EUROZ HARTLEYS

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BOT: Commercial Day Webinar

BOT.ASX | BOTANIX PHARMACEUTICALS LIMITED | HEALTHCARE | BIOTECHNOLOGY

PRICE	TARGET PRICE	RECOMMENDATION	ANALYST
A$0.275/sh	**A$0.330/sh**	**SPECULATIVE BUY**	**SETH LIZEE**
	(FROM A$0.300/sh)	(UNCHANGED)	SLIZEE@EUROZHARTLEYS.COM

Event

BOT held an investor webinar last week where it provided a comprehensive update on its Sofdra commercial launch plans ahead of FDA approval, anticipated June 20th.

Key executives spoke to the significant body of work now completed around sales, marketing, and payer engagement. Moreover, a guest speaker from the International Hyperhidrosis Society provided a compelling patient perspective, highlighting the need for new treatment options.

The company further highlighted ~350,000 units of Sofpironium bromide have been sold by its Japanese partner, Kaken Pharmaceuticals, in the last 12 months in Japan. This is significantly higher than any of our previous Japanese volume estimates.

Impact

We came away with increased confidence around the upcoming FDA approval decision and BOT's commercial strategy, with three areas that stood out:

- **FDA Approval** – FDA approval remains on track for late June, with a PDUFA date set for June 20th. On the webinar, BOT noted it had engaged with the FDA in recent weeks and continues to have a high level of confidence around securing approval.
- **Reimbursement** – BOT has pursued an early engagement approach with payers to provide patients with frictionless access, not only for the first fill but every refill. Further, payer feedback suggests coverage obstacles are few and manageable.
- **Prescription Refills** – BOT's distribution model, which includes plans to automatically ship refills, could significantly increase treatment adherence, potentially enabling higher unit volume and sales.

More broadly it is clear a large amount of work has now been completed behind the scenes (Figure 1) and that management are in a strong position to execute – we continue to note the team has collectively, developed, secured approval for, and commercialised over 30 dermatology products (Figure 2).

Further, the success of Sofpironium Bromide in Japan provides a compelling case study of its significant commercial potential in the United States. When applied to our estimate of US net pricing (US$540/month), 350,000 prescriptions would imply US$189m (~A$290m) of equivalent potential revenues in the United States.

Action

We maintain our Speculative Buy recommendation with an upgraded $0.33 Price Target (prev. $0.30), reflecting increased confidence around commercialisation.

We remain confident on BOT securing FDA approval, noting the complete response letter (CRL) received solely pertained to patient instructions (specifically the instructions paper and product carton wording) — a minor issue in the broader context.

Moreover, our analysis suggests in the 30-days leading up to an FDA new drug approval, ASX-listed companies have seen an average 30% re-rate in their share price (Figure 4).

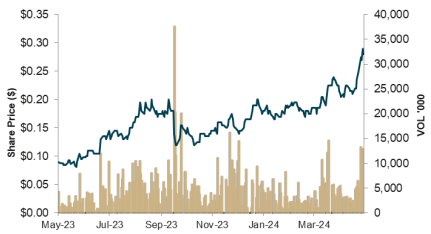
Catalysts

- FDA Approval - June 20th 2024
- Commercial Updates/Commercial Launch 1QFY25/First Sales 1QFY25

Share Price	0.275	A$/sh
Price Target	**0.33**	**A$/sh**
Valuation	0.33	A$/sh
Shares on issue	1,683	m, dil
Market Capitalisation	462.8	A$m
Enterprise Value	441.2	A$m
Debt	0.0	A$m
Cash (March'Q)	17.3	A$m
Unpaid capital	4.4	A$m

