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EUROZ HARTLEYS

BOT: Japanese Partner Reports Strong 2Q Sales; Upgrades Full Year Sales Target

BOT.ASX | BOTANIX PHARMACEUTICALS LIMITED | HEALTHCARE | BIOTECHNOLOGY

PRICE	TARGET PRICE	RECOMMENDATION	ANALYST
A$0.150/sh	**A$0.310/sh** (UNCHANGED)	**SPECULATIVE BUY** (UNCHANGED)	**SETH LIZEE** SLIZEE@EUROZHARTLEYS.COM

Event

BOT's Japanese pharmaceutical partner, Kaken Pharmaceuticals, has recently released their 2Q FY23 financial results. Link here.

Sales of Sofpironium Bromide (branded as "Ecclock") **grew 71% pcp to ¥700 million** in 2Q 2023. Moreover, **Kaken upgraded its 2023 full year sales target to ¥2.1 billion** (from ¥1.9 billion), implying +67% YoY growth.

Impact

These figures provide insight into the potential future sales of Sofpironium Bromide in the United States, underscoring the considerable market opportunity at hand.

Based on our analysis, we estimate Kaken sold ~72,000 prescriptions in 2Q, or +**287,000 prescriptions on an annualised basis** (Figure 4).

More so, when applied to our estimate of US pricing (US$540/month; net), this annualised 2Q prescription figure implies ~**A$239 million of annual revenues** in the United States (Figure 5).

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.

We provide the full analysis below.

Action

We maintain our Speculative Buy recommendation and $0.31/sh Price Target.

The ongoing success of Sofpironium Bromide in Japan, and the commercial look-through it suggests into the United States, is highly encouraging.

We continue to see a solid buying opportunity post the recent complete response letter (CRL).

As a reminder, the CRL solely pertained to patient instructions (specifically the instructions paper and product carton wording) — a minor issue in the broader context.

Compared to other ASX-listed cases of CRL's, BOT's appears to be the lowest risk and most manageable. Moreover, the same examples indicate most CRLs eventually secure approval (Figure 7), with precedent of a re-rate following refiling and into approval.

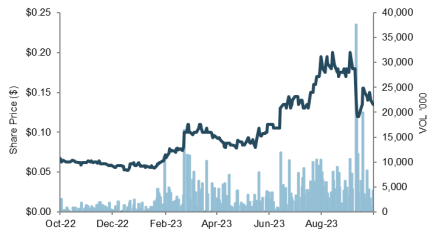
Catalysts

- 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	0.15	A$/sh
Price Target	**0.31**	**A$/sh**
Valuation	0.31	A$/sh
Shares on issue	1,588	m, dil
Market Capitalisation	238.1	A$m
Enterprise Value	219.7	A$m
Debt	0.0	A$m
Cash (Proforma)	10.3	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$m)	0.0	0.0	0.0
Op. Free Cash flow (...	-3.1	-1.3	37.0
EBITDA Growth (%)	-0.8	-3.6	12.2
NPAT Growth (%)	-0.7	-2.2	16.5
Normalised EPS (Ac)	-0.2	0.2	3.4
Norm. EPS growth (%)	-0.7	-2.2	16.5
PER (x)	-83.6	68.4	3.9
EV/EBITDA (x)	-135.7	52.0	3.9
EV/Revenue (x)	65.0	3.6	1.5
Net Cash (A$m)	7.6	16.5	53.7

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)	-83.6	68.4	3.9
PER (Fully diluted) (x)	-93.4	76.4	4.4
PER (Fully diluted, normalized) (x)	-93.4	76.4	4.4
P/CFPS (x)	-122.5	52.0	3.8
Price/NBV (x)	6.5	4.6	2.1
Price/NTA (x)	19.5	8.5	2.6
Dividend Yield (%)	0.0	0.0	0.0
EV/EBITDA (x)	-135.7	52.0	3.9
EV/EBIT (x)	-86.2	70.5	4.0
EV/Revenue (x)	65.0	3.6	1.5

Analysis

Japanese Partner Sales

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 1), the drug was the first ever product approved in Japan for Primary Axillary Hyperhidrosis.

Figure 1: ECCLOCK© Gel 5%, Product and Packaging

20g bottle

40g bottle

Source: Ecclock Website

Kaken has released their 2Q FY23 financial results, Link here.

