

Stock Focus

Botanix Pharmaceuticals (BOT-ASX)

E&P

Cashed Up for Sofdra Launch

Recommendation: Speculative Buy

Last price 0.33
Valuation 0.55

TSR

Upside to valuation	74.5%
Dividend yield	0.0%
Expected total SH return	74.5%

BOT-ASX share price history

Source: E&P Research, IRESS



Trading Data

Last price	0.33
Valuation	0.55
12 month range	AUD0.08 - AUD0.29
Market cap (\$m)	\$580
Enterprise value (\$m)	\$570
Shares outstanding (m)	1,429.8
Free float (%)	100.0
12 month return (historical)	209.0%

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Background

BOT announced the US FDA's approval of the new drug application (NDA) for Sofdra™ (sofipirionium) topical gel, 12.45% (20-June-2024), indicated for the treatment of primary axillary hyperhidrosis (PAH) in adults and children 9 years of age and older. Sofdra is poised to provide a new treatment option for PAH, with a novel and potentially disruptive model for marketing, reimbursement and distribution of a topical agent that eliminates many of the pain points experienced by dermatology product consumers. On the back of this FDA approval, BOT have completed a AU\$70M capital raise via an institutional placement.

Our Thinking

Feedback from recent conversations in the US with company management, industry experts, and Japanese partner, Kaken Pharmaceuticals, have all increased our confidence in the ability for Sofdra to gain and retain market share in the US. The additional capital injection will provide BOT with the ability to scale and optimise their marketing and sales execution. Risks remain on the success of payer negotiations and the ability to shift clinical attitudes to prioritise Sofdra in dermatologists treatment algorithm. But the targeted direct to consumer marketing utilising crossix data, coupled with telehealth-enabled and BOT's centralised pharmacy-supported access and distribution platform are interesting elements that, coupled with access to an engaged and informed bolus of initial patients from which the company can learn and improve, bodes well for a successful launch.

Valuation

We have updated our model to account for the NDA approval, taking the probability of regulatory success to 100% (from 97.5%). We also, increase our base case assumptions, for both timing and magnitude of peak sales, based on US trip feedback and the additional resources now available to the company. New earnings forecast rise 17% in FY25 and FY26 to AU\$36M and AU\$105M respectively. We spread an incremental ~AU\$60M of operational costs over an ~2 year period, adjusting for prior assumptions on use of funds. We note that significant cash buildup over the longer term will likely be redirected towards potential new in-licensing opportunities which we model with a 10% increase in DCF terminal value. Overall, the additional launch costs identified and the equity dilution from the raise are offset by the increased base case earnings assumptions and pipeline value resulting in no change to our valuation of \$0.55. We retain our Speculative Buy recommendation.

Yr to Jun (AUD)	23A	24E	25E	26E
Revenue	3.8	0.8	35.6	104.6
EBITDA	(9.0)	(11.7)	2.7	45.0
EBIT	(9.1)	(11.8)	2.6	44.6
Adj. NPAT	(9.1)	(11.7)	3.6	34.4
Adj. PE (x)	(41.0)	(39.8)	160.1	16.8
Adj. EPS	(0.01)	(0.01)	0.00	0.02
Adj. EPS growth	(41.5)	3.1	(124.9)	852.0
Valuation (blended)				0.55

Source: E&P Research

US Trip Feedback

The collective feedback from a) meeting with company management in Pennsylvania; b) discussions with patient society executive director; c) meeting with Kaken Pharmaceuticals; and d) pharmaceutical industry experts and insurance companies, have provided incremental confidence in the revenue model outlined by BOT.

Put simply: if patients are presented with an option between paying for an over the counter (OTC) topical anti-perspirant or receiving Sofdra, shipped to their homes monthly for free, and assuming the side effects are clearly articulated and manageable, then the choice for them is an obvious one. Persistency will depend on the tradeoff between the level of efficacy and burden, but the feedback received was that patients in this space tend to be compliant and persistent.

The Japanese experience from Kaken, where Ecclock (sofpironium bromide gel 5%) has been marketed since November 2020, was informative. The sales figures continue to grow, and further out-licensing deals have been completed by Kaken (Dong Wha Pharm; Korea). Current Ecclock sales are at ~¥2 B (~US\$12 B) and the company are targeting a tripling of this figure at peak. Kaken have identified Ecclock as a key element of their growth strategy and the companies #2 asset (after Clenafin [efinaconazole]). Some seasonal weakness was noted in the winter, where clothing layers can mask the artifacts of underarm sweat. It was also noted that patients need to see a doctor in Japan to receive a script for Ecclock, and these doctors are typically attached to urban hospitals, making access more challenging for some portions of the community. Patient feedback on Ecclock is promising, with reports that it is effective in reducing sweating, incites minimal stinging and a low incidence of adverse effects and appears to be popular, particularly with younger patients and women.

