EDISON

Telix Pharmaceuticals

Progress on clinical, regulatory and BD fronts

Clinical & regulatory update

Pharma & biotech

Telix has had a raft of announcements, marking its steady progress in a range of areas. Notably, the company received feedback from the FDA regarding the clinical briefing package to support an NDA for illumet, which it says should be ready in March or April 2020. Additionally, Telix will be expanding its pivotal ZIRCON study of TLX250-CDx to the US with the recent IND filing for the program. The company also provided a first look at its Phase I/II study of TLX101 for glioblastoma multiforme (GBM). Finally, it announced two separate deals for preclinical programs.

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	9.6	(28.1)	(11.1)	0.0	N/A	N/A
12/21e	82.8	52.0	19.7	0.0	7.3	N/A

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

NDA progress for illumet, IND accepted for ZIRCON

Telix is seeking NDA approval for illumet (TLX591-CDx) through the FDA's 505(b)2 pathway. The company received feedback FDA on whether the current package is sufficient on 24 February 2020, and believes it can satisfy the agency's requests with the existing data set. The full NDA is planned to be submitted 30–60 days from this date. Additionally, the FDA accepted an IND to expand its ZIRCON Phase III study (ongoing in Australia and the EU) to the US. The study is examining TLX250-CDx for kidney cancer imaging, and Telix expects to complete enrolment by mid-2020.

TLX101: No hang-ups in dosing yet

TLX101 is currently in the dose escalation portion of a Phase I/II study for GBM. As promised, Telix provided a clinical update at the end of 2019, which stated that all the patients treated so far (number undisclosed) had achieved stable disease (SD) and that no serious adverse events had been reported to date. The company expects the study to progress to the Phase II portion around mid-2020.

Multiple early-stage deals

Telix also recently announced two deals regarding early-stage assets for new indications. In the first, the company in-licensed the rights to a new targeted radiotherapy drug from AusHealth for A$30m in future milestones. AusHealth will continue to be responsible for clinical development. Also, Telix announced a deal to license some of its own assets from its antibody library to ATONCO for A$30m in future milestones, in the first out-licensing deal of Telix's intellectual property.

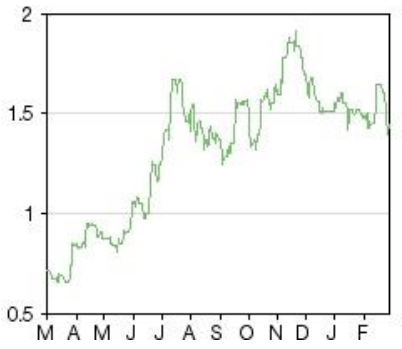
Valuation: Increased to A$450m or A$1.78/share

We have increased our valuation to A$450m or A$1.78 per basic share from A$448m or A$1.77/share. The increase is driven by rolling forward our NPVs and offset by lower net cash (A$42.5m) and an increase in SG&A costs, but we expect to update our valuation progress of the illumet submission and ongoing clinical studies.

28 February 2020

Price	**A$1.44**
Market cap	**A$364m**
	US$0.76/A$
Net cash (A$m) at 31 December 2019	42.5
Shares in issue	253m
Free float	67.6%
Code	TLX
Primary exchange	ASX
Secondary exchange	OTCMKTS

Share price performance



%	1m	3m	12m
Abs	(5.3)	(17.2)	104.3
Rel (local)	1.3	(14.6)	89.0
52-week high/low	A$1.91		A$0.66

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

Illumet NDA submission	March or April 2020
ZIRCON enrolled	Mid-2020
TLX101 Phase II start	Mid-2020

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Edison profile page

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Regulatory: Illumet NDA and ZIRCON IND progress

Telix announced in late December 2019 that it has submitted an NDA clinical briefing package to the FDA on illumet (TLX591-CDx) for the detection of prostate cancer. This package contains the experimental data intended to eventually be included in the completed NDA application if the FDA deemed it sufficient.

