EDISON

Telix Pharmaceuticals

Company outlook

Major developments coming up

Pharma & biotech

We expect 2020 to be a major turning point for Telix Pharmaceuticals. The regulatory submissions for illumet will determine whether the company will start commercial operations in 2021. The clinical groundwork for TLX-250-CDx is being laid in the ongoing pivotal Phase III ZIRCON study, which recently restarted in Europe and is expected to be fully enrolled by the end of 2020. Finally, the company has guided towards starting new clinical studies for TLX591 and TLX250 in late 2020, contingent on FDA feedback and financing. This report provides our clinical and commercial outlook.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/18	10.3	(15.7)	(6.8)	0.0	N/A	N/A
12/19	15.2	(31.1)	(11.9)	0.0	N/A	N/A
12/20e	12.0	(30.3)	(12.0)	0.0	N/A	N/A
12/21e	97.8	57.9	22.6	0.0	6.6	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

FDA grants TLX250-CDx breakthrough designation

The FDA has granted a breakthrough therapy designation for the company's renal cell carcinoma (RCC) imaging agent TLX250-CDx. The designation is reserved for products that meet a high unmet medical need and provides multiple avenues to expedite the approval process. The company will be able to submit its BLA on a rolling basis and it will receive fast-track status that shortens review times.

Additional data to be included in illumet NDA

The company reported on 10 June 2020 that it would be including additional data from recently published studies, including the proPSMA study we discussed in a previous report. The data from the proPSMA study are unequivocally supportive of PSMA target PET in prostate cancer, and the inclusion of this data should strengthen the application, although it will delay its initial review by six to eight weeks. We expect the NDA to be submitted in early to mid-Q320.

Illumet distribution expanded

The company continues to expand its commercial footprint in preparation for the commercial launch of illumet. It recently announced that it has signed a distribution agreement with PharmaLogic to distribute patient specific doses of the imaging agent. PharmaLogic is a regional pharmacy group with 27 nuclear pharmacies in the US Midwest and Northeast. This agreement is in addition to the company's other distribution agreements with Cardinal Health and United Pharmacy Partners.

Valuation: Increased to A$571m or A$2.25 per share

We increased our valuation to A$571m or A$2.25 per basic share, from A$522m or A$2.06 per basic share. This increase is due to us updating the epidemiological numbers in our model to reflect the latest projections from the WHO and NIH on renal and prostate cancers, and because we now include Breakthrough designation for TLX250-CDx. Otherwise our forecasts remain unchanged.

2 July 2020

Price	**A$1.50**
Market cap	**A$379m**
	US$0.66/A$
Estimated net cash (A$m) at 31 March 2020	33.3
Shares in issue	253.7m
Free float	71%
Code	TLX
Primary exchange	ASX
Secondary exchange	OTCMKTS

Share price performance

%	1m	3m	12m
Abs	7.9	39.7	16.8
Rel (local)	6.1	22.4	30.1
52-week high/low	A$1.91	A$0.80	

Business description

Telix Pharmaceuticals is a Melbourne-headquartered global biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or molecularly targeted radiation.

Next events

TLX591 FDA meeting	7 July 2020
Illumet NDA submission	Early to mid-Q320
ZIRCON enrolled	Year-end 2020

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Edison profile page

Investment summary

Company description: Diagnostics and therapeutics using MTR

Telix Pharmaceuticals is based in Melbourne, Australia, and focuses on the development of molecularly targeted radiation (MTR) products to image and treat cancer. It is approaching the launch of its first approved clinical product illumet (TLX591-CDx), a positron emission tomography (PET) tracer for the detection of prostate cancer. The product is currently available for research purposes, with A$3.6m sales in 2019. Telix has submitted an MAA for the product, and an NDA will be filed in early to mid-Q320. The company is in Phase III trials for its kidney cancer tracer TLX250-CDx (enrolment complete at YE20), and has an ongoing Phase I/II clinical study of its glioblastoma multiforme (GBM) treatment TLX101 (paused due to COVID-19). Finally, the company plans to re-enter the clinic with its prostate cancer therapeutic (TLX591) and its kidney cancer therapeutic (TLX250) by the end of 2020, contingent on financing and FDA feedback.

Valuation: Increased to A$571m or A$2.25 per share

We have increased our valuation to A$571m or A$2.25 per basic share, from A$522m or A$2.06 per basic share. Our model is largely unchanged save for updates to the epidemiological data for kidney and prostate cancer from the NIH and WHO, which have shown slightly higher rates than previous agency projections, as well as the addition of breakthrough therapy designation for TLX250-CDx. Our valuation is made using a risk adjusted NPV analysis using a 12.5% discount rate. Illumet is our highest value product (A$207m) at an 80% probability of success, followed by TLX591 (A$149m) at a 20% probability of success. We expect to update our valuation following the FDA meeting to discuss the TLX591 pivotal study (7 July 2020) and due to any subsequent partnering discussions.

Financials: Cash to 2021, partners needed for therapeutics

Our financial forecasts remain largely unchanged, except for small top line adjustments to reflect the updated epidemiology in our model. The company ended Q120 with A$33.3m estimated net cash, which should be sufficient to finance the company into 2021 and the FDA decision for illumet. We also include in 2021 A$91.2m in illustrative milestones associated with the licensing of its therapeutics TLX591 and TLX250. A deal (or deals) will be necessary to progress these programs in the clinic, and if the company is unable to secure such transaction(s) for them in 2021, we would expect a financing shortfall of around A$10m (in 2021) to maintain ongoing operations.

Sensitivities: Typical of the transition to commercial operations

Telix faces a series of risks associated with its clinical development as well as risks associated with the approval and launch of its first clinical product illumet. These risks are typical of companies at this stage. First, there is regulatory risk associated with the marketing applications for illumet, and although the clinical support for use of PSMA target PET imaging is strong, approval cannot be ensured. Also, once approved, we expect the product to face commercial competition as there are other similar products in development and a well-established (albeit inferior, in our view) standard of care. The company also faces the risks inherent in running clinical studies with its therapeutic development products. For the clinical programs to be successful, they must not only demonstrate safety and efficacy, but be superior to existing products. Finally, the company faces financial and partnering risk. We model the TLX591 and TLX250 pharmaceutical programs being partnered to continue their development, and if the company cannot secure attractive partnerships for these programs, it may need to seek financing on capital markets, which may lead to dilution (albeit it would be able to realise more of the products' downstream value).

Company description: Molecularly targeted radiation

Telix Pharmaceuticals is a developer of products designed to deliver MTR, which includes both radiologic imaging agents as well as radiopharmaceutical treatments. The company's products consist of a targeting agent (either antibodies or small molecules) that is loaded with either an imaging radionuclide or a cytotoxic radionuclide, and in this way each molecule has paired imaging and therapeutic programs (Exhibit 1). The most advanced product is Illumet (aka TLX591-CDx), the company's prostate cancer PET imaging agent targeting prostate specific membrane antigen (PSMA). The company has submitted an application for European marketing authorisation (MAA) and is planning to submit a US application (NDA) shortly. Telix has also developed a therapeutic (TLX591) targeting PSMA, which is entering the clinic pending FDA feedback and financing in late 2020. The company has also developed an agent (TLX250-CDx) to image clear cell renal cell carcinomas (ccRCC), which it has in Phase III with enrolment to complete by the end of 2020. TLX250-CDx also recently received breakthrough therapy designation from the FDA. The company also has a Phase II planned for the corresponding therapeutic (TLX250) and is guiding toward starting in late 2020 (financing permitting). Finally, the company has a therapeutic for the treatment of glioblastoma multiforme (TLX101) that is currently in a dose escalation/expansion Phase I/II study (although enrolment is currently paused on account of COVID-19).