Use of Funds

Due to an overly subscribed capital raising process, BOT have built a healthy war chest to launch Sofdra in the United States. The company's goal is to reach profitability within ~18 months without the need to come back to the market. The key elements of the AU \$70M capital allocations (excluding AU \$4.2 M fees) are outlined below:

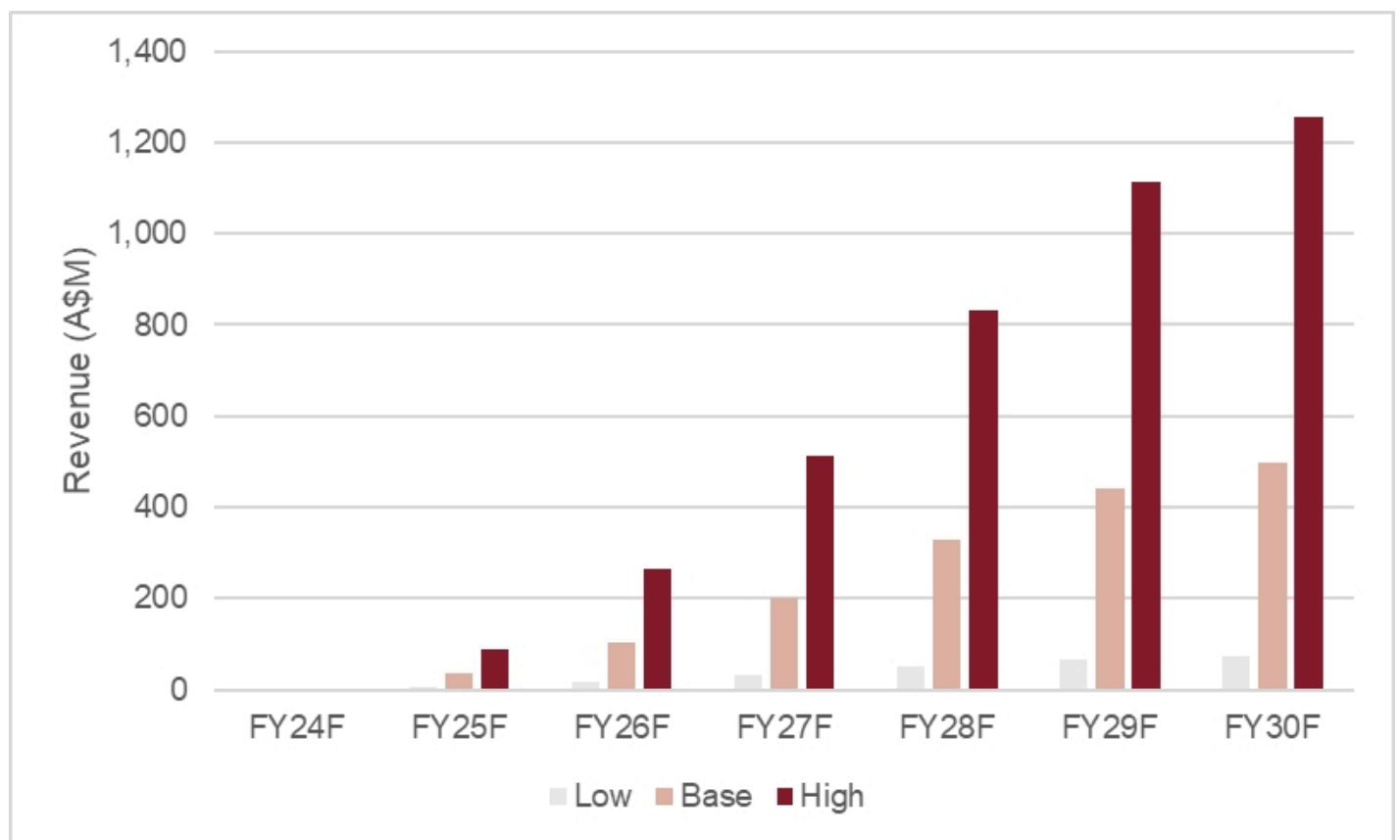
- AU\$17.5M for Salesforce and Marketing
 - An additional ~AU\$3M has been added to this in order to accelerate the launch ramp.
- AU\$17.5M for Digital Marketing Costs
 - The largest component of this spend will be on driving digital demand via metrics and media buys. A buffer in the budget will allow the company to scale or optimize their direct to consumer messaging.
 - Telemedicine is a smaller component at ~\$5-10k/month, and there is an opportunity to bolster the Lombard pharmacy service by providing concierges and managers, who can be flexed to keep up with demand.
- AU\$6M for Manufacturing and Logistics
 - With \$5M earmarked for API and \$1M for excipients, BOT want to ensure that pre-launch stocks will not be depleted. After launch, these production costs will move into COGS.
- AU\$6M for Quality Assurance
 - It is compulsory for pharmaceutical companies to conduct pharmacovigilance post drug launch.
 - These costs will be spent over time, mostly via external agencies (under strict internal management oversight).
 - Both monitoring and support staff need a level of medical training and experience, and therefore can be more costly than typical back-office staff.
- AU\$18.8M for Operational Expenses
 - BOT are aiming for a cohort of ~25 people within the company, separate to their sales force (also estimated to be ~25 people).
 - The money raised is expected to fund strategic operations to evaluate and rationalize new opportunities for in-licensing. The goal is to identify high IRR assets that could benefit synergistically from BOT's targeted direct-to-consumer marketing, telemedicine-enabled, and centralised pharmacy platform.