Key Metrics	**24F**	**25F**	**26F**
Revenue (A$m)	3.4	61.8	147.2
EBITDA (A$m)	-1.6	4.2	55.8
Reported NPAT (A$m)	-2.5	3.1	54.6
Norm NPAT (A$m)	-2.5	3.1	54.6
Gross CF (A$m)	-1.7	4.1	55.7
Capex (A$m)	0.0	0.0	0.0
Op. FCF (A$m)	-3.1	-1.3	37.0
EBITDA Gwth (%)	-0.8	-3.6	12.2
NPAT Gwth (%)	-0.7	-2.2	16.5
Norm EPS (Ac)	-0.2	0.2	3.5
Norm. EPS gwth (%)	-0.7	-2.2	16.5
PER (x)	-166.3	136.0	7.8
EV/EBITDA (x)	-272.6	104.4	7.9
EV/Revenue (x)	130.5	7.1	3.0
Net Cash (A$m)	19.7	18.6	55.7

Performance



Source: IRESS

Income Statement	24F	25F	26F
Net Sales	0.0	60.8	146.0
Royalties	0.9	1.0	1.2
Other (inc R&D)	2.5	0.0	0.0
Total Revenue	**3.4**	**61.8**	**147.2**
(-) COGS (inc. roy)	0.0	-14.6	-33.6
Gross Profit	**3.4**	**47.2**	**113.6**
(-) R&D	0.0	0.0	0.0
(-) SG&A	-5.0	-43.0	-57.8
EBITDA	**-1.6**	**4.2**	**55.8**
(-) D&A	-0.9	-1.1	-1.2
EBIT	**-2.5**	**3.1**	**54.6**
(-) Net finance	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0
PBT	**-2.5**	**3.1**	**54.6**
(-) Tax	0.0	0.0	0.0
NPAT	**-2.5**	**3.1**	**54.6**
(+/-) Adj.	0.0	0.0	0.0
Norm NPAT	**-2.5**	**3.1**	**54.6**

Cash Flow Statement	24F	25F	26F
NPAT	**-2.5**	**3.1**	**54.6**
(+) D&A	0.9	1.1	1.2
(+) Non-cash expenses	0.0	0.0	0.0
(-) Leases	-0.1	-0.1	-0.1
(+/-) Other	0.0	0.0	0.0
Gross Cash Flow	**-1.7**	**4.1**	**55.7**
(-) Capital expenditure	0.0	0.0	0.0
(+/-) Working capital	-1.3	-5.4	-18.6
Operating Free Cash Flow	**-3.1**	**-1.3**	**37.0**
(-) Acquisition	-12.1	0.0	0.0
(-) Milestone payment	0.0	0.0	0.0
(+) Placement	24.6	0.0	0.0
(+) Disposal	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0
Net Cash Flow	**9.4**	**-1.3**	**37.0**
BoP Net Cash / (Debt)	10.2	19.7	18.6
(+/-) Net Cash Flow	9.4	-1.3	37.0
(+/-) Other	0.1	0.1	0.1
EoP Net Cash / (Debt)	**19.7**	**18.6**	**55.7**

Balance Sheet	24F	25F	26F
Cash	19.7	18.6	55.7
Inventory	3.5	8.5	20.2
Receivables	0.6	7.2	16.6
Other	0.1	0.1	0.1
Current Assets	**23.9**	**34.3**	**92.5**
PP&E	0.0	0.0	0.0
Intangible	21.9	20.8	19.7
ROUA	0.0	0.0	0.0
Other	0.1	0.1	0.1
Non-current Assets	**22.1**	**21.0**	**19.7**
Total Assets	**45.9**	**55.3**	**112.3**
Payables	0.8	7.1	9.5
Lease liabilities	0.0	0.0	0.0
Provisions	0.2	0.2	0.2
Current Liabilities	**1.0**	**7.2**	**9.7**
Lease liabilities	0.0	0.0	0.0
Non-current liabilities	**0.0**	**0.0**	**0.0**
Total liabilities	**1.0**	**7.2**	**9.7**
Net Assets	**44.9**	**48.1**	**102.6**
Issued Capital	118.1	118.1	118.1
Reserves	6.4	6.4	6.4
Retained earnings	-79.5	-76.4	-21.8
Total equity	**45.0**	**48.1**	**102.7**

