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EUROZ HARTLEYS

BOT: Nothing To Sweat About

BOT.ASX | BOTANIX PHARMACEUTICALS LIMITED | HEALTHCARE | BIOTECHNOLOGY

PRICE	TARGET PRICE	RECOMMENDATION	ANALYST
A$0.140/sh	**A$0.310/sh** (FROM A$0.330/sh)	**SPECULATIVE BUY** (UNCHANGED)	**SETH LIZEE** SLIZEE@EUROZHARTLEYS.COM

Event

BOT has been issued a Complete Response Letter (CRL) from the US FDA for its New Drug Application (NDA) of Sofpironium Bromide (SB).

A CRL communicates that the FDA cannot approve the NDA in its current form and recommends actions required to support approval.

Impact

While this was not the desired outcome, it is far from a complete disaster.

The ONLY deficiency listed related to the patient instructions (a piece of paper inserted in the carton instructing how to use the product) and wording on the product carton.

Importantly, the **FDA raised NO issues with the most critical parts of the application – safety, efficacy, or manufacturing. No additional clinical studies are required either.**

The FDA has outlined the following requests within the CRL to support resubmission:

- Add the word "applicator" to the bottle.
- Reformat the instructions so it does not fold and revise the instructions to further simplify the guidance for application.
- Add "wash hands with soap and water immediately after use" on the outside of the carton and bottle; and
- Conduct a human factor study (this is not a clinical study) which demonstrates the revised instructions can be followed (ie patients understand how to use the drug).

BOT will now meet with the FDA and undertake the relatively minor activities required to resubmit the NDA by early Q1'CY24, with a target approval of mid-CY24.

The company is well funded to complete the resubmission with an anticipated delay in commercial launch from 1Q'CY24 of 3-6 months.

Consequently, we have pushed back our forecasts by circa 6 months to early FY25.

Action

We maintain our Speculative Buy recommendation with an updated $0.31/sh PT

While the delay is frustrating, the investment case remains intact. Further, the absence of any other issues in the CRL suggests an even greater likelihood of eventual approval.

Hence, we view any major weakness in the share price as a buying opportunity.

Moreover, we note BOT could attract opportunistic M&A interest from larger pharmaceutical companies who better understand the lower risks with this CRL.

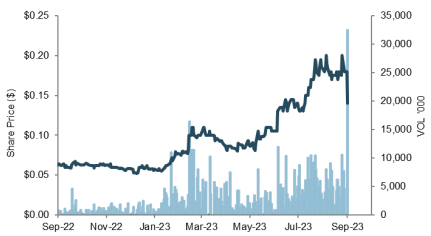
Catalysts

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

Share Price	0.14	A$/sh
Price Target	**0.31**	**A$/sh**
Valuation	0.31	A$/sh
Shares on issue	1,588	m, dil
Market Capitalisation	222.3	A$m
Enterprise Value	203.4	A$m
Debt	0.0	A$m
Cash (Proforma)	10.7	A$m
Unpaid capital	8.2	A$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$m)	-2.5	3.1	54.6
Normalised NPAT (A...	-2.5	3.1	54.6
Gross Cashflow (A$m)	-1.7	4.1	55.7
Capex (A$m)	0.0	0.0	0.0
Op. Free Cash flow (...	-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	3.4
Norm. EPS growth (%)	-0.7	-2.2	16.5
PER (x)	-78.1	63.9	3.6
EV/EBITDA (x)	-125.6	48.1	3.6
EV/Revenue (x)	60.1	3.3	1.4

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	12.5	10.0	0.0
(+) Disposal	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0
Net Cash Flow	**-2.7**	**8.7**	**37.0**
BoP Net Cash / (Debt)	10.2	7.6	16.5
(+/-) Net Cash Flow	-2.7	8.7	37.0
(+/-) Other	0.1	0.1	0.1
EoP Net Cash / (Debt)	**7.6**	**16.5**	**53.7**