Next steps

- Payer negotiations are ongoing with the list price originally discussed under an NDA, but BOT are moving towards publishing this number to the payer compendium. The aim is for a favourable net price after accounting for managed care and patient rebates, copays, pharmacy setup, logistics etc. We assume this net price at launch will be ~\$490, with an ~35% gross to net.
- Launch Preparation is underway with payer negotiations with account managers, clinician meetings, sales staff interviews underway, marketing preparation and utilisation of crossix data with partners to support target segmentation.
- The messaging for BOT's Patient Experience Program is currently being finessed to make "alpha" patients within the International Hyperhidrosis Society database aware of the opportunity.
- Further detail around the engagement with payers on pricing, as well as feedback on the progress on the Patient Experience Program is expected at a market update in mid-August.

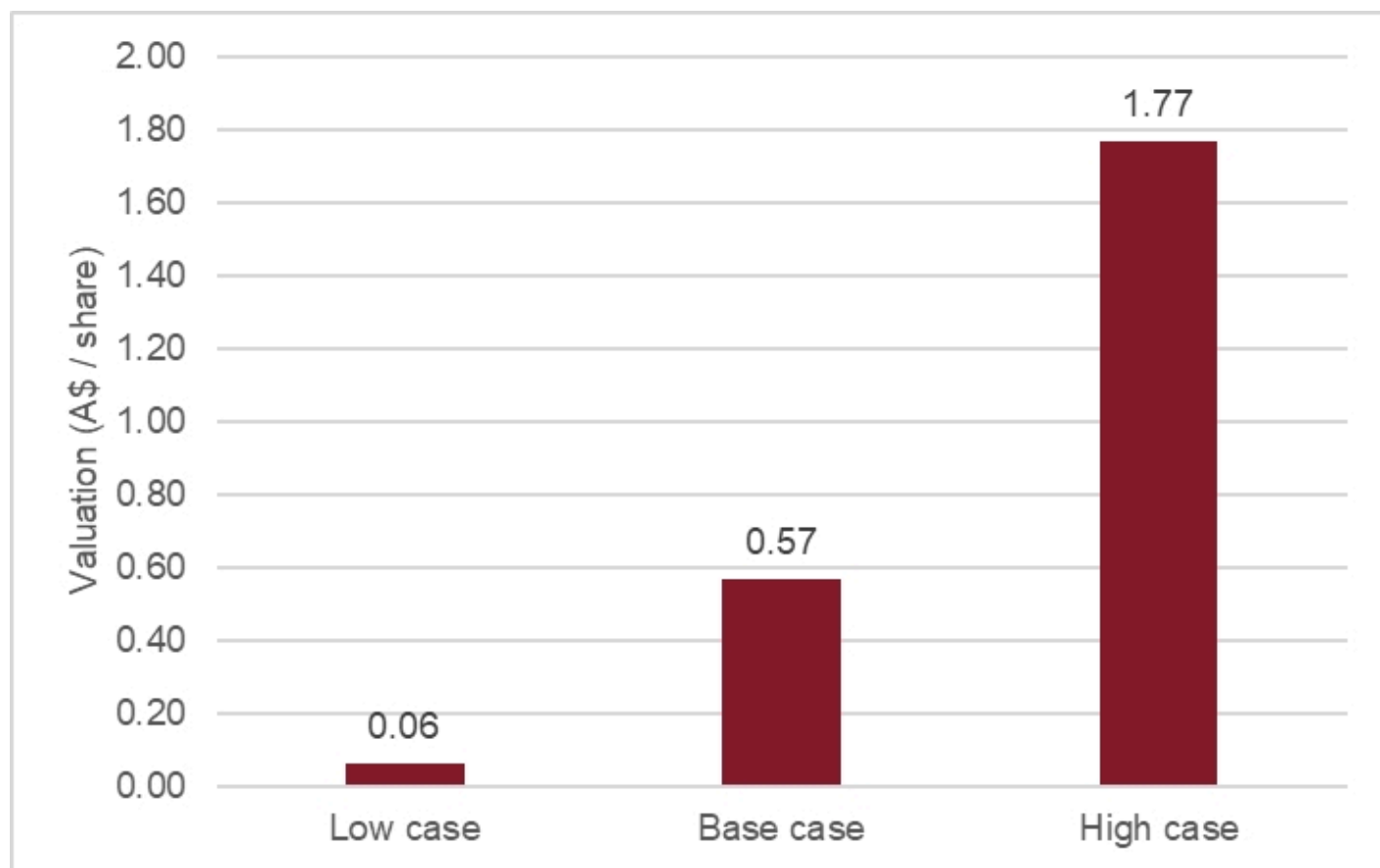
E&P Revenue Forecast and Valuation

Figure 2 - BOT Revenue Scenario Build



Source: E&P Research

Figure 3 - BOT Scenario Valuation



Source: E&P Research

Key Risks and Uncertainties

- Reimbursement from payers needs to be at a level that would justify the gross to net economics outlined by the company. There are several health economic questions that payers will be considering, including what the potential cost to their wallet could be in a "high" scenario. We await further details on the discussions to date. We are expecting a market update from BOT in ~mid-August.
- Patient and doctor acceptance is still an unknown, and will depend on a number of factors including tolerability and efficacy as well as ease of access and dissemination of compelling clinical evidence.
