EDISON

Telix Pharmaceuticals

ANMI and prostate Phase III

Prostate programmes boosted

Pharma & biotech

Telix Pharmaceuticals has added significant value by acquiring ANMI, the developer of its TLX591-CDx prostate cancer imaging kit and underlying 'cold kit' technology. It also announced plans to accelerate its TLX591 prostate cancer therapeutic into Phase III, based on a third-party review of clinical data that formed part of the Atlab acquisition in September. Following the ANMI acquisition we increase our valuation to A$380m (vs A$303m) or A$1.74 per share (vs A$1.43 per share). FDA agreement to the TLX591 Phase III design would likely prompt a further valuation uplift.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/17	0.4	(6.4)	(5.0)	0.0	N/A	N/A
12/18	10.3	(15.7)	(6.8)	0.0	N/A	N/A
12/19e	9.4	(24.1)	(11.0)	0.0	N/A	N/A
12/20e	9.4	(23.5)	(10.8)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding exceptional items.

Potential US filing for TLX591-CDx (illumet) in 2019

In December, Telix acquired its partner Advanced Nuclear Medicine Ingredients (ANMI), which developed the TLX591-CDx kit for labelling PSMA-11 with ^{68}Ga for prostate cancer imaging. The acquisition gives Telix full global rights to the kit, compared to its previous US-only JV. The kit is currently sold in the US and Europe as an investigational test for use in formal or informal studies. Telix is in discussions with the FDA and anticipates filing for US approval in 2019. New clinical studies are likely to be required before filing for approval in Europe; we model EU filing in 2021.

TLX591-CDx approval would boost value

Based on our global peak sales target of US$160m for TLX591-CDx, we value the global franchise at A$133m, vs A$56m for Telix's share of the pre-existing US joint venture. Our model indicates that gaining marketing authorisation and growing global sales from the current ~US$2m/year to US$160m by 2027 would deliver an impressive return on the acquisition consideration of €6m (A$9.4m) plus earn-outs.

Prostate therapeutic to be accelerated to Phase III

Following a review of the Atlab clinical data Telix has decided to accelerate its prostate cancer therapeutic programme directly to a Phase III study of the original radiolabelled huJ591 antibody. Its previous plan was for a Phase II study of its modified version of the antibody. The accelerated programme will allow Telix to capitalise on the current market opportunity in chemotherapy-naïve patients.

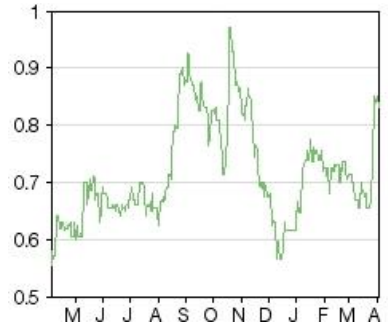
Valuation: A$380m or A$1.74 per share

We lift our valuation to A$380m (vs A$303m) or A$1.74/share (vs A$1.43/share). We have revised our model for the ANMI acquisition and the resultant move to 100% of global rights to TLX591-CDx (vs the prior US-only JV). We assume ex-US sales will match our US peak sales forecast of US$80m and an operating profit margin (before royalties) of 35% in the US and 25% in other territories. We will review our valuation if Telix gains FDA agreement to progress TLX591 to Phase III.

3 April 2019

Price	**A$0.83**
Market cap	**A$181m**
	US$0.76/A$
Gross cash (A$m) at 31 December 2018	25.8
Shares in issue	218.4m
Free float	58%
Code	TLX
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	16.1	27.7	44.3
Rel (local)	15.1	13.5	33.9
52-week high/low	A$0.97		A$0.56

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

IPAX-1 GBM Phase I/II interim results	Q319
TLX591-CDx (illumet) FDA approval filing	H219
TLX591 Phase III Go/No Go decision	H219

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Edison profile page

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Investment summary

Company description: Molecularly targeted radiation

Telix is a biotechnology company that is developing molecularly targeted pharmaceutical products for imaging (identified by 'CDx' suffix) and treating a range of cancers. It is developing TLX250-CDx and TLX250 for imaging and treating the kidney cancer known as clear cell renal cell carcinoma (ccRCC); TLX591-CDx (branded illumet in the US) and TLX591 for imaging and treating prostate cancer; and TLX101-CDx and TLX101 for imaging and treating brain cancer (TLX101-CDx will be used for studying the pharmacology of TLX101 but will not be developed for clinical use). TLX250-CDx, which now uses the ^{89}Zr radionuclide that produces sharper images, is in a confirmatory Phase III trial (ZIRCON). The TLX591-CDx prostate cancer imaging kit is available as an investigational imaging tool for use in clinical trials and a filing for US regulatory approval is expected during 2019. The TLX101 therapeutic agent is in a Phase I/II study.

Valuation: A$380m or A$1.74 per share

We value Telix at A$380m or A$1.74 per share, which includes our estimates of the future milestone payments and royalty streams for TLX250 and TLX591, plus profits from commercialisation of TLX250-CDx, TLX591-CDx and TLX101. Our rNPV calculation is based on the assumptions discussed below, such as target population, market uptake, pricing, R&D costs, market exclusivity expiry and calculated peak sales. Telix's strategy is to self-commercialise TLX250-CDx, TLX591-CDx and TLX101 due to the compact market structure for these products. For TLX591 and TLX250 its strategy is to seek a marketing partner to promote the products into the more dispersed urology market. One option for Telix would be to seek to partner TLX591 before initiating the planned Phase III study. Our scenario analysis suggests that progressing TLX591 to Phase III (subject to funding and regulatory approvals) could add around A$70m to our valuation, even after accounting for an estimated US$60m in development costs.

Financials: Funded until mid-2020

Telix reported a pre-tax loss of A$15.7m in 2018, its second year of operation. Expenses associated with R&D projects were A$18.7m, personnel expenses were A$4.9m and administration and consulting costs totalled A$4.3m. Our pre-tax loss estimates for 2019 and 2020 grow to A$24.3m and A$23.6m, respectively, mainly due to increased R&D expenditure as Telix progresses its clinical trial programme, partly offset by the Australian government's R&D rebate scheme. Telix had A$25.8m cash and equivalents at 31 December 2018 and is funded to mid-2020. However, we estimate that it may need additional funding in 2020 (we model A$15m of indicative debt). Additional funds would be needed to proceed with a TLX591 Phase III trial.