Sales of Sofpironium Bromide (branded as "Ecclock") **grew 71% pcp to ¥700 million** in 2Q 2023. Moreover, **Kaken upgraded its 2023 full year sales target to ¥2.1 billion** (from ¥1.9 billion), implying +67% YoY growth (Figure 2).

Figure 2: Kaken Segment Breakdown

7. Sales of Main Pharmaceuticals and Medical Devices (non-consolidated)

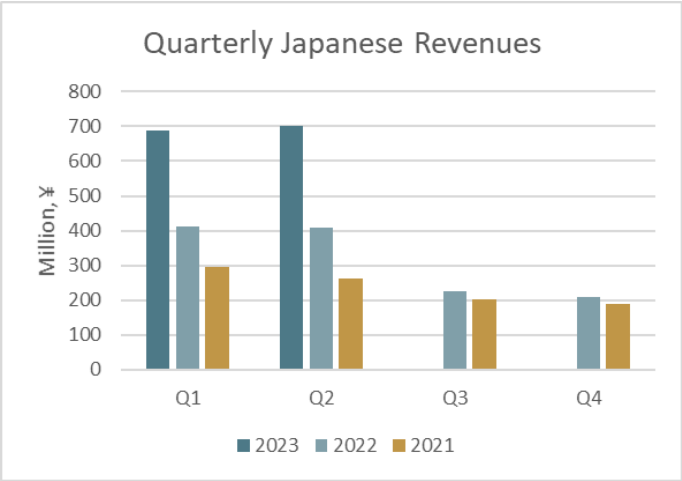
(amounts are rounded down to the nearest million Yen)

	FY2022 2Q	FY2022	FY2023 2Q	Change (%)	Revised plan FY2023	Change (%)	Plan FY2023
Onychomycosis treatment Clenafin	9,633	17,985	9,199	95.5%	17,700	98.4%	17,700
Anti-osteoarthritis agent Artz	8,673	17,062	8,929	103.0%	18,100	106.1%	18,000
Post-operative anti-adhesive Sepraflm	4,014	7,790	3,544	88.3%	7,000	89.9%	7,300
Wound-healing agent Fiblast	1,378	2,759	1,321	95.9%	2,700	97.9%	2,700
Primary axillary hyperhydrosis treatment Ecclock	823	1,257	1,387	168.4%	2,100	167.1%	1,900
Periodontal regenerative agent Regroth	444	891	442	99.6%	900	101.0%	900
Lumber disc herniation treatment Hernicore	209	392	188	89.9%	400	102.0%	400
Generic products (total)	4,190	8,201	4,024	96.0%	7,900	96.3%	7,900

Source: Kaken quarterly report
notes on reporting format: quarterly figures are quoted as year-to-date figures (e.g. 2Q figure reflects 1Q+2Q), and growth figures are quoted relative to 100% baseline (e.g. 168.4% is actually 68.4%) and are based on the 'quarterly' figure comparison.

We have compiled the quarterly japanese sales data for Sofpironium Bromide, marketed as Ecclock, in Figure 3. The data highlights robust and accelerating pcp growth.

Figure 3: ECCLOCK Quarterly Sales



Source: Kaken quarterly reports, EHL analysis

Using Japan's National Health Insurance (NHI) reimbursement price (¥4,874 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 4: Japanese Sofpironium Bromide Sales

Japanese Sofpironium Bromide Sales		FY20a	FY21a	FY22a	2Q'FY23a	2Q'FY23 Annualised	FY23 Target	FY20-23 %CAGR
ECCLOCK Gel Revenues	¥ million	170	950	1,257	700	2,800	2,100	131%
(/) Japanese Pricing	¥/month	9,748	9,748	9,748	9,748	9,748	9,748	
Implied Prescriptions	#*/pa	17,439	97,456	128,950	71,810	287,238	215,429	

*Source: Kaken pharmaceuticals quarterly report; EHL analysis; *Equivalent to 1 months' supply*

We estimate Kaken has a current annual run rate of +287,000 prescriptions based on 2Q revenues, and +215,000 based on the upgraded FY23 revenue target.

Applying an equivalent USA pricing we can extrapolate the revenues generated by this volume of prescriptions in the United States (Figure 5).

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).