Balance Sheet	24F	25F	26F
Cash	7.6	16.5	53.7
Inventory	3.5	8.5	20.2
Receivables	0.6	7.2	16.6
Other	0.1	0.1	0.1
Current Assets	**11.8**	**32.3**	**90.5**
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	**33.8**	**53.2**	**110.2**
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	**32.9**	**46.0**	**100.6**
Issued Capital	106.0	116.0	116.0
Reserves	6.4	6.4	6.4
Retained earnings	-79.5	-76.4	-21.8
Total equity	**32.9**	**46.0**	**100.6**

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	12.1	4.5	9.4
Quick ratio	10.0	3.4	7.4
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	-0.2	-0.4	-0.5
Returns			
ROIC	-5%	5%	38%
ROA	-8%	6%	50%
ROE	-8%	7%	54%

Share Data/Valuation	24F	25F	26F
Issued shares	1,421.2	1,421.2	1,421.2
Weighted ave shares	1,366.8	1,421.2	1,421.2
Fully diluted shares	1,587.5	1,587.5	1,587.5
Basic EPS	-0.2	0.2	3.8
YoY change	-74%	-222%	1652%
Fully diluted EPS	-0.2	0.2	3.4
YoY change	-75%	-222%	1652%
Fully diluted normalised EPS	-0.2	0.2	3.4
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	3.9
NBV/share	2.3	3.2	7.1
NTA/Share	0.8	1.8	5.7
Valuation			
PER (Basic) (x)	-78.1	63.9	3.6
PER (Fully diluted) (x)	-87.2	71.3	4.1
PER (Fully diluted, normalized) (x)	-87.2	71.3	4.1
P/CFPS (x)	-114.3	48.5	3.6
Price/NBV (x)	6.1	4.3	2.0
Price/NTA (x)	18.2	7.9	2.5
Dividend Yield (%)	0.0	0.0	0.0
EV/EBITDA (x)	-125.6	48.1	3.6
EV/EBIT (x)	-79.8	65.3	3.7
EV/Revenue (x)	60.1	3.3	1.4

Overview

The US Food and Drug Administration (FDA) has issued BOT a Complete Response Letter (CRL) for its New Drug Application (NDA) of Sofpironium Bromide.

A CRL communicates that the FDA cannot approve the NDA in its current form and recommends actions required to support approval.

In BOT's case, **the ONLY deficiency listed related to the patient instructions** (a piece of paper inserted in the carton instructing how to use the product) and wording on the product carton.

Importantly, the **FDA raised NO issues with the most critical parts of the application – safety, efficacy, or manufacturing.** Moreover, **NO additional clinical studies are required to support resubmission and approval.**

The FDA has outlined the following requests within the CRL to support resubmission:

- Add the word "applicator" to the bottle.
- Reformat the instructions so it does not fold and revise the instructions to further simplify the guidance for application.
- Add "wash hands with soap and water immediately after use" on the outside of the carton and bottle; and
- Conduct a human factor study (this is not a clinical study) which confirms the revised instructions can be followed (ie demonstrate patients understand how to use the drug).

Next Steps

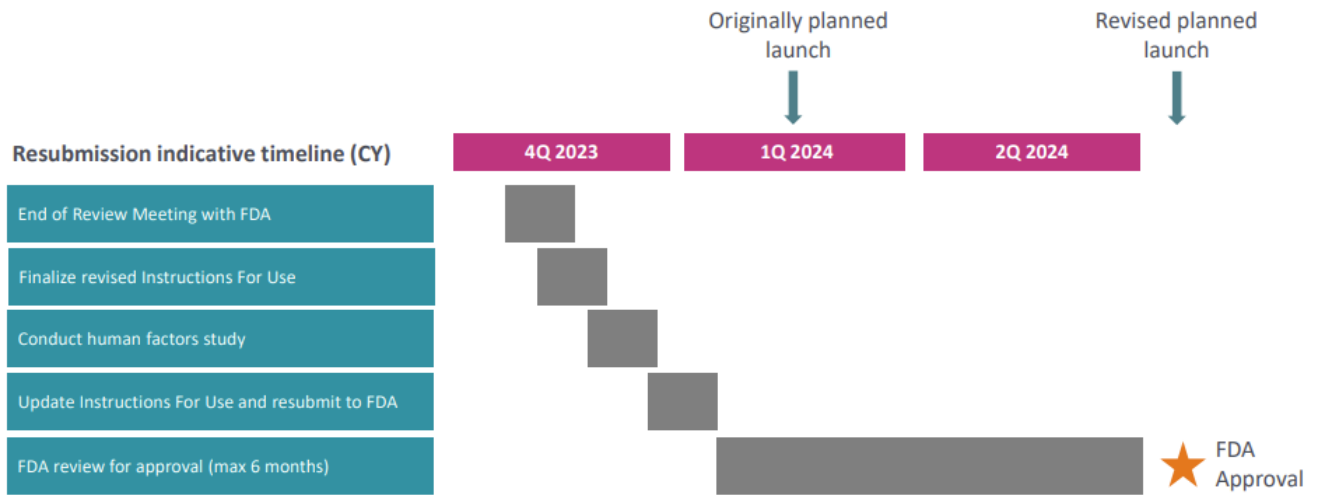
BOT will now meet with the FDA and undertake these relatively minor activities required to address the product use instructions and resubmit the NDA by early Q1'CY24, with a target approval of mid-CY24.

