EUROZ HARTLEYS

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BOT: Successful FDA Mid-Cycle Review

BOT.ASX | BOTANIX PHARMACEUTICALS LIMITED | HEALTHCARE

PRICE	TARGET PRICE	RECOMMENDATION	ANALYST
A$ 0.098	**A$ 0.280** (FROM A$ 0.270)	**SPECULATIVE BUY** (FROM SPECULATIVE BUY)	**SETH LIZEE** SLIZEE@EUROZHARTLEYS.COM

Event

BOT has successful completed its FDA mid-cycle review meeting for Sofpironium Bromide.

The company has raised $10 million via a single tranche placement at $0.09/sh, with funds to be allocated towards commercialisation activities ahead of FDA approval later this year.

Impact

The FDA communication read very positively, with no significant issues identified as part of the review process, including no major clinical safety issues or risk management issues.

Furthermore, the FDA confirmed no advisory board meeting would be required, adding that the application, in its view, presented no novel or complex regulatory issues. We continue to view this as a positive.

Finally, the FDA indicated that continued discussions will now focus on labelling, clinical outcome assessments, patient instructions and brand name.

In our view, this represents a substantial de-risking of the approval, as we view the progression towards labelling discussions amongst other items to infer the FDA is largely satisfied with the primary aspects of the review.

FDA approval remains on track for September this year.

Action

We maintain our Speculative Buy recommendation with an increased $0.28/sh. PT

BOT remains considerably undervalued in comparison to its peers and our risked valuation. This is in the face of an FDA approval decision in sight (further de-risked following mid cycle review) and data supporting commercial success.

We continue to point to supporting analysis:

- Sofpironium Bromide has proven itself in Japan, where its already approved and selling.
- We believe Sofpironium Bromide could potentially do +$100 million of sales in the USA based on the number of prescriptions the drug is currently doing through its partner in Japan, a country a third the size of the USA. (Figure 7).
- Management have developed, secured approval for, and commercialised +30 products.
- Our analysis suggests BOT may be the cheapest ASX-listed company to have filled for an FDA New Drug Application (on its first drug, Figure 2); and
- Companies undertaking an FDA review on their first drug have typically re-rated through the FDA review, seeing an average 102% re-rate and $760 million valuation by this time into the review. Whereas BOT has only re-rated 58%, and from a small base, with its $140 million valuation well below the peer average (Figure 4).

Outside of this, M&A remains a possibility ahead of an FDA decision, noting the last company management was involved in (Anacor Pharmaceuticals) was acquired by Pfizer for US$5.2 billion prior to FDA approval of its lead drug.

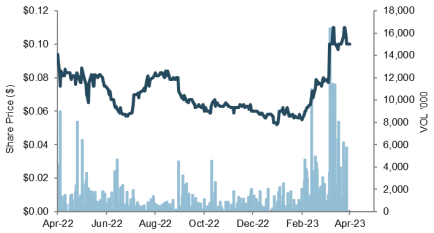
Catalyst

- **FDA Approval** – September 2023

Share Price	0.098	A$/sh
Price Target	0...	A$/sh
Valuation	0.28	A$/sh
Shares on issue	1,435	m, dil
Market Capitalisation	140.6	A$m
Enterprise Value	114.4	A$m
Debt	0.0	A$m
Cash (Pro-forma DecQ)	18.7	A$m
Unpaid cap	7.5	A$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