Sensitivities: Typical biotech risks apply

Telix is subject to typical biotech company risks, including unpredictable trial outcomes, regulatory decisions, success of competitors, financing and commercial risks. We assume that TLX250 and TLX591 will be out-licensed; therefore, our valuation is sensitive to potential licensing timing and actual deal terms. While Telix is commencing commercialisation of TLX591-CDx, it is still mainly a mid-stage drug developer, therefore in the foreseeable future most value creation will depend on successful R&D progress and any potential partnering activities. If the FDA requires Telix to conduct a prospective clinical study of TLX591-CDx, it could delay filing for full marketing approval by one to two years. We model the use of TLX591-CDx as a second-line test in prostate cancer patients following biochemical relapse when metastases cannot be detected by CT or MRI scans, but if it becomes a first-line test in these patients, the addressable market could be significantly larger.

Company description: Using radiation to target cancer

Telix Pharmaceuticals is based in Melbourne, Australia and focuses on the development of MTR products (also referred to as targeted radiopharmaceuticals) to image and treat cancer. The company was incorporated in January 2017 and listed on the Australian Stock Exchange (ASX) in November 2017 after raising A$50m (before costs) in an IPO. The company's founders, Christian Behrenbruch (CEO) and Andreas Kluge (CMO), are experienced executives and drug developers in the field of radiopharmaceuticals. The company's portfolio, which consists of a pipeline of in-licensed and acquired products as well as company-originated intellectual property, was described in detail in our initiation report and is summarised in Exhibit 1.

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	Phase III bridging study underway; ZIRCON Phase III due to fully enrol by Q419	Isotope changed from ^{124}I to ^{89}Zr to improve image quality.
TLX250 (therapeutic)	Kidney cancer (ccRCC)	CA-IX mAb ^{177}Lu	US Phase II planned	Phase II checkpoint inhibitor combo studies planned for 2019.
TLX591-CDx (imaging)	Prostate cancer	PSMA small molecule ^{68}Ga	DMF passed FDA review	Commercial sales as an investigational imaging test underway in the US and Europe. US approval filing expected in 2019.
TLX591 (therapeutic)	Prostate cancer	PSMA mAb ^{177}Lu	Phase III in planning (strategy revised in Q119)	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	Preliminary experience from Phase I/II dose-ranging study expected to report around Q319.

Source: Edison Investment Research, Telix. Note: *IMPD= investigational medicinal product dossier; mCRPC= metastatic castration-resistant prostate cancer; PSMA= prostate-specific membrane antigen; GBM= glioblastoma.

ANMI acquisition gives Telix 100% of TLX591-CDx

On 24 December Telix completed the acquisition of its Belgium-based partner ANMI, which developed the TLX591-CDx kit for producing ^{68}Ga-labelled PSMA-11 imaging agent for prostate cancer PET scans. Telix and ANMI had previously formed a JV for commercialising TLX591-CDx in the US, while ANMI retained 100% of the ex-US rights. TLX591-CDx is branded as illumet in the US.

The acquisition gives Telix control of the global rights to the TLX591-CDx kit. This would likely double the market opportunity for Telix in prostate cancer imaging, given that ex-US markets typically account for around 50% of global sales for pharmaceutical products. ANMI generated A$2.6m (~US$2m) revenue from sales of the ^{68}Ga-PSMA-11 cold kit as an investigational (unregistered) product in 2018.

Consideration comprised €3.15m (A$5m) of Telix shares at A$0.83 per share, €2m (A$3.1m) in cash, plus Telix assuming responsibility for €0.8m of debt. The debt comprises non-recourse repayable grants and development loans, mostly owed to the Belgian government and repayable on successful commercialisation. The total upfront consideration was €6.0m (A$9.4m).

Telix will also pay an earn-out equivalent to a low double-digit royalty on product sales for of five years after the first marketing approval of an ANMI product in either the US or EU. The royalty rate payable on US sales will be lower than other territories, in recognition of Telix's contribution to commercialisation in the US; we model a 10% royalty rate in the US and 12.5% elsewhere.

Telix now carries 100% of the risk and expense of the global development and commercialisation of TLX591-CDx, and will in turn reap 100% of the rewards (after earn-outs to ANMI shareholders) if TLX591-CDx is a commercial success.

PSMA-based PET imaging preferred in European guidelines

The European Association of Urology (EAU) has issued updated guidelines for managing prostate cancer, which foreground the advantages of PSMA-based PET scans (such as those performed using the TLX591-CDx labelling kit) compared to other PET imaging technologies. The updated guidelines list PSMA scans as the only PET imaging technology recommended for identifying metastatic disease in men with persistent prostate specific antigen (PSA) levels after prostate cancer surgery (radical prostatectomy). 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.

For a related patient population, men whose disease has returned after initial prostate surgery (biochemical recurrence), PSMA PET is recommended as the preferred PET for imaging technology. Fluciclovine PET and choline fluorocholine PET are only recommended to be used in these patients if PSMA PET/CT is not available.

The guidelines describe the strength of both of these ratings as weak, as the current evidence base is limited (we note that this does not necessarily imply that the clinical utility is weak). However, despite this, the recommendation that PSMA PET/CT should be used in preference to competing PET technologies should help make PSMA PET imaging routine clinical practice and therefore drive increased uptake of the TLX591-CDx ^{68}Ga-PSMA kit in Europe. Developing the clinical data to support a marketing approval application and submitting this to regulatory review will strengthen the evidence base.

Telix to pursue approval of TLX591-CDx in the US and Europe

Telix intends to seek regulatory approval to market TLX591-CDx in the US and Europe. It is in active discussions with the FDA regarding the nature of the evidence that would be required to support regulatory approval in the US. Based on discussions to date, management anticipates an NDA submission in 2019.