Exhibit 1: Telix development programmes

Product	Cancer	Molecular target, targeting agent, isotope	Stage	Notes
TLX250-CDx (imaging)	Kidney cancer (ccRCC)	CA-IX mAb ^{89}Zr	ZIRCON Phase III due to fully enrol by End of 2020	Isotope changed from ^{124}I to ^{89}Zr to improve image quality. FDA Breakthrough therapy designation
TLX250 (therapeutic)	Kidney cancer (ccRCC)	CA-IX mAb ^{177}Lu	US Phase II planned for late 2020	Phase II studies planned to test checkpoint inhibitor combo.
Illumet, aka TLX591-CDx (imaging)	Prostate cancer	PSMA small molecule ^{68}Ga	MAA submitted, NDA planned for Q220	Commercial sales as an investigational imaging test underway in the US and Europe. US and EU approval expected in 2021.
TLX591 (therapeutic)	Prostate cancer	PSMA mAb ^{177}Lu	Phase III in planning, FDA pre-IND meeting in July 2020	Phase III study of 177Lu-huJ591 planned in chemo naïve mCRPC, subject to FDA agreement and funding.
TLX101-CDx (imaging)	Brain cancer (GBM)	LAT-1 small molecule ^{124}I	Research use only	Use of TLX101-CDx will be limited to studying the pharmacology of TLX101.
TLX101 (therapeutic)	Brain cancer (GBM)	LAT-1 small molecule ^{131}I	IPAX-1 Phase I/II underway	IPAX-1 study paused until Sept/Oct 2020 due to COVID-19.

Source: Edison Investment Research, Telix Pharmaceuticals. Note: mCRPC= metastatic castration-resistant prostate cancer; PSMA= prostate-specific membrane antigen; GBM= glioblastoma; ccRCC= clear cell renal cell carcinoma.

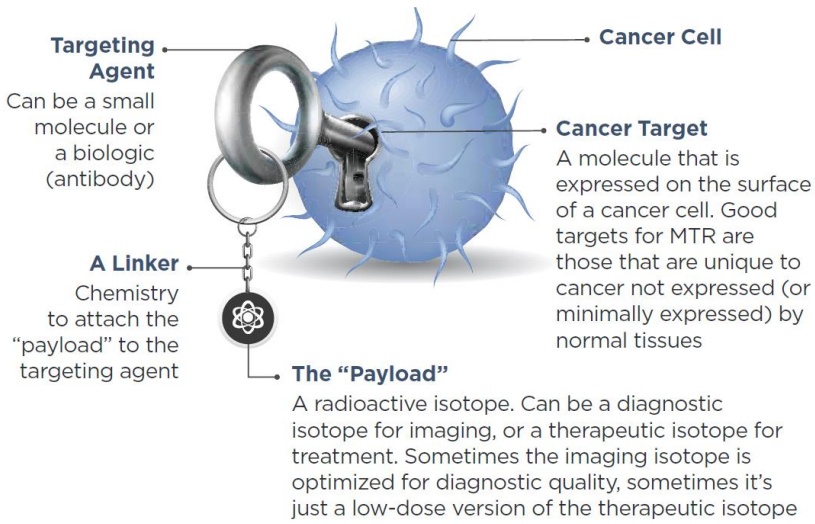
MTR to image and treat cancer

MTR products selectively deliver radiation to cells with molecular markers or targets that are over-expressed in cancer. The radiation can be used to facilitate imaging a tumour to diagnose or stage a patient, or may be a therapeutic dose to treat the cancer. MTR products enable medical imaging, for example PET, to determine the true extent of disease and can also evaluate whether a treatment target is present.

The MTR products in use or in development use a range different of radioactive isotopes and targeting modalities to detect cancer cells. For example, the most widely used PET imaging agent, ^{18}F -fludeoxyglucose (FDG), which is used for detecting and monitoring a range of cancers, relies on the fact that many tumours are metabolically active with a high glucose uptake. However, FDG PET is not very useful for imaging cancers such as prostate cancer that are not very metabolically active, or for organs where the signal from a tumour can be obscured by labelled FDG excreted in the urine.

Telix's MTR imaging agents target molecular markers that are overexpressed on particular cancers. Their specificity for cancer cells makes them particularly useful for identifying small metastases that cannot be detected by other methods and for monitoring patients for recurrence or metastatic spread of the disease. In the case of TLX250-CDx, a key intended application is for distinguishing between benign lumps and dangerous kidney cancers. For the case of illumet, PSMA imaging has been highlighted as a superior method of identifying small metastases that are missed with other agents.

Exhibit 2: How MTR works



Source: Telix Pharmaceuticals prospectus

Converting a diagnostic agent into a therapeutic is generally as simple as loading the targeting agent with a different radionuclide payload. Whereas nuclides used in imaging agents are chosen because they emit radiation that does not interact well with tissue (which limits damage and allows them to be seen outside the body), the nuclides used in therapeutics are typically chosen for their ability to deliver cytotoxic levels of radiation, but only over a very short distance, limiting damage to tissue surrounding the targeted tumour. In the case of Telix's programs these are the beta emitters ^{177}Lu and ^{131}I.

High-profile acquisitions of MTR programs highlight interest at big pharma

In December 2018, Novartis acquired Endocyte Therapeutics for US$2.1bn to obtain the Phase III stage targeted radiotherapeutic ^{177}Lu-PSMA-617. This product is similar to Telix's TLX591 in that it targets PSMA for the treatment of mCRPC. The product is currently in pivotal studies. Novartis previously acquired a different, earlier stage PSMA targeted radiopharmaceutical through its acquisition of Advanced Accelerator Applications (AAA), for US$3.9bn in 2018. However, this acquisition was primarily to obtain the latter's Lutathera (^{177}Lu dotatate) for the treatment of gastroenteropancreatic neuroendocrine tumours (GEP-NETs). Lutathera had US$0.4bn in sales in 2019.

In August 2019, Bracco Imaging completed the acquisition of Blue Earth Diagnostics equity for a US$450m valuation (plus an estimated US$25m in closing adjustments). Blue Earth was then a privately held developer of diagnostic imaging agents, with approximately US$140m in revenue expected in the first three quarters of 2019 (according to the announcement). Blue Earth's revenues at the time came from its prostate PET imaging agent, Axumin, which was approved by the FDA in 2016. Axumin is an amino acid-based imaging agent, which labels cancer cells based on their amino acid demands, but lacks the specificity of a truly targeted agent. The company is also developing a PSMA targeted PET diagnostic (denoted ^{18}F-rhPSMA-7), similar to Telix's illumet, as a

follow-on technology. The imaging agent is currently in Phase I testing, and the antibody is being investigated in preclinical studies for therapeutic purposes.

In another example, in February 2014 Bayer acquired Algeta for NOK16.2bn (~US$2.6bn). Algeta had developed Xofigo, a therapeutic radiopharmaceutical for patients whose prostate cancer had metastasized to their bones, which had been approved in the US and Europe in 2013. Bayer had previously entered a licensing agreement with Algeta in relation to Xofigo in 2009. The product had peak sales of €408m in 2017, prior to a decline in sales following the early termination of a clinical study involving the molecule.

Illumet: Evolving standard for prostate cancer testing

Telix's most advanced development program is for illumet (TLX591-CDx, ^{68}Ga-PSMA-11), the company's PET imaging agent for prostate cancer. Global rights to the product were acquired in 2018 with the acquisition of Advanced Nuclear Medicine Ingredients (ANMI) for €6.0m upfront and low double-digit royalties. The two companies previously had a joint venture to split US rights to the product, but Telix decided to acquire ANMI to obtain worldwide rights. TLX591-CDx is based on PSMA-11, a peptide ligand that binds to the PSMA protein. PSMA-11 labelled with the ^{68}Ga radio isotope has been widely used in academic medicine in Europe and Australia to image prostate cancer, and has been shown to be safe to use and to produce high-quality images (Exhibits 3 and 4). This includes ^{68}Ga-PSMA-11 kits purchased from ANMI/Telix as well as agents synthesised in academic labs. While the PSMA-11 targeting agent (ligand) is in the public domain, the chemistry for linking the ^{68}Ga radiolabel to the ligand and preparing the dose of the imaging agent with the TLX591-CDx kit utilises proprietary chemistry developed by ANMI.