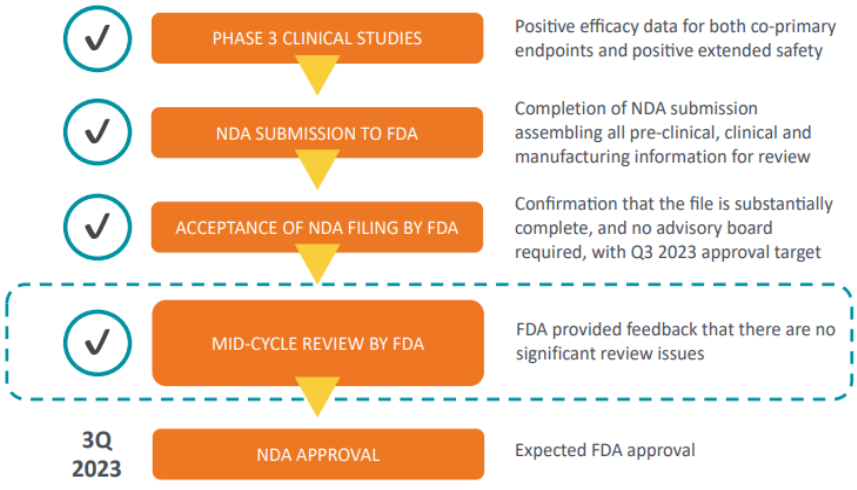


Source: Euroz Hartleys

Overview

- Sofpironium Bromide is the first and only new chemical entity developed to treat primary axillary hyperhidrosis, a medical condition which results in excessive and uncontrollable underarm sweating.
- The drug has successfully completed two phase 3 studies and a long term safety study, achieving statistical significance across all primary and secondary endpoints.
- Sofpironium Bromide is now in the process of being reviewed by the FDA, with approval targeted for September this year (Figure 1).
- Earlier this week BOT announced a successful FDA mid cycle review. This review provides FDA management and review teams with an opportunity to identify any material issues relating to the FDA New Drug Application review.
- The FDA communication read very positively, with no significant issues identified as part of the review process, including no major clinical safety issues or risk management issues.
- The FDA further confirmed no advisory board meeting would be required, adding that the application, in its view, presented no novel or complex regulatory issues. We continue to 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.
- Finally, the FDA indicated that continued discussions will now focus on labelling, clinical outcome assessments, patient instructions and brand name.
- In our view, this represents a substantial de-risking of the approval, as we view the progression towards labelling discussions amongst other items to infer the FDA is largely satisfied with the primary aspects of the review.
- In parallel, BOT has successfully raised $10 million via a single tranche placement of 111.1 million shares at $0.09/sh. These proceeds will be used to fund a number of activities in preparation for FDA approval, including supporting commercial launch.
- BOT had $8.7m in cash as of the december quarter. BOT is not due to make the next US$4m milestone payment to Fresh Tracks Therapeutics (previously Brickell Biotech) until the receipt of FDA approval (if received before 30th September, less due if thereafter).
- Other milestone payments due to Fresh Tracks are tied to net sales, and won't begin until net sales exceed US$75m per annum.

Figure 1: Sofpironium Bromide Timeline



Source: Company presentation

Cheapest FDA New Drug Application on the 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 secured an FDA approval, as shown below (Figure 2):

Figure 2: 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	13-Mar-23	521	1,148	120%
			Average	396	1,332	209%
			Min	113	260	
			Max	593	2,460	
BOT	Botanix	Sofpironium Bromide	n/a[3]	62	n/a[3]	n/a[3]

Source: EH analysis, company announcements, IRESS
Note: excludes CSL (diversified business), MYX (First drug approved prior to listing
[1]First approved product , [2]Fully diluted, [3]Not yet approved

While these companies vary in different ways, including disease areas, existing licensing agreements, ex-US approvals, and product portfolios, it's worth noting that they have both attracted significant valuations and undergone significant re-rates through the process.

On average these companies have seen a +200% re-rate over the FDA review process.

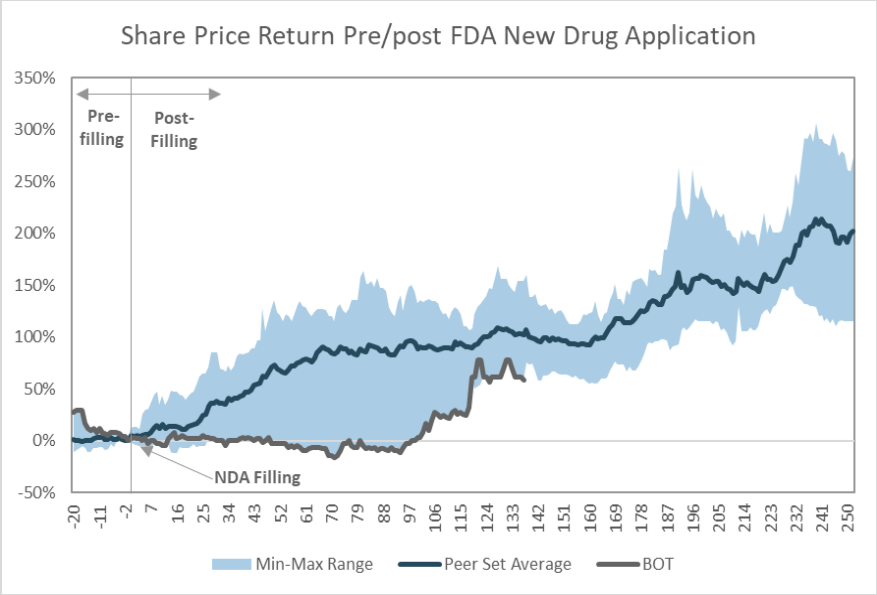
The table above (Figure 2) shows the market has paid between $110-600 million on the day of FDA New Drug Application (NDA) filling, and that upon receiving FDA approval, valuations ranged from $250 million to as high as $2.5 billion. This substantial increase in valuation underscores the importance of the FDA approval, and highlights the significant upside possible.

We saw this most recently with Neuren Pharmaceuticals, who upon receiving FDA approval last month on their rare disease drug Trofinetide (DAYBUE™), saw their share price leap nearly 19% on the day, with a further 45% increase seen by the end of the week, adding over $700m to its market cap, which currently stands at $1.7 billion.

