EDISON

Telix Pharmaceuticals

Earnings update

A look at future directions

Healthcare equipment & services

For the first time, Telix provided a profile of its deep pipeline outside its lead asset on its H120 earnings call. It presented the details of four assets derived from its existing pipeline, the majority of which are expected to be tested in the clinic before the end of the year. This provides a roadmap for the company beyond the upcoming potential approval for TLX591-CDx and completion of pivotal studies for TLX250-CDx.

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	15.0	(29.9)	(11.8)	0.0	N/A	N/A
12/21e	97.8	54.5	21.7	0.0	8.3	N/A

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

Moving closer to pivotal study of TLX591

Telix had a meeting with the FDA on 7 July 2020 to discuss the clinical development plan for its prostate cancer therapeutic, TLX591. Importantly, the agency agreed that selection of patients could be made using the company's analogous diagnostic TLX591-CDx, allowing Telix to target just PSMA expressing cancers. If the drug were approved on the basis of this study, we would expect assessment of PSMA status to be included on the label, which supports the company's 'theranostic' approach to development of diagnostic/therapeutic pairs.

Japanese bridging study initiated

The company announced in August 2020 that it had started enrolling patients in its Japanese study of TLX250-CDx. The study has a planned enrolment of 40 patients and is designed to serve as a bridging study with the ongoing Phase III ZIRCON study. Patient enrolment for the Japanese study is identical to ZIRCON and will be submitted with the ZIRCON data to support regulatory approval in Japan. The study has a planned completion date of August 2021, whereas ZIRCON is planned to have full enrolment at the end of 2020.

TLX591-CDx NDA expected in Q320

The date of reckoning for TLX591-CDx continues to approach. Telix has already filed an MAA for approval of TLX591-CDx in Europe and recently reiterated guidance that it plans to submit the NDA to the FDA in Q320. Following this submission, the FDA will have two months to accept the application followed by a 10-month review period.

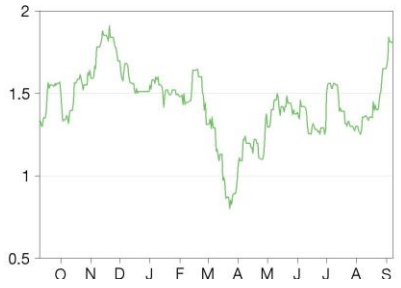
Valuation: Flat at A$567m or A$2.23

Our valuation is roughly flat at A$567m or A$2.23 per share (from A$571m or A$2.25 per share). We have increased our expected SG&A spend for 2020 to A$16.3m from A$13.7m because of a less than anticipated slowdown on account of COVID-19.

8 September 2020

Price	**A$1.80**
Market cap	**A$456m**
	US$0.66/A$
Net cash (A$m) at 30 June 2020	23.3
Shares in issue	253.3m
Free float	71%
Code	TLX
Primary exchange	ASX
Secondary exchange	OTMKTS

Share price performance



%	1m	3m	12m
Abs	32.8	26.8	40.1
Rel (local)	33.2	26.5	54.3
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-CDx NDA submission	Q320
ZIRCON enrolled	Year-end 2020
TLX591 Phase III start	Q420

Analyst

Nathaniel Calloway +1 646 653 7036

healthcare@edisongroup.com

Edison profile page

The next generation

For the first time, Telix profiled the drugs in its extended pipeline. This is an excellent time to introduce investors to the next generation of products as the company's lead programs approach approval. Four new products are included in the pipeline (along with an expanded approach to the existing diagnostic TLX250-CDx).

Three of these programs are expansions of the TLX591 technology. TLX591-Sx is a derivative of TLX591-CDx that has an additional fluorescent tag added to the molecule. This would allow the product to be used in fluorescence guided surgery, where tumorous mases can be differentiated from healthy tissue through the use of fluorescence. This product is expected to be in investigator-sponsored studies starting in Q320.

The company also developed TLX599-CDx which, like TLX591-CDx, is targeted against PSMA for prostate cancer imaging, but is labelled with a ^{99m}Tc nuclide used in single photon emission computed tomography (SPECT). The logic here is that while SPECT is a lower-resolution detection process than positron emission tomography (PET, for which TLX591-CDx is designed), SPECT is much more widely available on a global basis. This product is meant to be used in geographies that might not have access to PET and will be investigated in a global Phase II study, which is expected to initiate before the end of 2020.

Telix is also developing a direct follow-up to its prostate cancer therapy, TLX591, which it is calling TLX592. The new drug is a monoclonal antibody targeting PSMA that is engineered to clear the body 10 times faster. This is important because it is labelled with the ^{225}Ac nuclide, which has the potential to deliver a higher dose of radiation than the ^{177}Lu nuclide used in TLX591. The new drug could potentially be used in patients that have progressed on therapy using ^{177}Lu. It is slated to enter the clinic in Australia in Q320.