The product is currently commercially available in the US and Europe as a 'cold kit' for investigational use and the company reported delivery of 11,500 individual doses in 2019 for A$3.49m in revenue. The company is currently seeking European and US marketing approval for the product and submitted an MAA in April 2020. The company has delayed submission of an NDA slightly from previous guidance (of Q220) in order to include additional recently published data, including the landmark paper on the proPSMA study we discussed in our previous report. The NDA is now expected to be filed in early to mid Q320, but we believe the inclusion of these data should strengthen the application.

Exhibit 3: Examples of PSMA-11 imaging of low, medium and high prostate cancer tumour burden

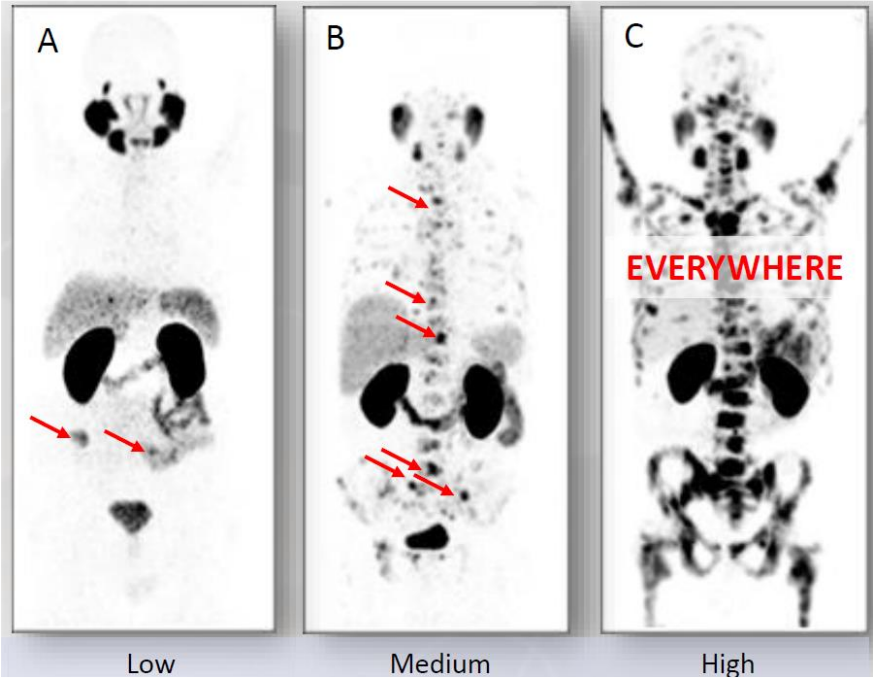
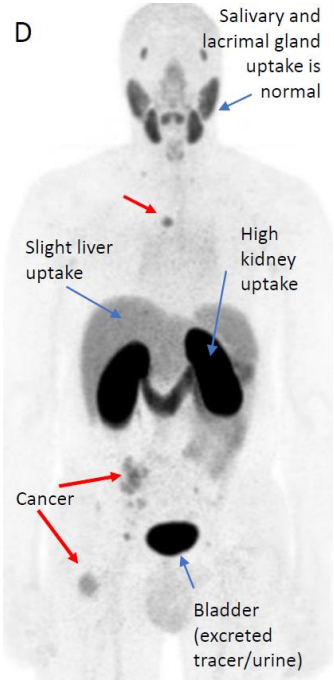


Exhibit 4: Typical biodistribution of PSMA-11 tracer



Source: Telix Pharmaceuticals. Note: Red arrows mark some of the more prominent prostate cancer tumours.

The pathway to market

Telix is currently seeking marketing approval for the illumet kit in the US and Europe. It submitted an MAA in April 2020 and intends to submit an NDA in Q320. These submissions are being made using a collection of prospective and retrospective clinical data including imaging data gathered in the ongoing VISION study performed by Endocyte/Novartis to support approval of their product ^{177}Lu-PSMA-617. Telix granted Endocyte access to the illumet kit to screen patients for the study. Telix previously met with the FDA in a pre-NDA meeting in February 2020, and reported that 'The FDA has provided detailed feedback on the clinical briefing package for the efficacy data, which the Company expects to be able to satisfy, based on the planned submission dataset.' Moreover, no safety red flags were raised. The company has not released specific feedback on its discussions with European regulators, but we expect the process to be similar. Approval decisions are expected in early 2021.

The company has also been laying the groundwork to support the commercialisation of illumet, including the necessary infrastructure and logistics. The company has signed three distribution agreements to date with PharmaLogic, United Pharmacy Partners and Cardinal Health. The last is significant because Cardinal is the largest distributor of nuclear medicine products in the US, with access to 80% or more of the US market (according to Telix).

It was also announced in May 2020 that the company entered into a collaboration with ARTMS Products, a producer of alternative isotope generation technology. The companies agreed to employ ARTMS's cyclotron technology to generate ^{68}Ga for use in illumet. ARTMS uses a ^{68}Zn target to generate ^{68}Ga in a hospital based medical cyclotron. The benefit is that ^{68}Zn is a readily available stable isotope as opposed to the typical ^{68}Ga source, ^{68}Ge. The generation of ^{68}Ge needs high energy protons beyond what can be produced in a cyclotron. Moreover, although considered a long-lived isotope, it cannot be stored indefinitely, with a half-life of 271 days. Using ^{68}Zn has the potential to simplify the supply chain and having an alternate source of ^{68}Ga may avoid potential

shortages. If ^{68}Ga-PSMA imaging gains traction, it will be important for many small to mid-sized hospitals to have an independent source of the nuclide, which the ARTMS technology can provide.

Additionally, in April 2020 the company announced that it had completed the previously announced acquisition of a radiopharmaceutical manufacturing facility in Seneffe, Belgium, from Eckert & Ziegler Strahlen und Medizintechnik. This transaction is important because it includes the necessary licences to manufacture a range of isotopes in Europe (Class IIA radiation licence, approval of Belgium's Federal Agency for Nuclear Control). Moreover, the licences allow the company to tap into key isotope supply chains for products produced elsewhere. The company stated that isotopes generated at this site will support the commercial sales of illumet and TLX250-CDx in Europe following their launches, although it will not be limited to these products and will be able to supply a range of isotope needs. More generally, the acquisition will allow the company to expand its R&D footprint. The transaction had a nominal fee of €1, but carried a decommissioning liability of €5.2m.

PSMA imaging becoming increasingly accepted

The use of PSMA targeted PET imaging is gaining prominence as a superior prostate imaging methodology in a range of diagnostic settings, eg initial staging, after biochemical recurrence to detect metatheses, etc. The historical standard of care has been bone scan and MRI to identify metastases, but the increased signal to noise of PSMA PET allows for the identification of smaller metastases, which is useful both at the initial staging of disease as well as following recurrence.

PSMA PET is currently recommended by the European Association of Urology (EAU) in its guidelines for the detection of residual disease following biochemical recurrence. Biochemical recurrence is when men show elevated prostate specific antigen (PSA) levels following surgical treatment for prostate cancer. Significantly, the guidelines do not recommend that the competing technologies such as ^{18}F-fluciclovine (Axumin, Blue Earth Diagnostics) or ^{18}F-fluorocholine be used for this application.

