EDISON

Telix Pharmaceuticals

Regulatory update

TLX591-CDx NDA submitted

Healthcare equipment & services

On 24 September 2020 Telix announced it had submitted its NDA to the FDA for approval of TLX591-CDx, its positron emission tomography (PET) imaging agent targeting prostate-specific membrane antigen (PSMA). The agency has a statutory 12 months to complete its assessment (two to accept the application and 10 to review). TLX591-CDx would be the company's first approved product and it is in preparations to be ready to launch the product in 2021, which includes establishing distribution and supply-chain relationships.

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	7.8	N/A

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

Clinical data package on over 600 patients

The company's NDA includes data on over 600 patients from multiple clinical studies. This includes efficacy data from over 400 patients gathered by Memorial Sloan Kettering Cancer Center, as well as safety data on over 200 patients from a clinical study performed by Endocyte and Novartis, which used TLX591-CDx to screen patients for their PSMA targeted therapeutic. Additionally, the package includes independent data from the landmark proPSMA study (and other literature), which provides substantial evidence of the utility of PSMA PET imaging.

Getting ready for launch

In addition to the current application, the company also submitted an MAA in April 2020. Telix is preparing for the commercial launch of the product and has established distribution agreements with PharmaLogic and Cardinal Health. It recently expanded this footprint with a newly announced agreement with IRE Elit for distribution in France. Additionally, Telix has acquired a radiopharmaceutical manufacturing facility in Seneffe, Belgium, to support its European isotope supply requirements (as well as R&D needs).

Valuation: A$567m or A$2.23 per share

Our valuation remains unchanged at A$567m or A$2.23 per share. The company reported A$23.3m net cash at the end of Q220, which we assume will be sufficient to reach the approval decision for TLX591-CDx.

28 September 2020

Price	**A$1.70**
Market cap	**A$432m**
	US$0.66/A$
Net cash (A$m) at 30 June 2020	23.3
Shares in issue	253.9m
Free float	71%
Code	TLX
Primary exchange	ASX
Secondary exchange	OTCMKTS

Share price performance

%	1m	3m	12m
Abs	13.0	31.4	8.7
Rel (local)	16.5	26.8	20.6
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

ZIRCON enrolled	Year-end 2020
TLX591 Phase III start	Q420
TLX591-CDx approval decision	Expected H121

Analyst

Nathaniel Calloway +1 646 653 7036

healthcare@edisongroup.com

Edison profile page

US marketing application submitted

The submission of the NDA in the US is a major milestone for Telix as it approaches the potential commercial launch of its first approved medical product. The product is currently available in the US and Europe for research use only and the company has seen steadily increasing sales in these channels, which we hope will translate to increased interest in the product if it is approved.

According to Telix's press release, the application is being submitted 'for the imaging of prostate cancer using PET'. We previously speculated over the precise indications for which the product would be submitted and, based on this language, we assume it has been submitted for the broadest label of simply 'prostate imaging', which would encompass any imaging need. This includes imaging after biochemical recurrence (which we consider to be the most well supported indication), as well as initial staging, and tracking drug response. We expect the agency to evaluate each of these scenarios and for it to be a matter of review. Our estimates conservatively include imaging after biochemical recurrence, but we may expand this later based on FDA feedback.

Both the current NDA and the previously submitted MAA are being made using a collection of prospective and retrospective clinical data. This includes a large data set (n>400) gathered by researchers at Memorial Sloan Kettering Cancer Center, as well as imaging data gathered in the VISION study (n>200) performed by Endocyte/Novartis to support approval of their product ^{177}Lu-PSMA-617, a PSMA targeted radiotherapeutic similar to Telix's therapeutic TLX591. Telix granted Endocyte access to the TLX591-CDx 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.

Telix has also been laying the groundwork to support the commercialisation of TLX591-CDx, including the necessary infrastructure and logistics. The company has previously signed distribution agreements with PharmaLogic 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). Telix also recently announced signing an agreement with IRE Elit for distribution in France.

Additionally, in April 2020 Telix announced it had completed the acquisition of a radiopharmaceutical manufacturing facility in Seneffe, Belgium, from Eckert & Ziegler Strahlen und Medizintechnik. The company stated that isotopes generated at this site will support the commercial sales of TLX591-CDx 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 Telix to expand its R&D footprint.

Valuation

Our valuation remains unchanged at A$567m or A$2.23 per share. The current application does alter any of our assumptions, but we may reconsider the precise market for TLX591-CDx based on feedback from the FDA.

Exhibit 1: 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

Our financial forecasts remain unchanged. Telix reported A$23.3m in net cash at the end of Q220, which we assume will be sufficient to reach the approval decision for TLX591-CDx.

Exhibit 2: 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, Edison Investment Research

General disclaimer and copyright

This report has been commissioned by Telix Pharmaceuticals and prepared and issued by Edison, in consideration of a fee payable by Telix Pharmaceuticals. Edison Investment Research standard fees are £49,500 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for 'wholesale clients' within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are 'wholesale clients' for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a 'personalised service' and, to the extent that it contains any financial advice, is intended only as a 'class service' provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the 'FPO') (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the 'publishers' exclusion' from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

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

London +44 (0)20 3077 5700
280 High Holbom
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