

Botanix Pharmaceuticals Ltd

(BOT \$0.083) Speculative Buy

EUROZ HARTLEYS

Analyst	Date	Price Target
Seth Lizee	17 th August 2022	\$0.25/sh

Sofpironium Bromide: Future Sales Look Through?

Key Points

Our analysis of newly published figures suggests BOT's lead drug (Sofpironium Bromide) could potentially do **A\$130m of sales in the United States 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 United States. This shown below:

Key Points

- 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 successfully completed two phase 3 studies and a long term safety study late last year, achieving statistical significance across all primary and secondary endpoints
- BOT is now looking to file for FDA approval this quarter (3Q CY22) - which if successful could see the drug approved in ~12 months' time (typical timeline)
- Management is highly experienced and in a positioned to execute having previously developed, secured FDA approval for, and commercialised over 30 dermatology products

Analysis - Significant US Sales Potential

- In 2020, Sofpironium Bromide (5% version) was approved and launched in Japan with an existing partner, Kaken Pharmaceuticals (TYO: 4521, \$1.6 billion Market cap)
- Launched under the brand name ECCLOCK® Gel 5% (shown below), the drug was the first ever product approved in Japan for Primary Axillary Hyperhidrosis



20g bottle



40g bottle

Source: ECCLOCK Website

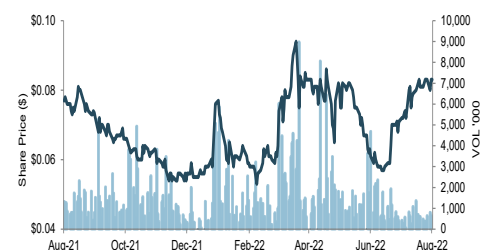
- In 2020, the drug was listed on Japan's National Health Insurance (NHI) drug reimbursement price list at ¥4,874/g (~US\$36) per 20g bottle (2 weeks supply)
- Early this month, Kaken released its Q1'FY22 results showing the company generated ¥413 million of sales from Sofpironium Bromide in the first quarter, which is over ¥1.6 billion on an annualised basis

Botanix Pharmaceuticals Ltd (BOT)

Share Price	0.083	A\$/sh
Price Target	0.25	A\$/sh
Valuation	0.25	A\$/sh
Shares on issue	1,042	m(dil)
Market Capitalisation	86.6	A\$m

Enterprise Value	72.2	A\$/m
Debt	Nil	A\$/m
Cash	7.3	A\$/m
Unpaid Capital	7.1	

Share Price Chart



Disclaimer

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

ASX Limited ABN 98 009 642 691 and its related bodies corporate ("ASX") did not prepare any part of the report and has not contributed in any way to its content. The role of ASX in relation to the preparation of this research report is limited to funding its preparation, by Euroz Hartleys Limited in accordance with the ASX Equity Research Scheme.

ASX does not provide financial product advice. The views expressed in this research report may not necessarily reflect the views of ASX. To the maximum extent permitted by law, no representation, warranty or undertaking, express or implied, is made and no responsibility or liability is accepted by ASX as to the adequacy, accuracy, completeness or reasonableness of the research report.

Euroz Hartleys Limited

All information and advice is confidential and for the private information of the person to whom it is provided and is provided without any responsibility or liability on any account whatsoever on the part of Euroz Hartleys Limited or any member or employee thereof. Refer to full disclaimer at the end of this document.

Botanix Pharmaceuticals Ltd

(BOT \$0.083) Speculative Buy

- Using the NHI reimbursement price and Kaken's quoted Sofpironium Bromide revenues, we can backward out the number of monthly prescriptions of ECCLOCK® Gel 5% in Japan, as shown below:

Japanese Sofpironium Bromide Sales		FY20a	FY21a	1Q'FY22a Annualised	FY22f	20-22 %CAGR
ECCLOCK Gel Revenues	¥ million	170	950	1,652	2,000	243%
(/) Japanese Pricing	¥/month	9,748	9,748	9,748	9,748	
Implied Prescriptions	#/pa	17,439	97,456	169,471	205,170	

*Equivalent 1 months supply

Source: Kaken Pharmaceuticals quarterly report, EHL estimates

- We estimate Kaken sold the equivalent of ~42,400 monthly prescriptions in Q1'FY22, which is nearly 170,000 prescriptions on an annualised basis
- Applying an equivalent US pricing we can extrapolate the revenues generated by this volume of prescriptions in the United States.
- We estimate Sofpironium Bromide could comfortably sell for ~US\$540/month (Net) in the United States, based on the pricing of its closest competitor Qbrexza® (we believe Sofpironium Bromide has a superior efficacy and safety profile, as illustrated at the bottom)