A recent landmark study was published in *The Lancet,* adding significantly to the clinical evidence supporting the use of ^{68}Ga-PSMA-11.[1] Despite ample support in the literature, this study is the first randomised, controlled, prospective, multicentre study to examine PSMA's utility in PET-CT. The study enrolled 302 men in two arms to receive PSMA PET-CT and conventional imaging. The study randomised 302 high-risk patients (295 with follow-up), of which 87 had nodal or distant metastases, and accuracy was assessed as first-line identification of these metastases. The PSMA PET-CT arm showed dramatically higher accuracy than conventional imaging (92% vs 65%; p<0·0001), driven by much higher sensitivity (85% vs 38%) and modest improvement in specificity (98% vs 91%). The increased signal for PET-CT also translated into much improved detection of metastases: the AUC (receiver operating characteristic area under the curve) was 91% vs 59% for nodal metastases and 95 vs 75% for distant metastases. Moreover, these PET-CT results were more actionable and there were more management changes in this arm (28% vs 15%; p=0.008). This was achieved with less total radiation exposure (8.4 vs 19.2 mSv p<0·001). These data are some of the most robust that have been gathered to date supporting the use of ^{68}Ga-PMSA-11 for detection of prostate cancer, and the authors concluded that it is a superior replacement for conventional imaging.

These top-line results are similar to those seen from meta-analyses of PSMA (Exhibit 5).[2] While the sensitivity of fluciclovine/Axumin is high the specificity is relatively low, which means there will be a

[1] Hofman MS, et al. (2020) Prostate-specific membrane antigen PET-CT in patients with high-risk prostate cancer before curative-intent surgery or radiotherapy (proPSMA): a prospective, randomized, multicentre study. *Lancet* 395 1208–1216.

[2] Evans et al. (2018) Prostate cancer–specific PET radiotracers: A review on the clinical utility in recurrent disease. *Pract Rad Oncol* 8, 28–39.

high number of false positive reports. For comparison, Exhibit 5 also includes ^{18}F-FDG, which is widely used to detect metabolically active cancers such as lung, colorectal and breast cancers, but is not a sensitive test for prostate cancer, which is less metabolically active than many other cancers.

Exhibit 5: Sensitivity and specificity of radiotracers for detecting prostate cancer recurrence

	PSMA	Choline	Fluciclovine	Axumin (FDA label)*	^{18}F -FDG	ProstaScint
Sensitivity	86%	85–89%	87%	95%	26–57%	49%
Specificity	86%	88–89%	66%	31%		71%

Source: Edison Investment Research; Evans et al. *Practical Radiation Oncology* (2018) 8, 28–39; Taylor et al. *Trends in Urology & Men's Health* 2014 5(3), 34–37; ProstaScint product label. Note: Sensitivity and specificity for Axumin calculated by Edison from data in the Axumin Prescribing Information label.

A key advantage of PSMA imaging agents is that they are more sensitive than other agents for detecting metastases in biochemically recurrent prostate cancer where the PSA levels are low (ie when the tumours are small). In the meta-analysis, the sensitivity of PSMA PET for detecting recurrent prostate cancer metastases in men with low PSA levels (<2.0ng/ml) was 67%, vs 41% for fluciclovine and 34% for choline. Given it is these small metastases that are the most difficult to detect with standard imaging methods, we expect the increased sensitivity in this patient group will see PSMA PET become the preferred imaging technology for recurrent prostate cancer.

Competitive environment

We expect illumet to face commercial competition following approval as there are several other PSMA targeting probes in development. Progenics has an 18F labelled PSMA PET tracer (called PyL) that has completed Phase III studies and is planned to be submitted to the FDA for approval in early Q320. The private UK company Theragenics completed Phase III trials of its 68Ga PSMA tracer (THG-001) in October 2019 and is also planning an NDA submission. Blue Earth (as a Bracco subsidiary) continues to develop its ^{18}F-rhPSMA-7 tracer, which is currently in two pivotal Phase III studies. Although there are potentially some minor performance differences between products, we assume for all intents and purposes that they will be functionally equivalent. The ability to gain market share in this environment with multiple similar products will largely depend on marketing and the distribution footprint.

Prostate cancer incidence

According to the National Cancer Institute, prostate cancer is the second most common cancer in men; it is expected to account for 191,130 new cases and 33,330 deaths in the US in 2020, while 3.2 million men in the US are estimated to be living with a diagnosis of prostate cancer. Globocan predicts that in 2020 there will be 1,356,000 new cases and 379,000 deaths from prostate cancer worldwide, while in the EU and UK that year there will be 385,280 new cases and 83,910 deaths. At diagnosis, the disease is localised to the prostate in 76% of cases, while it has spread to regional lymph nodes in 13% of cases, and has metastasised elsewhere in the body in a further 6% of cases (staging is unknown in 4% of cases). While the overall five-year survival rate is very high at 97.8%, the prognosis ranges from a five-year relative survival of up to 100% for patients diagnosed with localised tumours to only 30% for patients who have metastatic disease at diagnosis.

TLX591: Leveraging PSMA targeting as a treatment

Telix is also developing a radiopharmaceutical targeting PSMA for the treatment of prostate cancer, TLX591 (aka ^{177}Lu-DOTA-rosopatamab). The targeting moiety for TLX591 is different than illumet because it employs the huJ591 monoclonal antibody (as opposed to the PSMA-11 peptide in

illumet). The huJ591 antibody was developed by Atlab Pharma, which Telix acquired in 2018. Atlab conducted a number of clinical trials of a single cycle of treatment with ^{177}Lu labelled huJ591 (called ^{177}Lu-J591 or ATL101), in conjunction with Weill Cornell. When ^{177}Lu-J591 was administered as a single infusion, the maximum tolerated dose was 70mCi/m^2 and 11–12% of subjects treated at 65mCi/m^2 or 70mCi/m^2 achieved at least a 50% reduction in PSA count.

The tolerability was improved in a subsequent study by splitting the total dose into two fractions administered two weeks apart. The total dose tolerated as two fractions was higher at 80–90mCi/m^2 (2×40mCi or 2×45mCi with the option of GCSF white blood cell growth factor). The higher total fractionated dose was also more efficacious; 21% of subjects treated at the recommended Phase II dose (RP2D) experienced a 50% reduction in PSA, including 29% of subjects treated at the highest dose of 2×45mCi.[3]

In a separate study when a single cycle of fractionated ^{177}Lu-J591 was administered in combination with multiple cycles of docetaxel chemotherapy, 11 of 15 (73%) subjects achieved at least a 50% reduction in PSA levels.[4]

In each study of ^{177}Lu-J591 the dose-limiting toxicity was reversible myelosuppression, a condition where bone marrow activity is decreased, resulting in fewer red blood cells, white blood cells and platelets. In the Phase I study of dose fractionated ^{177}Lu-J591, 36 of 49 (74%) subjects treated in all six dose cohorts had grade 3/4 haematological toxicity, while 19 of 33 (58%) of subjects treated at the RP2D had the more severe grade 4 haematological toxicity. In the docetaxel combo study, 20% experienced grade 4 neutropenia without fever, while 13% experienced grade 4 thrombocytopenia.

Overall, the studies showed that fractionated ^{177}Lu-J591 is tolerated with subsequent PSA declines and reversible myelosuppression. The falls in white blood cell counts were severe but did not result in fever (so-called febrile neutropenia, which can be life-threatening). While the haematological toxicity/myelosuppression increases the risk of bleeding events or infection, it is generally considered manageable, and drugs are available (eg filgrastim). However, neutropenia can result in a delay in subsequent chemotherapy treatment if the patient progresses despite MTR therapy.

Clinical pathway

Based on a review of the clinical data gathered by Atlab, Telix has concluded that there is sufficient support to perform a registrational Phase III study on TLX591. The planned study PROSTACT will be randomised and placebo controlled and test the product as a second-line treatment for mCRPC in combination with standard of care (vs standard of care alone), after progression on a 'novel androgen axis' drug (eg Xtandi, enzalutamide, Pfizer). The study is planned to enrol patients across multiple centres in the US and Australia.

