EUROZ HARTLEYS

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FDA NEW DRUG APPLICATION (NDA) FORMALLY UNDER REVIEW

BOT.ASX | BOTANIX PHARMACEUTICALS LIMITED | HEALTHCARE

PRICE	TARGET PRICE	RECOMMENDATION	ANALYST
A$ 0.06	**A$ 0.27** (FROM A$ 0.27)	**SPECULATIVE BUY** (FROM SPECULATIVE BUY)	**SETH LIZEE** SLIZEE@EUROZHARTLEYS.COM

Event

BOT has successfully received confirmation from the FDA that the Sofpironium Bromide New Drug Application (NDA) is now formally under review.

Impact

This FDA communication initiates the formal review process, and follows BOT's earlier September NDA submission. The FDA confirmed there were no filing review issues identified and that the NDA was sufficiently complete to permit substantive review.

The FDA has granted Sofpironium Bromide a standard review (as expected), approval for the product remains on track for 3Q CY23.

Additionally, the FDA confirmed they do not believe that an advisory committee meeting is required, we indicatively view this as a positive, considering advisory committees are sometimes convened to assist in the review of complex applications or when opinions of independent experts/public is viewed as important to the FDA decision making process.

In the meantime, we can expect a mid-cycle review in 1Q CY23, which will provide further feedback on the progress of the FDA review.

Overall, we view this is as yet another milestone met, bringing BOT one step closer to potential FDA approval, and in time commercialisation.

Furthermore, as previously announced, the receipt of a positive day-74 letter triggers a US$2m milestone payment to Fresh Tracks Therapeutics (formerly Brickell Biotech).

Action

Speculative Buy, $0.27 Price Target

BOT remains very cheap and continues to trade at a significant discount to peers, this is despite the company making solid progress with its lead asset Sofpironium Bromide amongst other recent positive news.

Our analysis suggests BOT may be the cheapest ASX-listed company to have filled for an NDA (on its first asset) with the FDA (Figure 1).

Furthermore, companies undertaking an FDA review on their first drug have typically re-rated through the process, re-rating an average +60% by the day-74 response per our analysis, whereas BOT has traded sideways over this same timeframe (Figure 2).

We believe Sofpironium Bromide could potentially do +A$130m of sales in the USA within its first year based on the number of prescriptions the drug is currently doing through its partner in Japan, a country which has a population nearly a third the size of the USA.

Management is in a solid position to execute, with the highly experienced team having previously developed, secured FDA approval for, and commercialised +30 products.

In our view, the takeaway from all of this is that there is significant upside to the current share price if BOT is even modestly successful.

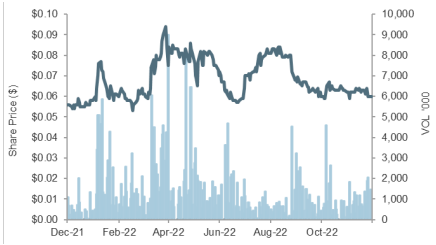
Catalyst

- Mid-cycle review – 1Q CY23
- FDA Approval – 3Q CY23

Share Price	0.06	A$/sh
Price Target	**0.27**	**A$/sh**
Valuation	0.27	A$/sh
Shares on issue	1,283	m, Dil
Market Capitalisation	77.0	A$m
Enterprise Value	53.8	A$m
Debt (Pro-forma)	0.0	A$m
Cash (Pro-forma)	15.4	A$m
Unpaid cap	7.8	A$m

Directors & Management	
Vince Ippolito	Chair
Matthew Callahan	ED
Dr William Bosch	ED
Dr Stewart Washer	ED
Danny Sharp	NED
Howie Mckibbon	COO
Dr Patricia Walker	CMO
Anthony Robinson	VP
Dr Jack Hoblitzell	SVP
Dr Ira Lawrence	Adv.
Dr Clarence Young	Adv.
Lynda Berne	Adv.

