Botanix Pharmaceuticals Ltd

(BOT $0.067) Speculative Buy

EUROZ HARTLEYS

Analyst	Date	Price Target
Seth Lizee	13th May 2022	$0.25/sh ▲ from $0.17/sh

Transformational Acquisition

Event

BOT has announced it's acquired Sofpironium Bromide, a novel dermatology asset.

Sofpironium Bromide gel 15% is the first and only new chemical entity developed to treat primary axillary hyperhidrosis, a medical condition which results in excessive underarm sweating.

The drug has been developed to be a best-in-class, once daily, topically administered therapy.

The acquisition is highly complementary to BOT's existing dermatology pipeline, and consistent with its strategy to be a leading dermatology company.

Key highlights of the asset acquired:

- **Late Stage** – Successfully completed pivotal phase III studies
- **Registration Ready** – FDA fillings this year (2H CY22)
- **De-Risked** – Already approved & launched in Japan with existing partner
- **Significant Market Opportunity** – Worth ~1.6 billion pa, est. 15 million suffers, treatment landscape prime for disruption
- **Attractive Terms** – Minimal upfront payment (US$3m) with back-ended milestone payments and royalties

Impact

We believe the acquisition is highly value accretive, we conservatively estimate Sofpironium Bromide to be worth ~$161 million ($0.15/sh.) to BOT. This is on top of the company's existing dermatology (Acne, Atopic Dermatitis, Rosacea) and antimicrobial pipeline which we value at a further $113 million ($0.11/sh.).

Key risks now stand around execution. We view a sale/acquisition or licensing deal as the primary avenue for BOT, with a pathway of going-to-market themselves if that doesn't eventuate, which we note will come with additional funding requirements and execution risks.

Nevertheless, we believe BOT's management team and board of directors are more than capable to execute on all options. The team as a whole has developed, secured approval for, and commercialised over 30 dermatology products.

Action

Speculative Buy, Price Target upgraded to $0.25/sh. (from $0.17/sh.)

If BOT can delivery successful commercial and clinical outcomes, we believe the stock can trade above our Price Target.

Botanix Pharmaceuticals Ltd	Year End 30 June	
Share Price	**0.067**	**A$/sh**
Price Target	**0.25**	**A$/sh**
Valuation	0.25	A$/sh
Shares on issue	1043.3m, diluted	
Market Capitalisation	69.9	A$m
Enterprise Value	50.7	A$m
Debt (Jun'21)	0.0	A$m
Cash (Pro-forma)	12.2	A$m
Unpaid cap	7.1	A$m
Turnover	5.2m	sh/day
12 Mth Hi-Lo	0.045-0.19	A$/sh
Balance date	June 30th	

Directors & Management

Vince Ippolito	Exec Chair & President
Matthew Callahan	Executive Director
Dr William Bosch	Executive Director
Dr Stewart Washer	Executive Director
Danny Sharp	NED
Howie Mckibbon	Chief Commercial Officer
Dr Patricia Walker	Chief Medical Adviser
Anthony Robinson	VP of Development
Dr Jack Hoblitzell	SVP of Pharm. Dev.
Dr Ira Lawrence	Clinical & Regulatory Adv.
Dr Clarence Young	Chief Med Adv., Antimicrobials
Lynda Berne	Commercial Adv., Antimicrobials

Company details

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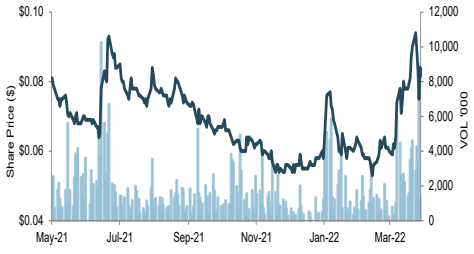
Share Price Chart



Disclaimer

This analyst declares that he has a beneficial interest in Botanix Pharmaceuticals Ltd.