On 24 February 2020, the company reported that it had received 'positive' feedback from the FDA on the package. According to the company: '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.' This suggests that the FDA asked for additional analyses of the data, but that Telix does not believe that additional clinical studies will be required. This is supported by the company's timeline in which it will be submitting the completed NDA 30–60 days after the feedback. It also noted that the FDA said that the safety dataset in the submission was sufficient as is (subject to formal NDA review).

The agency previously agreed with Telix that the product could be submitted under the 505(b)2 pathway, which allows certain data not collected by the sponsor to be included in the application. This seems reasonable considering the significant amount of prior research into prostate-specific membrane antigen (PSMA) targeted imaging and the widespread study of the PSMA-11 molecule on which the drug is based.

Additionally, Telix announced that it had filed an IND with the FDA to start the Phase III ZIRCON study of TLX250-CDx for the detection of renal cancer, and this application was accepted on 23 January 2020. The study is already ongoing in Australia and the EU, and the current IND will expand it to the US. The ZIRCON study is designed to be a confirmatory study using the ^{89}Zr radioligand in the product instead of the previously developed ^{125}I version of the product. The ^{89}Zr version of the product has lower radiation exposure, allowing for higher dosing and improved signal. The company previously completed a 10-patient bridging study in 2018 confirming the improved signal and safety. The ZIRCON study is expected to enroll 250 patients and enrollment is expected to be complete by the end of Q220.

Clinical update on TLX101, expect Phase II mid-2020

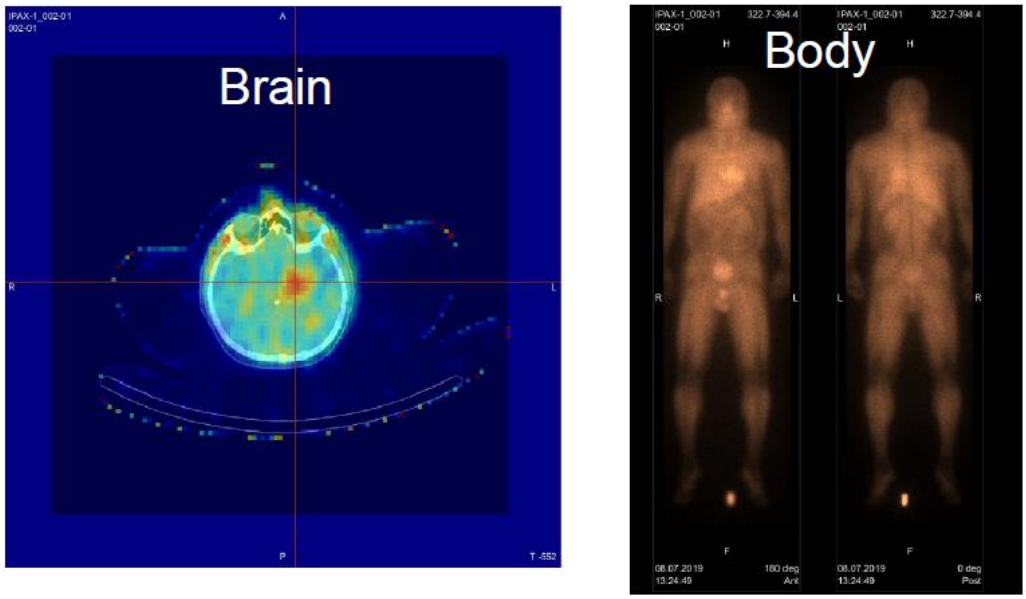
Telix is currently investigating TLX101 for the treatment of GBM in its Phase I/II study called IPAX-1. The study is currently in the dose escalation Phase I portion, where the maximum tolerated dose of drug will be found and will determine future dosing in the Phase II portion and onwards. In addition to TLX101, patients will receive 18 weeks of external radiation therapy according to the study protocol. The company provided an update on the progress of the trial to date in December 2019.