Performance



Source: IRESS

Analysis - Cheapest NDA Filing on ASX?

- We have attempted to explore what the market has paid for companies in this position in the past (specifically, companies securing approval on their first drug)
- In our analysis, we found 7 ASX listed companies that have previously (or are in the process) secured an FDA approval, as shown below (Figure 1):

Figure 1: Peer comparables

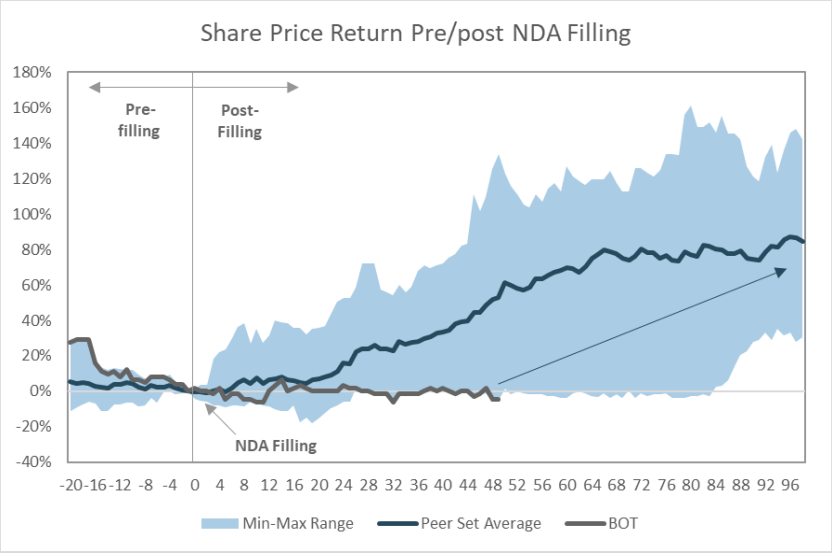
				Market Cap (A$m)[2]		
Ticker	Company	Product[1]	Approval Date	NDA-filling	FDA Approval	%change
ACR	Acrux	Evamist©	31-Jul-07	113	260	130%
PXS	Pharmaxis	Aridol©	6-Oct-10	260	561	116%
CUV	Clinuvel	SCENESSE©	9-Oct-19	593	2,232	276%
TLX	Telix	Illuccix©	20-Dec-21	491	2,460	401%
NEU	Neuren	Trofinetide	n/a[3]	521	n/a[3]	n/a[3]
			Average	396	1,378	231%
			Min	113	260	
			Max	593	2,460	

[1] *First approved product*
[2] *Fully diluted*
[3] *Not Yet approved (currently under review)*

Source: EHL analysis, company announcements, IRESS
[note: excludes CSL (diversified business) & MYX (first drug approved before listed)]

- Whilst these companies are in varying positions (different disease areas, some with licensing agreements already in place, ex. US approvals, and/or multiple other products) – indicatively, the market has paid ~A$110-600 million on FDA NDA filing day (pre- FDA approval) and ~A$250-2,500 million upon FDA approval.
- BOT trades well below every single comp listed above with a fully diluted $77 million market cap, which per our analysis would make it one of the cheapest ASX companies seeking FDA approval on their first drug
- Taking this analysis a step further, we can see these same companies have on average seen a progressive re-rate through the FDA review process, whereas BOT has traded sideways over this same time period (Figure 2).

Figure 2: Peer comparables, share price performance



Source: EHL analysis, company announcements, IRESS

- The company in our view has been priced to failure, this is in spite of various recent achievements, and the backing of a highly experienced management team who have previously developed, secured FDA approval for, and commercialised over 30 dermatology products.
- The takeaway from all of this is that there is significant upside to be captured if BOT is even modestly successful.

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Botanix Pharmaceuticals Limited (BOT.ASX) | Price A$0.06 | Target price A$0.27 | Recommendation Speculative Buy;

Price, target price and rating as at 08 December 2022 (not covered)*

Additional disclosures

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