
GP Margin	27%	61%	74%	72%	70%
Administration and coporate costs	-6.8	-8.9	-10.7	-12.8	-15.4
Employment costs	-9.0	-15.6	-15.9	-16.2	-16.5
R&D costs	-21.2	-23.1	-44.0	-49.0	-49.0
Non cash liability adjustment	-2.3	-7.3	0.0	0.0	0.0
Other income and expenses	11.4	8.6	17.6	0.0	0.0
Total Expenses	-27.8	-46.2	-53.0	-78.0	-80.9
EBITDA	-26.9	-43.1	-42.3	-11.5	36.4
Depreciation & Amortisation	-4.2	-4.9	-4.5	-4.5	-4.5
EBIT	-31.1	-47.9	-46.8	-16.0	31.9
Interest expense	0.0	0.0	0.0	0.0	0.0
Pre tax profit	(31.1)	(47.9)	(46.8)	(16.0)	31.9
Tax benefit	3.3	3.0	0.0	0.0	0.0
Reported NPAT	**(27.9)**	**(44.9)**	**(46.8)**	**(16.0)**	**31.9**

Cashflow (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Gross cashflow	-23.3	2.0	-43.0	-21.6	27.4
Net interest	0.0	-0.1	0.0	0.0	0.0
Other operating cash flows	0.0	-0.1	0.0	0.0	0.0
Operating cash flow	-23.3	1.9	-43.0	-21.6	27.4
Payment for PPE	-0.4	-0.3	-2.0	-2.0	-2.0
Payment for intangibles	-0.1	-0.1	0.0	0.0	0.0
Payments for businesses acquired	0.0	-0.3	0.0	0.0	0.0
Other	0.0	-0.4	0.0	0.0	0.0
Free cash flow	-23.8	0.8	-45.0	-23.6	25.4
Proceeds from issuance	45.3	35.2	0.0	0.0	0.0
Movement in borrowings	0.0	-0.9	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Other payments	-1.6	-1.9	0.0	0.0	0.0
Change in cash held	19.9	33.2	-45.0	-23.6	25.4
Cash at beginning of period	23.7	44.6	77.8	32.8	9.2
FX adjustment	-1.0	0.0	0.0	0.0	0.0
Cash at year end	44.6	77.8	32.8	9.2	34.7

Balance Sheet (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Cash	44.6	77.9	32.8	9.2	34.7
Receivables	12.1	12.4	13.0	15.5	28.1
Inventory	0.5	0.6	1.0	1.0	1.0
Other current assets	1.5	2.7	3.5	4.6	5.9
Property, Plant and Equipment	1.9	4.8	6.3	7.8	9.3
Intangibles	41.9	59.2	55.2	51.2	47.2
Right of use assets	-	-	-	-	-
Other non current assets	0.1	0.2	0.2	0.2	0.2
Total assets	102.6	157.8	112.1	89.5	126.4
Trade payables	9.2	10.9	12.0	5.3	10.3
Contingent consideration	16.4	25.1	25.1	25.1	25.1
Lease liabilities	1.4	1.8	1.8	1.8	1.8
Other liabilities	3.8	7.9	7.9	8.0	8.0
Contract Liabilities	-	30.7	30.7	30.7	30.7
Borrowings	0.8	0.4	0.4	0.4	0.4
Provisions	0.9	2.0	2.0	2.1	2.2
Total Liabilities	32.5	78.8	79.9	73.4	78.5
Net Assets	70.1	79.0	32.2	16.1	47.9
Share capital	115.9	167.1	167.1	167.1	167.1
Reserves	2.3	4.9	4.9	4.8	4.7
Accumulated losses	(48.1)	(93.0)	(139.8)	(155.8)	(123.9)
Shareholders Equity	70.1	79.0	32.2	16.1	47.9

Valuation Ratios (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Reported EPS (cps)	-11.9	-17.5	-16.7	-5.7	11.4
Normalised EPS (cps)	-11.9	-17.5	-16.7	-5.7	11.4
EPS growth (%)	na	na	na	na	na
PE(x)	**nm**	**nm**	**nm**	**nm**	**48.2**
EV/EBIT (x)	nm	nm	-32.0	-93.2	46.9
P/NTA (x)	49.2	77.5	- 66.7	- 43.8	2,076.4
Book Value Per Share (cps)	27.7	28.2	11.5	5.7	17.1
Price/Book (x)	19.8	19.4	47.8	95.5	32.1
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0%	0%	0%	0%	0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	na	na	na	na	2%
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	net cash	net cash	net cash	net cash	net cash
Gearing	0%	0%	0%	0%	0%
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	-	-	-	-	-

Doses	FY19	FY20	FY21e	FY22e	FY23e
Dose Sales					
mCRPC imaging (TLX-591 CDx)	-	-	2,000	16,600	26,200
Renal Imaging (TLX250 CDx)	-	-	-	-	6,000
mCRPC Therapy (TLX 591)	-	-	-	-	-
Dose sales	-	-	2,000	16,600	32,200
Revenues $m					
mCRPC imaging (TLX-591 CDx)	-	-	12.0	93.0	143.1
Renal Imaging (TLX250 CDx)	-	-	-	-	25.5
mCRPC Therapy (TLX 591)	-	-	-	-	-
	-	-	12.0	93.0	168.6

Interim Results	1H20	2H20	1H21e	2H21e
Revenues	1.6	3.6	2.5	12.0
EBIT	-16.9	-26.2	-27.2	-15.1

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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