The European Medicines Agency considers ^{68}Ga-PSMA-11 to be a drug whereas the FDA considers it to be an active pharmaceutical ingredient (API). Due to this distinction, Telix expects that it will need to do further clinical studies before filing for approval in Europe. As a consequence, we model filing in Europe in 2021, two years later than in the US.

ANMI technology potentially applicable to other Telix products

ANMI has several other pipeline products that are synergistic with Telix's focus on urological diseases.

The availability of a GMP-grade ^{177}Lu radiopharmaceutical precursor means that Telix's TLX591 could potentially be developed in kit form to be used to produce the final radiolabelled product, rather than relying on centrally-manufactured product. This could potentially be a point of differentiation from Novartis/Endocyte's PSMA-617, which is currently being investigated in a Phase III trial in 750 prostate cancer patients, and which is expected to be distributed as a centrally manufactured, labelled product ready for use.

Providing the products as a 'cold kit' which can be radiolabelled on site would make the therapy as well suited to smaller clinics as it is to large hospital sites, because it does not require access to a cyclotron to generate the radioisotope or a centralised manufacturing facility to generate the therapeutics product.

TLX591 prostate cancer therapeutic accelerated

In September 2018, Telix completed the anticipated acquisition of Atlab Pharma for ~US$10m (in shares and warrants), to strengthen its IP position and gain access to clinical data and know-how related to its TLX591 prostate cancer therapeutic programme.

Atlab had previously conducted a number of clinical trials of ^{177}Lu-huJ591 in prostate cancer, in conjunction with Professor Neil Bander's lab at Weill Cornell Medical Centre (WCMC), and had licensed the huJ591 anti-PSMA (prostate specific membrane antigen) antibody technology from WCMC. As part of the acquisition of Atlab, Telix brought in a third-party contract research organisation (CRO), ABX, to asses and verify the Atlab clinical study data.

Review of Atlab data highlights potential for further development of ^{177}Lu-huJ591

Following the review of the Atlab/WCMC data, Telix concluded that the safety and efficacy data from prior clinical studies of ^{177}Lu-huJ591 were sufficiently promising to justify progressing the original, unmodified huJ591 antibody directly into a Phase III study in chemotherapy-naïve patients with metastatic castration resistant prostate cancer (CRPC).

The analysis of the historical data by ABX confirmed that when the dose of ^{177}Lu-huJ591 was fractionated (ie split into two doses administered two weeks apart), the efficacy and tolerability of the treatment was improved. In particular, the patients who received the highest two doses of fractionated therapy survived much longer than patients who had been treated at lower doses. The difference in survival was most dramatic for patients who had not had prior treatment with chemotherapy drugs (ie were chemotherapy-naïve).

The original huJ591 antibody, which will be radiolabelled with lutetium (^{177}Lu), will now be known as TLX591.

The company's enhanced version of the huJ591 mAb (which was previously known as TLX591), will now be developed as a follow-on or backup product known as TLX592. TLX592 will be labelled with the alpha-particle emitting radioisotope Actinium-225 (^{225}AC). Telix expects the second-generation TLX592 product to have toxicity and efficacy advantages over TLX591.

Telix had previously planned to investigate TLX592 in a Phase I/II study, before progressing to Phase III.

Targeting chemotherapy-naïve patients makes commercial sense

The proposal to target use of huJ591 in chemotherapy-naïve patients makes sound commercial sense, in our view, because there is currently a potential opportunity to be first to market for this patient population.

On the other hand, if Telix was to follow the more typical approach of seeking an initial approval as a salvage therapy for patients who have already failed prior chemotherapy treatment, it could potentially be competing for market share with an established PSMA-targeted radiotherapeutic in Endocyte/Novartis's PSMA617. Endocyte is already well-advanced in its VISION Phase III study of PSMA 617 in mCRPC patients who have failed first-line chemotherapy (NCT03511664). The VISION study is expected to report top-line data in H220.

The Atlab/WCMC data: A closer look

Atlab conducted a number of studies of prostate cancer patients treated with ^{177}Lu-huJ591 (which it called ATL101), in conjunction with WCMC[1]. This included both "single shot" dosing where the full dose of ^{177}Lu-huJ591 was administered as a single infusion, and fractionated dosing, where the total dose was split into two fractions that were administered two weeks apart.

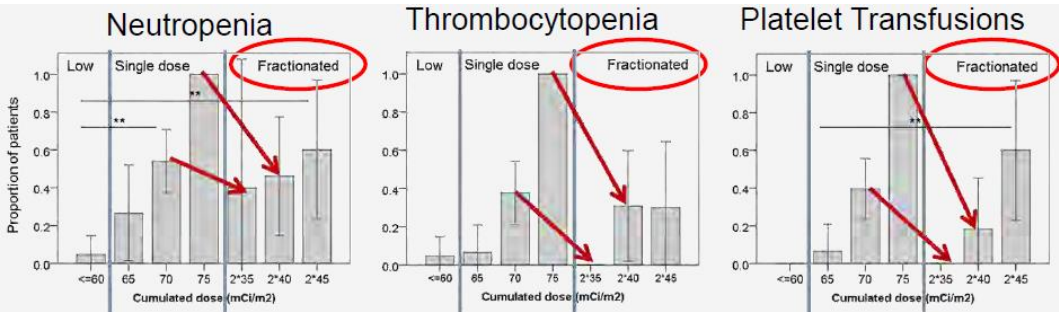
Fractionated dosing improved tolerability and efficacy

When ^{177}Lu-huJ591 was administered as a single infusion, the maximum tolerated dose (MTD) was 70 mCi/m^2 and 11–12% of subjects treated at 65 or 70 mCi/m^2 achieved at least a 50% reduction in PSA count (referred to as a biochemical response). 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.

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 80–90 mCi/m^2 (2x40 mCi/m^2 or 2x45 mCi/m^2 with the option of GCSF white blood cell growth factor). Exhibit 2 shows that the drop in white blood cell counts (neutropenia) and platelet counts (thrombocytopenia) was much less when a total dose of 70 mCi/m^2 was fractionated into 2x35 mCi/m^2 than when it was administered as a single shot treatment.