Performance Ratios	24F	25F	26F
Growth & Margins			
Revenue Growth	-12%	1727%	138%
EBITDA Growth	-82%	-361%	1220%
EBIT Growth	-72%	-222%	1652%
Net Profit Growth	-72%	-222%	1652%
Margins			
EBITDA margin	-48%	7%	38%
EBIT margin	-75%	5%	37%
Net profit margin	-75%	5%	37%
Effective tax rate	0%	0%	0%
Liquidity			
Capex/depreciation	0.0	0.0	0.0
Current ratio	24.5	4.8	9.6
Quick ratio	24.6	3.6	7.6
Receivable days	60.0	42.5	41.1
Payable days	60.0	60.0	60.0
Risk Measures			
Dividend Cover	na	na	na
Payout ratio	0%	0%	0%
Net interest cover	na	na	na
Net debt/equity	-0.4	-0.4	-0.5
Returns			
ROIC	-4%	5%	37%
ROA	-6%	6%	49%
ROE	-6%	6%	53%

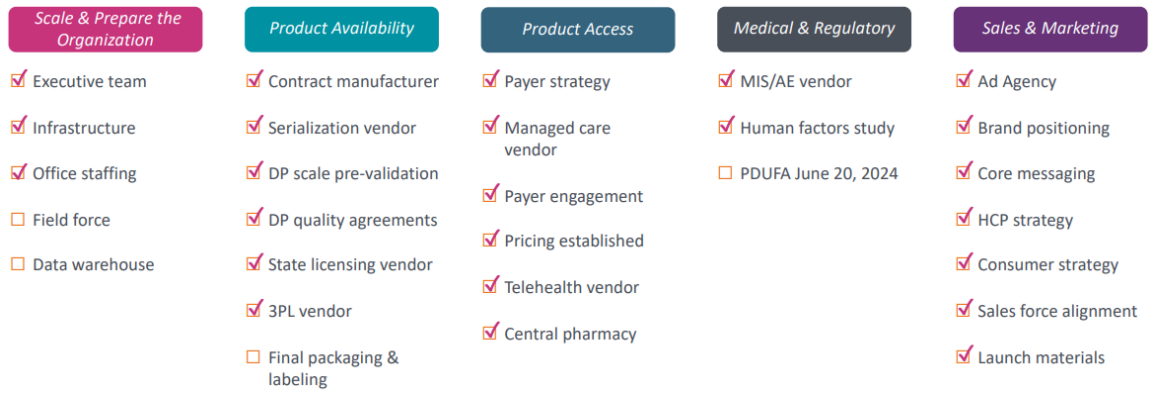
Share Data/Valuation	24F	25F	26F
Issued shares	1,575.1	1,575.1	1,575.1
Weighted ave shares	1,443.8	1,575.1	1,575.1
Fully diluted shares	1,575.1	1,575.1	1,575.1
Basic EPS	-0.2	0.2	3.5
YoY change	-77%	-222%	1652%
Fully diluted EPS	-0.2	0.2	3.5
YoY change	-75%	-222%	1652%
Fully diluted normalised EPS	-0.2	0.2	3.5
YoY change	-75%	-222%	1652%
Dividend/share	0.0	0.0	0.0
Franking	na	na	na
Gross cash flow/share	-0.1	0.3	3.5
NBV/share	2.9	3.1	6.5
NTA/Share	1.5	1.7	5.3
Valuation			
PER (Basic) (x)	-170.0	139.0	7.9
PER (Fully diluted) (x)	-170.0	139.0	7.9
PER (Fully diluted, normalized) …	-170.0	139.0	7.9
P/CFPS (x)	-248.8	105.6	7.8
Price/NBV (x)	9.6	9.0	4.2
Price/NTA (x)	18.8	15.9	5.2
Dividend Yield (%)	0.0	0.0	0.0
EV/EBITDA (x)	-272.6	104.4	7.9
EV/EBIT (x)	-173.1	141.6	8.1
EV/Revenue (x)	130.5	7.1	3.0

Commercial Day Webinar

Last Wednesday, BOT held an investor webinar where the company provided a comprehensive update on its Sofdra commercial launch plans ahead of FDA approval, anticipated the 20th of June 2024.

