

BOT: Positive FDA End of Review Meeting

BOT.ASX | BOTANIX PHARMACEUTICALS LIMITED | HEALTHCARE | BIOTECHNOLOGY

PRICE
A\$0.175/sh

TARGET PRICE
A\$0.300/sh
(UNCHANGED)

RECOMMENDATION
SPECULATIVE BUY
(UNCHANGED)

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Event

BOT has received the expected feedback from the FDA on its Type A "end of review" meeting request regarding the *Sofdra* (Sofpironium Bromide) new drug application (NDA) review.

Impact

Feedback was positive.

The FDA confirmed the planned content of materials proposed by BOT would be acceptable, with NO additional materials requested for the resubmission of the *Sofdra* NDA package.

These materials are limited to:

- Revised patient instructions for use ("IFU").
- New human factors validation study protocol and report.
- Updated use-related risk analysis and updated draft prescribing information.
- Carton and container labels; and
- Proposed proprietary name (*Sofdra*) submission.

BOT will also bring forward the annual safety update to the FDA including the pharmacovigilance report from Japan and any new safety findings reported in the scientific literature (which would otherwise usually be filed in March each year).

All these materials are either prepared or will be finalised in preparation for the planned resubmission in early 1Q CY2024, enabling a targeted approval in mid-CY2024.

Action

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

We continue to see a solid buying opportunity post the recent complete response letter (CRL).

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.

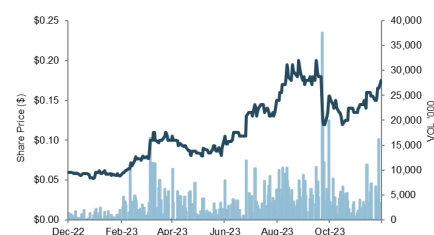
Compared to other ASX-listed cases of CRL's, BOT's appears to be the lowest risk and most manageable. Moreover, the same examples indicate most CRLs eventually secure approval, with precedent of a re-rate following refiling and into approval.

Catalysts

- Finalise Instructions for Use / Conduct Human Factor Study - 4Q CY23
- Re-submit to FDA - 1Q CY24
- FDA Approval - Mid CY24

Share Price	0.175	A\$/sh	
Price Target	0.30	A\$/sh	
Valuation	0.30	A\$/sh	
Shares on issue	1,684	dil, m	
Market Capitalisation	294.7	A\$m	
Enterprise Value	265.0	A\$m	
Debt	0.0	A\$m	
Cash (Proforma)	23.0	A\$m	
Unpaid capital	6.7	A\$m	
Key Financial 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 Cashflow (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 growth (%)	-0.8	-2.2	16.5
PER (x)	-105.8	86.6	4.9
EV/EBITDA (x)	-163.7	62.7	4.8
EV/Revenue (x)	78.4	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	Growth & Margins			
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%
Total Revenue	3.4	61.8	147.2	EBIT Growth	-72%	-222%	1652%
(-) COGS (inc. roy)	0.0	-14.6	-33.6	Net Profit Growth	-72%	-222%	1652%
Gross Profit	3.4	47.2	113.6	Margins			
(-) 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%
EBITDA	-1.6	4.2	55.8	Net profit margin	-75%	5%	37%
(-) D&A	-0.9	-1.1	-1.2	Effective tax rate	0%	0%	0%
EBIT	-2.5	3.1	54.6	Liquidity			
(-) 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
PBT	-2.5	3.1	54.6	Quick ratio	24.6	3.6	7.6
(-) Tax	0.0	0.0	0.0	Receivable days	60.0	42.5	41.1
NPAT	-2.5	3.1	54.6	Payable days	60.0	60.0	60.0
(+/-) Adj.	0.0	0.0	0.0	Risk Measures			
Norm NPAT	-2.5	3.1	54.6	Dividend Cover	na	na	na
Cash Flow Statement	24F	25F	26F	Payout ratio	0%	0%	0%
NPAT	-2.5	3.1	54.6	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	Returns			
(-) Leases	-0.1	-0.1	-0.1	ROIC	-4%	5%	37%
(+/-) Other	0.0	0.0	0.0	ROA	-6%	6%	49%
Gross Cash Flow	-1.7	4.1	55.7	ROE	-6%	6%	53%
(-) Capital expenditure	0.0	0.0	0.0	Share Data/Valuation	24F	25F	26F
(+/-) Working capital	-1.3	-5.4	-18.6	Issued shares	1,541.1	1,541.1	1,541.1
Operating Free Cash Flow	-3.1	-1.3	37.0	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%
Net Cash Flow	9.4	-1.3	37.0	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
EoP Net Cash / (Debt)	19.7	18.6	55.7	NBV/share	2.9	3.1	6.7
				NTA/Share	1.5	1.8	5.4
Balance Sheet	24F	25F	26F	Valuation			
Cash	19.7	18.6	55.7	PER (Basic) (x)	-105.8	86.6	4.9
Inventory	3.5	8.5	20.2	PER (Fully diluted) (x)	-115.6	94.6	5.4
Receivables	0.6	7.2	16.6	PER (Fully diluted, normalized) (x)	-115.6	94.6	5.4
Other	0.1	0.1	0.1	P/CFPS (x)	-154.9	65.7	4.8
Current Assets	23.9	34.3	92.5	Price/NBV (x)	6.0	5.6	2.6
PP&E	0.0	0.0	0.0	Price/NTA (x)	11.7	9.9	3.2
Intangible	21.9	20.8	19.7	Dividend Yield (%)	0.0	0.0	0.0
ROUA	0.0	0.0	0.0	EV/EBITDA (x)	-163.7	62.7	4.8
Other	0.1	0.1	0.1	EV/EBIT (x)	-104.0	85.1	4.9
Non-current Assets	22.1	21.0	19.7	EV/Revenue (x)	78.4	4.3	1.8
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				

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Botanix Pharmaceuticals Limited (BOT.ASX) | Price A\$0.175 | Target price A\$0.300 | Recommendation Speculative Buy;

Price, target price and rating as at 04 December 2023 (not covered)*

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