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Key Catalyst

- BTX1204A (Atopic Dermatitis) Proof of concept results – Q2 CY22
- BTX1801 (Antimicrobial) phase 2b kick off – Q2 CY22
- BTX1702 (Rosacea) phase 1b/2a results – Mid 2022
- NDA Submission (Sofpironium Bromide) – 2H CY22
- FDA Day 74 Review Letter (Sofpironium Bromide) – 2H CY22
- FDA Mid-Cycle Review (Sofpironium Bromide) – 1H CY23
- FDA Approval (Sofpironium Bromide) – 2H CY23

Analysis

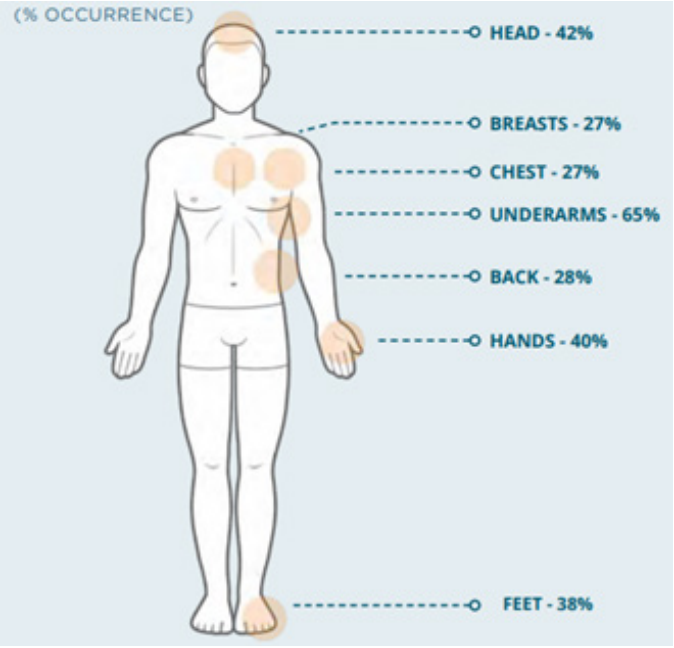
Hyperhidrosis

Hyperhidrosis is a medical condition characterised by excessive sweating, beyond what the body needs to maintain normal temperature.

The disease is estimated to affect upwards of 15 million people in the United States alone, with an estimated 4.25 million diagnosed by medical practitioners.

Hyperhidrosis is characterised as either primary (the main disease area of focus in this research), or secondary.

Most commonly beginning around the ages of 12-17, primary Hyperhidrosis occurs as a result of overstimulation of the nervous system (purely a physiological condition, not psychological). The condition can occur on various regions of the body, with underarms (axillary) being the most common area (65% occurrence). As shown below:



Source: BOT presentation

Secondary hyperhidrosis affects the entire body and can be caused by various factors, including an underlying medical condition or prescription medication.

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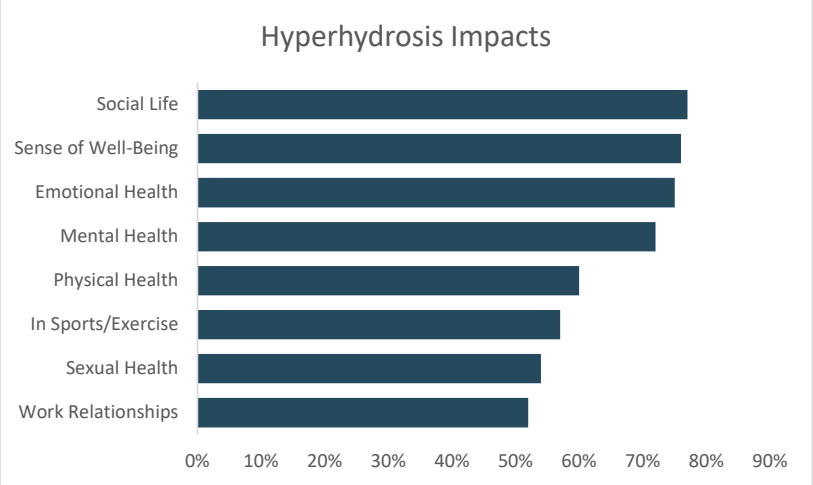
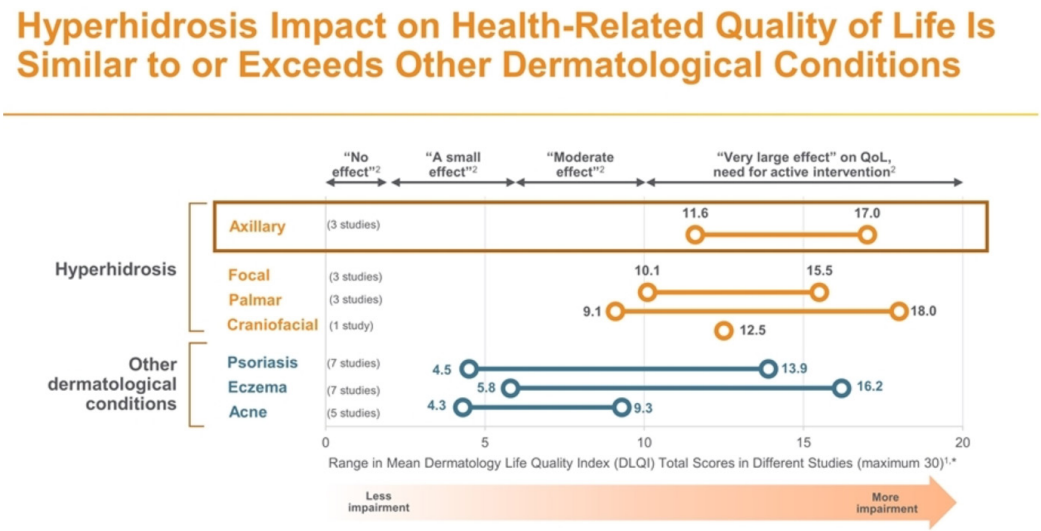
Whilst Hyperhidrosis might sound trivial, the condition is very much real, posing a significant impact on the daily lives of suffers. We note a 2016 study highlighted the severe and pervasive impact the disease had



Source: Hamm H. et al. Dermatology 2006

Furthermore, the impact on quality of life is similar to or exceeds other dermatology conditions.



Source: Dermira presentation

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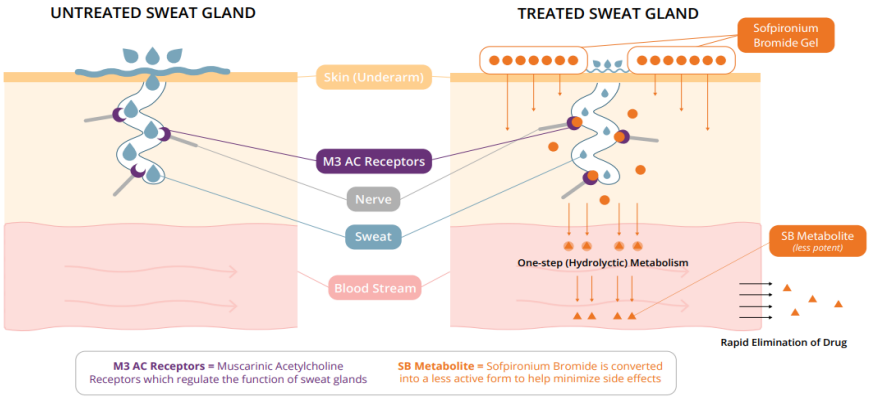
Mechanism of Action

Sofpironium Bromide is a type of retrometabolic anticholinergic therapy. The drug works by blocking the action of acetylcholine, a type of neurotransmitter which transfers signals between cells and drives how the body functions. By blocking this chemical (In this case, Muscarinic Acetylcholine receptors), Sofpironium Bromide can prevent sweat glands from activating, and as a result reduce hyperhidrosis. Critically, the retrometabolic aspects allows for the drug to act locally and be rapidly metabolized into a less active form – this enabling higher doses of the drug with minimal systematic side effects.

This is detailed in the diagram below:



Source: BOT presentation

Existing Product landscape – Lacking & Prime for Disruption

Treatment options are limited, with no new chemical entity ever approved for the treatment of hyperhidrosis.

Existing options fall into four broad categories which include:

Source: BOT presentation

These existing treatments come with various downfalls, including:

- Lack of efficacy (Don't work very well)
- Poor side effects; and
- Lack of insurance coverage (high out of pocket costs)

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We further highlight these downfalls in the table below:

Category	Mechanism of Action	Products	Side effects / Downfalls
Topical anti-perspirants	Mechanically obstructs the sweat glands	Aluminium chloride	Mixed efficacy
		Drysol®/Certain-Dri®/SweatBlock®	Can cause burning and stinging
Older systemic oral drugs	Interferes with nerve signals to the sweat glands	Anticholinergics (Glycopyrronium etc)	Intolerable side effects (inc. dry mouth, constipation, etc)
		Beta Blockers	
Reformulation of older systemic drugs	Competitively binds the relevant sweat gland receptors	Qbrexza®	Dry mouth, inflammation, burning, and stinging
Botox injections	Inhibits release of messenger chemical triggering sweating	Botox®	Pain during injections
		Dysport®	Limited insurance coverage (high out of pocket costs
Thermal energy	Delivers thermal energy to the sweat glands	miraDry®	High out of pocket costs
			Common side effects include swelling redness and pain
Surgery	Interrupts transmission of nerve signals – removes/injures sweat glands	Endoscopic thoracic sympathectomy (ETS)	High cost
		Excision, curettage, liposuction, and laser	Pain, infection, more sweating elsewhere

Source: BOT presentation, EHL analysis

This analysis highlights how the existing treatment continuum is prime for disruption, with new and better treatments needed.

Demand for better treatments are evident by the impact of hyperhidrosis on quality of life, with a 2016 study (Hamm H. et al. Dermatology) stating:

> *"... Over half (54%) of respondents say that they would **pay anything** for a treatment to stop their excessive sweating..."""*

We view Qbrexza® as being the main competitor product in market, having been approved and launched in recent years. However, we believe Sofpironium Bromide has superior efficacy with more favourable safety profiles.

The table below substantiates this view, demonstrating Sofpironium Bromide has a superior efficacy (Based on baseline reduction in sweat production). Specifically, Sofpironium Bromide reduced sweat production by 28.3% more than Qbrexza.

	Sofpironium Bromide						QBREXZA (glycopyrronium) cloth					
Study	CARDIGAN I (Phase 3)			CARDIGAN II (Phase 3)			ATMOS I (Phase 3)			ATMOS I (Phase 3)		
	SB, 15%	Vehicle	p-value	SB, 15%	Vehicle	p-value	GT, 2.4%	Vehicle	p-value	GT, 2.4%	Vehicle	p-value
subjects (n)	n=173	n=177		n=180	n=171		n=229	n=115		n=234	n=119	
Design	Randomised, placebo			Randomised, placebo			Randomised, placebo			Randomised, placebo		
Duration	6wk treat, 2wk follow up			6wk treat, 2wk follow up			4wk treat			4wk treat		
Reduction in sweat prod. From baseline (mg)*	-129.5	-99.3	0.002	-145.9	-131.7	0.030	-104.9	-91.9	0.065	-110.3	-92.2	<0.001
Safety Summary												
Any TEAEs (Prop. %)	35.8%	13.1%		45.0%	13.5%		54.2%	28.9%		57.8%	35.6%	
Early termination due TEAEs (Prop. %)	2.9%	-		5.0%	-		3.5%	0.9%		3.9%	-	
Treatment-Emergent Adverse Events (TEAEs)												
Dry mouth	20 (11.6%)	-		31 (17.2%)	2 (1.2%)		43 (18.9%)	4 (3.5%)		68 (29.3%)	9 (7.6%)	
Blurred Vision	9 (5.2%)	-		21 (11.7%)	1 (0.6%)		8 (3.5%)	-		8 (3.4%)	-	
Application Site Pain	11 (6.4%)	3 (1.7%)		18 (10.0%)	2 (1.2%)		20 (8.8%)	11 (9.6%)		20 (8.6%)	11 (9.3%)	
Application Site Erythema	9 (5.2%)	1 (0.6%)		14 (7.8%)	-		41 (18.3%)	18 (15.8%)		36 (15.7%)	21 (17.9%)	
Burning/Stinging	2 (1.2%)	-		6 (3.3%)	1 (0.6%)		31 (13.8%)	14 (12.3%)		33 (14.3%)	25 (21.4%)	
Application Site Prutitis	11 (6.4%)	1 (0.6%)		4 (2.2%)	1 (0.6%)		17 (7.6%)	9 (7.9%)		20 (8.7%)	5 (4.3%)	
Oropharyngeal pain	-	-		-	-		9 (4.0%)	2 (1.8%)		17 (7.3%)	1 (0.8%)	

**Endpoint from baseline to end of trial*
SB = Sofpironium Bromide
GT = Glycopyrronium tosylate (QBREXZA [glycopyrronium] cloth)
Source: Brickell SEC Fillings, BOT announcements, QBREXZA publications (ATMOS-1, ATMOS-2 results)

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Sofpironium Bromide is also shown to have lower incidences of treatment-emergent adverse events (TEAEs), with significantly lower incidences of dry mouth specifically (a key anticholinergic-related adverse event).

Significant Market Opportunity

Hyperhidrosis represents a significant new market opportunity for BOT.