The company has a meeting with the FDA to discuss the design and implementation of the PROSTACT study on 7 July 2020. This meeting with the FDA will inform us whether the study will be sufficient to support approval, and potentially other aspects of its design such as enrolment. We also expect the company to seek outside financing to support the TLX591 clinical program, potentially through the licensing of the product or portions of the rights. If a positive FDA recommendation and financing can be secured, the study is planned to initiate in Q420.

[3] Tagawa et al; ASCO 4 June 2016. J *Clin Oncol* 34, 2016 (suppl 15; abstr 5022)

[4] Batra et al; ASCO Genitourinary Cancers Symposium 2015. *J Clin Oncol* 33, 2015 (suppl 7; abstr 199)

TLX250-CDx: Filling the gaps in kidney cancer testing

Telix is developing TLX250-CDx as an imaging agent to detect ccRCC, which is the most common and aggressive form of kidney cancer; ccRCC comprises around 70–75% of all kidney cancers. TLX250-CDx uses a radiolabelled antibody that binds to carbonic anhydrase 9 (CA-IX), which is highly expressed on the surface of over 90% of ccRCC tumours, but is not detectable in normal kidney tissues. CA-IX is also highly expressed in a range of other cancers including lung, cervical, ovarian, oesophageal and breast carcinomas.[5]

TLX250-CDx is based on the mAb girentuximab (cG250) that Telix in-licensed from Wilex in 2017. Wilex developed an ^{124}I-labelled version of girentuximab for imaging with PET, which it named Redectane. In the studies conducted by Wilex, PET/CT scans were done two to six days (average five days) after Redectane infusion.

Wilex conducted a US-based Phase III study of Redectane in 196 patients with renal masses that were scheduled for surgical resection. In 2010 the study reported sensitivity and specificity for ccRCC of 86% and 87%, respectively.[6] While the sensitivity and specificity for Redectane were significantly higher than for the contrast-enhanced CT scans (CECT), the study missed one of its four primary endpoints because the specificity was not significantly higher than the pre-specified arbitrary target of 75% (p=0.057). This miss was due to the smaller than intended number of non-ccRCC patients in the study (53 vs the expected 63 non-ccRCC patients). Despite the 16/0 positive ODAC vote regarding the potential usefulness of an imaging test with the characteristics of Redectane, the FDA declined to approve Redectane and requested that Wilex undertake a confirmatory Phase III study; due to funding limitations Wilex did not conduct the requested study.

The switch to Zircon

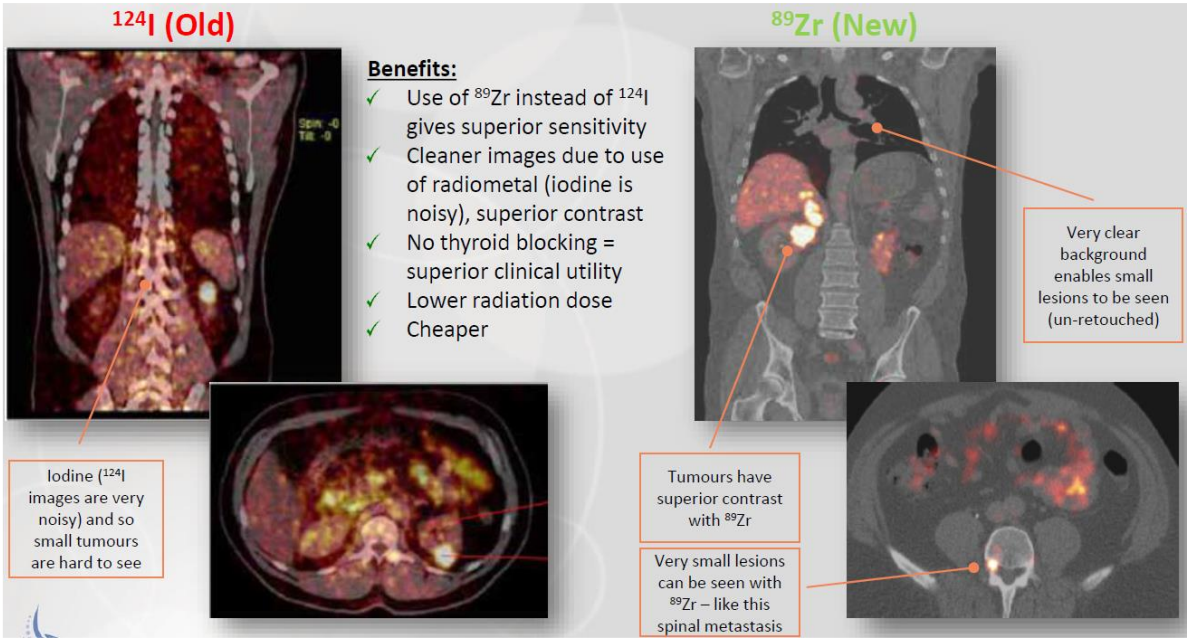
Telix has improved on the Wilex imaging product by replacing the ^{124}I radiolabel with ^{89}Zr. ^{89}Zr is a radio metal that becomes charge-trapped in the cytoplasm after the antibody bound to the CA-IX antigen on the surface is internalised and broken down within the cell, in contrast to ^{124}I, which is quickly released from the cell. The improved signal to noise provided by ^{89}Zr is seen in Exhibit 6.

The company confirmed the safety of ^{89}Zr (while gathering further evidence of its performance) in a a 10-patient bridging study comparing radiation exposure between the two nuclides. It found that ^{89}Zr imaging resulted in 25–30% less radiation exposure with improved signal quality.

[5] Pastorekova S. & Zavada J (2004) Carbonic anhydrase IX (CA IX) as a potential target for cancer therapy. *Can Ther* 2, 245–262

[6] Divgi CR, et al. (2012) Positron emission tomography/computed tomography identification of clear cell renal cell carcinoma: results from the REDECT trial. *J Clin Oncol* 31, 187–194.

Exhibit 6: TLX250-CDx produces much sharper images of ccRCC than the old Wilex product



Source: Telix Pharmaceuticals

The product is currently being tested in the registrational Phase III ZIRCON study. The study is an open-label trial with a target enrolment of 250 patients and is being performed at centres across Australia, Europe and the US. The primary endpoint of the study is to evaluate the sensitivity and specificity of TLX250-CDx, using histology as the gold standard. Enrolment has been delayed as a result of COVID-19, but the company announced that it is reopening its recommenced enrolment in Europe as of 18 June 2020. It is currently guiding towards the study being fully enrolled by the end of 2020.

The company announced on 1 July 2020 that TLX250-CDx has received breakthrough therapy designation from the FDA. The goal of the breakthrough designation programme is to shorten the review times for products that provide a substantial improvement over what is already available, which as the only diagnostic product candidate of its kind, TLX250-CDx certainly qualifies for. It allows for increased attention from the FDA along several avenues. First, the product will receive a fast track status, which allows the company to interact with the agency on an increased and more frequent basis. This should make the preparation of the product's BLA move more smoothly. Moreover, the BLA can be submitted on a rolling basis, as individual packages of data are completed by the company. The FDA will review and provide feedback on these data packages as they come in. An additional benefit of breakthrough designation (outside of fast track) is that it allows for the company to use an expedited clinical design. This may allow product candidates with this status to be assessed using alternative endpoints such as biomarkers. Considering that the pivotal ZIRCON study is well underway, this aspect is unlikely to impact the current clinical trajectory, but it may still allow for a more flexible review process.

A test to identify whether a kidney lump is a cancer

The NIH estimates 74,750 new patients will contract kidney cancer in 2020 in the US, and Globocan estimates 100,970 new cases in the EU and UK. Of these, 80% are expected to develop ccRCC. ccRCC is four times as likely to develop distant metastases as the other less common,

non-clear cell subtypes.[7] This means the key thing to know about a suspicious renal mass is whether or not it is ccRCC. This is becoming more important given that renal masses are increasingly being detected as incidental findings to abdominal imaging done for other reasons.