Although tolerability was improved by fractionated dosing, manageable reversible bone marrow suppression was still a frequent observation. In the study of dose fractionated ^{177}Lu-huJ591, 36/49 (74%) subjects treated in all six dose cohorts had grade 3/4 haematological toxicity, while 19/33 (58%) subjects treated at the RP2D had the more severe grade 4 haematological toxicity. The bone marrow suppression was of short duration, with platelet counts recovering within 9–12 weeks of the initiation of treatment.

Exhibit 2: Fractionated dosing reduces haematologic toxicity



Source: Telix Pharmaceuticals

Efficacy improved

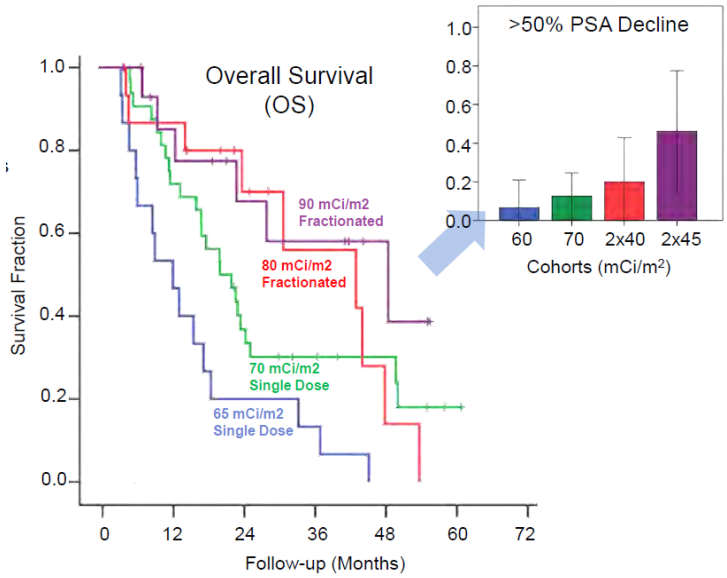
In addition to improved tolerability, the higher total doses that were able to be administered as a result of dose fractionation resulted in improved efficacy; 21% of subjects who received the second-highest dose (2x40 mCi) and 46% of subjects treated at the highest dose of 2x45 mCi/m^2 experienced a 50% reduction in PSA (Exhibit 3, right hand side box).[2] This compares to response rates of less than 15% for the maximum tolerated single shot doses (65 and 70 mCi/m^2).

1 This summary draws on the new data analysis included in recent company announcements, as well as an earlier summary of fractionated dosing presented in a ASCO abstract in June 2016 (Tagawa et al; J Clin Oncol 34, 2016 suppl 15; abstr 5022).

2 The response rates reported from the current analysis of fractionated therapy are higher than the ITT response rates reported for the study in an ASCO abstract in June 2016 (Tagawa et al; J Clin Oncol 34, 2016 suppl 15; abstr 5022), which we summarised in our initiation report in August 2018. The current analysis appears to have focused on patients who completed both fractionated dose components and

Exhibit 3 also shows that the overall survival (OS) was higher for patients in the highest two fractionated dose cohorts. Median OS of 42.9 months and 48.4 months for the 2x40 mCi/m^2 and 2x45 mCi/m^2 cohorts compared to 11.9 months and 19.9 months for the 65 and 70 mCi/m^2 single-shot cohorts.

Exhibit 3: Higher response rates and longer survival with fractionated dosing



Source: Telix Pharmaceuticals

We also note that a 2016 analysis of the available survival data of the fractionated dosing cohorts showed a statistically significantly longer OS for patients treated with the two highest doses compared to the lower doses of fractionated therapy (28 months vs 15 months, p=0.004).[3]

A retrospective subset analysis suggested that there may have been a greater survival benefit from high-dose fractionated therapy with 177Lu-HuJ591 in chemotherapy-naïve patients than in patients who had failed prior chemotherapy treatment. Exhibit 4 shows that the median survival for chemotherapy-naïve patients who underwent high-dose fractionated therapy was ~48 months, which was approximately twice that for patients who had received single-shot therapy.

While post-chemo patients who received the highest dose of fractionated therapy also survived longer than patients who had received either high or low dose single-shot therapy, the difference in median survival was not as dramatic as for chemotherapy-naïve patients (Exhibit 5).

underwent a subsequent response assessment, in order to better understand the potential benefit of fractionated therapy. Response rates in the abstract (13% for 2x40 mCi/m^2 and 29% for 2x45 mCi/m^2) were presented on an intention to treat (ITT) basis, which included all patients who commenced the study, regardless of whether or not they had completed both fractionated doses or undergone response assessments.

3 Tagawa et al; J Clin Oncol 34, 2016 suppl 15; abstr 5022; ASCO abstract

Exhibit 4: Survival in chemotherapy-naïve mCRPC patients

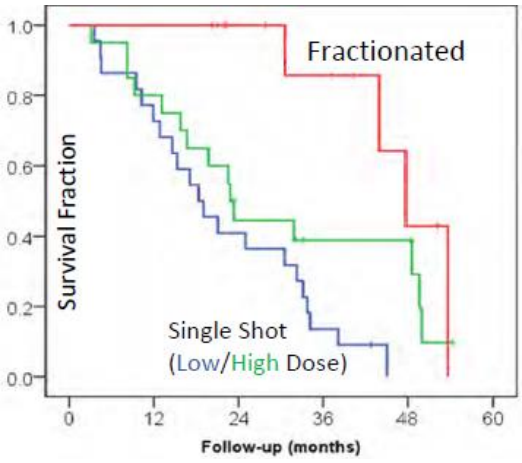
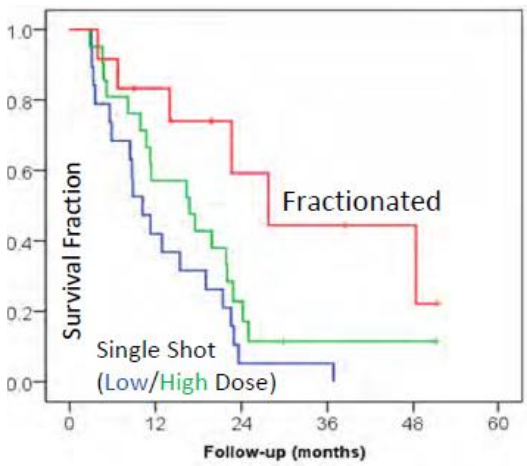


Exhibit 5: Survival in post-chemotherapy mCRPC patients



Source: Telix Pharmaceuticals. Red line = pooled data for 2x40 and 2x45 mCi/m^2 fractionated therapy; green line = pooled data for 65 and 70 mCi/m^2 single-shot therapy.