According to this analysis, **BOT with its $140 million fully diluted market cap would make it one of the cheapest ASX listed companies seeking FDA approval on their first drug.**

We can take this analysis a step further, and see these companies progressively re-rate through the FDA review process, trading up an average 102% by this point in the review, whereas BOT has only traded up 58% (Figure 3).

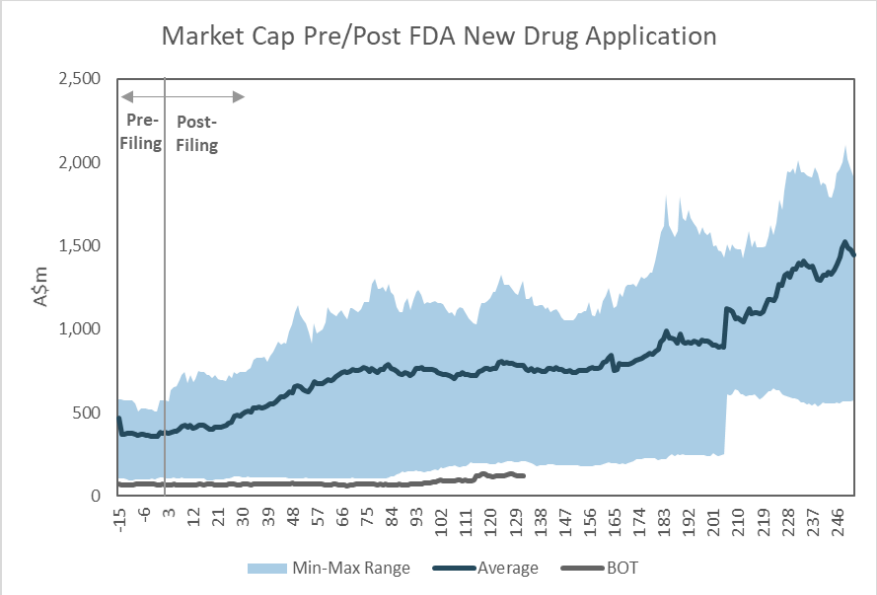
Figure 3: Peer Comparables, Share Price Performance



Source: EH analysis, company announcements, IRESS

Moreover, the re-rate of BOT's share price remains from a very small base. This is put in perspective in the chart below (Figure 4), where BOT continues to trade well below the peer valuation range, with the average valuation at this point being ~$760 million, which is significantly higher than BOT's current fully diluted $140 million market cap.

Figure 4: Peer Comparables, Market Cap performance



Source: EH analysis, company announcements, Bloomberg LP

We are still of the view that the company is being priced for failure, or close to it, in spite of the various recent achievements, and the backing of a highly experienced management team who have previously developed, secured approval for, and commercialised over 30 products.

Future Sales Look Through: Significant U.S. Potential

In late 2020, Sofpironium Bromide was approved and launched in Japan with an existing partner, Kaken Pharmaceuticals. Launched under the brand ECCLOCK© Gel 5% (Figure 5), the drug was the first ever product approved in Japan for Primary Axillary Hyperhidrosis.

Figure 5: ECCLOCK© Gel 5%, Product and packaging

20g bottle

40g bottle

Source: Ecclock website

Earlier this year, Kaken released its 3Q'FY22 results, showing the company had generated ¥1.05 Trillion of sales year to date from Sofpironium Bromide, with guidance of ¥1.4 Trillion of sales for the full financial year 2022.

Using Japan's National Health Insurance (NHI) reimbursement price (¥4,874 [~US$37] per 20g bottle [2 weeks supply]) and Kaken's quoted Sofpironium Bromide revenues, we can backward out the implied number of prescriptions of ECCLOCK© Gel 5% in Japan (where 1 script = 1 month's supply), as shown below:

Figure 6: Japanese Sofpironium Bromide Sales

Japanese Sofpironium Bromide Sales		FY20a	FY21a	FY22TD Annualised	FY22e	20-22 %CAGR
ECCLOCK Gel Revenues	¥ million	170	950	**1,399**	1,400	187%
(/) Japanese Pricing	¥/month	9,748	9,748	**9,748**	9,748	
Implied Prescriptions	#*/pa	17,439	97,456	**143,482**	143,619	

Source: Kaken pharmaceuticals quarterly report, EH analysis
**Equivalent 1 month's supply*

We estimate Kaken has a current annual run rate of +143,000 prescriptions

Applying an equivalent USA pricing we can extrapolate the revenues generated by this volume of prescriptions in the United States (Figure 7).

We estimate Sofpironium Bromide could comfortably sell for ~US$540/month (Net pricing) in the United States, this based on the pricing of its closest competitor Qbrexza© (US$720/script gross price), a product which we believe has an inferior efficacy and safety profile compared to Sofpironium Bromide.

In our view, this estimate is supported by recent independent market analysis from Triangle Insights Group, where in a blinded survey commercial payers indicated a high likelihood for coverage if Sofpironium Bromide is priced appropriately. Noting they felt Sofpironium Bromide addresses an unmet need for more therapeutics.