The company remains confident on securing FDA approval, with a significant body of work now having been completed around sales, marketing, and payer engagement (Figure 1).

Figure 1: Sofdra Launch Preparation Activities



Source: Company presentation

Speakers included key BOT executives, who together have developed, secured approval for, and commercialized over 30 dermatology products (Figure 2), including:

- Vince Ippolito – Executive Chairman
- Dr Howie McKibbon – Chief Executive Officer
- Dr Patricia Walker – Chief Medical Officer
- Matt Callahan – Executive Director
- John Schohl – VP Managed Markets
- Dr Boris Meyerson – Chief Business Officer

Figure 2: BOT Management Team Experience

Source: Company presentation

The webinar also included a guest speaker, Lisa Pieretti, executive director and founding member of the International Hyperhidrosis Society, who provided a patient perspective of hyperhidrosis – noting that clinicians currently have limited treatment options.

We have provided key highlights from the webinar with attaching analysis below.

FDA Approval

FDA approval remains on track for late June, with a PDUFA date set for the 20th of June 2024.

The company noted in the webinar that they have engaged with the FDA in recent weeks and continue to have a high level of confidence around securing FDA approval.

As we have illustrated in past research, we remain confident on FDA approval given the complete response letter (CRL) received solely pertained to patient instructions (specifically the instructions paper and product carton wording) — a minor issue in the broader context.

Moreover, ASX-listed instances of CRL's aren't that all uncommon (Figure 3), with some observations:

- Out of the drugs listed below, we note most were eventually approved despite receiving a complete response letter (or multiple letters), with only one withdrawn.
- Moreover, it's clear the deficiencies listed in these other examples are much more significant then BOT's. We would go further to say BOT has one of the most manageable and low risk CRL's out of all of these comparisons.

Figure 3: Instances of Complete Response Letters by ASX Companies

Company	Ticker	Drug	Type	CRL Date	Listed deficiencies/requests	Current Status
Pharmaxis	PXS	Aridol	NDA	29-Dec-09	Manufacturing, revised Labelling, agreement to post marketing requirements	Approved
pSivida	PVA	Iluvien	NDA	23-Dec-10	Further data analysis, manufacturing	Approved
QRxPharma	QRX	Moxduo	NDA	27-Jun-12	Request for additional information with regard to safety and efficacy	Withdrawn
Mesoblast	MSB	Remestemcel-L	BLA	2-Oct-20	Request for additional study	Under review
Mayne Pharma Group	MYX	Nuvaring	ANDA	6-Oct-20	Details not provided	Approved
Aft Pharmaceuticals	AFP	Maxigesic	NDA	9-Nov-20	Manufacturing, Labelling	Approved
Cyclopharm	CYC	Technegas	NDA	28-Jun-21	Better defining and validating unique characteristics, production, delivery; manufacturing and dosimetry	Approved

*Source: Company announcements, EH analysis, *non exhaustive, as only lists first instances of CRL, noting some applications received multiple CRL's*

We have also attempted to explore how other ASX-listed companies traded in the final lead up to and on FDA approval, specifically companies securing FDA approval on their first drug. In our analysis, we were able to find 6 ASX-listed companies that fit this criteria, as shown below (Figure 4):

Figure 4: ASX Comparables

				Market Cap	% Price Change
Ticker	Company	Product	Approval Date	FDA-Approval	30 days pre-approval
ACR	Acrux	Evamist©	31-Jul-07	260	33%
PXS	Pharmaxis	Aridol©	6-Oct-10	561	24%
CUV	Clinuvel	SCENESSE©	9-Oct-19	2,232	68%
TLX	Telix	Illuccix©	20-Dec-21	2,460	13%
NEU	Neuren	DAYBUE©	13-Mar-23	1,148	25%
CYC	Cyclopharm	Technegas®	2-Oct-23	269	20%
			Average	**1,155**	**30%**