The company is currently enrolling patients under two treatment regimens, a single dose of drug and a fractionated dose where the same quantity is administered in three separate injections over the course of three weeks. At the current time, both regimens have a total radiation exposure of 2GBq, but dose escalations of up to 8GBq are planned (if needed in three patient cohorts). The company reported in the update that the fractionated dosing appears to be working better based on preliminary data, and we therefore expect doses to be administered this way going forward.

The safety and efficacy data provided so far have been limited, but the company did note that SD responses were seen in all patients enrolled to date, although the number treated and the current dosing cohort were not disclosed. Moreover, no serious adverse events (SAEs) have been seen and no hematologic toxicity has been observed. Consistent with earlier data, imaging has shown a

clear localization of the drug to the tumor site at this dose (Exhibit 1), which is encouraging for the safety profile as toxicity to organ systems outside the brain is likely to be limited.

Exhibit 1: SPECT imaging brain localization of TLX101



Source: Telix Pharmaceuticals

The company did not disclose whether it had escalated above the 2GBq starting dose, but it did provide an updated timeline for the progress of the study, which suggests it is close to determining the Phase II dose and moving forward. It expects to finalize this dose in Q220, and stated that it will then present the Phase I data to the FDA for review and will initiate the Phase II portion of the study in mid-2020.

Multiple exploratory deals

In addition to Telix's recent clinical and regulatory progress, it has begun the process of exploring future indications and new directions for the company with some recently announced deals. Announced in October 2019, the first deal is a collaboration with AusHealth using its APOMAB platform. The platform is designed to develop antibodies targeting the Sjögren syndrome type B antigen (SSB, aka the Lupus La protein). Patients with Sjögren syndrome and lupus often develop antibodies against the protein, which is normally found inside cells but revealed on cell death. According to AusHealth, the La/SSB protein is also expressed by distressed cancer cells such as those found in patients who have been pre-treated with chemotherapeutic agents. The goal is to use antibodies against SSB to deliver targeted radiation to dying or distressed tumor cells.

AusHealth is a private company owned by the Central Adelaide Local Health Network aimed at promoting research in the network. AusHealth will lead the clinical development of the platform, targeting new indications such as lung and ovarian cancer. Telix will make an initial investment of A$300,000 to fund the early stages, and A$30m in clinical and commercial milestones in exchange for worldwide rights.

Telix announced an additional deal in December 2019 in which it would license its antibody portfolio to French startup ATONCO to investigate potential therapies for bladder cancer. This is the first time Telix has out-licensed its portfolio. The deal includes A$30m in development milestones payable to Telix, undisclosed royalties, and Telix receives an option to reacquire the program. We know relatively little about the company' partner ATONCO, outside that it is a targeted radiation company based in France.

Valuation

Our valuation has increased slightly to A$450m or A$1.78 per basic share from A$448m or A$1.77/ share. The increase in valuation from rolling forward our NPVs is offset by lower net cash (at A$42.5m) and an increase to SG&A costs (see below). There are no other significant changes to our models. We expect to update our valuation with the continued progress of the company's programs in the clinic (such as further readouts on TLX101) and on the regulatory front (such as FDA feedback on the illumet NDA).

Exhibit 2: Valuation of Telix

	Peak sales (US$m)	Likelihood (%)	rNPV (A$m)	rNPV/ share (A$)
TLX250-CDx kidney cancer imaging:	75	75%	65.3	$0.26
TLX250 kidney cancer therapeutic:	460	20%	60.4	$0.24
TLX591-CDx prostate cancer imaging	160	80%	143.1	$0.56
TLX591 prostate cancer therapeutic:	1,050	20%	126.2	$0.50
TLX101 brain cancer therapeutic	520	10%	42.6	$0.17
SG&A			-29.9	-$0.12
Portfolio total			407.6	$1.61
Net Cash (Q319)			42.5	$0.17
Enterprise total			450.0	$1.78