Figure 7: Est. Equivalent US Revenues

Equivalent U.S. Revenues		FY20a	FY21a	FY22TD Annualised	FY22e	20-22 %CAGR
Indicative Japanese Scripts	#/pa*	17,439	97,456	**143,482**	143,619	187%
(x) US Pricing	US$/unit*	540	540	**540**	540	
Equivalent US Revenues	US$m	9.4	52.6	**77.5**	77.6	
Equivalent US Revenues**	A$m	14.5	81.0	**119.2**	119.3	

Source: EH estimates
**Equivalent 1 month's supply, **0.65 AUD/USD Fx*

Indicatively, this implies Sofpironium Bromide could do circa A$120m of annual revenues in the United States based on our estimate of Kaken's annualised prescription volumes.

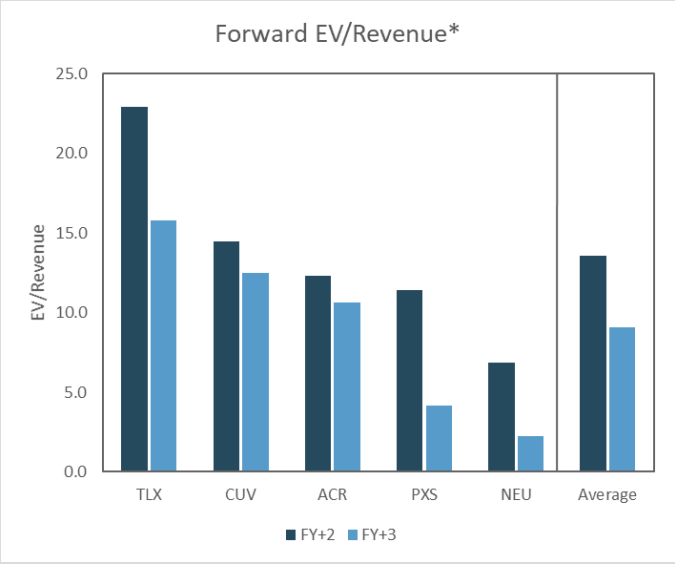
Additionally, this is based on Japanese prescription volumes, the United States has a population nearly 3x larger than Japan – which would suggest even larger potential prescription volumes and sales are possible.

Peer Trading Metrics

Considering the significant USA sales potential illustrated above, we have explored what multiples the market has paid in the past for similar companies.

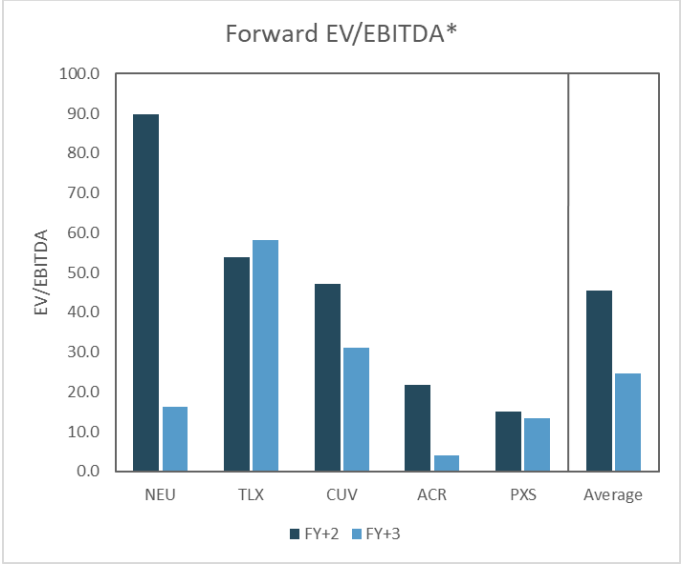
The diagrams below (Figure 7 & 9) illustrates forward trading metrics of the companies identified in the earlier ASX-listed FDA New Drug Application analysis (specifically companies securing approval on their first drug), where the multiples calculated are based on historical analyst forecasts from the date of FDA approval.

Figure 8: Forward EV/Revenue Metrics



*Source: EH analysis, company announcements, Factset consensus**
**forward estimates from time of respective FDA approval*
FY+2 = 2yrs post approval, FY+3 = 3yrs post approval

Figure 9: Forward EV/EBITDA Metrics



*Source: EH analysis, company announcements, Factset consensus**
**forward estimates from time of respective FDA approval*
FY+2 = 2yrs post approval, FY+3 = 3yrs post approval

Acknowledging these businesses vary in different ways (business model, disease areas, existing licensing agreements, ex-US approvals, and product portfolios), indicatively the market has paid:

- 7x to 23x (14x average) 2-year forward Revenues; and
- 15x to 90x (45x average) 2-year forward EBITDA