Finally, Telix has developed a derivative of TLX101 using an alpha emitter ^{211}At that it is calling TLX102. The goal with this product is to target multiple myeloma, which also expresses the LAT-1 target of the drug. However, because multiple myeloma is a much more diffuse disease, the nuclide was switched to an alpha emitter to limit collateral damage. This product is planned to enter the clinic in H221.

Exhibit 1: Telix extended pipeline

Core Technology	R&D Enhancement	Technology Collaborators	Development Status
TLX101	**TLX102** : ^{211}At "alpha" variant of TLX101 for multiple myeloma	Osaka University, Japan University of Nantes, France	• FDA orphan drug granted • Preparing for first-in-human
TLX591-CDx	**TLX591-Sx**(1) : Addition of a fluorescing agent for image-guided surgery	German Cancer Found'n (DKFZ) Univ. of Heidelberg, Germany	• IP license option exercised • First investigator-led clinical studies in Q3 2020 (Germany)
TLX591-CDx	**TLX599-CDx**: Chemistry for ^{99m}Tc for "rest of world" PSMA imaging where PET is not available	Instituto Nacional de Investigaciones Nucleares, Mexico	• Commencing Phase II study in Q3, 2020 (International)
TLX591	**TLX592**: Antibody Pk-engineered to support use with ^{225}Ac "alpha" therapy	Abzena Ltd	• Commencing first-in-human studies in Australia, Q3 2020 (subject to approvals)
TLX250-CDx	Exploration of clinical potential to image other cancers, beyond renal cancer	GenesisCare, Australia Radboud Univ., Netherlands ATONCO, France	• Investigator-led studies ongoing

Source: Telix Pharmaceuticals

TLX591-CDx NDA: What will the market be?

Telix is making regulatory progress on multiple fronts. At the forefront is the upcoming submission of the NDA for TLX591-CDx, which the company expects to complete in Q320. One question that we are waiting the answer to is what precise initial indication(s) the US marketing application will be submitted for, as PSMA imaging can be used in a range of diagnostic settings.

The company previously completed its MAA submission in May 2020, for the indication of imaging after biochemical recurrence. Biochemical recurrence is when men show elevated prostate specific antigen (PSA) levels following surgical treatment for prostate cancer. PSMA PET is recommended by the European Association of Urology in its guidelines for the detection of residual disease following biochemical recurrence. Of the patients that are diagnosed with prostate cancer in a given year (191,930[1] in the US, 473,240 in Europe)[2] approximately 25–30% will later have a biochemical recurrence. We consider this indication to be the most supported by the literature and governing bodies.

However, earlier in 2020 the landmark proPSMA study[3] was published describing the use of PSMA in the initial staging of the disease, which we discussed in our previous report. The company announced in June 2020 it would be adding additional data to its US NDA submission from the proPSMA study (and potentially others), we assume to support approval for a broader label. The proPSMA study specifically focused on the initial staging of high risk patients, which correspond to 31.2% of initial diagnoses. We expect initial staging in high-risk patients to be an indication included in the US NDA.

A third potential indication is using TLX591-CDx to monitor for the response to therapy. This is roughly analogous to a role of PSA testing in the current regime, in which patients undergoing treatment are routinely screened to gauge if they are responding to the drugs. We would expect this to be limited primarily to metastatic castration resistant patients (mCRPC), which has an estimated incidence of 42,970 cases in the US per year.[4]

A final option for the upcoming NDA submission is the company will seek approval broadly for all forms of prostate cancer imaging, irrespective of context. This would include all of the above indications and ones we have not anticipated. We do not know if the company has sufficient data to support such a broad label, but we expect that some of the current preparations for submission are evaluating this possibility. At the very least we expect the product to be submitted for initial staging in high risk patients, and also for biochemical recurrence. It is important to note that if the company seeks approval for an indication that is too broad for the FDA, it may receive a refusal to file (RTF) letter or a complete response letter, but it would be able to resubmit quickly with a more restrictive label. We conservatively model the product exclusively for biochemical recurrence at this time, but may expand this depending on what is included in the NDA.

Other regulatory progress

In another regulatory note, Telix has filed its drug master file (DMF) with the FDA for TLX101, its experimental treatment for glioblastoma multiforme (GMB). A DMF is a confidential document that

[1] NIH SEER database.

[2] Globocan 2018.

[3] 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.