In the US alone, there are an estimated 15.5 million people suffering with hyperhidrosis. This broken into further subsets as shown below:

Hyperhidrosis Addressable Market	US Prevalence	
Total Prevalence	4.8%	15.5m
Seek Medical Advice	2.5%	8.0m
Diagnosed	1.3%	4.3m
Severe	0.9%	3.0m
Axillary	0.7%	2.2m

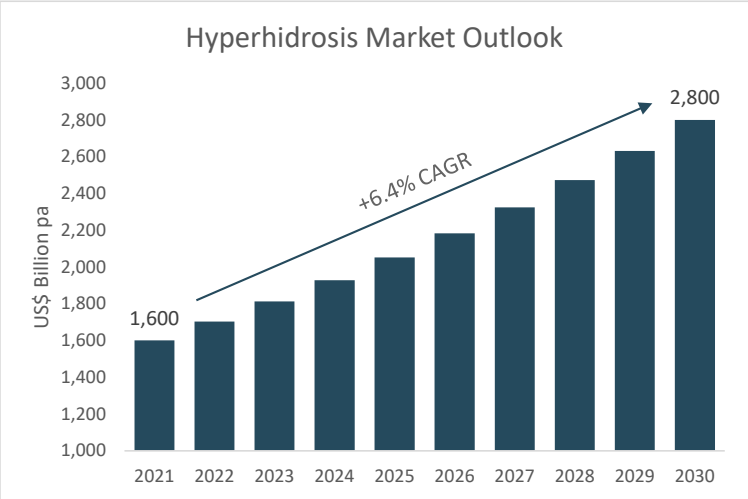
Source: EHL analysis, BOT presentation, Hamm H. et al. Dermatology 2006

We estimate Sofpironium Bromide's target patient population to be ~2.2 million people in the United states, this being the estimated number of patients with severe axillary hyperhidrosis (aka the severe subset of Sofpironium Bromide's target indication).

We estimate a 1% market penetration would translate to ~US$143 million.

We further note, there is additional potential for BOT to expand Sofpironium Bromide into other indications outside of the axillary target, as well as developing a paediatric version of the drug using a lower dosage (we note the approved Japanese version is based on a lower dosage [5%], highlighting this paediatric potential).

We further note the current treatment market is worth ~$1.6 billion dollars per annum, and is expected to grow at a 6% CAGR to reach $2.8 billion by 2030.



Source: BOT presentation, EHL analysis

The market is dominated by medications, representing ~85% of sales.

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Clinical Studies – Pivotal Studies completed, Regulatory Filling Approaching

Sofpironium Bromide has been successfully evaluated in pivotal phase 3 studies and a long term safety study.

Positive results were reported in late 2021, where Sofpironium Bromide achieved statistical significance across all primary and secondary endpoints.

Two phase 3 studies (CARDIGAN I and II) were completed in 700 patients over a 6 week treatment period, an additional 48-week safety study was also done in a further 300 patients.

Overall, results showed a once a day topical admission of Sofpironium Bromide gel 15% elicited early, sustained, and significant improvements in signs and symptoms of primary axillary hyperhidrosis across all efficacy measures.

Across all studies, there were no treatment related serious adverse events, with any adverse events being transient and mild to moderate in nature

Key study highlights (based on pooled data) include:

- All Primary and secondary endpoints achieved statistical significance
- 85% of subjects had a clinically meaningful 1-point change in the patient reported outcome measure, with 55% registering a more rigorous 2-point change
- Over 60% had a 50% or greater reduction in sweat production and the clinically meaningful 1-grade change
- Average reduction in sweat at week 6 was ~138mg

The long term safety studies also showed efficacy continued to improve on average from commencement to week 48.

We have summarised primary and secondary endpoint results of CARDIGAN I and II phase 3 studies below:

Study	CARDIGAN I (Phase 3)			CARDIGAN II (Phase 3)			Pooled Data (CARDIGAN I and II)		
	SB, 15%	Vehicle	p-value	SB, 15%	Vehicle	p-value	SB, 15%	Vehicle	p-value
subjects (n)	n=173	n=177		n=180	n=171		n=353	n=348	
Design	Randomised, placebo			Randomised, placebo					
Duration	6wk treat, 2wk follow up			6wk treat, 2wk follow up					
Co-Primary Efficacy Endpoints									
≥2-Point improvement in HDSN-Ax (Prop. %)	49.3%	29.4%	<0.001	63.7%	47.0%	0.003	60.0%	39.7%	<0.0001
Reduction in sweat prod. From baseline (mg)	-129.5	-99.3	0.002	-145.9	-131.7	0.030	-138.1	-114.5	0.0002
Secondary Efficacy Endpoints									
≥1-Point improvement in HDSN-Ax (Prop. %)	82.8%	69.5%	0.005	89.9%	80.8%	0.020	84.60%	72.30%	0.0002
≥1-Point improvement in HDSN-Ax & ≥70% reduction in sweat production (Prop. %)	32.1%	10.2%	<0.0001	35.5%	21.4%	0.006			
≥1-Point improvement in HDSN-Ax & ≥50% reduction in sweat production (Prop. %)	54.3%	33.3%	<0.001	68.7%	54.6%	0.014			

Source: Brickell SEC Fillings, BOT announcements

Plans are now to submit a New Drug Approval (NDA) to the FDA in 2H 2022, with anticipated approval in 2H 2023 (assuming a 12 month review process)

The timeline of key FDA events is:

- NDA submission – 2H 2022
- Day 74 review letter from FDA – 2H 2022
- FDA feedback on proposed trade name – 1H 2023
- FDA mid-cycle review – 1H 2023

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Existing Partnership – Asset De-risked

Going into regulatory filling, Sofpironium Bromide has been de-risked, having already been approved by the Japanese equivalent of the FDA (PMDA) and recently launched by the existing partner, Kaken Pharmaceuticals (Kaken) in Japan.

Kaken is a $1.7 billion Japanese listed (TYO: 4521) Pharmaceutical company.

Under an existing licensing agreement, Kaken has the rights to commercialise Sofpironium Bromide in Japan, South Korea, China and certain other Asian Countries.

Kaken received approval from Japanese regulators in September 2020 following a successful pivotal phase 3 study it independently completed.

The product was launched later that year as a 5% Sofpironium Bromide gel, under the brand name ECCLOCK. The drug is priced at ¥4,874/ 20g bottle (~US$37), significantly lower than anticipated US pricing.

ECCLOCK is the first topical pharmaceutical for treatment of primary axillary hyperhidrosis in Japan. The drug is on Japan's National Health Insurance drug reimbursement price list.

Sales are quickly growing, with the drugs 2-week prescription limit (required in japan for new drugs) lifted in late 2021.

As of its most recent financial reports, Kaken's ECCLOCK sales are up 559% YoY to ¥950 million (~US$7.3m), with the company targeting to double sales to ¥2 Billion (~US$15.3m) in FY22.

BOT is entitled to 25% of the royalties and milestone payments paid to Brickell from Kaken.

As a result, we would expect BOT to receive royalties in the near term. However, we don't anticipate these to be very material initially.

IP protection

Intellectual property is covered by various different patent families, as shown in the diagram below:

COMPOSITION OF MATTER

- US patent issued with claims covering compounds, compositions, and methods of use (expires 2027, excluding PTE)
- US non-provisional and national stage applications filed covering crystalline forms and manufacturing process of Sofpironium Bromide; already issued in Japan (expiry not before 2040)

METHOD OF DOSING

- US patent issued with claims covering uses of Sofpironium Bromide for treatment of hyperhidrosis (expires 2034)
- National stage filings pending or allowed (granted in EP, JP & CA)

FORMULATION

- US patents issued with claims covering novel topical compositions and uses for treatment of hyperhidrosis (expires 2034)
- PCT filed (national stages pending and available) covering Japan commercial formulation

APPLICATOR SYSTEM

- US provisional utility application filed for the novel applicator system (expires 2039)
- Design application filed in US (and other key jurisdictions) covering the applicator and container system (expiry not before 2034)

Source: BOT Presentation

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Current patents are due to expire between 2030 and 2040.

We believe Sofpironium Bromide is potentially eligible to extend a select patent term per the Hatch-Waxman Act. This act allows for pharmaceutical patents, specifically the term of one patent to be extended for a portion of the time lost during clinical testing (time between IND application and NDA submission), plus the entire period spent by the FDA approving the NDA.

We estimate this could be worth an extra 3 to 4 years of additional patent life.

If successful, BOT could extend the more powerful composition of matter patent out to 2030, possibly as far as 2031. This would further increase the value Sofpironium Bromide.

Transaction Overview –Attractively Structured

BOT has acquired all assets owned or controlled by Brickell primarily related to Sofpironium Bromide, including its interest in a license for Sofpironium Bromide

The transaction includes an upfront payment, milestone payments and royalties payable to Brickell, structured as follows:

- US$3m upfront
- US$2m if positive 'Day-74 letter' received from FDA (after NDA filling)
- Up to US$4m if FDA approval received before 30th September 2023 (down to zero if after 17th Feb 2024)
- US$4m upon EU/UK marketing approval (from regulatory agencies)
- Milestone payments when net sales exceed US$75m, capped at US$160m (which imply more than US$1.8bn in net sales to BOT); and
- Aggregate royalties payable from 12%, rising towards 20%, above US$500m annual net sales

The company will additionally reimburse some development expenses incurred in recent months.

BOT will assume responsibility for future development of Sofpironium Bromide, including filling for approval with the FDA and other international regulatory authorities (ex. far east Asia).

Strategy – Various Avenues to Realise Value

We see various avenues to realise value, including:

- **Sale / Acquisition** - The sale or acquisition of an individual program or the company (BOT) as a whole. This is the most rapid way to realise value.
- **Licensing Deal** – out-licensing a product(s) to a larger pharmaceutical company in exchange for a potential upfront payment, development/ sales milestones and royalties.
- **Go-to-Market** – We explore this pathway below, we continue to believe it is second to sale or out-licensing, however note the company is prepared to undertake this option.

We view a sale/acquisition or licensing deal as the primary avenue for BOT. This pathway represents the lowest risk and most rapid way to realise value.

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Recent transactions suggest there is appetite from larger pharmaceutical companies to acquire or in-license products such as BOT's Sofpironium Bromide.

We note Qbrexza was purchased in 2020 as part of a transaction where its developer Demira was acquired for a total consideration of US$1.1 billion by Eli Lilly.

Later in 2021, Fortress Biotech executed an asset purchase agreement with Eli Lilly for Qbrexza. Fortress paid a US$12.5 million upfront fee, with up to US$144 million in sales milestone, and a tiered royalty of 40-30% in first 2 years with 12-19% thereafter.

As we've previously discussed, Qbrexza is a topical treatment for primary axillary hyperhidrosis (same indication as Sofpironium Bromide). We have also outline in previous sections how we believe Sofpironium Bromide to be a superior product, having greater efficacy (in reduction of sweat production) and a more favourable safety profile. All of this highlights the real potential for Sofpironium Bromide.

We don't anticipate any deals being done prior to FDA approval, as prospective partners are unlikely to take unknown risks during key periods like NDA filling and approval.

However, should no deals arise we believe BOT is capable to go-to-market itself. The trade off being significantly more risk around funding and execution.

We believe BOTs management and board are more than capable to execute, with the combined team having developed, secured approval for, and commercialised over 30 dermatology products.

Additionally, the dermatology market differs from more general treatment areas. Commercialising a dermatology drug doesn't require a massive sales force covering +100,000 general practitioners. In contrast, dermatologist make up a very small group (~1.3% of physicians), with only ~12.5k dermatologist in the US (per the AAMC). Within this there will likely be a smaller sub-group which writes most of the prescriptions. All of this means BOT could bring a new product to market with a relatively small sales force, reducing the need to spend huge sums of money.

Around getting payers coverage, we believe there is a good probability of getting reasonable coverage, as Qbrexza has been able to achieve broad insurance coverage.

Notwithstanding, independently going to market will come with significantly higher risks around execution, as well as sourcing funding.

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Forecasts

As part of our analysis, we have forecasted potential sales and cashflows of Sofpironium bromide. We have modelled both potential commercial pathways, either independently going-to-market or out licensing. We have kept this analysis simple by only modelling sales in the US.

Go-to-Market Scenario	Units	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Adressable Patient Population	'000s	2,210	2,276	2,345	2,415	2,487	2,562	2,639	2,718	2,800	2,884
Growth	%		3%	3%	3%	3%	3%	3%	3%	3%	3%
Market Penetration	%			0.6%	1.6%	2.9%	3.8%	4.5%	5.0%	5.0%	2.5%
Patients Treaded	'000s	0	0	13	37	72	97	117	136	140	72
Annual Treatment Price	US$	8,640	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%	25%
Net Annual Treatment Price	US$	6,480	6,480	6,480	6,480	6,480	6,480	6,480	6,480	6,480	6,480
Net Sales	US$m	0	0	84	243	467	631	761	881	907	467
Cost of Sales	US$m		-2	-96	-194	-280	-252	-152	-176	-181	-93
Gross Income	US$m	0	-2	-13	49	187	379	609	705	726	374
Margin	%			-15%	20%	40%	60%	80%	80%	80%	80%
Royalties Payable	US$m	0	0	-10	-29	-60	-92	-118	-142	-147	-60
Milestone Payable	US$m	-2	-8	0	-10	-30	-50	-70	0	0	0
Pre Tax Cash Flow	US$m	-2	-10	-23	9	97	236	420	562	578	314
Tax Payable	US$m	0	0	0	0	-9	-71	-126	-169	-173	-94
After Tax Cash Flow	US$m	-2	-10	-23	9	88	165	294	394	405	220