HuJ591 can be safely combined with standard docetaxel chemotherapy

Telix is well placed to pursue development in chemotherapy-naïve patients because Atlab has already demonstrated that a single cycle of fractionated ^{177}Lu-huJ591 can be safely administered in combination with multiple cycles of docetaxel chemotherapy. Docetaxel is the standard-of-care first-line chemotherapy treatment for mCRPC.

In a study where a single cycle of fractionated ^{177}Lu-huJ591 was administered in combination with a multiple cycles of docetaxel chemotherapy, 11/15 (73%) of subjects achieved at least a 50% reduction in PSA levels[4]. The MTD in combination with docetaxel was identified as 2x40 mCi/m^2.

In the docetaxel combo study, 20% of subjects experienced grade 4 neutropenia without fever, while 13% experienced grade 4 thrombocytopenia. Given that both docetaxel and TLX591 both cause neutropenia when administered as single agents, it is encouraging to see that the combination therapy did not appear to increase the incidence of neutropenia. However, we expect neutropenia and other bone marrow abnormalities to be monitored closely in the Phase III study.

Longer survival reported for huJ591 than PSMA617

If approved, TLX591 (^{177}Lu-huJ591) may face competition in the prostate cancer space from Endocyte's small molecule therapeutic ^{177}Lu-PSMA-617, which also binds to the PSMA receptor (Endocyte was acquired by Novartis for~US2.1bn in December 2018). In June 2018 Endocyte enrolled the first patient in a 750-patient global Phase III study of ^{177}Lu-PSMA-617 in patients with PSMA-positive mCRPC who had failed or refused prior chemotherapy. The dose in the Phase III study is 7.4GBq every six weeks for up to six cycles. Endocyte is using Telix's TLX591-CDx kit to screen patients for enrolment into the trial.

Endocyte reported preliminary data at ASCO in June 2018 from a Phase II study of PSMA617 in patients who had progressed after conventional therapies, including 88% who had progressed after chemotherapy. Interim results from 50 patients after a median of four cycles of PSMA617 included 62% (31/50) with at least a 50% PSA decline, including 40% with a PSA decline of at least 80%. Rates of grade 3–4 haematological toxicities reported included thrombocytopenia (10%), anaemia (10%) and neutropenia (6%). The treatment was well tolerated, with the most common side effect being grade 1–2 dry mouth reported by 68% of subjects (66% grade 1, 2% grade 2).

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

In an earlier report on the first 30 patients in the study, 14 of 17 (82%) patients with measurable lymph node or soft tissue lesions achieved a measurable response on radiological imaging[5].

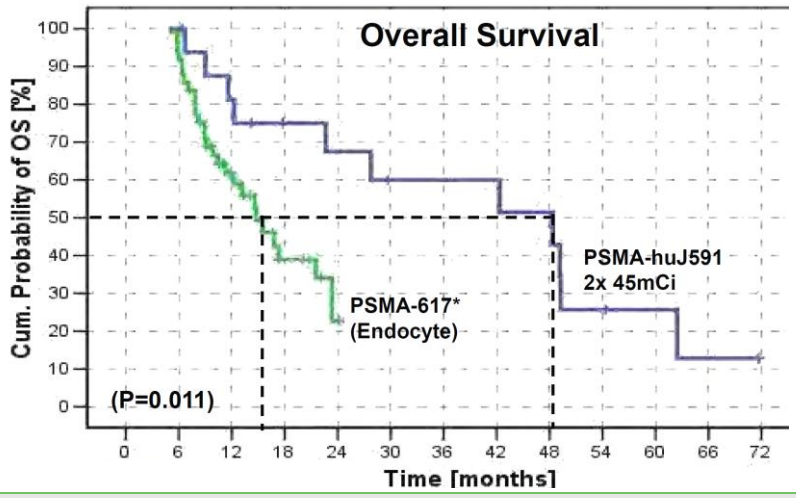
Despite the high response rates, the median OS rates reported from PSMA617 studies have typically been 15 months or less[6,7]. This compares to 43–48 months for high-dose fractionated TLX591, including ~28 months in post chemotherapy patients and ~48 months in chemotherapy-naïve patients (see previous pages).

Exhibit 6 illustrates the difference in OS between patients who received high-dose fractionated 177Lu-huJ591 in the Atlab study, and an earlier retrospective German multicentre study of PSMA-617. The median OS in the German study was ~15 months, vs 48 months for 2x45 mCi/m^2 huJ591.

Given the absence of randomised control arms in either study and the fact that there have been no direct comparisons between the two therapies, these retrospective, cross-trial comparisons do not allow any firm conclusions to be drawn as to whether the observed differences in survival reflect differences in the patient populations studied or differences in the efficacy of the two treatments.

However, despite these caveats, a randomised, controlled study to investigate whether the longer survival reported for patients treated with high-dose fractionated 177Lu-huJ591 was due to positive effects of the therapy seems to justified, in our view. Telix's proposed Phase III study aims to address this question.

Exhibit 6: Cross-trial comparison of survival between ^{177}Lu-HuJ591 and PSMA-617 (Endocyte/Novartis)



Source: Telix Pharmaceuticals

Strategy for getting TLX591 Phase III started

Telix is currently developing a clinical protocol for the Phase III study of TLX591, in collaboration with its Medical Advisory Board. Initial guidance is for a trial of approximately 550 subjects, targeting chemotherapy-naïve patients who have progressed on androgen deprivation therapy. We anticipate that patients undergoing treatment with standard first-line chemotherapy agent docetaxel would be randomised to either a TLX591 treatment arm or a control arm (the trial could be open label due to the difficulty of masking radioactive therapies). The randomised Phase III could be preceded by a non-randomised safety run-in study to obtain additional safety data about the use of the proposed Phase III dose in combination with docetaxel.