Source: EH analysis, fully diluted, company announcements, IRESS. Note: excludes CSL (diversified business), MYX & PVA (first drug(s) approved prior to listing)

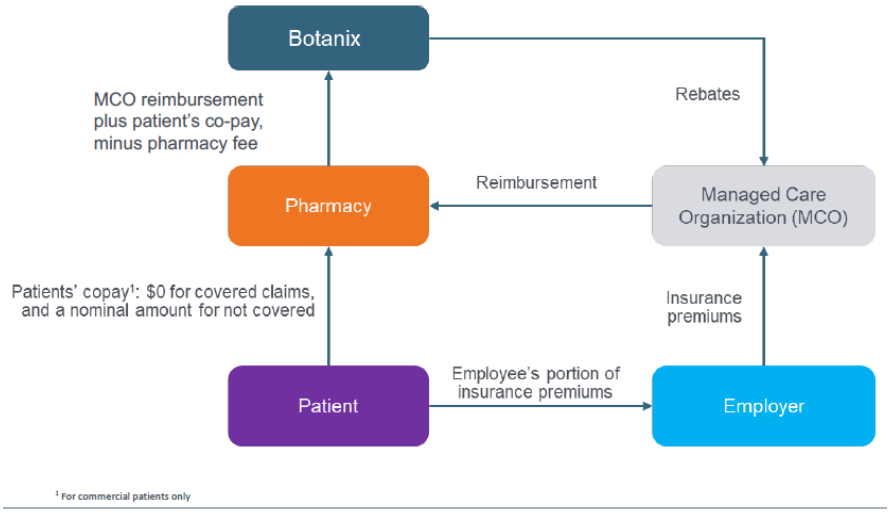
While these companies vary in a number of different ways, on average, they saw a 30% re-rate in the 30-days leading up to FDA approval.

Reimbursement / Coverage

BOT has pursued an early engagement approach with payers to provide patients with frictionless access to Sofdra, not only for the first fill but every refill.

This strategy includes plans to have a $0 co-pay (i.e. out of pocket payment) for covered claims and a nominal amount for non-covered claims (figure 5).

Figure 5: Illustrative Reimbursement Process



Source: Company presentation

Further, payer feedback suggests coverage obstacles are few and manageable. For instance, management noted in the webinar these could include things like:

- Requiring a physician's confirmation of a hyperhidrosis diagnosis; and/ or
- Verification that the patient has previously tried and failed a standard treatment such as DRYSOL (a low-cost prescription aluminium chloride drug) – most patients likely to have already done this.

Looking ahead, the company intends to execute contracts with contracting PBMs and downstream clients in two phases (Figure 6).

Figure 6: Key Payer Account Prioritization and Engagement Timing

Phase 1 Accounts		
--	Zinc Health	35.1M
--	Caremark PCS	2.1M
--	Ascent Health	22.6M
--	Express Scripts	1.2M
--	Emisar Health	27M
--	OptumRx Government	750k
--	Kaiser	8.1M
Emisar	United Healthcare	12.6M
Zinc	Aetna Health	6M
Ascent	Cigna	9M
Zinc	Elevance (Anthem)	6.1M
Ascent	Prime Therapeutics	33.5M