[4] Scher H, et al. (2015) Prevalence of Prostate Cancer Clinical States and Mortality in the United States: Estimates Using a Dynamic Progression Model. *PLoS One* 10, e0139440.

outlines the specifics of a drug's manufacture and formulation. Although not documents that are 'approved', DMFs are referenced in a variety of applications at the agency, eg NDAs, INDs. Other parties, such as academic investigators, can reference DMFs when seeking approval to run investigator-sponsored trials, for instance, and the file gives them a way to provide adequate information to the FDA without having access to the proprietary information.

Telix has also been meeting with regulatory authorities regarding the planned clinical development of TLX591. TLX591 is the companion therapeutic to TLX591-CDx (although it is of a different composition), and the company is planning a pivotal clinical study. Both products target the prostate cancer biomarker PSMA, but whereas TLX591-CDx is linked to a PET tracer, TLX591 is designed to deliver molecularly targeted radiation treatment. Following a meeting with the FDA in July 2020, Telix reported that it had reached a consensus with the agency regarding multiple aspects of the design of the study. Importantly, TLX591-CDx could be used in the study to identify patients with PSMA expressing cancers. This is important because the drug is more likely to show a definitive signal of efficacy (if it exists) in this enriched patient population. Also importantly, if the drug is eventually approved, screening for PSMA status will likely be included on the drug label, making TLX591-CDx a companion diagnostic for the product. This is the core premise of Telix's 'theranostic' development strategy in which it uses one platform for the development of radiolabelled diagnostics and targeted radiation therapies, and is indicative of the synergies to this approach. The company has guided towards starting the Phase III study in Q420.

The ZIRDAC-JP study

The company announced in June 2020 that it was restarting patient enrolment in its ongoing study of TLX250-CDx for detection of clear cell renal cell carcinoma (ccRCC) following disruptions earlier in the year due to COVID-19 (the ZIRCON study). More recently, in August 2020, Telix announced that it was expanding the clinical program for TLX250-CDx to a new study in Japan, the ZIRDAC-JP study. ZIRDAC-JP is a bridging study, meaning it is designed to supplement data from the ZIRCON study for submission in Japan. The PMDA in Japan requires that marketing submissions for new products include data that represents Japan demographically, and one way of ensuring this is by carrying out a small study in Japan using the same or a very similar protocol to that used in other geographies. The study has a planned enrolment of 40 patients and a target completion date of August 2021. The ZIRCON study is planned to reach complete enrolment by the end of 2020, so we would expect Telix to begin preparing marketing submissions shortly thereafter.

Rates of renal cancer in Japan are lower on an age-adjusted basis (7.2 per 100,000 vs 10.9 in the US), but this difference diminishes when considering the ageing Japanese population (18.9 per 100,000 crude rate). It is therefore an attractive market for TLX250-CDx and other cancer diagnostics. GLOBOCAN 2018 estimates that 25,000 new patients will be diagnosed with the disease in Japan in 2020.

New collaborations in guided radiation

In July 2020, Telix announced that it had entered into a strategic collaboration with RefleXion, in which Telix's diagnostics will be evaluated for use with RefleXion's external-beam radiotherapy platform. The RefleXion X1 machine is a guided radiation machine that uses PET to precisely target radiation beams at cancers. This is roughly analogous to other forms of guided radiation therapy such as MRI-LINAC (Magnetic Resonance Imaging Guided Linear Accelerator). The X1 device has the potential to use targeted radiation to treat relatively small metastases, which would be missed with other irradiation techniques. The combination with Telix's tracers is a natural one because they have the potential to provide substantially better signal detection than other tracers such as ^{18}F-

fluorodeoxyglucose (FDG). We consider this collaboration largely exploratory at this point, but believe it is important for Telix to ensure that its technology is paired with innovative new applications of PET-CT in this rapidly evolving field.

Later in September 2020, the company announced a collaboration with Varian Medical Systems, a major developer of external radiation therapy solutions. The goal of the collaboration is to use the data gathered by Telix on PSMA-targeted PET imaging with Varian's radiation treatment planning platform. The Eclipse system is the current manifestation of this software suite, which uses imaging from MRI, PET and other sources to help plan a range of different radiation treatments, and identify optimal beam paths and other parameters. Unlike the RefleXion system, this analysis is performed separately from the imaging and treatment. It is important for PSMA imaging and the data from TLX591-CDx to be integrated into the platform because it will allow for the seamless integration of this new prostate imaging methodology into the existing radiotherapy workflow in the future.

Valuation

Our valuation is roughly flat at A$567m or A$2.23 per share from A$571m or A$2.25 per share previously. We have rolled forward our NPVs, but this increase was offset by lower net cash ($23.3m at the end of Q220 compared to $33.3m previously) and an increase to our unallocated SG&A costs (A$41m from A$32.1m, more information below). Our fundamental assumptions regarding the company's development programs remain unchanged. We are not adding any of the products from the extended pipeline to our valuation at the moment, as we consider them highly exploratory, but may do so in the future if they gain traction in the clinic.