5 Hofman et al 2018. The Lancet Oncology, 19(6) 825–833

6 Sandhu et al, ASCO 2018, poster P5040

7 Awang et al. Radiation Oncology (2018) 13:98

The company's indicative timeline for preparing for the study includes:

- March 2019 – submit information package to FDA summarising the clinical data for 177Lu-huJ591 and requesting an end of Phase II meeting to formally review the data and establish a Phase III roadmap.
- May/June 2019 – Request FDA meeting to obtain guidance on Phase II trial protocol; the trial will also require registration with the TGA to enable recruitment in Australia
- August/September 2019 – release of radiolabelled huJ591 suitable for early patient recruitment in Australia.
- Q419 – file Investigational New Drug (IND) with the FDA for the Phase III study
- Late 2019/early 2020 – initiate Phase III study

We estimate that a trial of this size would cost in excess of US$50m and we include an indicative trial cost of US$60m in our evaluation of Phase III trial scenarios. Telix does not have sufficient capital to fund the Phase III study, but has indicated that it would not seek additional capital until it has agreement from the FDA to proceed with the study.

We note that one option to fund the study without diluting existing shareholders would be to seek a licensing deal with a pharma partner who would fund part or all of the cost of the Phase III study.

Given that the initiation of the study is contingent on Telix receiving consent from regulators to undertake the study, including the US FDA and Australia's TGA, we have not included the accelerated development programme Phase III for TLX591 in our base-case valuation model. However, we have explored the potential impact of the accelerated development proposal for TLX591 in a scenario analysis.

Potential advantages of the accelerated development programme for TLX591 include:

- Larger addressable market due to targeting earlier-stage chemotherapy-naïve patients
- Higher anticipated market penetration due to anticipated lack of direct competition from other radio-therapeutics in the near term
- Higher anticipated royalty rate if Telix funds Phase III development.

TLX592 to be developed with an alpha-emitting radionuclide

Over the past two years Telix has re-engineered the original huJ591 antibody to optimise its attributes. It has been re-humanised, stability/affinity optimised, and re-engineered to have better properties for radioactive drug use. One important change is that Telix has modified the constant region of the huJ591 mAb to stop it binding to the Fc receptor on white blood cells. As a result, TLX592 is cleared from the bloodstream much more rapidly, which is expected to reduce haematologic toxicity; the haematologic toxicity of radiolabelled mAbs has been attributed to their longer circulation time (serum half-life of around one week vs around 48-hour clearance for radiolabelled peptides).

Telix has collaborated with Nihon Medi-Physics Co (NMP), a Japanese manufacturer and supplier of radiopharmaceuticals, to develop an Actinimum-225 (^{225}Ac) labelled version of TLX592 (engineered huJ591), utilising NMP's novel linker chemistry.

^{225}Ac is an alpha-emitting radionuclide. Alpha particles are relatively large particles that have much higher energy to damage cancer cells, but deposit their energy over a shorter range than other types of radionuclides. The short range (<100µm) reduces the damage to nearby normal cells. This is expected to make alpha emitters superior for treating small, highly disseminated metastases (micro-metastases). The short range also makes alpha-emitters safer for medical staff and for the patient's friends and family and less radiation shielding is needed.

^{225}Ac-TLX592 is being developed as a second-generation or follow-on product that has the potential to be both better tolerated and more efficacious than ^{177}Lu-TLX591. Telix is undertaking IND-enabling studies as a stepping stone to testing ^{225}Ac-TLX592 in the clinic.

Additional alpha-emitting therapeutics in development

Telix is also developing alpha-labelled versions of two other pipeline molecules. The first of these is TLX202 (^{211}At-labelled IPA), which could potentially enter the clinic in late 2019 in an investigator-initiated study in multiple myeloma. The second is ^{225}Ac-TLX251 (engineered girentuximab), which is in early preclinical development for testicular cancer.

Other key programmes continue to progress

While this report has focused on prostate cancer, Telix is also making good progress with its other key programmes.

^{89}Zr-TLX250-CDx for PET imaging of renal cancer

Telix expects to complete enrolment in the ZIRCON Phase III study of TLX250-CDx (^{89}Zr-gerintuximab) for imaging ccRCC by the end of 2019. We expect the primary application of TLX250-CDx to be to help distinguish between ccRCC (the most serious form of kidney cancer) and other renal masses, as part of the initial diagnostic workup.

The Phase III study is planned to recruit ~250 patients undergoing surgery to remove suspicious kidney masses in up to 25 sites in Europe, Australia and the US (enrolment in the US is subject to regulatory approval). Additional sites in Canada and Turkey may also be added to drive patient volume.

The Phase III was preceded by the 10-patient ZIR-dose bridging study to compare the dose of radiation absorbed by patients treated with TLX250-CDx to historical dosimetry data from patients treated with the older ^{125}I-labelled version of the imaging agent (^{125}I-girentuximab).

Interim data from the first five patients treated in the bridging study showed that the the change of isotope from ^{124}I to ^{89}Zr has reduced the dose of radiation absorbed by the patient by approximately 25% and that the TLX250-CDx product that contained 10mg of girentuximab targeting antibody was superior to the 5mg product. Recruitment in the ZIR-dose study was completed in December.

Phase I/II study of ^{131}I-TLX101 for treatment of recurrent GBM

The IPAX-1 Phase I/II trial of TLX101 in patients with glioblastoma (GBM) is recruiting from sites which have a significant number of suitable patients. The EU/Australian study at seven centres is expected to report preliminary experience around Q319.

The Phase I/II dose-ranging study is evaluating the safety, tolerability, dosing schedule and preliminary efficacy of single or repeated injections of TLX101 in patients whose GBM has recurred following previous treatment. It is intended to recruit at least 35, and potentially up to 55, subjects in the study.

Subjects will be administered TLX101 in conjunction with external beam radiation therapy, in order to capitalise on the fact that, in addition to delivering the ^{123}I radioisotope directly to GBM tumour cells, TLX101 also acts as a radio-sensitiser, increasing the sensitivity of cells to radiation.