Phase 2 Accounts					
CVS	Federal Employees Health Benefit	5.5M	Ascent	Premera	1.1M
Zinc	Wellmark	950k	Ascent	Medical Mutual OH	560k
Zinc	CareFirst BCBS	1M	Emisar	Independence BC	1M
Zinc	BCBS MA	1.3M	Ascent	Emblem Health	400k
Zinc	Blue Shield CA	1.8M	Ascent	Kroger PBM	700k
Emisar	BCBS SC	400k	Emisar	BCBS AZ	380k
Ascent	HCSC Members	5.5M	Ascent	BCBS MN	735k
Ascent	Horizon BCBS NJ	500k	Ascent	BCBS KS	294k
Ascent	Florida Blue	1.2M	Emisar	BCBS Kansas City	376k
Ascent	Regence / Cambia	1.1M	Emisar	BCBS Michigan	170k
Ascent	BCBS NC	730k	Ascent	Elixir PBM	850k
Ascent	BCBS AL	1.2M	FLRx	Lifetime Healthcare	800k
Ascent	BCBS LA	700k	--	Procare/MC21	560k
Ascent	HMSA Hawaii	385k	--	Dividend Group/ MedImpact	1M
Ascent	Humana Health	600k	Ascent	BCBS Highmark	190k

Key: Rx Contracting PBM | Phase 1 Account | Phase 2 Account | Total Lives

Source: Company presentation

Refills

BOT's distribution model, which includes plans to automatically ship refills, could significantly increase treatment adherence, potentially enabling higher volume and sales.

In contrast, traditional models rely on patients to manually refill their prescriptions each month. This can lead to varying levels of treatment adherence. For instance, if a patient delays their refill by just five days a month, they would miss out on two prescriptions each year.

Manufacturing / Logistics

Sofdra is commercial manufacturing ready, with the product to be manufactured by CPL in Canada. Further, BOT noted it has a third-party logistics provided (3PL) in place to manage inventory and fulfil orders

Japan Case Study

In late 2020, Sofpironium Bromide was approved and launched in Japan with an existing partner, Kaken Pharmaceuticals.

Launched under the brand ECCLOCK© Gel 5% (Figure 7), the drug was the first ever product approved in Japan for Primary Axillary Hyperhidrosis.

Figure 7: ECCLOCK© Gel 5%, Product and Packaging

Source: company presentation

BOT disclosed in last week's webinar that **Kaken has sold ~350,000 units of Sofpironium Bromide ("branded Ecclock") in the last 12 months**, this figure is significantly higher than any of our previous japanese unit volume estimates.

This is clearly very positive, illustrating Kaken has been able to mobilise a significant numbers of new patients even in its third year of launch.

Applied to our estimate of US net pricing (US$540/month), 350,000 prescriptions would translate into US$189m (~A$290m) of equivalent USA revenues.

We estimate Sofpironium Bromide could sell for ~US$540/month (net pricing) in the United States, this based on the pricing of its closest competitor Qbrexza© (US$720/script gross price).

Moreover, we note the United States has a population nearly 3x larger than Japan, and that the incidence and prevalence of hyperhidrosis between both countries is similar - which could suggest even larger potential prescription volumes and sales are possible in the United States.

Forecasts

The table below illustrates a summary of our US Sofpironium Bromide forecasts.

Figure 8: US Sofpironium Bromide (SB) Forecasts

US SB Forecasts	Units	FY2025	FY2026	FY2027	FY2028	FY2029	FY2030	FY2031	FY2032	FY2033
Prescriptions Sold	**'000s**	**72.0**	**168.0**	**228.0**	**276.0**	**312.0**	**348.0**	**384.0**	**420.0**	**456.0**
Implied Patients Treated	'000s	6.0	14.0	19.0	23.0	26.0	29.0	32.0	35.0	38.0
… Market penetration	%	0.2%	0.4%	0.5%	0.6%	0.7%	0.8%	0.9%	0.9%	1.0%
… Growth	%		133%	36%	21%	13%	12%	10%	9%	9%
Wholesale Pricing (WAC)	US$/script	720	742	764	787	810	835	860	886	912
...Price escalation	%		3%	3%	3%	3%	3%	3%	3%	3%
Net pricing (net)	US$/script	540	556	573	590	608	626	645	664	684
...Gross-to-net	%	25%	25%	25%	25%	25%	25%	25%	25%	25%
Net Sales	**US$m**	**38.9**	**93.4**	**130.6**	**162.9**	**189.6**	**217.9**	**247.6**	**278.9**	**311.9**
(-) COGS	**US$m**	**-7.4**	**-16.8**	**-22.2**	**-26.1**	**-28.4**	**-32.7**	**-37.1**	**-41.8**	**-46.8**
Gross Profit	**US$m**	**31.5**	**76.6**	**108.4**	**136.8**	**161.2**	**185.2**	**210.5**	**237.1**	**265.1**
…Gross Margin	%	81%	82%	83%	84%	85%	85%	85%	85%	85%
(-) SG&A	**US$m**	**-27.5**	**-37.0**	**-39.2**	**-44.8**	**-47.4**	**-49.0**	**-49.5**	**-55.8**	**-62.4**
…as % of Net sales	%	71%	40%	30%	28%	25%	23%	20%	20%	20%
(-) Royalty	**US$m**	**-1.9**	**-4.7**	**-6.5**	**-8.1**	**-9.5**	**-10.9**	**-12.4**	**-13.9**	**-15.6**
…as % of Net sales	%	5%	5%	5%	5%	5%	5%	5%	5%	5%
Operating Income	**US$m**	**2.0**	**35.0**	**62.7**	**83.9**	**104.3**	**125.3**	**148.6**	**167.4**	**187.2**

