EUROZ HARTLEYS

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Goodbye Sweat: Sofdra FDA Approval and Funding for US Launch Secured

BOT.ASX | BOTANIX PHARMACEUTICALS LIMITED | HEALTHCARE | BIOTECHNOLOGY

PRICE	TARGET PRICE	RECOMMENDATION	ANALYST
A$0.335/sh	**A$0.470/sh** (FROM A$0.330/sh)	**BUY** (FROM SPECULATIVE BUY)	**SETH LIZEE** SLIZEE@EUROZHARTLEYS.COM

Euroz Hartleys has acted as Lead Manager for a capital raising completed for Botanix Pharmaceuticals (BOT), for which it will earn fees.

Event

BOT's lead asset, Sofdra™ (Sofpironium) topical gel, 12.45% has secured FDA approval for the treatment of primary axillary hyperhidrosis (excessive sweating) in adults and children 9 years and older.

In parallel, the company has successfully completed a $70.0 million single tranche placement at $0.30 to fully fund the launch and commercialisation of Sofdra in the USA.

Impact

FDA approval is a major milestone and de-risking event, paving the way for Sofdra's launch in the USA and the company's transition into a revenue generating business.

Sofdra is the first and only new chemical entity approved by the FDA for treating primary axillary hyperhidrosis – presenting a novel safe and effective solution for patients who lack options. Almost 9 in 10 patients had a clinically meaningful result from using Sofdra.

The market opportunity for Sofdra is significant. Hyperhidrosis is the third largest dermatology condition in the USA (after acne and atopic dermatitis), with approx. ~10m patients with axillary hyperhidrosis. This includes ~3.7m currently seeking treatment and ~6.3m not. Importantly, hyperhidrosis is a recognized medical condition by insurers.

BOT is targeting to launch a patient experience program in Q3'CY24 with first revenues expected in Q4'CY24. The company has outlined a two-prong commercialisation strategy, **informed by managements extensive experience in +30 previous drug launches.**

- **Direct sales force** – Deploy a 25-person dermatologist focused sales force into key geographies in Q1'CY25 to convert the ~3.7m patients seeking treatment; and
- **Digital/Telemedicine** – Engage and diagnose patients digitally through telemedicine channel, where the first prescription and refills are mailed directly to the patient.

We have updated our forecasts to reflect first sales in Q4C'Y24 (prev mid-CY24), as well as adding digital sales. We now model BOT capturing 1% of the ~3.7m patients seeking treatment and 0.3% of the other ~6.3m patients not, within a decade, and assuming an average 12 scripts per patient, or if more conservatively put, 2% and 0.6% assuming 6 scripts. This arrives us to ~673k peak Sofdra scripts, or US$474m peak sales by FY34.

We note BOT's Japanese partner, Kaken, has sold ~350k units of Sofpironium Bromide in the last 12 months alone. This in its 4th year of sales, in a country ~1/3rd the size of the USA with similar disease prevalence - highlighting the conservatism in our forecasts.

Action

We **upgrade to a Buy Recommendation with an increased $0.47 Price Target**, broadly reflecting the de-risking of securing FDA approval and changes to our modelling.

We note there is potential upside in our digital sales forecast. For instance, increasing our peak digital penetration of the ~6.3m patients to 1% (from 0.3% modelled) and assuming 12 scripts per patients, increases our valuation to $0.76, subject to other assumptions.

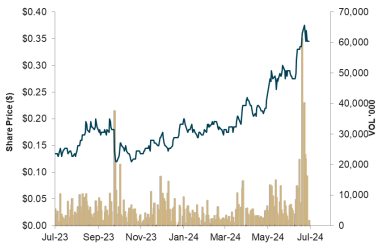
Catalysts

- Manufacturing/Packaging Q3'CY24 / Patient Experience Program Q3'CY24 / First Sales Q4'CY24 / Telemedicine launch Q4'CY24 / Salesforce Deployment Q1'CY25

Share Price	0.335	A$/sh
Price Target	**0.47**	**A$/sh**
Valuation	0.47	A$/sh
Shares on issue	1,916	m, dil
Market Capitalisation	642.0	A$m
Enterprise Value	550.3	A$m
Debt	0.0	A$m
Pro Forma Cash	87.3	A$m
Unpaid capital	4.4	A$m

Key Metrics	**25F**	**26F**	**27F**
Revenue (A$m)	29.3	120.8	201.7
EBITDA (A$m)	-14.5	34.7	95.5
Reported NPAT (A$m)	-14.7	34.0	86.2
Norm NPAT (A$m)	-14.7	34.0	86.2
Gross CF (A$m)	-14.6	34.6	87.2
Capex (A$m)	0.0	0.0	0.0
Op. FCF (A$m)	-21.9	20.5	79.0
EBITDA Gwth (%)	0.5	-3.4	1.7
NPAT Gwth (%)	0.6	-3.3	1.5
Norm EPS (Ac)	-0.8	1.8	4.5
Norm. EPS gwth (%)	0.6	-3.3	1.5
PER (x)	-41.3	17.8	7.0
EV/EBITDA (x)	-38.0	15.8	5.8
EV/Revenue (x)	18.8	4.6	2.7
Net Cash (A$m)	58.4	79.1	158.2

Performance



Source: IRESS

Income Statement (A$m)	24F	25F	26F	27F
Net Sales	0.0	27.8	119.6	200.4
Royalties	0.9	1.0	1.2	1.4
Other (inc R&D)	2.5	0.4	0.0	0.0
Total Revenue	**3.4**	**29.3**	**120.8**	**201.7**
(-) COGS (inc. roy)	0.0	-7.0	-28.7	-46.1
Gross Profit	**3.4**	**22.3**	**92.1**	**155.7**
(-) R&D	-1.0	0.0	0.0	0.0
(-) SG&A	-11.8	-36.8	-57.4	-60.1
EBITDA	**-9.4**	**-14.5**	**34.7**	**95.5**
(-) D&A	0.0	-0.2	-0.7	-1.2
EBIT	**-9.4**	**-14.7**	**34.0**	**94.4**
(-) Net finance	0.0	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0	0.0
PBT	**-9.4**	**-14.7**	**34.0**	**94.4**
(-) Tax	0.0	0.0	0.0	-8.2
NPAT	**-9.4**	**-14.7**	**34.0**	**86.2**
(+/-) Adj.	0.0	0.0	0.0	0.0
Norm NPAT	**-9.4**	**-14.7**	**34.0**	**86.2**

Cashflow Statement (A$m)	24F	25F	26F	27F
NPAT	**-9.4**	**-14.7**	**34.0**	**86.2**
(+) D&A	0.0	0.2	0.7	1.2
(+) Non-cash expenses	1.5	0.0	0.0	0.0
(-) Leases	-0.1	-0.1	-0.1	-0.1
(+/-) Other	0.0	0.0	0.0	0.0
Gross Cash Flow	**-8.0**	**-14.6**	**34.6**	**87.2**
(-) Capital expenditure	0.0	0.0	0.0	0.0
(+/-) Working capital	-1.1	-7.3	-14.1	-8.2
Operating Free Cash Flow	**-9.1**	**-21.9**	**20.5**	**79.0**
(-) Acquisition	-12.1	0.0	0.0	0.0
(-) Milestone payment	0.0	0.0	0.0	0.0
(+) Placement	91.1	0.0	0.0	0.0
(+) Disposal	0.0	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0	0.0
Net Cash Flow	**69.8**	**-21.9**	**20.5**	**79.0**
BoP Net Cash / (Debt)	10.2	80.1	58.4	79.1
(+/-) Net Cash Flow	69.8	-21.9	20.5	79.0
(+/-) Other	0.1	0.1	0.1	0.1
EoP Net Cash / (Debt)	**80.1**	**58.4**	**79.1**	**158.2**

Balance Sheet (A$m)	24F	25F	26F	27F
Cash	80.1	58.4	79.1	158.2
Inventory	3.5	6.9	14.2	12.6
Receivables	0.6	6.4	14.9	24.9
Other	0.1	0.1	0.1	0.1
Current Assets	**84.3**	**71.8**	**108.2**	**195.8**
PP&E	0.0	0.0	0.0	0.0
Intangible	22.9	22.7	22.0	20.9
ROUA	0.0	0.0	0.0	0.0
Other	0.1	0.1	0.1	0.1
Non-current Assets	**23.0**	**22.8**	**22.1**	**20.9**
Total Assets	**107.3**	**94.6**	**130.3**	**216.7**
Payables	1.0	3.0	4.7	4.9
Lease liabilities	0.0	0.0	0.0	0.0
Provisions	0.2	0.2	0.2	0.2
Current Liabilities	**1.2**	**3.2**	**4.9**	**5.1**
Lease liabilities	0.0	0.0	0.0	0.0
Non-current liabilities	**0.0**	**0.0**	**0.0**	**0.0**
Total liabilities	**1.2**	**3.2**	**4.9**	**5.1**
Net Assets	**106.1**	**91.4**	**125.4**	**211.6**
Issued Capital	186.0	186.0	186.0	186.0
Reserves	6.4	6.4	6.4	6.4
Retained earnings	-86.4	-101.0	-67.0	19.2
Total equity	**106.1**	**91.4**	**125.5**	**211.6**

Performance Ratios	24F	25F	26F	27F
Growth & Margins				
Revenue Growth	-12%	766%	313%	67%
EBITDA Growth	5%	54%	-340%	175%
EBIT Growth	4%	56%	-332%	177%
Net Profit Growth	3%	56%	-332%	153%
Margins				
EBITDA margin	-278%	-49%	29%	47%
EBIT margin	-278%	-50%	28%	47%
Net profit margin	-278%	-50%	28%	43%
Effective tax rate	0%	0%	0%	9%
Liquidity				
Capex/depreciation	0.0	0.0	0.0	0.0
Current ratio	70.2	22.6	22.2	38.4
Quick ratio	76.9	21.4	19.9	37.0
Receivable days	60.0	80.0	45.0	45.0
Payable days	30.0	30.0	30.0	30.0
Risk Measures				
Dividend Cover	na	na	na	na
Payout ratio	0%	0%	0%	0%
Net interest cover	na	na	na	na
Net debt/equity	-0.8	-0.6	-0.6	-0.7
Returns				
ROIC	-6%	-11%	19%	31%
ROA	-9%	-16%	26%	40%
ROE	-9%	-16%	27%	41%

Share Data/Valuation	24F	25F	26F	27F
Issued shares	1,808	1,808	1,808	1,808
Weighted ave shares	1,560	1,808	1,808	1,808
Fully diluted shares	1,916	1,916	1,916	1,916
Basic EPS	-0.5	-0.8	1.9	4.8
YoY change	-25%	56%	-332%	153%
Fully diluted EPS	-0.5	-0.8	1.8	4.5
YoY change	-23%	56%	-332%	153%
Fully diluted norm EPS	-0.5	-0.8	1.8	4.5
YoY change	-23%	56%	-332%	153%
Dividend/share	0.0	0.0	0.0	0.0
Franking	na	na	na	na
Gross cash flow/share	-0.4	-0.8	1.9	4.8
NBV/share	5.9	5.1	6.9	11.7
NTA/Share	4.6	3.8	5.7	10.5
Valuation				
PER (Basic) (x)	-64.3	-41.3	17.8	7.0
PER (Fully diluted) (x)	-68.2	-43.8	18.9	7.5
PER (Fully diluted, norm) (x)	-68.2	-43.8	18.9	7.5
P/CFPS (x)	-75.4	-41.5	17.5	6.9
Price/NBV (x)	5.7	6.6	4.8	2.9
Price/NTA (x)	7.3	8.8	5.9	3.2
Dividend Yield (%)	0.0	0.0	0.0	0.0
EV/EBITDA (x)	-58.6	-38.0	15.8	5.8
EV/EBIT (x)	-58.5	-37.5	16.2	5.8
EV/Revenue (x)	162.7	18.8	4.6	2.7

FDA Approval

The US Food and Drug Administration (FDA) has approved BOT's lead asset, Sofdra™ (Sofpironium) topical gel, 12.45% for the treatment of primary axillary hyperhidrosis (excessive sweating) in adults and children 9 years and older.

Figure 1: Sofdra Logo

Sofdra (sofpironium) topical gel, 12.45%

Source: Sofdra.com

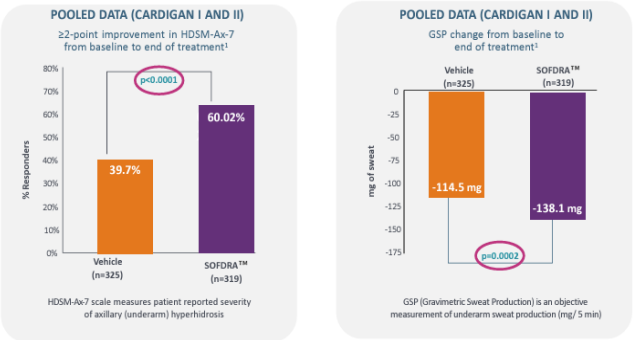
Figure 2: Sofdra Bottle

Source: Sofdra.com

The approval was supported by successful results from two pivotal Phase 3 studies across 701 patients with primary axillary hyperhidrosis (referred to as 'CARDIGAN I and II'). In these studies, Sofdra met all co-primary (Figure 3) and secondary endpoint (Figure 4) with clinically and statistically meaningful changes from baseline.

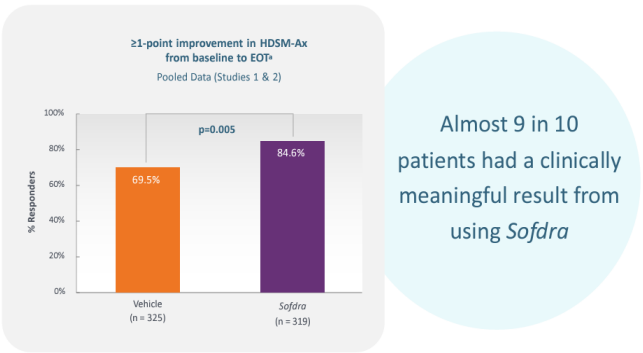
Almost 9 in 10 patients had a clinically meaningful result from using Sofdra.

Figure 3: Co-Primary Endpoints



Source: Company presentation

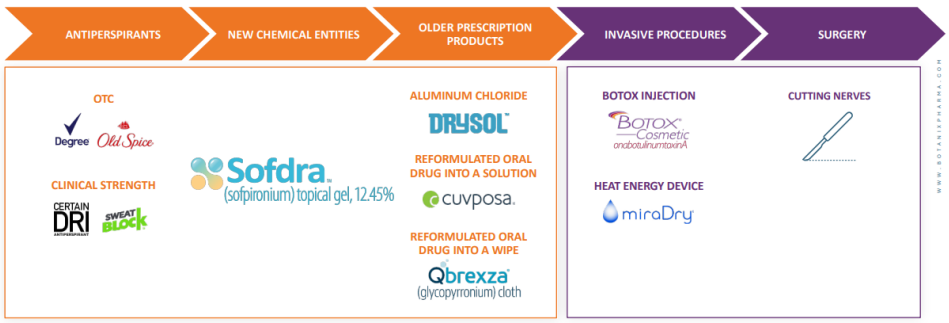
Figure 4: Secondary Endpoint



Source: Company presentation

Sofdra is now the first and only new chemical entity approved by the FDA for the treatment of primary axillary hyperhidrosis, a major development for hyperhidrosis sufferers, who currently have few effective options (Figure 5).

