



# BOT: FDA Resubmission Ahead of Schedule

**BOT.ASX | BOTANIX PHARMACEUTICALS LIMITED | HEALTHCARE | BIOTECHNOLOGY**

PRICE  
**A\$0.170/sh**

TARGET PRICE  
**A\$0.300/sh**  
(UNCHANGED)

RECOMMENDATION  
**SPECULATIVE BUY**  
(UNCHANGED)

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## Event

BOT has successfully resubmitted the FDA New Drug Application (NDA) for Sofdra (Sofpironium Bromide) ahead of schedule (originally planned for 1Q CY24).

Anticipated FDA approval has been brought forward to late 2Q CY24.

## Impact

The FDA now has 30 days to confirm that BOT's resubmission constitutes a "Complete Response" to its letter, initiating the NDA review period.

Notably, the FDA will also clarify whether the review is a:

- Class 1 - 6 month review (expected); or
- Class 2 - 2 month review (less expected)

BOT is expecting a Class 1, 6-month review, implying FDA approval late 2Q CY24.

The resubmission follows the successful human factors (HF) validation study, in which all participants successfully prepared and correctly applied Sofdra gel to their armpits in accordance with the revised instructions for use (IFU).

In parallel, commercial preparations for launch are underway, with the company targeting a launch shortly after approval.

BOT is focused on engaging US payers (insurers) around contracting and pricing, preparing patient and physician-focused launch marketing and sales materials, testing telemedicine and supply chain elements, and finalising sales strategies.

## Action

We maintain our **Speculative Buy recommendation and \$0.30/sh Price Target**.

The earlier than expected FDA NDA resubmission is highly encouraging, indicative of management under promising and over delivering.

We continue to see a solid buying opportunity following the Complete Response Letter (CRL) received in September.

As a reminder, the CRL solely pertained to patient instructions (specifically the instructions paper and product carton wording) — a minor issue in the broader context.

Compared to other ASX-listed cases of CRL's, BOT's appears to be the lowest risk and most manageable. Moreover, the same examples indicate most CRLs eventually secure approval, with precedent of a re-rate following refiling and into approval.

## Catalysts

- NDA Confirmation - within 30 days
- FDA Approval - late 2Q CY24

Share Price	0.17	A\$/sh
<b>Price Target</b>	<b>0.30</b>	<b>A\$/sh</b>
Valuation	0.30	A\$/sh

Shares on issue	1,684	m, dil
Market Capitalisation	286.3	A\$m
Enterprise Value	256.1	A\$m
Debt	0.0	A\$m
Cash (Proforma)	23.4	A\$m
Unpaid capital	6.7	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 Growth (%)	-0.8	-3.6	12.2
NPAT Growth (%)	-0.7	-2.2	16.5
Normalised EPS (Ac)	-0.2	0.2	3.2
Norm. EPS gwth (%)	-0.8	-2.2	16.5
PER (x)	-102.8	84.1	4.8
EV/EBITDA (x)	-158.2	60.6	4.6
EV/Revenue (x)	75.7	4.1	1.7
Net Cash (A\$m)	19.7	18.6	55.7

## Performance



Source: IRESS

Income Statement	24F	25F	26F	Performance Ratios	24F	25F	26F
Net Sales	0.0	60.8	146.0	<b>Growth &amp; Margins</b>			
Royalties	0.9	1.0	1.2	Revenue Growth	-12%	1727%	138%
Other (inc R&D)	2.5	0.0	0.0	EBITDA Growth	-82%	-361%	1220%
<b>Total Revenue</b>	<b>3.4</b>	<b>61.8</b>	<b>147.2</b>	EBIT Growth	-72%	-222%	1652%
(-) COGS (inc. roy)	0.0	-14.6	-33.6	Net Profit Growth	-72%	-222%	1652%
<b>Gross Profit</b>	<b>3.4</b>	<b>47.2</b>	<b>113.6</b>	<b>Margins</b>			
(-) R&D	0.0	0.0	0.0	EBITDA margin	-48%	7%	38%
(-) SG&A	-5.0	-43.0	-57.8	EBIT margin	-75%	5%	37%
<b>EBITDA</b>	<b>-1.6</b>	<b>4.2</b>	<b>55.8</b>	Net profit margin	-75%	5%	37%
(-) D&A	-0.9	-1.1	-1.2	Effective tax rate	0%	0%	0%
<b>EBIT</b>	<b>-2.5</b>	<b>3.1</b>	<b>54.6</b>	<b>Liquidity</b>			
(-) Net finance	0.0	0.0	0.0	Capex/depreciation	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0	Current ratio	24.5	4.8	9.6
<b>PBT</b>	<b>-2.5</b>	<b>3.1</b>	<b>54.6</b>	Quick ratio	24.6	3.6	7.6
(-) Tax	0.0	0.0	0.0	Receivable days	60.0	42.5	41.1
<b>NPAT</b>	<b>-2.5</b>	<b>3.1</b>	<b>54.6</b>	Payable days	60.0	60.0	60.0
(+/-) Adj.	0.0	0.0	0.0	<b>Risk Measures</b>			
<b>Norm NPAT</b>	<b>-2.5</b>	<b>3.1</b>	<b>54.6</b>	Dividend Cover	na	na	na
<b>Cash Flow Statement</b>	<b>24F</b>	<b>25F</b>	<b>26F</b>	Payout ratio	0%	0%	0%
<b>NPAT</b>	<b>-2.5</b>	<b>3.1</b>	<b>54.6</b>	Net interest cover	na	na	na
(+) D&A	0.9	1.1	1.2	Net debt/equity	-0.4	-0.4	-0.5
(+) Non-cash expenses	0.0	0.0	0.0	<b>Returns</b>			
(-) Leases	-0.1	-0.1	-0.1	ROIC	-4%	5%	37%
(+/-) Other	0.0	0.0	0.0	ROA	-6%	6%	49%
<b>Gross Cash Flow</b>	<b>-1.7</b>	<b>4.1</b>	<b>55.7</b>	ROE	-6%	6%	53%
(-) Capital expenditure	0.0	0.0	0.0	<b>Share Data/Valuation</b>	<b>24F</b>	<b>25F</b>	<b>26F</b>
(+/-) Working capital	-1.3	-5.4	-18.6	Issued shares	1,541.1	1,541.1	1,541.1
<b>Operating Free Cash Flow</b>	<b>-3.1</b>	<b>-1.3</b>	<b>37.0</b>	Weighted ave shares	1,426.8	1,541.1	1,541.1
(-) Acquisition	-12.1	0.0	0.0	Fully diluted shares	1,684.0	1,684.0	1,684.0
(-) Milestone payment	0.0	0.0	0.0	Basic EPS	-0.2	0.2	3.5
(+) Placement	24.6	0.0	0.0	YoY change	-76%	-222%	1652%
(+) Disposal	0.0	0.0	0.0	Fully diluted EPS	-0.2	0.2	3.2
(+/-) Other	0.0	0.0	0.0	YoY change	-76%	-222%	1652%
<b>Net Cash Flow</b>	<b>9.4</b>	<b>-1.3</b>	<b>37.0</b>	Fully diluted normalised EPS	-0.2	0.2	3.2
				YoY change	-76%	-222%	1652%
BoP Net Cash / (Debt)	10.2	19.7	18.6	Dividend/share	0.0	0.0	0.0
(+/-) Net Cash Flow	9.4	-1.3	37.0	Franking	na	na	na
(+/-) Other	0.1	0.1	0.1	Gross cash flow/share	-0.1	0.3	3.6
<b>EoP Net Cash / (Debt)</b>	<b>19.7</b>	<b>18.6</b>	<b>55.7</b>	NBV/share	2.9	3.1	6.7
<b>Balance Sheet</b>	<b>24F</b>	<b>25F</b>	<b>26F</b>	NTA/Share	1.5	1.8	5.4
Cash	19.7	18.6	55.7	<b>Valuation</b>			
Inventory	3.5	8.5	20.2	PER (Basic) (x)	-102.8	84.1	4.8
Receivables	0.6	7.2	16.6	PER (Fully diluted) (x)	-112.3	91.9	5.2
Other	0.1	0.1	0.1	PER (Fully diluted, normalized) ...	-112.3	91.9	5.2
<b>Current Assets</b>	<b>23.9</b>	<b>34.3</b>	<b>92.5</b>	P/CFPS (x)	-150.5	63.9	4.7
PP&E	0.0	0.0	0.0	Price/NBV (x)	5.8	5.5	2.6
Intangible	21.9	20.8	19.7	Price/NTA (x)	11.4	9.6	3.2
ROUA	0.0	0.0	0.0	Dividend Yield (%)	0.0	0.0	0.0
Other	0.1	0.1	0.1	EV/EBITDA (x)	-158.2	60.6	4.6
<b>Non-current Assets</b>	<b>22.1</b>	<b>21.0</b>	<b>19.7</b>	EV/EBIT (x)	-100.5	82.2	4.7
<b>Total Assets</b>	<b>45.9</b>	<b>55.3</b>	<b>112.3</b>	EV/Revenue (x)	75.7	4.1	1.7
Payables	0.8	7.1	9.5				
Lease liabilities	0.0	0.0	0.0				
Provisions	0.2	0.2	0.2				
<b>Current Liabilities</b>	<b>1.0</b>	<b>7.2</b>	<b>9.7</b>				
Lease liabilities	0.0	0.0	0.0				
<b>Non-current liabilities</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>				
<b>Total liabilities</b>	<b>1.0</b>	<b>7.2</b>	<b>9.7</b>				
<b>Net Assets</b>	<b>44.9</b>	<b>48.1</b>	<b>102.6</b>				
Issued Capital	118.1	118.1	118.1				
Reserves	6.4	6.4	6.4				
Retained earnings	-79.5	-76.4	-21.8				
<b>Total equity</b>	<b>45.0</b>	<b>48.1</b>	<b>102.7</b>				

## Forecasts

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

**Figure 1: US Sofpironium Bromide (SB) Forecasts**

US SB Forecasts	Units	FY2025	FY2026	FY2027	FY2028	FY2029	FY2030	FY2031	FY2032	FY2033
<b>Prescriptions Sold</b>	<b>'000s</b>	<b>72.0</b>	<b>168.0</b>	<b>228.0</b>	<b>276.0</b>	<b>312.0</b>	<b>348.0</b>	<b>384.0</b>	<b>420.0</b>	<b>456.0</b>
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%
<b>Net Sales</b>	<b>US\$m</b>	<b>38.9</b>	<b>93.4</b>	<b>130.6</b>	<b>162.9</b>	<b>189.6</b>	<b>217.9</b>	<b>247.6</b>	<b>278.9</b>	<b>311.9</b>
<b>(-) COGS</b>	<b>US\$m</b>	<b>-7.4</b>	<b>-16.8</b>	<b>-22.2</b>	<b>-26.1</b>	<b>-28.4</b>	<b>-32.7</b>	<b>-37.1</b>	<b>-41.8</b>	<b>-46.8</b>
<b>Gross Profit</b>	<b>US\$m</b>	<b>31.5</b>	<b>76.6</b>	<b>108.4</b>	<b>136.8</b>	<b>161.2</b>	<b>185.2</b>	<b>210.5</b>	<b>237.1</b>	<b>265.1</b>
...Gross Margin	%	81%	82%	83%	84%	85%	85%	85%	85%	85%
<b>(-) SG&amp;A</b>	<b>US\$m</b>	<b>-27.5</b>	<b>-37.0</b>	<b>-39.2</b>	<b>-44.8</b>	<b>-47.4</b>	<b>-49.0</b>	<b>-49.5</b>	<b>-55.8</b>	<b>-62.4</b>
...as % of Net sales	%	71%	40%	30%	28%	25%	23%	20%	20%	20%
<b>(-) Royalty</b>	<b>US\$m</b>	<b>-1.9</b>	<b>-4.7</b>	<b>-6.5</b>	<b>-8.1</b>	<b>-9.5</b>	<b>-10.9</b>	<b>-12.4</b>	<b>-13.9</b>	<b>-15.6</b>
...as % of Net sales	%	5%	5%	5%	5%	5%	5%	5%	5%	5%
<b>Operating Income</b>	<b>US\$m</b>	<b>2.0</b>	<b>35.0</b>	<b>62.7</b>	<b>83.9</b>	<b>104.3</b>	<b>125.3</b>	<b>148.6</b>	<b>167.4</b>	<b>187.2</b>

Source: EH estimate

\*based on 12 scripts/pa

\*\*based on 3.7m target patient population

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Botanix Pharmaceuticals Limited (BOT.ASX) | Price A\$0.170 | Target price A\$0.300 | Recommendation Speculative Buy;

*Price, target price and rating as at 21 December 2023 (\* not covered)*

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