The company has stated they are currently preparing an updated Instructions For Use document, which reflects the FDA's guidelines and feedback, and are moving quickly to schedule the human factors validation study required for resubmission.

The company is well funded to complete the resubmission with an anticipated delay in commercial launch from 1Q'CY24 of 3-6 months.

The expected timeline to resubmission is outlined as follows (Figure 1).

Figure 1: Updated Approval and Commercial Launch Timeline



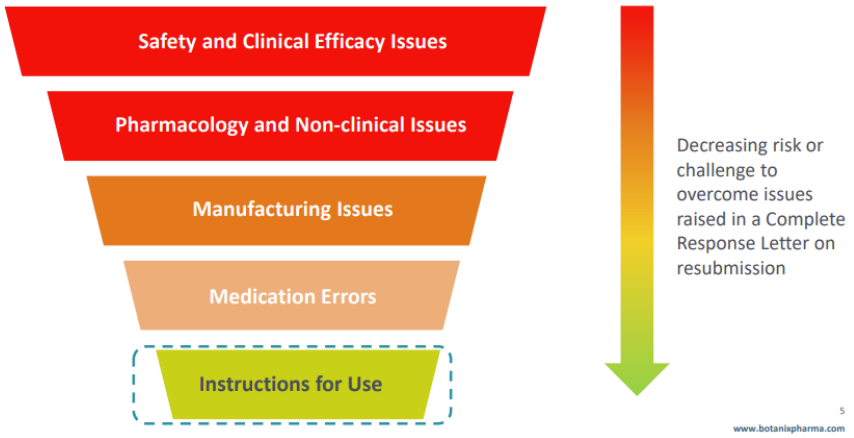
Source: Company presentation

Analysis

Complete Response Letters can be issued in relation to various issues, some more significant than others (Figure 2).

In the case of BOT, we believe the deficiencies listed are very manageable and low risk.

Figure 2: Potential CRL Deficiencies



Source: company presentation

We can further demonstrates this by comparing BOTs complete response letter to other ones received in the past by ASX companies (Figure 3).

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	Under review

Source: Company announcements, EHL analysis
**Non exhaustive, as only lists the first instance of CRL, noting some of the applications received multiple CRLs*

Out of the drugs listed above, we note most were eventually approved despite receiving a complete response letter (or multiple letters), with only one withdrawn.

Moreover, it is very clear the deficiencies listed in these other examples are much more significant then the ones BOT has received. We would go further to say BOT has one of the most manageable and low risk CRL's out of all of these comparisons.

Forecasts

As a consequence of the delay in approval, we have pushed back our forecasts by circa 6 months. We had previously modelled a commercial launch in early CY24, we now anticipate a launch around mid CY24 (early FY25).

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

Figure 4: US Sofpironium Bromide 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 estimate
**based on 12 scripts/pa*
***based on 3.7m target patient population*

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The companies and securities mentioned in this report, include:

Botanix Pharmaceuticals Limited (BOT.ASX) | Price A$0.140 | Target price A$0.310 | Recommendation Speculative Buy;

Price, target price and rating as at 27 September 2023 (not covered)*

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