Figure 5: Treatment Landscape



Source: company presentation

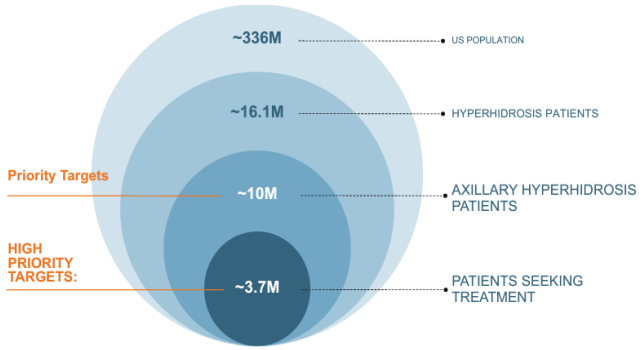
Commercialisation Strategy

The market opportunity for Sofdra is significant, with hyperhidrosis representing the third largest dermatology condition in the United States (after acne and atopic dermatitis).

There are an estimated 10 million patients with axillary (underarm) hyperhidrosis in the United States (Figure 6), which can be split into two groups:

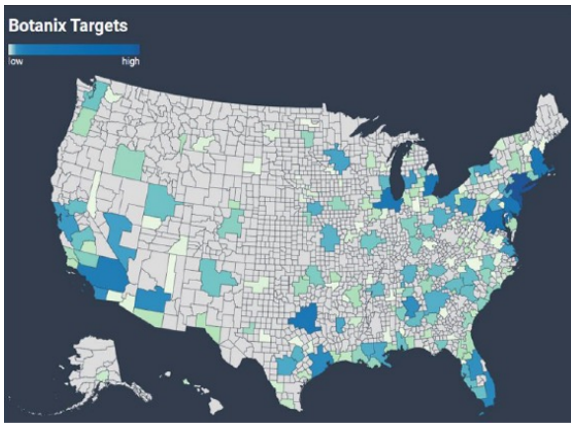
- ~3.7 million patients seeking treatment (visited a doctor in the last 12 months for axillary hyperhidrosis); and
- ~6.3 million patients not actively seeking treatment (either previously or not yet diagnosed).

Figure 6: USA Hyperhidrosis Total Addressable Market



Source: Company presentation

Figure 7: Key Target Geographies

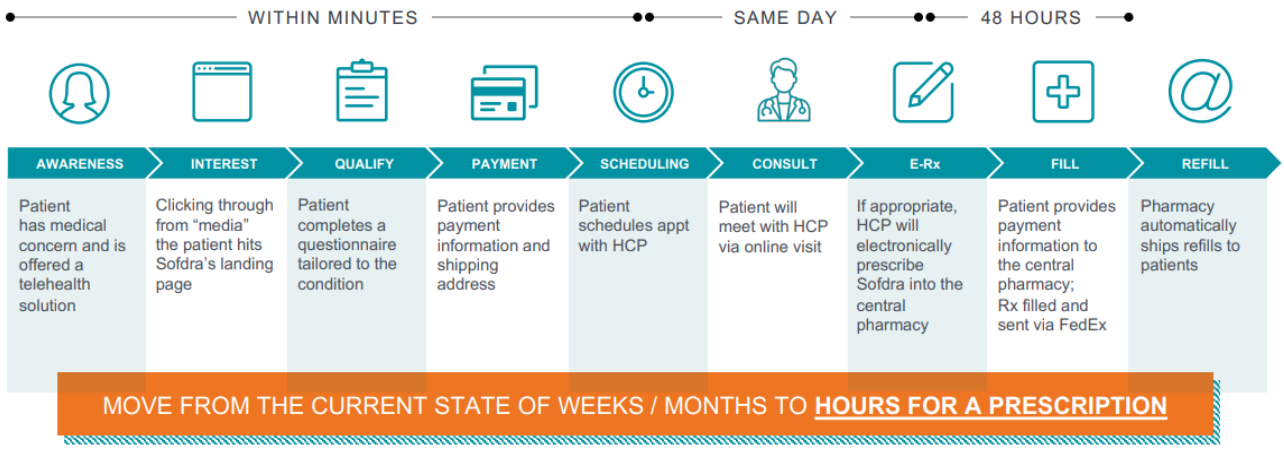


Source: Company presentation

The company has outlined a two-prong commercialisation strategy, with the goal of reaching both patient groups, which includes:

- **Direct Sales Force** - Deploy a 25-person sales force into key geographies (Figure 7) in Q1 CY25, which will call on dermatologists to convert a percentage of the 3.7 million existing patients seeking treatment; and
- **Digital/Telemedicine** – Engage and diagnose patients digitally, where the first prescription and refills are mailed directly to the patient (Figure 8). This will look to activate a percentage of the other ~6.3 million patients with hyperhydrosis.