Exhibit 2: Valuation of Telix

	Peak sales (US$m)	Likelihood (%)	rNPV (A$m)	rNPV/share (A$)
TLX250-CDx kidney cancer imaging:	80	85%	93.6	$0.37
TLX250 kidney cancer therapeutic:	500	20%	74.4	$0.29
TLX591-CDx prostate cancer imaging	180	80%	211.7	$0.83
TLX591 prostate cancer therapeutic:	1,090	20%	153.2	$0.60
TLX101 brain cancer therapeutic	510	10%	51.8	$0.20
SG&A			(41.0)	($0.16)
Portfolio total			543.6	$2.14
Net cash (Q220)			23.3	$0.09
Enterprise total			567.0	$2.23

Source: Telix reports, Edison Investment Research

Financials

Telix reported that in July 2020 it received an A$11.4m R&D tax rebate, higher than our previous estimates of A$8.4m, which has increased our expected 2020 revenue to A$15.0m (from A$11.9m). The company reported a loss after tax of A$18.3m for the first half of 2020. It spent A$8.6m on R&D and $9.9m on SG&A. We have increased our SG&A forecasts for FY20 (to A$16.3m from A$13.7m previously). We previously expected a greater reduction in operations on account of the COVID-19 pandemic, and are pleased to see the pace of developments in spite of this.

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	3,630	97,773
Other (includes R&D tax rebate)	10,142	11,693	11,400	0
Revenue	10,337	15,178	15,030	97,773
R&D expenses	(18,692)	(21,162)	(21,750)	(21,250)
SG&A expenses	(9,150)	(15,800)	(16,274)	(16,762)
Other	0	0	0	0
EBITDA	(17,505)	(24,327)	(25,643)	59,761
Operating Profit (before amort. and except.)	(18,992)	(24,078)	(26,023)	58,692
Intangible Amortisation	0	(4,236)	(4,309)	(4,309)
Exceptionals	0	0	0	0
Operating Profit	(18,992)	(28,314)	(30,332)	54,383
Net Interest	304	(2,310)	446	79
Profit Before Tax (norm)	(15,714)	(31,122)	(29,886)	54,462
Profit Before Tax (reported)	(15,714)	(31,122)	(29,886)	54,462
Tax benefit	1,884	3,255	0	707
Profit After Tax (norm)	(13,830)	(27,867)	(29,886)	55,169
Profit After Tax (reported)	(13,830)	(27,867)	(29,886)	55,169
Average Number of Shares Outstanding (m)	202.1	233.4	253.5	253.8
EPS - normalised (c)	(6.84)	(11.94)	(11.79)	21.74
EPS - diluted (c)	(6.84)	(11.94)	(11.78)	21.21
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	40,852	43,928	43,062	38,155
Intangible Assets	39,451	41,948	37,638	33,329
Tangible Assets	226	1,899	5,341	4,744
Investments	1,175	82	82	82
Other				
Current Assets	35,856	58,679	21,848	87,862
Stocks	643	542	446	446
Debtors	8,436	12,071	11,778	378
Cash	25,771	44,598	7,865	85,279
Other	1,007	1,468	1,759	1,759
Current Liabilities	(8,242)	(10,625)	(3,224)	(7,932)
Creditors	(6,893)	(9,218)	(181)	(4,889)
Short term borrowings	(1,133)	(490)	(489)	(489)
Other	(216)	(917)	(2,554)	(2,554)
Long Term Liabilities	(15,562)	(21,902)	(19,875)	(19,875)
Long term borrowings	(596)	(1,641)	(666)	(666)
Other long-term liabilities	(14,966)	(20,261)	(19,209)	(19,209)
Net Assets	52,904	70,080	41,810	98,211
CASH FLOW				
Operating Cash Flow	(21,065)	(23,314)	(37,021)	77,099
Net Interest	316	(19)	446	79
Tax	0	0	0	707
Capex	0	(403)	(644)	(471)
Acquisitions/disposals	(2,693)	(65)	0	0
Equity Financing	0	43,890	419	0
Dividends	0	0	0	0
Other	0	0	(218)	0
Net Cash Flow	(23,442)	20,089	(37,018)	77,414
Opening net debt/(cash)	(48,414)	(24,042)	(42,467)	(6,710)
HP finance leases initiated	0	0	0	0
Other	(929)	(1,664)	1,261	0
Closing net debt/(cash)	(24,042)	(42,467)	(6,710)	(84,124)

Source: Telix reports, Edison Investment Research

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia