



# BOT: FDA Approval On Track For Late June

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

PRICE  
**A\$0.175/sh**

TARGET PRICE  
**A\$0.30/sh**  
(UNCHANGED)

RECOMMENDATION  
**SPECULATIVE BUY**  
(UNCHANGED)

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## Event

The FDA has accepted BOT's New Drug Application (NDA) resubmission of *Sofdra* (Sofpironium Bromide) as a complete response.

Further, the FDA confirmed the resubmission is a class-2 response (6-months review period from December submission) as expected, placing approval on target for late June.

## Impact

FDA approval remains on track for late June 2024.

In parallel, commercial preparations for launch remain underway, with the company targeting a rapid launch following approval.

BOT has been 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

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.

Supporting this view, we continue to note ASX-listed CRL's aren't all that uncommon, with observations: 1) Most eventually get approved, and 2) BOT's appears to be the lowest risk and most manageable.

Moreover, there is precedent of a re-rate throughout review and into approval.

## Catalysts

- FDA Approval - Late June 2024
- Commercial Launch/First US Sales

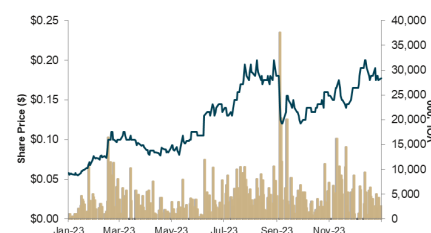
Share Price	0.175	A\$/sh
Price Target	<b>0.30</b>	<b>A\$/sh</b>
Valuation	0.30	A\$/sh

Shares on issue	1,684	m, dil
Market Capitalisation	294.7	A\$m
Enterprise Value	264.5	A\$m
Debt	0.0	A\$m
Cash (Proforma)*	24.9	A\$m
Unpaid capital	5.3	A\$m

\*Inc options/R&D

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	3.2
Norm. EPS gwth (%)	-0.8	-2.2	16.5
PER (x)	-105.8	86.6	4.9
EV/EBITDA (x)	-163.5	62.6	4.7
EV/Revenue (x)	78.2	4.3	1.8
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)	-105.8	86.6	4.9
Receivables	0.6	7.2	16.6	PER (Fully diluted) (x)	-115.6	94.6	5.4
Other	0.1	0.1	0.1	PER (Fully diluted, normalized) ...	-115.6	94.6	5.4
<b>Current Assets</b>	<b>23.9</b>	<b>34.3</b>	<b>92.5</b>	P/CFPS (x)	-154.9	65.7	4.8
PP&E	0.0	0.0	0.0	Price/NBV (x)	6.0	5.6	2.6
Intangible	21.9	20.8	19.7	Price/NTA (x)	11.7	9.9	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)	-163.5	62.6	4.7
<b>Non-current Assets</b>	<b>22.1</b>	<b>21.0</b>	<b>19.7</b>	EV/EBIT (x)	-103.8	84.9	4.8
<b>Total Assets</b>	<b>45.9</b>	<b>55.3</b>	<b>112.3</b>	EV/Revenue (x)	78.2	4.3	1.8
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>				

## Analysis

We remain confident on BOT securing FDA approval.

BOT's complete response letter (CRL) solely pertained to patient instructions (specifically the instructions paper and product carton wording) — a minor issue in the broader context.

ASX-listed instances of CRL's aren't that all uncommon (Figure 1), 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 than 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 1: 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

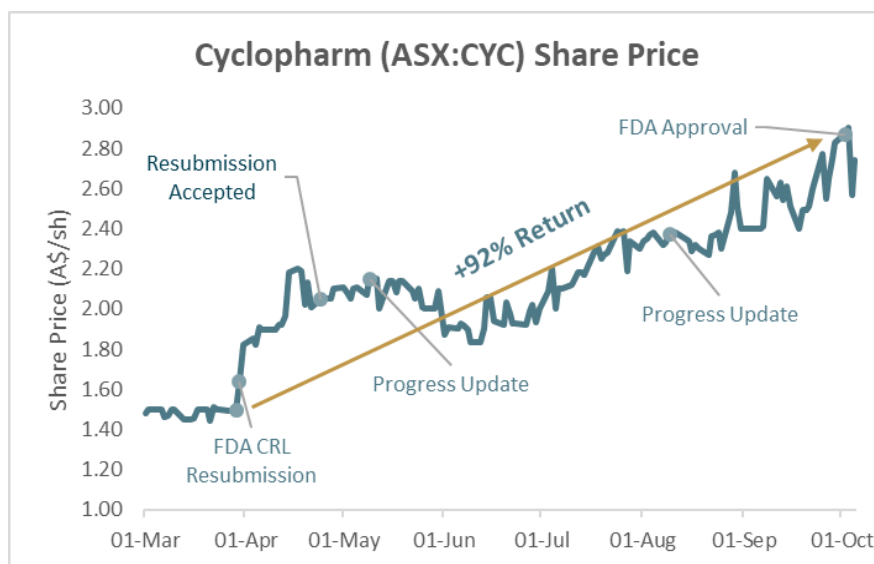
Source: Company announcements, EH analysis

\*Non exhaustive, as only lists the first instance of CRL, noting some of the applications received multiple CRLs

The most recent example of a CRL being approved is Cyclopharm (ASX: CYC), which received FDA approval for its 'Technegas' product in early October 2023. CYC originally received a CRL in June 2021.

From refiling to FDA approval, the CYC share price nearly doubled (Figure 2).

**Figure 2: Cyclopharm (CYC) Share Price**



Source: IRESS, EH analysis

## Forecasts

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

**Figure 3: 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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*Price, target price and rating as at 22 January 2024 (\* not covered)*

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