TLX250 for treatment of metastatic ccRCC

Manufacturing of clinical trial product for the TLX250 therapeutic is currently underway. Further studies of TLX250 (^{177}Lu-girentuximab) in combination with immunotherapy are expected to commence in 2019. TLX250 is being developed as a treatment for metastatic ccRCC. In previous studies TLX250 demonstrated progression-free survival of ~8[8,9] months in patients with advanced metastatic ccRCC with no other treatment options.

Sensitivities

Telix is subject to typical biotech company development risks, including the unpredictable outcome of trials, regulatory decisions, success of competitors, financing and commercial risks. Our model assumes that TLX250 and TLX591 will be out-licensed; therefore, our valuation is sensitive to potential licensing timing and actual deal terms. While Telix is commencing commercialisation of TLX591-CDx, it is still mainly a mid-stage drug developer, therefore in the foreseeable future most value creation will depend on successful R&D progress and any potential partnering activities, although the timing of licensing deals is typically difficult to forecast. Telix's new strategy to progress TLX591 to a Phase III in chemo-naïve patients is dependent on agreement from regulators and obtaining funding for the study; approval from the FDA to commence the study would be a significant milestone which would likely see us adopt the Phase III strategy into our base-case valuation model. If the FDA requires Telix to conduct a prospective clinical study of TLX591-CDx rather than utilising existing scans, then that could delay filing for full marketing approval by one to two years. Predicting utilisation of PSMA-PET imaging such as TLX591-CDx in prostate cancer is challenging; we model a scenario where it is used as a second-line test when metastases cannot by detected by CT or MRI scans, but if it becomes a first line test in prostate cancer patients with biochemical relapse, or if patients typically undergo repeated PET scans, the market could be significantly larger.

Valuation

Our risk-adjusted DCF valuation has increased to A$380m from A$303m. Valuation per share has increased to A$1.74 per share (vs A$1.43 per share) as the increase in NPV significantly outweighs the estimated 6.1m shares issued as consideration to ANMI shareholders. After dilution for options and warrants on issue, our fully diluted valuation is A$1.68 per share (vs A$1.40 per share).

We have revised our model to account for the ANMI transaction consideration and the resultant move to 100% of the global rights to TLX591-CDx (vs prior US-only JV). We have added US$5m to R&D expenses up to 2022 to cover our estimate of the cost of clinical studies and regulatory filing for TLX591-CDx in Europe. We have rolled forward our DCF model for the new financial year and have increased our forecast SG&A expenses to reflect the 2018 outcome. Our other valuation assumptions are unchanged.

Prior to the ANMI acquisition Telix's rights to TLX591-CDx were restricted to the US market where it shared revenue with ANMI. With Telix now holding global rights to TLX591-CDx we have included rest-of-world (RoW) sales of the product, including modest sales as an investigational reagent. We assume that RoW peak sales will be similar to our forecast US peak sales of US$80m, but that marketing approval and peak sales lag the US by two years (European approval in 2022 vs 2020 in the US; peak sales in 2025 and 2027 in the US and Europe respectively). We assume that Telix

8 Stillebroer, et al, 2012. European Urology, Volume 64, Issue 3, 478 - 485

9 Muselaers, et al. 2015. European Urology, Volume 69, Issue 5, 767 - 770

earns a profit margin equal to 35% of net TLX591-CDx sales in the US (before royalties) and 25% in other territories. We apply an 80% probability of success in the US, and a lower 65% probability in Europe due to the likely requirement for further clinical studies before approval in that region.

Exhibit 7 shows our market assumptions for TLX250, TLX250-CDx, TLX591, TLX591-CDx and TLX101 imaging and therapeutic products, and the rNPV for each product. We have offset the risk-adjusted trial cost against revenue for each indication.

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

	Base case likelihood (%)	rNPV (A$m)	rNPV/share (A$)	Assumptions
TLX250-CDx kidney cancer imaging	75%	51.4	$0.24	Global peak sales of US$70m. For the US, assumes 65,300 kidney cancer cases/year, 50% candidates for imaging, 25% penetration; for the EU assumes 93,000 cases/year, 50% candidates for imaging, 20% penetration; pricing US$3,500 per patient, 30% discount in Europe; launch 2021; 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%	52.8	$0.24	Global peak sales of US$470m. For the US assumes 65,300 kidney cancer cases/year, 20% eligible for treatment, 20% penetration; for the EU assumes 93,000 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. R&D cost: A$4m for two small company funded Phase II studies, then out-license.
TLX591-CDx (illumet) prostate cancer imaging	65–80%	133.0	$0.61	US peak sales of US$80m assuming 165,000 new cases/year, 75% candidates for imaging; 15% penetration; revenue US$3,500 per test; commercial launch as investigational test 2018, FDA approval 2020; assume profit margin (before royalties) equal to 35% of net sales in US and 35% elsewhere. RoW peak sales US$80m (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. R&D cost: US$2m for a Phase III study based on re-read of existing scans. US$5m for European clinical study and filing.
TLX591 prostate cancer therapeutic	20%	110.0	$0.50	Global peak sales of US$1,080m. For the US assumes 29,400 deaths/year, 90% eligible for treatment, 15% penetration; for the EU assumes 84,000 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. R&D cost: A$20m for Phase II, then out-license.
TLX101 brain cancer therapeutic	10%	38.6	$0.18	Global peak sales of US$530m 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 to 2024		(6.9)	($0.03)	
Portfolio total		**378.9**	**$1.74**	
Net cash end FY18e		1.3	$0.01	
Enterprise total		**380.2**	**$1.74**	

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.

TLX591 Phase III scenario

We have investigated the impact that progressing TLX591 into a Phase III study in combination with docetaxel would have on our valuation. We modelled a scenario where Telix obtains FDA agreement for the Phase III study and funds the Phase III study itself, and licences to a partner after completing the Phase III study. 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% probability of success (vs 20% under the base case scenario). 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 $A70m (A$0.32/share) to our valuation, after accounting for the trial costs.