Unfortunately, in many cases current imaging techniques are unable to distinguish between ccRCC and benign tumours or less aggressive forms of kidney cancer. Surgical excision is the standard treatment of suspicious renal masses in patients who are otherwise healthy. A meta-analysis of 26 studies found that 15% of surgically resected renal masses were in fact benign[8] (non-cancerous), so many patients are having unnecessary surgery.

At a meeting in 2012, the FDA's Oncologic Drugs Advisory Committee (ODAC) concluded a test that could distinguish between ccRCC and other kidney masses would be useful when deciding how to manage renal masses. The ODAC concluded the test would be useful in the 20–30% of patients where the renal mass was considered indeterminate following examination by other imaging techniques such as ultrasound or CT. It was considered likely to be particularly useful for small lesions (1–2cm) and for larger lesions in patients with poor overall health where the risks of surgery are greater.

To date, no such test meeting these criteria has been approved. FDG-PET has limited utility for diagnosis of primary RCC as the renal uptake is likely to be masked by the excretion of the agent in the urine[9]; it is more useful for detecting metastases distant from the kidney. A number of small studies have shown the benefit of using the mitochondrial imaging agent ^{99m}Tc-sestamibi single photon emission CT (SPECT) to identify mitochondrial-rich benign and indolent (slow growing) renal masses.[10] As ^{99m}Tc-sestamibi is already used for clinical investigations of myocardial perfusion and for the detection of parathyroid adenomas, it could potentially also be used to aid in the identification of benign/indolent renal masses in the clinic if sufficient evidence becomes available to justify its use. However, the lower image resolution of SPECT imaging means that it is not well suited to imaging small lesions. In addition, ^{99m}Tc-sestamibi would not be suitable for any of the other potential applications of TLX250-CDx, such as detection of ccRCC metastases, assessing response to therapy or screening for suitability for TLX250 MTR therapy.

TLX250

Telix is also developing TLX250, an MTR therapeutic targeting ccRCC. TLX250 is based on a modified and improved version of the mAb girentuximab (cG250) labelled with the isotope ^{177}Lu. Wilex completed two clinical studies of ^{177}Lu-cG250 in patients with metastatic ccRCC. The two studies provided encouraging evidence of efficacy, with 78% and 68% of patients achieving responses of stable disease or better in the three months after the first course of treatment in the Phase I and Phase II studies, respectively. One of the 14 patients in the Phase II study achieved a partial response. While the treatment was generally well tolerated, a high proportion of subjects experienced myelosuppression (low levels of white blood cell production in the bone marrow). We expect Telix to seek to optimise the dosing regimen (both amount and interval) in future studies to in order to reduce the incidence of this side effect. The company's experience with MTR therapies in prostate cancer will help inform the programme to optimise the dosing regimen.

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7 Kim SP, et al.(2011) Outcomes and clinicopathologic variables associated with late recurrence after nephrectomy for localized renal cell carcinoma. *Urol* 78. 1101–1106.

8 Corcoran AT, et al (2013) A Review of Contemporary Data on Surgically Resected Renal Masses--Benign or Malignant? *Urol* 81, 707–13.

9 Sankineni S, et al (2016) Imaging of renal cell carcinoma. *Urologic Oncol: Sem Orig Inv* 34, 147–155.

10 Tzortzakakis A, et al. (2017) Visual evaluation and differentiation of renal oncocytomas from renal cell carcinomas by means of 99mTc-sestamibi SPECT/CT. *EJNMMI Res* 7, 29

Potential for combination with checkpoint inhibitors

The treatment algorithm for RCC has changed rapidly with the introduction of immune checkpoint inhibitors (eg PD-1, PD-L1 and CTLA4 inhibitors), which as a class have varying degrees of activity treating the disease alone or in combination with each other. Many investigations are still ongoing into the scope of the role of these drugs in treatment of the disease and regimens are approved for both the first and second line treatment of advanced RCC. These drugs have gained widespread acceptance, but there remains ample room for improvement. For instance, Opdivo (nivolumab, Bristol-Meyers Squibb) only showed a 21.5% overall response rate in second line treatment of advanced RCC (compared to 3.9% for everolimus).

All future clinical studies of TLX250 will likely be in combination with checkpoint inhibitors. There is reason to believe that the combination may have a synergistic effect. There is evidence to suggest that the cellular damage induced by radiation can increase the immunogenicity of a cancer, and therefore increase its response to checkpoint inhibitors. However, this effect has primarily been studied in the context of traditional radiotherapy.[11] A randomised trial provided direct evidence that radiation therapy can enhance responses to checkpoint inhibitor therapy. In the PEMBRO-RT study in 64 patients with lung cancer, combining external beam radiation therapy with the ICI pembrolizumab improved the overall response rate (ORR) to 41% vs 19% for pembrolizumab alone. Median progression-free survival (PFS) was 6.4 months for the combo vs 1.8 months for pembrolizumab alone (HR 0.55, p=0.04)[12].

The current clinical plan for TLX250 is to evaluate it in two Phase II studies. STARLITE-1 will examine the drug in combination with both Keytruda (pembrolizumab; Merck) and Inlyta (axitinib; Pfizer), and STARLITE-2 will examine it with both Opdivo and Yervoy (ipilimumab; Bristol-Myers Squibb). The company is preparing IND applications for these studies currently, which it plans to have submitted by mid-2020 to support initiation of these studies in late 2020. As with TLX591, we expect that the ability to progress these studies will be contingent on financing.

TLX101

The company's final development program is TLX101, which is being investigated for the treatment of glioblastoma multiforme (GBM). The drug was obtained by the company through the acquisition of the privately held German company Therapeia in 2017. TLX101 is a radiolabelled amino acid analogue (4-[^{131}I]iodo-L-phenylalanine, also known as ^{131}I-IPA), which is a small molecule that rapidly crosses the blood-brain barrier. TLX101 is taken up by the membrane-bound L-amino acid transporter 1 (LAT1), which is over-expressed in gliomas including GBM. This allows the tissue-specific accumulation of the ^{131}I therapeutic radionuclide inside the cancer cells. The ^{131}I radiolabel is used because it readily crosses the blood-brain barrier, whereas a charged radiometal such as ^{177}Lu does not.

In addition, preclinical studies show that unlabelled IPA is a radio-sensitiser, ie, it increases the sensitivity of cells to radiation. In studies in an animal model where GBM tumours were growing in the brain of rats, combining TLX101 with external-beam radiation therapy (EBT) was much more effective than either therapy alone.[13]

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[11] Pilones KA, et al. (2014) Combination of Radiotherapy and Immune Checkpoint Inhibitors. *Sem Rad Oncol* 25, 28–33.

[12] Theelen et al 2018, ASCO abstract 9023.

[13] Samnick S, et al (2009) Efficacy of Systemic Radionuclide Therapy with p-131I-Iodo-L-Phenylalanine Combined with External Beam Photon Irradiation in Treating Malignant Gliomas. *J Nucl Med* 50, 2025–2032.

Telix also received TLX101-CDx during the Therapeia acquisition, which uses IPA labelled with the radionuclide ^{124}I for PET imaging, which Telix will use as a research tool to study the pharmacology of TLX101. PET imaging of patients with commercially available MTR diagnostics that cross the blood brain barrier and are taken up by LAT1, such as ^{18}F-FET or ^{18}F-flucyclovine (FACBC), could potentially be used to screen patients for enrolment in the upcoming clinical trials of TLX101.