Figure 8: Planned Digital/Telemedicine Sales Channel

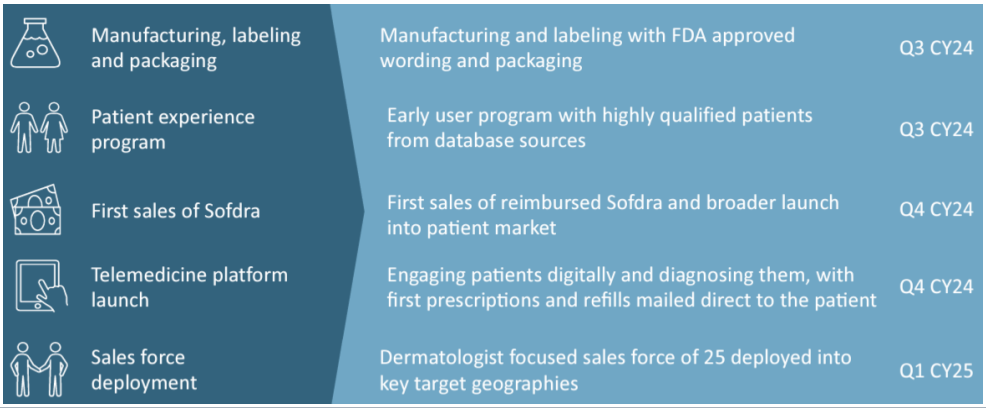


Source: Company presentation

The company is targeting first Sofdra sales in Q4'CY24.

The timing of indicative launch milestones are as follows (Figure 9).

Figure 9: Sofdra Indicative Launch Milestones



Source: Company presentation

The company intends to first launch a patient experience program with highly qualified patients. This will see patients guided through BOT's telemedicine and payer reimbursement process to gain early access and be the first commercial users of Sofdra.

Following this, a broader launch is targeted to occur in early Q4'CY24.

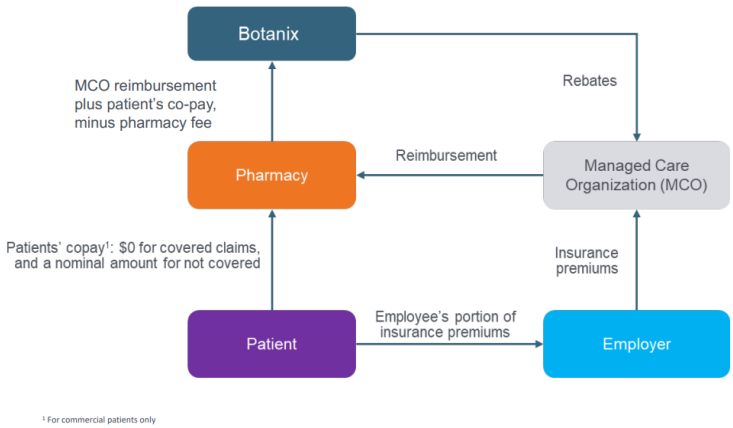
Reimbursement

Sofdra reimbursement is well advanced. As the company previously outlined in their May investor webinar, BOT has pursued an early engagement approach with payers to provide patients with frictionless access.

Coverage obstacles appear few and manageable, with things BOT has noted some insurers may require being:

- Rebate off the Sofdra list price and confirmation of hyperhidrosis diagnosis; or
- That the patient has already tried Drysol (a standard treatment, which we would expect most patients to have likely already done).