Source: EH estimates

**based on 12 scripts/pa*

***based on 3.7m target patient population*

Valuation and Price Target

We maintain our Speculative Buy recommendation with an upgraded $0.33 Price Target (prev. $0.30), reflecting increased confidence around commercialisation.

We have reduced the discount rate of our Sofdra NPV from 15% to 13% to reflect this increased confidence around commercialisation.

We have risked the NPV of sofdra by 10% to account for FDA approval risk.

Our sum of the parts (SOP) valuation is illustrated below.

Figure 9: SOP Valuation

Asset	Indication	Risking (r)	Risked Val. (rNPV)	
		%	A$m	A$/sh*
Sofdra	**Hyperhidrosis**	**90%**	**445**	**0.26**
BTX1503	Acne	27%	53	**0.03**
BTX1801	Antimicrobial	23%	33	**0.02**
BTX1702	Rosacea	6%	5	**0.00**
BTX1204A	Atopic Derm.	6%	4	**0.00**
Net Cash		100%	17	**0.01**
Unpaid Capital		100%	4	**0.00**
Total			**560**	**0.33**

Source: EH estimate, fully diluted

The risks surrounding unsuccessful regulatory, commercial and or clinical (in the case of secondary programs) outcomes drives our speculative Buy recommendation.

Personal disclosures

We hereby certify that all of the views expressed in this report accurately reflect our personal views about the subject company or companies and its or their securities, and we are not in possession of, nor does this Research contain any inside information.

No part of our compensation was, is or will be directly or indirectly, related to the specific recommendations or views expressed by the authoring Analyst in this research, nor has there been any adverse or undue influence on the Analyst in the preparation of this report.

Company disclosures

The companies and securities mentioned in this report, include:

Botanix Pharmaceuticals Limited (BOT.ASX) | Price A$0.275 | Target price A$0.330 | Recommendation Speculative Buy;

Price, target price and rating as at 13 May 2024 (not covered)*

Additional disclosures

The analyst declares that they have a beneficial interest in: Botanix Pharmaceuticals Limited (BOT.ASX)

Euroz Hartleys declares that it has provided corporate advice during the last year and has received a fee for these services from: Botanix Pharmaceuticals Limited (BOT.ASX)

Euroz Hartleys declares that it has acted as underwriter to, and/or arranged an equity issue in, and/or been engaged in a capital raising during the last year. Euroz Hartleys has received a fee for these services from: Botanix Pharmaceuticals Limited (BOT.ASX)

Euroz Hartleys has received an allocation of shares and/or options as part of our fee for the provision of Corporate services. These holdings are maintained in our Nominee company, and may present a potential benefit to Euroz Hartleys when sold for: Botanix Pharmaceuticals Limited (BOT.ASX)

Other disclosures, disclaimers and certificates