- The Japanese experience is a useful read, but the caveat is that Ecclock is a 5% formulation of sofipronium bromide, whereas Sofdra is 12.5%. This could lead to material differences in both efficacy (on the upside) and side effect profile (on the downside).
- Direct to consumer marketing, if done correctly in a way that speaks to the needs of consumers, could be a very powerful tool. But if the marketing is not executed well, then the product could be seen as another "me too" in a space that has left many patients jaded and disappointed.

Botanix Pharmaceuticals, Speculative Buy, VALUATION 0.55

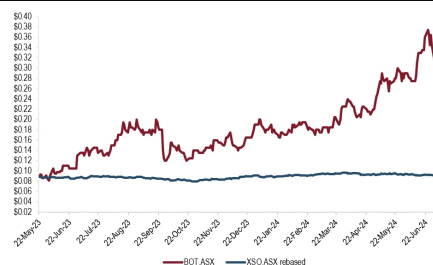
INVESTMENT THESIS

Botanix Pharmaceuticals (ASX:BOT) is a dermatology company based in Philadelphia and Phoenix, USA which is progressing its lead product, sofpironium bromide (SB), 15% gel (which will be sold as 'Sofdra', pending FDA approval) for the treatment of primary axillary hyperhidrosis (PAH; excessive underarm sweating) through US regulatory and marketing approval. Hyperhidrosis represents a sizeable clinical unmet need, affecting more than 1 in 20 people globally at varying degrees of severity, with PAH in roughly half of these cases.

SB is the first and only new chemical entity developed to treat primary axillary hyperhidrosis, and is positioned to be a leading first line and second line therapy for patients with this condition. Sofdra achieved statistical significance on all primary and secondary endpoints and was found to have a favourable safety profile in Phase 3 pivotal studies and in a 48-week long term safety study. The US FDA approved the NDA for Sofdra in June 2024 and launch is anticipated in Q3 24 CY.