IPA labelled with a different radioisotope, ^{123}I, has previously been investigated for SPECT imaging of high-grade gliomas. It showed uptake and prolonged retention and promising diagnostic performance. In an academic study in 100 patients with glioma the sensitivity to detect glioma was 88% with specificity for glioma of 95%. The sensitivity for high-grade gliomas (mainly GBM) was 93%, therefore the vast majority of GBM patients should be eligible for therapy with TLX101.

A total of 11 patients have been treated with ^{131}I-IPA (TLX101) on a compassionate use basis in two institutions in Germany. Baum et al (2011)[14] reported that among two patients with low-grade glioma treated with TLX101, one experienced a reduction in tumour volume over 10 months, with progression occurring 10 months after therapy. The second patient showed stable disease on MRI and PET during the three-month follow-up period. There was no clinically detected toxicity. Company data shows that, subsequent to the published study, the second patient was treated with ^{131}I-IPA + 68 Gy EBT, which resulted in a measurable (40%) reduction in tumour volume and clinical improvement including the cessation of epileptic fits. In addition, a patient with GBM who was treated with 6 GBq ^{131}I-IPA + 68 Gy EBT achieved histologically confirmed tumour eradication,[15] although the patient died eight months later from (unrelated) gastrointestinal bleeding.

The IPAX-1 study

The company is currently in the dose escalation phase of an open-label Phase I/II study of TLX101 called IPAX-1 across five centres in Australia and Europe. The planned recruitment for the Phase I dosing portion of the study is 22 patients, with a planned expansion to 10 more patients once the Phase II dose has been found. However, the COVID-19 pandemic has delayed the progression of the program, and the clinical study is currently paused until it can safely be resumed, which the company estimates will be possible in September or October 2020. The company is currently forecasting that initial data from the Phase I portion will be available around the end of 2020.

GBM incidence

GBM is the most common and most aggressive primary malignant tumour of the brain and spinal cord. Approximately 11,000 patients are diagnosed with GBM each year in the US, representing 46% of all brain and CNS cancers.[16] GBM tumours are characterised by invasive and diffuse growth, which makes complete surgical removal difficult. Standard treatment for GBM entails maximal surgical resection of the tumour followed by radiotherapy with concurrent chemotherapy with temozolomide followed by adjuvant chemotherapy with the same drug to treat the residual infiltrative component of the tumour. Despite this aggressive treatment, the disease invariably returns, resulting in a five-year survival rate of only 5%.[17] Options for treating recurrent GBM include bevacizumab (Avastin), alternating electric field therapy (Optune), surgery and EBT.[18]

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14 Baum RP, et al (2011) Systemic Endoradiotherapy with Carrier-Added 4-[131I]Iodo-L-Phenylalanine: Clinical Proof-of-Principle in Refractory Glioma. *Nucl Med Mol Imaging* 45, 299–307.

15 https://www.therapeia.info/en/therapy/

16 Ostrom QT, et al. (2015) CBTRUS Statistical Report: Primary Brain and Central Nervous System Tumors Diagnosed in the United States in 2008–2012. *Neuro Oncol* 17, Suppl 4 iv1-iv62.

17 Ostrom QT, et al. (2015) CBTRUS Statistical Report: Primary Brain and Central Nervous System Tumors Diagnosed in the United States in 2008–2012 *Neuro-Oncol* 17, iv1–iv62.

18 https://www.cancer.net/cancer-types/brain-tumor/treatment-options

Sensitivities

The risks faced by Telix are similar to other biopharma companies transitioning from clinical development to commercial operations. The company's lead product illumet is currently under review at the EMA and expected to be submitted to the FDA for approval shortly, and there exists the unavoidable regulatory risk. Although limited clinical data on illumet specifically has been released publicly, the clinical support in the literature for PSMA imaging is substantial, which gives us confidence in the submission. The company's therapeutic development programs carry increased clinical risk given their earlier stage of development and greater potential for adverse effects. We also expect the company to face a series of commercial risks. Illumet in particular may have several competitors as there are no less than three other companies developing PSMA targeted PET tracers at a similar stage of development. For comparison, we are unaware of any other companies developing CA-IX targeting PET tracers to compete with TLX250-CDx. Finally, the company will need to secure financing to advance its therapeutics programs, either through licensing agreements or on the capital markets. We include A$91.2m in putative milestones from such a licensing/partnering agreement in our model, which would cover future expenses of these programs, but the company faces dilution risk if it is unable to secure such a deal with favourable terms (albeit it could then potentially recognize the full value of these assets without sharing some of the economic value with a partner/licensee).

Valuation

We have increased our valuation to A$571m or A$2.25 per basic share, from A$522m or A$2.06 per basic share. We have updated our model with the latest epidemiological data from the NIH and WHO (presented above), which have shown slightly higher rates of prostate and kidney cancer than previous agency projections. Additionally, we have adjusted our model for TLX250-CDx to account for Breakthrough designation: we have increased the probability of success to 85% from 75% and we now expect a slightly earlier launch (albeit still in 2022). This has the effect of increasing the NPV for the product by approximately A$10m. Otherwise our models remain unchanged. These numbers and our other assumptions are outlined in Exhibit 7.

Exhibit 7: Telix sum-of-the-parts DCF

	Base case likelihood (%)	rNPV (A$m)	rNPV/share (A$)	Assumptions
TLX250-CDx kidney cancer imaging	85%	91.6	0.36	Global peak sales of US$80m. For the US, assumes 73,750 kidney cancer cases/year, 50% candidates for imaging, 25% penetration; for the EU assumes 100,970 cases/year, 50% candidates for imaging, 20% penetration; pricing US$3,500 per patient, 30% discount in Europe; launch 2022; assume profit margin after deducting royalty to Wilex equal to 30% of net sales. R&D cost: A$12m to compete Phase III.
TLX250 kidney cancer therapeutic	20%	72.2	0.28	Global peak sales of US$500m. For the US assumes 73,750 kidney cancer cases/year, 20% eligible for treatment, 20% penetration; for the EU assumes 100,970 cases/year, 20% eligible, 16% penetration; pricing US$70k per patient, 30% discount in Europe; launch 2024 – biologicals market exclusivity to 2036 in US, 2034 in Europe; assume receives 12% net royalty after out-licensing.
Illumet (TLX591-CDx) prostate cancer imaging	80%	206.9	0.82	US peak sales of US$90m assuming 191,930 new cases/year, 75% candidates for imaging; 15% penetration; revenue US$3,500 per test; commercial launch as investigational test 2018, FDA approval 2021; assume profit margin (before royalties) equal to 35% of net sales in US and 35% elsewhere. RoW peak sales US$90m (same as US); European approval 2022. Royalty payable to ANMI vendors for five years after first approval assumed to be 10% in the US and 12.5% elsewhere. Likelihood of success 80% in the US and 65% elsewhere.
TLX591 prostate cancer therapeutic	20%	148.7	0.59	Global peak sales of US$1,090m. For the US assumes 33,330 end-stage patients/year, 90% eligible for treatment, 15% penetration; for the EU assumes 83,910 deaths/year, 90% eligible 12% penetration; pricing US$70k per patient, 30% discount in Europe; launch 2025 – biologicals market exclusivity to 2037 in US, 2035 in Europe; assume 12% net royalty after out-licensing.
TLX101 brain cancer therapeutic	10%	50.7	0.20	Global peak sales of US$510m assuming annual US incidence of GBM of 11,000 cases, 90% eligible for therapy, 25% penetration; EU GBM incidence 21,500, 90% eligible, 15% penetration; pricing US$70k per patient, 30% discount in Europe; launch 2025; 15% royalty on net sales. R&D cost: A$6m for Phase I/II, A$25m for Phase III.
SG&A		(32.1)	(0.13)	
Portfolio total		**538.0**	**2.12**	
Net cash (Q120 est.)		33.3	0.13	
Enterprise total		**571.3**	**2.25**	

Source: Edison Investment Research. Note: NPV adjusted for tax at an effective tax rate of 25%. We assume that the addressable markets grow at 3% per year. We show net royalty rate or profit margin after deducting estimated trailing royalties to IP holders.