Equivalent U.S. Revenues		FY20a	FY21a	1Q'FY22a Annualised	FY22e
Indicative Japanese Scripts	#/pa*	17,439	97,456	169,471	205,170
(x) US Pricing	US\$/unit*	540	540	540	540
Equivalent US Revenues	US\$m	9.4	52.6	91.5	110.8
Equivalent US Revenues**	A\$m	13.5	75.2	130.7	158.3

*Equivalent 1 months supply

**0.7 AUD/USD Fx

Source: EHL estimates

- Indicatively, this implies Sofpironium Bromide could do in excess of A\$130m of revenues in the United States based on Kaken's annualised actual Q1 prescription volumes, and nearly \$160m based on its FY22 forecasted prescription volumes
- We note this is also based on Kaken's first year of unrestricted sales (Japan has 2-week prescription limit on new drugs for the first year) - typically sales will grow rapidly in the first 3-5yrs before peaking
- 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
- To put this all into in perspective - Clinuvel Pharmaceuticals (ASX: CUV), which has a ~\$1 billion market cap, is forecasted to do ~A\$64 million (~US\$45m) in revenues in FY'22

US Addressable Market

- Hyperhidrosis affects upwards of 15 million people in the United States alone
- The treatments market is currently worth \$1.6 billion and projected to grow to \$2.8 billion by 2030
- Sofpironium Bromide's target patient population is estimated to be ~3.7 million people in the United States, equal to the estimated number of patients with severe axillary hyperhidrosis seeking treatment
- As stated previously, we estimate Sofpironium Bromide could comfortably sell for ~US\$540/month (Net) in the United States, based on the pricing of its closest competitor Qbrexza®
- Even modest market penetration can translate into significant revenues

Euroz Hartleys Limited

All information and advice is confidential and for the private information of the person to whom it is provided and is provided without any responsibility or liability on any account whatsoever on the part of Euroz Hartleys Limited or any member or employee thereof. Refer to full disclaimer at the end of this document.

Botanix Pharmaceuticals Ltd

(BOT \$0.083) Speculative Buy

EUROZ HARTLEYS

- The table below illustrates the revenues possible from Sofpironium Bromide in the United States

		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

*Based on 3.7m target patient population

**Based on \$540/month (Net) pricing

Source: EHL Estimates

Clinical Comparison: Sofpironium Bromide vs Qbrexza® (main competitor)

- The table below illustrates Sofpironium Bromide has superior efficacy (based on baseline reduction in sweat production), and lower incidence of treatment-emergent adverse events.

Study	Sofpironium Bromide						Qbrexza (glycopyrronium) cloth					
	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 Pruritus	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 Filings, BOT announcements, Qbrexza publications (ATMOS-1, ATMOS-2 results)

- Our research note from the 13th May 2022 provides a more exhaustive analysis

Investment Thesis

Botanix Pharmaceuticals Ltd (BOT) is a pharmaceutical company looking to shake up big markets in dermatology and antimicrobials. The company has a mature development pipeline, with its lead product Sofpironium Bromide to file for FDA approval in Q3 CY22. This is in addition to a series of other programs in clinical studies, which leverage the unique properties of synthetic cannabinoid, in conjunction with a proprietary drug delivery system.

We believe the market is pricing these programs as failures, or close to it, whereas our analysis suggests the opposite. The prize, should individual programs ultimately be successful, is huge. We anticipate the stock will trade up as we approach the multiple catalyst due this year, if BOT can deliver successful clinical and commercial outcomes, we believe the stock can trade above our price target, perhaps substantially.

Development Pipeline shown below:

INDICATION	PRODUCT	PHASE 1	PHASE 1B	PHASE 2	PHASE 3	APPROVED	STATUS (CY)	
Axillary Hyperhidrosis (excessive underarm sweating)	Sofpironium Bromide	[Progress bar: Phase 1, 1B, 2, 3]						FDA approval filing planned for 3Q 2022
Moderate to severe acne	BTX 1503	[Progress bar: Phase 1, 1B, 2]						Phase 3 study commencement pending
Rosacea	BTX 1702	[Progress bar: Phase 1, 1B, 2]						Phase 2 study planned for completion 3Q 2022
Atopic Dermatitis	BTX 1204A	[Progress bar: Phase 1, 1B, 2]						Canine study planned for completion 3Q 2022
Antimicrobial	BTX 1801	[Progress bar: Phase 1, 1B, 2]						Phase 2 study preparing for launch in 2H 2022

Euroz Hartleys Limited

All information and advice is confidential and for the private information of the person to whom it is provided and is provided without any responsibility or liability on any account whatsoever on the part of Euroz Hartleys Limited or any member or employee thereof. Refer to full disclaimer at the end of this document.

Copyright & Distribution

The material contained in this communication (and all attachments) is prepared for the exclusive use of clients of Euroz Hartleys Limited (ACN 104 195 057) only.

Euroz Hartleys Limited is the holder of an Australian Financial Services Licence (AFSL 230052) and is a participant of the Australian Securities Exchange Group, Cboe and NSX.

The information contained herein is confidential. If you are not the intended recipient no confidentiality is lost by your receipt of it. Please delete and destroy all copies, and contact Euroz Hartleys Limited on (+618) 9488 1400. You should not use, copy, disclose or distribute this information without the express written authority of Euroz Hartleys Limited.

Disclaimer & Disclosure

Euroz Hartleys Limited, and their associates declare that they deal in securities as part of their securities business and consequently may have an interest in the securities recommended herein (if any). This may include providing equity capital market services to the issuing company, hold a position in the securities, trading as principal or agent and as such may effect transactions not consistent with the recommendation (if any) in this report.

Euroz Hartleys Limited declares that they may have separately or jointly acted as an underwriter, arranger, co-arranger or adviser in equity capital raisings, and will have received a fee for its services, from or any company mentioned within this report during the last 12 months.

You should not act on any recommendation issued by Euroz Hartleys Limited without first consulting your investment adviser in order to ascertain whether the recommendation (if any) is appropriate, having regard to your objectives, financial situation and needs. Nothing in this report shall be construed as a solicitation to buy or sell a security, or to engage in or refrain from engaging in any transaction.

Euroz Hartleys Limited believes that the information and advice contained herein is correct at the time of compilation, however we make no representation or warranty that it is accurate, complete, reliable or up to date, nor do we accept any obligation to correct or update the opinions in it. The opinions expressed are subject to change without notice. No member of Euroz Hartleys Limited accepts any liability whatsoever for any direct, indirect, consequential or other loss arising from any use of this material.

We cannot guarantee that the integrity of this communication has been maintained, is free from errors, virus interception or interference.

The author of this publication, Euroz Hartleys Limited, its directors and their associates from time to time may hold shares in the security/securities mentioned in this Research document and therefore may benefit from any increase in the price of those securities. Euroz Hartleys Limited, and its Advisers may earn brokerage, fees, commissions, other benefits or advantages as a result of transactions arising from any advice mentioned in publications to clients.

To view the Euroz Hartleys' Quick Comment Disclaimers, please visit the below links:

<https://www.eurozhartleys.com/wp-content/uploads/August-Resources-Disclaimers.pdf>

<https://www.eurozhartleys.com/wp-content/uploads/August-Industrials-Disclaimers.pdf>

Analyst Certification

We hereby certify that all of the views expressed in this report accurately reflect our personal views about the subject company or companies and its or their securities, and we are not in possession of, nor does this Research contain any inside information.

No part of our compensation was, is or will be directly or indirectly, related to the specific recommendations or views expressed by the authoring analyst in this research, nor has any attempt been made to influence this Research.

Contact Details

Euroz Hartleys Limited +61 8 9488 1400

Research Analysts

Gavin Allen - Head of Research	+61 8 9488 1413
Mike Millikan - Resources Analyst	+61 8 9268 2805
Kyle De Souza - Resources Analyst	+61 8 9488 1427
Michael Scantlebury - Resources Analyst	+61 8 9268 2837
Steven Clark - Resources Analyst	+61 8 9488 1430
Trent Barnett - Senior Analyst	+61 8 9268 3052
Harry Stevenson - Industrials Analyst	+61 8 9488 1429
Seth Lizee - Research Analyst	+61 8 9488 1414

Euroz Hartleys Limited

All information and advice is confidential and for the private information of the person to whom it is provided and is provided without any responsibility or liability on any account whatsoever on the part of Euroz Hartleys Limited or any member or employee thereof. Refer to full disclaimer at the end of this document.