NEAR TERM CATALYSTS

- US Launch
- Quarterly US sales figures
- Japanese Ecclock sales
- Impact of competition sales growth
- Further clinical safety and efficacy data



FINANCIAL SUMMARY

Botanix Pharmaceuticals						BOT-ASX							
As at:	10/07/2024					Recommendation:	Speculative Buy					Share Price:	0.33
Year end	Jun	2023A	2024E	2025E	2026E	Year end	Jun	2023A	2024E	2025E	2026E		
INCOME STATEMENT						CASH FLOW							
Imaging		0.1	0.8	35.6	104.6	EBITDA		(9.0)	(11.7)	2.7	45.0		
Other operating revenue		3.7	0.0	0.0	0.0	(Increase)/decrease in NWC		(6.7)	1.7	(9.6)	(17.3)		
Sales & service revenue		3.8	0.8	35.6	104.6	Net interest paid		(0.0)	0.1	1.5	1.3		
General/admin expenses		(2.7)	(3.2)	(3.5)	(3.7)	Net tax paid		3.7	0.0	(0.5)	(11.5)		
Employee expenses		(1.5)	(2.6)	(11.5)	(28.0)	Operating cash flow		(12.1)	(10.0)	(6.0)	17.5		
R&D expenses		(5.7)	(2.2)	(3.0)	(3.6)	Capex		(0.0)	(0.0)	(0.9)	(2.6)		
Other income/(expense)		(2.9)	(4.6)	(13.2)	(19.1)	Net disposals/(acquisitions)		(7.0)	(17.2)	(5.0)	(5.0)		
EBITDA		(9.0)	(11.7)	2.7	45.0	Investing cash flow		(7.1)	(17.3)	(5.9)	(7.6)		
EBIT		(9.1)	(11.8)	2.6	44.6	Share issues/(buybacks)		22.2	92.8	0.0	0.0		
Net interest income/(expense)		(0.0)	0.1	1.5	1.3	Lease payments		(0.1)	0.0	0.0	0.0		
Profit before tax		(9.1)	(11.7)	4.1	45.9	Financing cash flow		22.0	92.8	0.0	0.0		
Tax		0.0	0.0	(0.5)	(11.5)	Net change in cash		2.9	65.5	(11.9)	9.9		
Underlying NPAT		(9.1)	(11.7)	3.6	34.4	Free cash flow		(12.1)	(9.9)	(5.1)	20.1		
Other post-tax items		(0.0)	0.0	0.0	0.0	Year end	Jun	2023A	2024E	2025E	2026E		
Reported NPAT		(9.2)	(11.7)	3.6	34.4	BALANCE SHEET							
Year end	Jun	2023A	2024E	2025E	2026E	Cash & cash equivalents		10.3	75.6	63.7	73.6		
EPS AND DIVIDENDS						Trade & other receivables		0.5	0.2	1.3	3.4		
Weighted avg shares (m)		1,154	1,430	1,780	1,780	Inventories		3.1	3.1	15.0	30.9		
Weighted avg dil. shares (m)		1,154	1,430	1,780	1,780	Other current assets		0.1	0.1	0.1	0.1		
Reported EPS (AUD \$ps)		(0.01)	(0.01)	0.00	0.02	Total current assets		14.0	79.1	80.2	108.0		
Adjusted EPS (AUD \$ps)		(0.01)	(0.01)	0.00	0.02	Property, plant & equipment		0.1	0.1	0.4	1.9		
Adj. EPS growth (%)		(41.5)	3.1	(124.9)	852.0	Right of use asset		0.0	0.0	0.0	0.0		
Year end	Jun	2023A	2024E	2025E	2026E	Goodwill		10.7	28.3	33.3	38.3		
TRADING MULTIPLES AND RETURNS						Other non-current assets		0.1	0.0	0.0	0.0		
EV / sales		151.1	741.0	16.0	5.4	Total non-current assets		10.9	28.4	33.7	40.2		
EV / EBITDA		(63.2)	(48.6)	215.0	12.7	Total assets		24.8	107.5	113.9	148.2		
EV / EBIT		(62.4)	(48.5)	220.1	12.8	Trade & other payables		1.7	2.2	5.5	6.2		
Adj. PE		(41.0)	(39.8)	160.1	16.8	Current lease liabilities		0.0	0.0	0.0	0.0		
ROE		(58.8)	(18.2)	3.4	27.3	Other current liabilities		0.2	0.1	0.1	0.1		
Year end	Jun	2023A	2024E	2025E	2026E	Total current liabilities		1.9	2.3	5.6	6.3		
CAPITAL STRUCTURE AND LEVERAGE						Total liabilities		1.9	2.3	5.6	6.3		
Net debt/(cash)		(10.3)	(75.6)	(63.7)	(73.6)	Ordinary share capital		93.5	185.9	185.9	185.9		
Net debt / equity (%)		(44.7)	(71.9)	(58.6)	(51.4)	Reserves & other equity		6.4	7.8	7.8	7.8		
Net debt / EBITDA (x)		1.1	6.4	(24.1)	(1.6)	Retained profits		(76.9)	(88.6)	(85.0)	(50.6)		
Source: Company data, E&P estimates						Total shareholder's equity		23.0	105.2	108.8	143.2		
						Total equity		23.0	105.2	108.8	143.2		