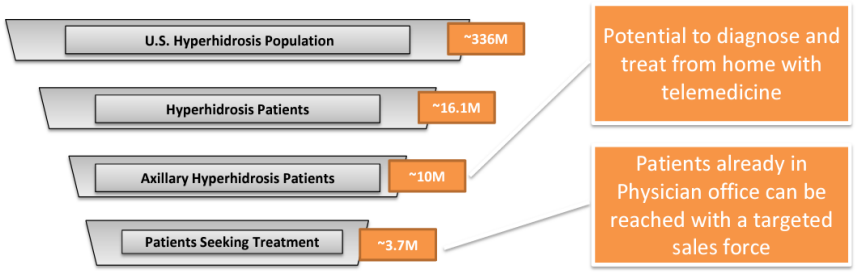
This highlight the potential valuation upside if BOT can deliver an even modestly successful commercial launch of Sofpironium Bromide. On the flipside, based on BOT's current $140 million market cap, it equally implies the very low expectations priced into the share price.

U.S. Hyperhidrosis Market Opportunity

The hyperhidrosis treatment market is currently worth $1.6 billion per annum and is projected to grow to $2.8 billion by 2030. However, given the current lack of effective treatment options, with no new chemical entity ever approved, we think this could be considerably larger.

Hyperhidrosis affects upwards of 16 million people in the United States alone, with 10 million of these people suffering from the axillary (under arm) form (Figure 10), the indication BOT is seeking FDA approval for Sofpironium Bromide under.

Figure 10: US Hyperhidrosis Prevalence



Source: company presentation

We see Sofpironium Bromide's target patient population as being equal to the estimated number of severe axillary hyperhidrosis patients seeking treatment, which in the United States represents circa 3.7 million individuals. That said, telemedicine and its potential to both diagnose and treat potential patients from home could expand this target to include all 10 million axillary hyperhidrosis sufferers (Figure 10).

Using the same pricing point we established previously for Sofpironium Bromide (US$540/month net price), based on the pricing of its closest competitor Qbrexza©, we can quickly see how even modesty market penetration translates into significant revenues (Figure 11).

Figure 11: Market Penetration Sensitivity

		Market Penetration*				
		0.5%	1.0%	2.5%	5.0%	10.0%
Implied Prescriptions	#/mth	18,500	37,000	92,500	185,000	370,000
Implied Annual Sales**	US$m	120	240	599	1,199	2,398

Source: EH estimates
**Based on 3.7 million target patient population, ** based on US$540/month (Net)*

We can further sensitise these revenues by the assumed prescription selling price, as shown below (Figure 12):

Figure 12: Market Penetration Sensitivity

Revenue Sensitvity						
		Market Penetration*				
		0.5%	1.0%	2.5%	5.0%	10.0%
Monthly Net Pricing (US$/month/Script)	300	67	133	333	666	1,332
	400	89	178	444	888	1,776
	540	120	240	599	1,199	2,398
	600	133	266	666	1,332	2,664
	700	155	311	777	1,554	3,108

Source: EH estimates
**Based on 3.7 million target patient population*

Commercial Pathways

We see three main pathways for BOT to realise the value of Sofpironium Bromide:

1. **Go-to-market** – Commercialising inhouse. More execution risk, however retains greater upside.
2. **Licensing Deal** – License Sofpironium Bromide to a suitable pharmaceutical partner in exchange for a potential upfront payment, sales milestones and royalties.
3. **Asset Sale/Takeover** – Sale of Sofpironium Bromide or takeover of BOT. Represents the most rapid way to realise value.

Following the successful mid-cycle review and institutional placement, BOT is now in stronger position to progress any of these pathways.

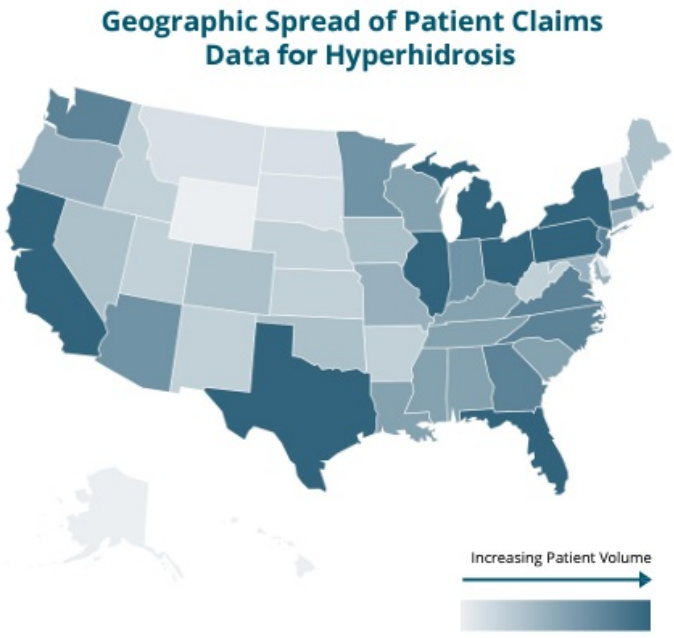
Importantly, what splits BOT apart from some of its peers, is its capacity to go-to-market and execute on a commercial strategy in house. This places BOT in a significantly stronger negotiating position, as the company is not dependent on securing a licensing agreement or selling the asset to an external party.