Source: Telix Pharmaceuticals reports, Edison Investment Research

Financials

Telix reported cash receipts of A$3.49m for the 12 months ending 31 December 2019, following $4.4m in order for illumet for research purposes. Total revenue for the period (including R&D rebates of A$11.7m) was A$15.2m. SG&A costs increased on a yearly basis to A$15.8m compared to A$9.15m for 2018, largely due to increased professional fees and salaries. We carry a large portion of these costs forward into 2020 and beyond. We assume this is because of increased investment in the ongoing clinical programs and regulatory submissions. The company ended 2019 with A$42.5m in net cash. We expect the company to license its assets for eventual commercialization and continue to include A$79.2m in illustrative milestones in 2021 associated with the licensing of TLX591 and TLX250. We do not expect the company to need additional capital based on these estimates, or even if milestone payments are lower than we anticipate. If the company cannot secure a marketing deal for these products, we would expect it to incur additional costs associated with the commercial buildout and additional financing may then be needed.

Exhibit 3: Financial summary

A$'000s	2018	2019	2020e	2021e
Year end 31 December	AASB	AASB	AASB	AASB
PROFIT & LOSS				
Sales, royalties, milestones	195	3,485	1,975	82,789
Other (includes R&D tax rebate)	10,142	11,693	7,600	0
Revenue	10,337	15,178	9,575	82,789
R&D expenses	(18,692)	(21,162)	(19,750)	(12,250)
SG&A expenses	(9,150)	(15,800)	(13,699)	(14,110)
Other	0	0	0	0
EBITDA	(17,505)	(24,327)	(23,874)	56,429
Operating Profit (before amort. and except.)	(18,992)	(24,078)	(24,254)	56,105
Intangible Amortisation	0	(4,236)	(4,309)	(4,309)
Exceptionals	0	0	0	0
Operating Profit	(18,992)	(28,314)	(28,563)	51,796
Net Interest	304	(2,310)	446	178
Profit Before Tax (norm)	(15,714)	(31,122)	(28,117)	51,973
Profit Before Tax (reported)	(15,714)	(31,122)	(28,117)	51,973
Tax benefit	1,884	3,255	0	(1,987)
Profit After Tax (norm)	(13,830)	(27,867)	(28,117)	49,987
Profit After Tax (reported)	(13,830)	(27,867)	(28,117)	49,987
Average Number of Shares Outstanding (m)	202.1	233.4	253.4	253.4
EPS - normalised (c)	(6.84)	(11.94)	(11.10)	19.72
EPS - diluted (c)	(6.84)	(11.94)	(11.10)	19.24
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	40,852	43,929	39,340	34,807
Intangible Assets	39,451	41,948	37,639	33,330
Tangible Assets	226	1,899	1,619	1,395
Investments and other	1,175	82	82	82
Current Assets	35,856	58,679	27,228	87,020
Stocks	643	542	0	0
Debtors	8,436	12,071	7,978	378
Cash	25,771	44,598	17,782	85,174
Other	1,007	1,468	1,468	1,468
Current Liabilities	(8,242)	(10,625)	(1,505)	(5,545)
Creditors	(6,893)	(9,218)	(99)	(4,139)
Short term borrowings	(1,133)	(490)	(489)	(489)
Other	(216)	(917)	(917)	(917)
Long Term Liabilities	(15,562)	(21,902)	(21,902)	(21,902)
Long term borrowings	(596)	(1,641)	(1,641)	(1,641)
Other long term liabilities	(14,966)	(20,261)	(20,261)	(20,261)
Net Assets	52,904	70,081	43,161	94,379
CASH FLOW				
Operating Cash Flow	(21,065)	(23,314)	(27,162)	69,301
Net Interest	316	(19)	446	178
Tax	0	0	0	(1,987)
Capex	0	(403)	(100)	(100)
Acquisitions/disposals	(2,693)	(65)	0	0
Equity Financing	0	43,890	0	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(23,442)	20,089	(26,816)	67,392
Opening net debt/(cash)	(48,414)	(24,042)	(42,467)	(15,652)
HP finance leases initiated	0	0	0	0
Other	(929)	(1,664)	1	0
Closing net debt/(cash)	(24,042)	(42,467)	(15,652)	(83,044)

Source: Telix Pharmaceuticals reports, Edison Investment Research

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