We expect to update our assumptions with the upcoming approval decisions for Illumet as well as readouts from the ongoing ZIRCON and IPAX-1 clinical studies. Moreover, we may update our assumptions as the path forward for TLX591 becomes clearer. The planned Phase III study is contingent on positive feedback from the upcoming FDA meeting (7 July 2020). We currently model the program being licensed shortly thereafter to support the trial, but we have an alternative scenario model in which the company would fund and complete a Phase III trial itself, and only seek a licensing deal after completing Phase III. Key changes to assumptions under this scenario are a higher royalty rate for a post-Phase III deal (17% net royalty vs 12% for post Phase II) and a 35% current probability of success (vs 20% under the base case scenario); this higher probability would be due to a lower assumed partnership risk (ie there is less partnership risk if the company waits until after completing the Phase III before exploring licensing/partnership deals). We assume that the cost of the TLX591 development programme would be A$83m (US$60m) vs A$20m under the base case. Based on these assumptions, we estimate that progressing TLX591 directly to a self-funded Phase III could potentially add approximately A$67m (A$0.27/share) to our valuation.

Financials

Our financial forecasts remain largely unchanged, save for slight top-line adjustments to reflect the updated epidemiology in our model. We estimate that the company ended Q120 with A$33.3m net cash. We believe that this will be sufficient to finance the company into 2021 and the approval decisions of illumet. We also include in 2021 A$91.2m in illustrative milestones associated with the licensing of its therapeutics TLX591 and TLX250. A deal (or deals) will be necessary to progress these programs in the clinic, and if the company is unable to secure such transaction(s) for them in

2021, we would expect a financing shortfall of around A$10m (in 2021) to maintain ongoing operations before the cost of advancing TLX591 and TLX250.

Exhibit 8: Financial summary

A$'000s	2018	2019	2020e	2021e
Year end 31 December	AASB	AASB	AASB	AASB
PROFIT & LOSS				
Sales, royalties, milestones	195	3,485	3,637	97,800
Other (includes R&D tax rebate)	10,142	11,693	8,400	0
Revenue	10,337	15,178	12,037	97,800
R&D expenses	(18,692)	(21,162)	(21,750)	(21,250)
SG&A expenses	(9,150)	(15,800)	(13,699)	(14,110)
Other	0	0	0	0
EBITDA	(17,505)	(24,327)	(26,066)	62,440
Operating Profit (before amort. and except.)	(18,992)	(24,078)	(26,446)	62,042
Intangible Amortisation	0	(4,236)	(4,309)	(4,309)
Exceptionals	0	0	0	0
Operating Profit	(18,992)	(28,314)	(30,755)	57,732
Net Interest	304	(2,310)	446	151
Profit Before Tax (norm)	(15,714)	(31,122)	(30,309)	57,883
Profit Before Tax (reported)	(15,714)	(31,122)	(30,309)	57,883
Tax benefit	1,884	3,255	0	(608)
Profit After Tax (norm)	(13,830)	(27,867)	(30,309)	57,275
Profit After Tax (reported)	(13,830)	(27,867)	(30,309)	57,275
Average Number of Shares Outstanding (m)	202.1	233.4	253.5	253.8
EPS - normalised (c)	(6.84)	(11.94)	(11.95)	22.57
EPS - diluted (c)	(6.84)	(11.94)	(11.95)	22.02
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	40,852	43,928	48,710	44,474
Intangible Assets	39,451	41,948	46,638	42,329
Tangible Assets	226	1,899	1,990	2,063
Investments	1,175	82	82	82
Other				
Current Assets	35,856	58,679	25,321	92,773
Stocks	643	542	0	0
Debtors	8,436	12,071	8,778	378
Cash	25,771	44,598	15,075	90,927
Other	1,007	1,468	1,468	1,468
Current Liabilities	(8,242)	(10,625)	(1,588)	(6,296)
Creditors	(6,893)	(9,218)	(182)	(4,890)
Short term borrowings	(1,133)	(490)	(489)	(489)
Other	(216)	(917)	(917)	(917)
Long Term Liabilities	(15,562)	(21,902)	(31,336)	(31,336)
Long term borrowings	(596)	(1,641)	(2,075)	(2,075)
Other long term liabilities	(14,966)	(20,261)	(29,261)	(29,261)
Net Assets	52,904	70,080	41,108	99,615
CASH FLOW				
Operating Cash Flow	(21,065)	(23,314)	(30,072)	76,779
Net Interest	316	(19)	446	151
Tax	0	0	0	(608)
Capex	0	(403)	(471)	(471)
Acquisitions/disposals	(2,693)	(65)	0	0
Equity Financing	0	43,890	140	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(23,442)	20,089	(29,957)	75,851
Opening net debt/(cash)	(48,414)	(24,042)	(42,467)	(12,511)
HP finance leases initiated	0	0	0	0
Other	(929)	(1,664)	1	0
Closing net debt/(cash)	(24,042)	(42,467)	(12,511)	(88,363)

Source: Telix Pharmaceuticals reports, Edison Investment Research

Contact details	Revenue by geography
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Management team

CEO: Christian Behrenbruch	CMO: Colin Hayward
Dr Behrenbruch has 20 years of healthcare entrepreneurship and executive leadership experience. He has previously served in a CEO or executive director capacity at Mirada Solutions, CTI Molecular Imaging (now Siemens Healthcare), Fibron Technologies and ImaginAb, Inc. He is a former director of Momentum Biosciences LLC, Siemens Molecular Imaging Ltd, Radius Health Ltd (now Adaptix) and was the former chairman of Cell Therapies P/L (a partnership with the Peter MacCallum Cancer Centre). Chris is currently a director of Factor Therapeutics (ASX:FTT) and Amplia Therapeutics P/L. He is chairman of the Monash Engineering and IT Foundation Board and is an adjunct professor at Monash University.	Dr Hayward joined Telix with over 20 years of global pharmaceutical, biotechnology and drug development experience and leads the company's medical affairs, regulatory, clinical operations and pharmacovigilance activities on a global basis. Prior to joining Telix, Dr Hayward was the chief medical officer of Premier Research (North Carolina, US), a leading global contract research organisation (CRO) specialising in the biopharmaceutical and specialty pharmaceutical areas of clinical research. Dr Hayward has held a series of senior medical, executive and board-level roles with F. Hoffmann-La Roche, Myriad Genetics, Prism Ideas Ltd and Symprove Ltd.
CBO: David Cade	**CFO: Douglas Cubbin**
David joined Telix in October 2019 as chief business officer and head of investor relations. Prior to joining Telix, David worked at Cochlear Limited where he served as chief medical officer leading the quality, regulatory, clinical research and medical affairs functions of the company. Prior to Cochlear, David spent many years at Sirtex Medical Limited, an ASX-listed oncology company where he served as chief medical officer and in other roles across the US, Europe and Australia. Earlier in his career David trained in surgery at Monash Medical Centre in Melbourne and worked at management consultancy, Booz & Company across the Asia-Pacific region.	Mr Cubbin is a certified practicing accountant (CPA) with 30 years of experience in finance and executive roles in diverse industry sectors, including healthcare, financial services, building, transport/logistics and telecommunications. He is a fellow of the Australian Society of CPAs and a graduate of the Institute of Company Directors. Doug has spent the last 11 years in CFO, COO, commercial and business development roles in nuclear medicine. Prior to that Doug, was the group CFO of DHL (Australia-Pacific). From 2013 to 2016, Doug was the chairman of Australian Nuclear Science and Technology Organisation (ANSTO), Nuclear Medicine Pty Ltd and the general manager of business development at ANSTO.

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Andreas Kluge	9.72
Elk River Holdings	9.72
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