As a result, we have confidence that any agreement, if executed, will be from a position of strength.

That said, even if BOT ultimately does do a licensing deal or sell the asset, either way the company will still need to prepare a commercial strategy ahead of FDA approval, with the idea of having a turnkey solution for any future partner or owner of the asset.

BOT has targeted to launch Sofpironium Bromide in an efficient and cost-effective manner, targeting a focused prescriber base made up of active patients. This in mind, the company has already begun building its capabilities to support the launch of Sofpironium Bromide, with this further supported by the funds raised in the placement.

Figure 13: Geographic Spread of Patient Claims, Hyperhidrosis



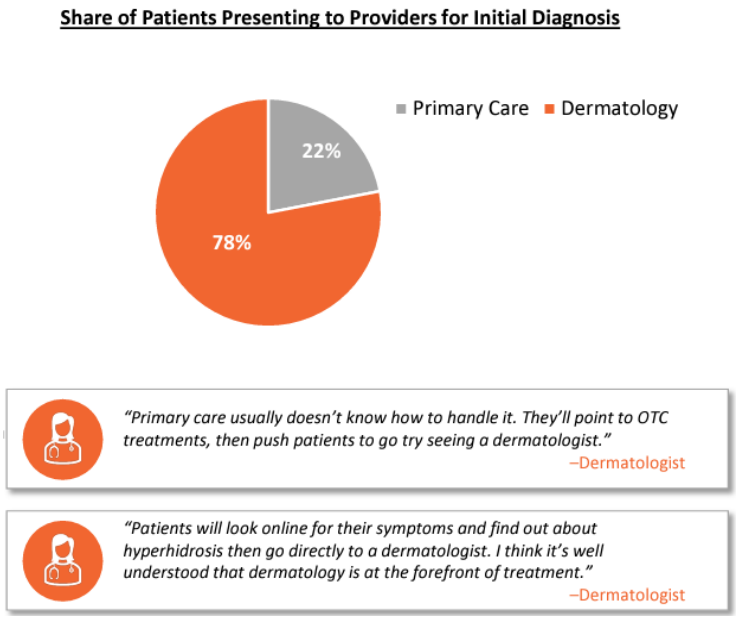
Source: Company presentation

Outside of having a direct salesforce targeting physicians, BOT has also stated a regionally targeted digital campaign could reach the vast majority of patients, and that these patients could be diagnosed online and referred directly to a pharmacy partner for fulfillment.

Importantly, BOT is aiming to have a closed loop process to maintain continuity of care.

We note the majority (~78%) of patients seeking care for hyperhidrosis (~3.7 million estimated patients in the USA) present directly to dermatologist, who are widely recognised as the primary provider for its treatment (Figure 14).

Figure 14: Share of Patients Presenting to Providers for Initial Diagnosis



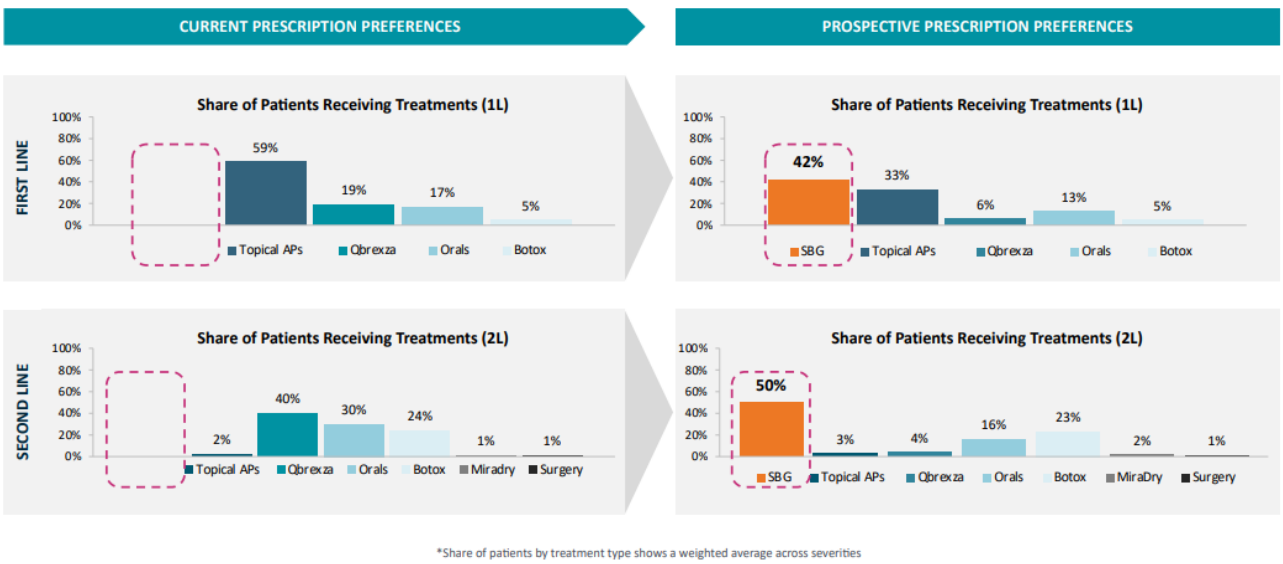
Source: Company presentation, Triangle Insights Group