RESEARCH RECOMMENDATION DEFINITIONS

Positive	Stock is expected to outperform the S&P/ASX 200 over the coming 24 months.
Neutral	Stock expected to perform in line with the S&P/ASX 200 over the coming 24 months.
Negative	Stock is expected to underperform the S&P/ASX 200 over the coming 24 months.
Speculative Buy	Stock has limited history from which to derive a fundamental investment view or its prospects are highly dependent on event risk, e.g. Successful exploration, scientific breakthrough, high commodity prices, regulatory change, etc. Consequently, the stock is considered a high-risk investment which may be prone to high volatility in share price movements, have a greater risk of capital loss and/or the stock may have low liquidity.
Suspended	Stock is temporarily suspended due to compliance with applicable regulatory and/or E&P policies in circumstances where E&P is acting in an advisory capacity.
Not Rated	Stock is not included in our investment research universe.

Research Criteria Definitions

Recommendations are primarily determined with reference to how a stock ranks relative to the S&P/ASX 200 on the following criteria:

Valuation	Composite of Rolling 12-month prospective multiples and discounted cash flow (DCF), or DCF for resource stocks.
Earnings Outlook	Forecast 2-year EPS growth.
Earnings Momentum	Percentage change in the current consensus EPS estimate for the stock (rolling 1-year forward basis) over the consensus EPS estimate for the stock 3 months ago.
Shareholder Returns	Composite of forecast ROE (rolling 1-year forward basis) and the percentage change in ROE over 2 years.
Debt Servicing Capacity	Rolling 12-month EBIT Interest Cover ratio.
Cyclical Risk	Qualitative assessment of the 2-year outlook for a stock/industry's profit cycle.
Industry Quality	Qualitative assessment of an industry's growth/returns potential and company specific management capability.
Financial Transparency	If we don't understand it, we won't recommend it.

For stocks where Evans and Partners does not generate its own forecasts, Bloomberg consensus data is used. Analysts can introduce other factors when determining their recommendation, with any material factors stated in the written research where appropriate.

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AVG	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has been appointed Lead Manager to an offering of securities of the company or its affiliates, for which it will receive a fee.
BOT	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has been appointed Manager to an offering of securities of the company or its affiliates, for which it will receive a fee.
BST	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has provided advisory services to the company in the last 12 months, for which it received a fee.
CCR	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has arranged, managed or co-managed an offering of securities of the company or its affiliates in the past 12 months, for which it received a fee.
CD1	E&P Financial Group Limited (E&P) partly and/or wholly owns or controls entities that provide services in relation to CD Private Equity Fund I (CD1) for which they receive fees. Evans and Partners is a wholly owned subsidiary of E&P. Directors or employees of E&P and/or its related bodies corporate are directors of the entities that provide services in relation to CD1. Each individual receives remuneration from E&P and/or its related

entities. A subsidiary of E&P is currently providing services under a transitional services agreement with K2 Asset Management Holdings Limited, the Responsible Entity.