Figure 10: Illustrative Reimbursement Process



Source: Investor Webinar, May 2024

Commercially insured patients will pay $0 as their co-pay (i.e. out of pocket), once insurance is cleared.

Placement

The company also successfully completed a $70.0 million single tranche placement through the issue of 233.3 million shares at $0.30/sh.

The capital raised is expected to fully fund the launch and commercialisation of Sofdra in the United States, with the use of funds as follows (Figure 11).

Figure 11: Placement Use of Funds

Uses	A$m
Sales force and marketing infrastructure	~$17.5 million
Digital marketing costs and telemedicine platform	~$17.5 million
Manufacturing and logistics	~$6 million
Quality assurance, pharmacovigilance and support services	~$6 million
Operating expenses	~$18.8 million
Costs of the Placement[1]	~$4.2 million
Total use of funds	**~$70 million**

Note: The above table is a statement of current intentions as at the date of this Presentation. As with any budget, intervening events and new circumstances have the potential to affect the manner in which the funds are ultimately applied. The Board of Botanix reserves the right to alter the way in which the funds are applied on this basis.

Source: Company presentation

Forecasts

We have updated our modelling. Our forecasts now align with BOT's indicative launch milestone timings, including first sales in Q4'CY24 (we previously modelled mid-CY24).

Additionally, we have now incorporated digital sales into our forecasts, whereas we previously only modelled sales based on the ~3.7 million patients actively seeking treatment. We now model BOT capturing the following market shares:

- 1% of the ~3.7 million patients actively seeking treatment over a decade assuming 12 prescriptions per patient (or if more conservatively put, 2% market penetration based on 6 prescriptions per patient); and
- 0.3% of the other ~6.3 million patients not actively seeking treatment over a decade, also assuming an average 12 prescriptions per patient (or otherwise put, 0.6% based on 6 prescriptions per patient)

This arrives us to ~673,000 peak annual Sofdra prescriptions, or US$474 million in peak net sales by FY2034.

The table below illustrates a summary of our US Sofdra forecasts, which we now model over a 10-year commercial period.

Figure 12: US Sofdra Forecasts

US Sofdra Forecasts	Units	FY2025	FY2026	FY2027	FY2028	FY2029	FY2030	FY2031	FY2032	FY2033	FY2034
Prescriptions Sold	**'000s**	**33.3**	**138.8**	**225.6**	**309.6**	**385.2**	**457.9**	**525.5**	**585.2**	**631.8**	**672.5**
… Growth	%		317%	63%	37%	24%	19%	15%	11%	8%	6%
Implied Direct Penetration*	%	0.1%	0.2%	0.4%	0.5%	0.6%	0.7%	0.8%	0.9%	1.0%	1.0%
Implied Digital Penetration**	%	0.0%	0.0%	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%	0.3%	0.3%
Wholesale Pricing (WAC)	US$/script	720	742	764	787	810	835	860	886	912	939
...Price escalation	%		3%	3%	3%	3%	3%	3%	3%	3%	3%
Net pricing (net)	US$/script	540	556	573	590	608	626	645	664	684	705
...Gross-to-net	%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
Net Sales	**US$m**	**18.0**	**77.2**	**129.3**	**182.7**	**234.1**	**286.6**	**338.9**	**388.6**	**432.2**	**473.8**
(-) COGS	**US$m**	**-3.6**	**-14.7**	**-23.3**	**-31.1**	**-37.5**	**-43.0**	**-50.8**	**-58.3**	**-64.8**	**-71.1**
Gross Profit	**US$m**	**14.4**	**62.5**	**106.0**	**151.6**	**196.7**	**243.6**	**288.0**	**330.3**	**367.4**	**402.8**
…Gross Margin	%	80%	81%	82%	83%	84%	85%	85%	85%	85%	85%
(-) SG&A	**US$m**	**-23.8**	**-37.0**	**-38.8**	**-50.2**	**-58.5**	**-64.5**	**-67.8**	**-77.7**	**-86.4**	**-94.8**
…as % of Net sales	%	132%	48%	30%	28%	25%	23%	20%	20%	20%	20%
(-) Royalty	**US$m**	**-0.9**	**-3.9**	**-6.5**	**-9.1**	**-11.7**	**-14.3**	**-16.9**	**-19.4**	**-21.6**	**-23.7**
…as % of Net sales	%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%
Operating Income	**US$m**	**-10.3**	**21.7**	**60.7**	**92.2**	**126.4**	**164.8**	**203.3**	**233.2**	**259.3**	**284.3**