This is significant as unlike more common specialities, there is a relatively small number of dermatologists in the United States, representing less than 1.3% of all physicians, or roughly ~12,500 dermatologists (according to AAMC). Furthermore, a smaller subset of these physicians would likely be writing the majority of prescriptions.

Altogether, this means BOT can cover the majority of dermatologist with a very small sales force.

Furthermore, market research indicates dermatologist would consider prescribing Sofpironium Bromide to ~40-50% of axillary hyperhidrosis patients, largely displacing other topicals and some oral drugs (Figure 15).

Figure 15: Dermatologist Treatment Preferences and Anticipated Future Sofpironium Bromide Prescribing



*Share of patients by treatment type shows a weighted average across severities

Source: Company presentation, Triangle Insights Group, SBG: Sofpironium Bromide Gel

Forecasts

As part of our analysis, we have modelled potential sales and cash flows of Sofpironium Bromide in the United States. We have modelled both the in-house go-to-market and out-license commercial pathways. While these forecasts are based on high-level, and in some cases, conservative assumptions, we will look to refine them as we approach commercial launch. Nevertheless, these estimates should provide valuable insight into the indicative commercial potential of Sofpironium Bromide.

Figure 16: Go-to-Market Model

Go-to-Market Scenario	Units	2023	2024	2025	2026	2027	2028	2029	2030	2031
Addressable Patient Population	'000s	3,811	3,925	4,043	4,164	4,289	4,418	4,551	4,687	4,828
Growth	%	3%	3%	3%	3%	3%	3%	3%	3%	3%
Market Penetration	%		0.3%	0.7%	1.3%	1.9%	2.5%	3.0%	3.0%	3.0%
Patients Treated	'000s	0	13	27	54	81	109	135	140	144
Annual Treatment Price	US$	8,640	8,640	8,640	8,640	8,640	8,640	8,640	8,640	8,640
Growth	%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Gross to Net discount	%	25%	25%	25%	25%	25%	25%	25%	25%	25%
Net Annual Treatment Price	US$	6,480	6,480	6,480	6,480	6,480	6,480	6,480	6,480	6,480
Net Sales	US$m	0	85	175	348	525	704	876	907	934
Cost of Sales	US$m	-2	-90	-123	-174	-184	-176	-175	-181	-187
Operating Income	US$m	-2	-4	53	174	341	528	701	726	747
Margin	%		-5%	30%	50%	65%	75%	80%	80%	80%
Royalties Payable	US$m	0	-10	-21	-42	-71	-107	-141	-147	-153
Milestone Payable	US$m	-4	-4	-10	-30	-50	-70	0	0	0
Pre Tax Cash Flow	US$m	-6	-19	22	102	220	351	559	578	595
Tax Payable	US$m	0	0	0	-17	-66	-105	-168	-173	-178
After Tax Cash Flow	US$m	-6	-19	22	85	154	246	392	405	416

Source: EH analysis

Our key assumptions include:

- Commercial launch in 2024 (post FDA approval).
- 8-year forecasts period (with potential for sales beyond this date).
- 3.7 million target patient population (subset of 16 million overall hyperhidrosis patients who are currently seeking treatment), 3% annual growth.
- 3% peak market share.
- US$540/script net pricing (1 script per month), based on: US$720 gross price (same price as closest competitor Qbrexza), 25% Gross-to-Net discount (very conservative, typically 10-20%), no price escalation.
- 80% peak margins (excl. Royalties & milestone payments), we have forecasted conservatively high costs in the initial years noting potential for these estimates to be significantly lower. We will look to refine these forecasts over time.
- Conservatively assume all US$160m in sale milestone payments are made, despite final payment (amount not disclosed) not being made until net sales exceed US$1.8 billion per annum, as a result milestone payments will likely be significantly less.