Source: EHL estimates

We have made the following key assumptions in our model:

- Commercial launch 2024
- 8 year economic period
- 2.2m addressable patient population, 12 scripts per year
- 5% peak market share
- US$720 per script (same as Qbrexza), 25% Gross-to-net discount
- 80% peak gross margin (ex. Royalties, milestone payments)

Botanix Pharmaceuticals Ltd

(BOT $0.067) Speculative Buy

EUROZ HARTLEYS

Out-License Scenario	Units	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Adressable Patient Population	'000s	2,210	2,276	2,345	2,415	2,487	2,562	2,639	2,718	2,800	2,884
Growth	%		3%	3%	3%	3%	3%	3%	3%	3%	3%
Market Penetration	%			0.4%	1.3%	2.5%	3.8%	5.0%	5.0%	5.0%	1.3%
Patients Treaded	'000s	0	0	9	30	62	96	132	136	140	36
Annual Treatment Price	US$	8,640	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%	25%
Net Annual Treatment Price	US$	6,480	6,480	6,480	6,480	6,480	6,480	6,480	6,480	6,480	6,480
Net Sales	US$m	0	0	57	196	403	623	855	881	907	234
Royalties receivable	US$m	0	0	6	20	48	80	115	119	123	25
Upfront	US$m			50							
Sales Milestones	US$m				10	30	50	70			
Total Cashflow	US$m	0	0	56	30	78	130	185	119	123	25
Net to BOT	US$m	0	0	42	22	59	98	139	89	92	19
Milestones Payable	US$m	-2	-8								
Pre Tax Cash Flow	US$m	-2	-8	42	22	59	98	139	89	92	19
Tax Payable	US$m	0	0	0	-3	-18	-29	-42	-27	-28	-6
After Tax Cash Flow	US$m	-2	-8	42	19	41	68	97	63	65	13

Source: EHL estimates

In modelling a potential out-licensing scenario, we have assumed a deal would be done post FDA approval. 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, 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 Brickell is amended. We have simply assumed BOT pays 25% of the upfront payment , milestone payments and royalties received to Brickell.

We have assumed US$50m upfront, sale milestone payments equal to the deal done with Brickell (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.

Botanix Pharmaceuticals Ltd

(BOT $0.067) Speculative Buy

EUROZ HARTLEYS

Valuation and Price Target

We maintain our Speculative Buy recommendation with an upgraded $0.25/sh. Price Target

We have upgraded our Valuation and Price Target following BOT's acquisition of Sofpironium bromide. We have added the new asset to our sum of the parts (SOP) valuation, as shown below:

Program	Risking	Risked Valuation (rNPV)	
	%	A$m	A$/sh.
Sofpironium Bromide	85%	161	0.15
BTX1503	27%	73	0.07
BTX1801	23%	32	0.03
BTX1702	6%	5	0.00
BTX1204A	6%	4	0.00
Corporate O/H	100%	-23	-0.02
Net Cash (pro-forma)	100%	12	0.01
Total		**263**	**0.25**

Source: EHL estimates

We now view Sofpironium bromide as the main driver of value for BOT.

We have valued Sofpironium bromide using a risked Net Present Value (rNPV), based on a blend of both commercial scenarios previously modelled. This is shown below:

Scenario	Discount Rate	NPV	Risking (r)	rNPV	
	%	A$m	%	A$m	A$/sh.
Go-to-Market	35%	205	85%	174	0.17
Out-license	20%	174	85%	148	0.14
Blend (average)				161	0.15

Source: EHL estimates

We have discounted our cashflows using a 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 85% to account for FDA approval risk.

We note, there is scope for the applied discount rate to decrease as BOT de-risks, this could imply significantly higher valuations.

Equally, we have previously articulated the upside possible in our forecasts, which could also imply significantly higher valuations.

We have maintained our forecasts for BOTs existing dermatology and antimicrobial programs (see Initiation, 9th August 2021). We have also valued these individual programs with a risked NPV, using a 35% discount rate and the applied risking rates shown in the SOP table above (based on respective statistical likelihood of development and approval).

We have included corporate overhead (Corp O/H) into our valuation.

The risks surrounding unsuccessful clinical and commercial outcomes of these programs further drive our **Speculative Buy** recommendation.

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