*Source: EH estimate, *based on ~3.7 million existing patients seeking treatment, assuming 12 prescriptions per patient, **based on other ~6.3 million patients not seeking treatment (i.e. digital opportunity), assuming 12 prescriptions per patient.*

In contrast, we are reminded BOT's Japanese partner, Kaken Pharmaceuticals, has sold ~350,000 units of Sofpironium Bromide (branded "Ecclock") in the last 12 months alone.

We note this has been achieved in Kaken's 4th year of sales, in a country roughly 1/3rd the size of the United States with similar rates of disease prevalence - all of which we believe highlights the conservatism in our forecasts

Valuation and Price Target

We have upgraded our Recommendation to a Buy with an increased $0.47 Valuation and Price Target.

Our valuation has increased following the successful FDA approval of Sofdra and changes to our modelling and other assumptions, net of dilution from the placement to launch and commercialisation Sofdra in the United States.

Our updated valuation is shown below:

Figure 13: Valuation

Asset	*Valuation (NPV10)*	*Valuation (NPV10)*
	A$m	A$/sh**
Sofdra	**808**	**0.42**
Net Cash*	87	0.05
Unpaid Capital	4	0.00
Total	900	0.47

*Source: EH estimate, *pro-forma, **fully diluted*

Our Sofdra valuation is based on a Net Present Valuation (NPV) of our US forecasts using a 10% discount rate. We do not include a terminal value in our valuation.

Following FDA-approval we have removed the risking factor from our Sofdra Valuation. We also reduced the discount rate to 10% given BOT is now expected to be fully funded to commercialise Sofdra in the United States. Further, we have rolled forward our valuation into the new FY.

Further, we have changed our valuation to be centered on Sofdra. Additional upside is present from BOT's development pipeline of products for a range of dermatology conditions.

Key risks are now centered around the commercialisation of Sofdra in the United States.

Sensitivity Analysis

We note there is potential upside in our digital sales forecast. For instance, increasing our peak digital market penetration of the ~6.3m patients not seeking treatment to 1% (from the 0.3% modelled) and assuming 12 scripts per patients for simplicity, increases our valuation to $0.76 (Figure 15).

Clearly all of this remains subject to various other assumptions.

Figure 14: Peak Direct Market Penetration Valuation (NPV10) Sensitivity

NPV10 Valuation		Peak Direct Market Penetration (~3.7m patients seeking treatment)				
		0.5%	1.0%	1.5%	2.0%	2.5%
Avg. scripts per patient	3	0.20	0.24	0.28	0.31	0.35
	6	0.24	0.31	0.39	0.47	0.55
	9	0.28	0.39	0.51	0.62	0.74
	12	0.31	0.47	0.62	0.78	0.93

Source: EH estimate, fully diluted NPV10 valuation

Figure 15: Peak Digital Market Penetration Valuation (NPV10) Sensitivity

NPV10 Valuation		Peak Digital Market Penetration (~6.3m patients not seeking treatment)				
		0.00%	0.30%	0.50%	0.75%	1.00%
Avg. scripts per patient	3	0.34	0.37	0.40	0.42	0.45
	6	0.34	0.41	0.45	0.50	0.55
	9	0.34	0.44	0.50	0.58	0.66
	12	0.34	0.47	0.55	0.66	0.76

Source: EH estimate, fully diluted NPV10 valuation

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

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Botanix Pharmaceuticals Limited (BOT.ASX) | Price A$0.335 | Target price A$0.470 | Recommendation BUY;

Price, target price and rating as at 01 July 2024 (not covered)*

Additional disclosures

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