Figure 17: Out-license Model

Out-License Scenario	Units	2023	2024	2025	2026	2027	2028	2029	2030	2031
Addressable Patient Population	'000s	3,811	3,925	4,043	4,164	4,289	4,418	4,551	4,687	4,828
Growth	%	3%	3%	3%	3%	3%	3%	3%	3%	3%
Market Penetration	%		0.3%	0.7%	1.3%	1.9%	2.5%	3.0%	3.0%	3.0%
Patients Treated	'000s	0	13	27	54	81	109	135	140	144
Annual Treatment Price	US$	8,640	8,640	8,640	8,640	8,640	8,640	8,640	8,640	8,640
Growth	%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Gross to Net discount	%	25%	25%	25%	25%	25%	25%	25%	25%	25%
Net Annual Treatment Price	US$	6,480	6,480	6,480	6,480	6,480	6,480	6,480	6,480	6,480
Net Sales	US$m	0	85	175	348	525	704	876	907	934
Royalties receivable	US$m	0	9	18	41	66	93	118	123	127
Upfront	US$m		50							
Sales Milestones	US$m			10	30	50	70	0	0	0
Total Cashflow	US$m	0	59	28	71	116	163	118	123	127
Net to BOT	US$m	0	44	21	53	87	122	89	92	95
Milestones Payable	US$m	-4	-4							
Pre Tax Cash Flow	US$m	-4	40	21	53	87	122	89	92	95
Tax Payable	US$m	0	0	-4	-16	-26	-37	-27	-28	-29
After Tax Cash Flow	US$m	-4	40	17	37	61	85	62	65	67

Source: EH analysis

In modelling a potential out-licensing scenario, we have assumed a deal would be done post FDA approval. However, we note a deal could occur at any time, including during the FDA review process.

We conservatively model the same forecasts as our previous go-to-market scenario. We note there is scope for sales to grow faster and ultimately be larger if a deal is done with a larger party, as a significantly larger pharmaceutical company would likely have greater resources at hand to market the new drug.

We assume under this out-license scenario, the previous agreement with Fresh Tracks Therapeutics (previously Brickell Biotech) is amended. We have simply assumed BOT pays 25% of the upfront payment, milestone payments and royalties received to Fresh Tracks.

We have assumed US$50m upfront, sale milestone payments equal to the deal done with Fresh Tracks (US$160m total), and a tiered royalty starting from 10% and increasing to 15%. Similarly, we believe there is scope for all of these to be higher, considering the significant sales potential.

Valuation and Price Target

We maintain our Speculative Buy recommendation with an upgraded $0.28/sh. Price Target.

Following the positive FDA mid-cycle review, which we considered to have de-risked the final FDA approval, we have reduced our valuation risking for Sofpironium Bromide. Consequently, as a net result of both this de-risking and the dilution of the placement, our overall valuation has increased.

Our sum of the parts (SOP) valuation (Figure 18) is shown below:

Figure 18: SOP Valuation

Asset	*Indication*	*Risking (r)*	*Risked Val. (rNPV)*	
		%	A$m	A$/sh*
Sofpironium Bromide	**Hyperhidrosis**	**90%**	**305**	**0.21**
BTX1503	Acne	27%	53	0.04
BTX1801	Antimicrobial	23%	32	0.02
BTX1702	Rosacea	6%	4	0.00
BTX1204A	Atopic Derm.	6%	4	0.00
Corporate O/H		100%	-24	-0.02
Net Cash		100%	19	0.01
Unpaid Capital		100%	7	0.01
Total			**400**	**0.28**

*Source: EH estimates, *Fully diluted*

Sofpironium Bromide is BOT's most advanced and de-risked asset, furthermore it remains the main value drive for BOT, and as a result is our main focus.

We have arrived at Sofpironium Bromide valuation using a blended valuation of both commercial scenarios modelled, which we respectively value using a risked Net Present Value (rNPV). This shown below:

Figure 19:

Scenario	Discount Rate	NPV	Risking (r)	Risked Val. (rNPV)	
	%	A$m	%	A$m	A$/sh*
Go-to-Market	35%	409	90%	368	0.26
Out-license	20%	269	90%	242	0.17
Blend		**339**		**305**	**0.21**

*Source: EH estimate, *Fully diluted*

We have discounted our cashflows using a conservative discount rate between 20% and 35%. Considering the higher risks surrounding execution and funding for the go-to-market scenario, we have applied a significantly higher 35% discount rate.

We have conservatively risked both NPV's by 90% to account for FDA approval risk.

We note there is scope for the applied discount rate to decrease as BOT de-risks, this would imply significantly higher valuations, as shown in the sensitivity analysis below:

Figure 20: Sofpironium Bromide Valuation, Discount Rate Sensitivity

Discount Rate	Units	10%	15%	20%	25%	30%	35%
Go-to-Market	A$m	1,423	1,079	831	648	512	409
Out-license	A$m	405	327	269	224	190	163
Blended Valuation	**A$m**	**914**	**703**	**550**	**436**	**351**	**286**

Source: EH estimate, un-risked

Additionally, we previously articulated the upside possible in our forecasts, which could equally drive higher valuations.

We broadly maintain our forecasts for BOT's existing dermatology and antimicrobial programs (see initiation for further details).

The risks surrounding unsuccessful regulatory, commercial, and or clinical outcomes from these programs drive our Speculative Buy recommendation.

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Botanix Pharmaceuticals Limited (BOT.ASX) | Price A$0.098 | Target price A$0.280 | Recommendation Speculative Buy ;

Price, target price and rating as at 05 April 2023 (not covered)*

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