Financials

Telix reported a pre-tax loss of A$15.7m in 2018, its second year of operation. Expenses associated with R&D projects were A$18.7m, personnel expenses were A$4.9m and administration and consulting costs totalled A$4.3m. Our pre-tax loss estimates for 2019 and 2020 grow to A$24.3m and A$23.6m, respectively, mainly due to increased R&D expenditure as Telix progresses its clinical trial programme, partly offset by the Australian government's R&D rebate scheme. Telix has received an advance/overseas R&D tax finding totalling A$55.2m regarding the eligibility for the rebate of overseas R&D expenditure that is essential to Telix's programmes but cannot be executed in Australia by Australian vendors and service providers.

Telix had A$25.8m cash and equivalents at 31 December 2018 and is funded to mid-2020. However, we estimate that it may need additional funding in 2020 (we model A$15m of indicative debt). Additional funds would be needed to proceed with a TLX591 Phase III trial.

Exhibit 8: Financial summary

A$000s	2017	2018	2019e	2020e
Year end 31 December	AASB	AASB	AASB	AASB
PROFIT & LOSS				
Sales, royalties, milestones	0	195	1,398	2,129
Other (includes R&D tax rebate)	403	10,142	8,000	7,320
Revenue	403	10,337	9,398	9,449
R&D expenses	(2,977)	(18,692)	(20,000)	(19,000)
SG&A expenses	(3,538)	(9,150)	(9,373)	(9,654)
Other	(291)	0	0	0
EBITDA	(6,403)	(17,505)	(19,975)	(19,205)
Operating Profit (before GW and except.)	(6,403)	(18,992)	(20,021)	(19,261)
Intangible Amortisation	(4)	0	(4,309)	(4,309)
Exceptionals	0	0	0	0
Operating Profit	(6,407)	(18,992)	(24,330)	(23,571)
Net Interest	30	304	258	31
Profit Before Tax (norm)	(6,377)	(15,714)	(24,072)	(23,540)
Profit Before Tax (reported)	(6,377)	(15,714)	(24,072)	(23,540)
Tax benefit	0	1,884	0	0
Profit After Tax (norm)	(6,377)	(13,830)	(24,072)	(23,540)
Profit After Tax (reported)	(6,377)	(13,830)	(24,072)	(23,540)
Average Number of Shares Outstanding (m)	128.0	202.1	218.4	218.4
EPS - normalised (c)	(4.98)	(6.84)	(11.02)	(10.78)
EPS - diluted	(4.98)	(6.84)	(11.02)	(10.78)
Dividend per share (A$)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	1,549	40,852	36,597	32,332
Intangible Assets	1,508	39,451	35,142	30,832
Tangible Assets	5	226	281	325
Investments	35	1,175	1,175	1,175
Current Assets	49,545	35,856	10,375	7,333
Stocks	0	643	0	0
Debtors	339	8,436	6,294	5,614
Cash	48,759	25,771	3,074	712
Other	447	1,007	1,007	1,007
Current Liabilities	(1,468)	(8,242)	(1,419)	(1,455)
Creditors	(1,123)	(6,893)	(70)	(106)
Short term borrowings	(345)	(1,133)	(1,133)	(1,133)
Other	0	(216)	(216)	(216)
Long Term Liabilities	(332)	(15,562)	(15,560)	(30,560)
Long term borrowings	0	(596)	(596)	(15,596)
Other long term liabilities	(332)	(14,966)	(14,964)	(14,964)
Net Assets	49,293	52,904	29,993	7,649
CASH FLOW				
Operating Cash Flow	(6,060)	(21,065)	(22,853)	(17,293)
Net Interest	29	316	258	31
Tax	0	0	0	0
Capex	(6)	0	(100)	(100)
Acquisitions/disposals	4	(2,693)	0	0
Equity Financing	55,561	0	0	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	49,528	(23,442)	(22,696)	(17,362)
Opening net debt/(cash)	1,115	(48,414)	(24,042)	(1,345)
HP finance leases initiated	0	0	0	0
Other	0	(929)	(2)	0
Closing net debt/(cash)	(48,414)	(24,042)	(1,345)	16,017

Source: Edison Investment Research, Telix Pharmaceuticals accounts

Contact details	Revenue by geography
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Board and Management

CEO and managing director: Christian Behrenbruch	Chairman: Kevin McCann
Dr Christian 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. Christian holds a DPhil (PhD) in biomedical engineering from the University of Oxford, an executive MBA jointly awarded from New York University, HEC Paris and the London School of Economics (TRIUM Programme) and a Juris Doctor (law) from the University of Melbourne.	Mr Kevin McCann is chairman of Citadel Group (ASX: CGL) and the Sydney Harbour Federation Trust. He is a member of the Male Champions of Change, a pro chancellor and fellow of the Senate of the University of Sydney, co-vice chair of the New Colombo Plan Reference Group, a director of the US Studies Centre, director and member of the Advisory Board of Evans and Partners and chair of the National Library of Australia Foundation. In the previous three years, Kevin has been chairman of Macquarie Group (ASX: MQG) and Macquarie Bank (ASX: MBL).
Executive director and chief medical officer: Andreas Kluge	**Non-executive director: Mark Nelson**
Dr Andreas Kluge has 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 Dresden, Germany. He is also founder and was founding CEO of ABX GmbH (www.abx.de), one of the leading manufacturers of radiopharmaceutical precursors globally. Andreas is further founder, general manager and medical director for Therapeia, an early-stage development company in the field of neuro-oncology, which was acquired by Telix. Andreas 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 is chairman and co‑founder of the Caledonia Investments Group, and a director of the Caledonia Foundation. He is chairman of Art Exhibitions Australia, a director of Kaldor Public Art Projects and serves as a governor of the Florey Neurosciences Institute. Previously Mark was a director of the Howard Florey Institute of Experimental Physiology and Medicine, and served on the Commercialisation Committee of the Florey Institute. Mark was educated at the University of Melbourne and University of Cambridge (UK).

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Elk River Holdings Pty Ltd as trustee for The Behrenbruch Family Trust	11.3
FIL Investment Management (Hong Kong)	9.0

Companies named in this report

Novartis, Endocyte

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