CD2	E&P Financial Group Limited (E&P) partly and/or wholly owns or controls entities that provide services in relation to CD Private Equity Fund II (CD2) for which they receive fees. Evans and Partners is a wholly owned subsidiary of E&P. Directors or employees of E&P and/or its related bodies corporate are directors of the entities that provide services in relation to CD2. Each individual receives remuneration from E&P and/or its related entities. A subsidiary of E&P is currently providing services at cost under a transitional services agreement with K2 Asset Management Holdings Limited, the Responsible Entity.
CD3	E&P Financial Group Limited (E&P) partly and/or wholly owns or controls entities that provide services in relation to CD Private Equity Fund III (CD3) for which they receive fees. Evans and Partners is a wholly owned subsidiary of E&P. Directors or employees of E&P and/or its related bodies corporate are directors of the entities that provide services in relation to CD3. Each individual receives remuneration from E&P and/or its related entities. A subsidiary of E&P is currently providing services at cost under a transitional services agreement with K2 Asset Management Holdings Limited, the Responsible Entity.
CGHE	The Investment Manager (IM) of Claremont Global Fund (Fund), and Evans and Partners Pty Ltd (EAP) are wholly owned subsidiaries of E&P Financial Group Limited (E&P) and related bodies corporate. The IM will receive fees for services provided to the Fund. The Portfolio Managers of the Fund are employees of E&P and/or its related bodies corporate. Each individual receives remuneration from E&P and/or its related entities.
CVC	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has been appointed Lead Manager to an offering of securities of the company or its affiliates, for which it will receive a fee.
CGUN	The Investment Manager (IM) of Claremont Global Fund (Fund), and Evans and Partners Pty Ltd (EAP) are wholly owned subsidiaries of E&P Financial Group Limited (E&P) and related bodies corporate. The IM will receive fees for services provided to the Fund. The Portfolio Managers of the Fund are employees of E&P and/or its related bodies corporate. Each individual receives remuneration from E&P and/or its related entities.
EXP	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, is currently providing advisory services to the company, for which it may receive a fee.
EYE	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has arranged, managed or co-managed an offering of securities of the company or its affiliates in the past 12 months, for which it received a fee.
GBP	An employee of Evans and Partners Pty Ltd is a non-executive director of Global Petroleum Limited.
GCI	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has arranged, managed or co-managed an offering of securities of the company or its affiliates in the past 12 months, for which it received a fee.
HUB	The Issuer has appointed Evans and Partners Pty Ltd as Broker to an on-market buy-back. Accordingly, Evans and Partners Pty Ltd may be restricted from giving sellers advice in respect to a sale of this security.
IMM	Evans and Partners Pty Ltd is a related entity of E&P Financial Group Limited (E&P). An independent member of the E&P Investment Committee is a Non-Executive Director of Immutep Limited.
JDO	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has arranged, managed or co-managed an offering of securities of the company or its affiliates in the past 12 months, for which it received a fee.
LE.US	A director of E&P Financial Group Limited, the ultimate holding company of Evans and Partners Pty Ltd, is a director of Lands' End Inc.
MAQ	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has arranged, managed or co-managed an offering of securities of the company or its affiliates in the past 12 months, for which it received a fee.
MOT	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has arranged, managed or co-managed an offering of securities of the company or its affiliates in the past 12 months, for which it received a fee.
MXT	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has arranged, managed or co-managed an offering of securities of the company or its affiliates in the past 12 months, for which it received a fee.
NAB	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has arranged, managed or co-managed an offering of securities of the company or its affiliates in the past 12 months, for which it received a fee.
OFX	The Issuer has appointed Evans and Partners Pty Ltd as Broker to an on-market buy-back. Accordingly, Evans and Partners Pty Ltd may be restricted from giving sellers advice in respect to a sale of this security.
PYC	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has arranged, managed or co-managed an offering of securities of the company or its affiliates in the past 12 months, for which it received a fee.

QRI	E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, has arranged, managed or co-managed an offering of securities of the company or its affiliates in the past 12 months, for which it received a fee.
SWM	The company has completed a conditional share sale agreement to acquire Prime Media Group Limited (PRT). E&P Capital Pty Limited, a related entity of Evans and Partners Pty Ltd, provided advisory services to PRT, for which it received a fee. A director of E&P Financial Group Limited is a director of Seven West Media Limited.
URF	A subsidiary of E&P Financial Group Limited currently has a commercial relationship with the Responsible Entity (RE) owned by the US Masters Residential Property Fund (URF), for which it receives a fee in relation to a transitional services arrangement to provide operational assistance for a period post RE appointment.

RESEARCH ANALYST CERTIFICATION

I, David Nayagam and Gretel Janu, hereby certify that all views expressed in this publication reflect my personal views about the subject theme and/or relevant company securities, and no attempt has been made by any other person to influence the views or themes contained within; and I am not in receipt of inside information and this publication does not contain any inside information. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

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