Figure 5: Est. Equivalent US Revenues

Equivalent U.S. Revenues		FY20a	FY21a	FY22a	2Q'FY23a	2Q'FY23 Annualised	FY23 Target	FY20-23 %CAGR
Indicative Japanese Scripts	#/pa*	17,439	97,456	128,950	71,810	287,238	215,429	131%
(x) US Pricing	US$/unit*	540	540	540	540	540	540	
Equivalent US Revenues	US$m	9.4	52.6	69.6	38.8	155.1	116.3	
Equivalent US Revenues**	A$m	14.5	81.0	107.1	59.7	238.6	179.0	

*Source: EHL analysis; *Equivalent to 1 months' supply; **0.65 AUD/USD*

Indicatively, this implies Sofpironium Bromide could do circa A$239 million of annual revenues in the United States based on our estimate of Kaken's annualised 2Q prescription volumes.

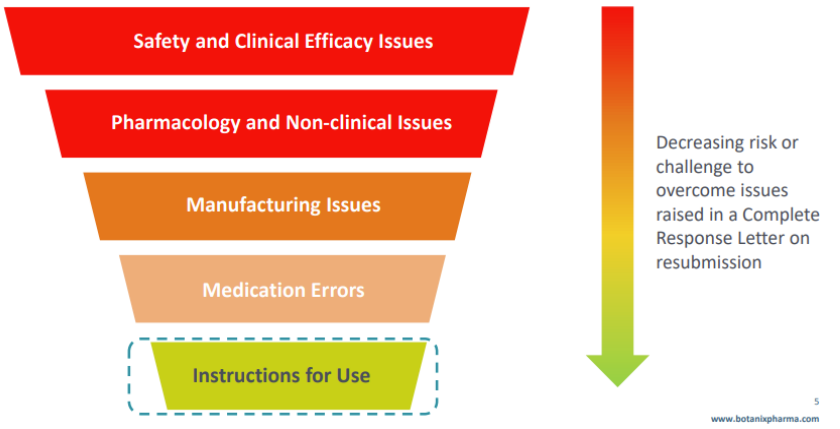
Additionally, this is based on Japanese prescription volumes, the United States has a population nearly 3x larger than Japan – which would suggest even larger potential prescription volumes and sales are possible.

FDA Communication

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

Complete Response Letters can be issued in relation to various issues, some more significant than others (Figure 6).

Figure 6: Potential CRL Deficiencies



Source: company presentation

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).

BOT has indicated it will meet with the FDA in November/December to confirm resubmission guidance.

Moreover, the company has confirmed it remains on track to resubmit the NDA by early 1Q CY 2024, with a target approval of mid-CY 2024.

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

We can further demonstrates this by comparing BOT's complete response letter to other ones received in the past by ASX companies (Figure 7).

Figure 7: 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	Approved

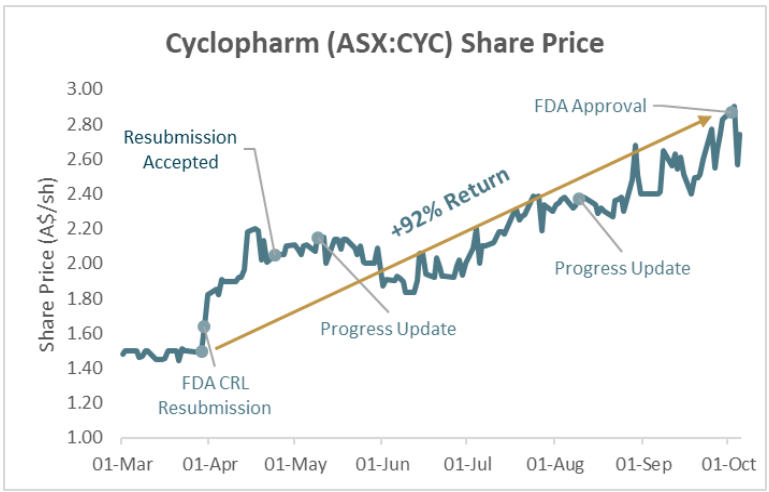
Source: Company announcements, EHL analysis
**Non exhaustive, as only lists the first instance of CRL, noting some of the applications received multiple CRLs*

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.

The most recent example is Cyclopharm (ASX: CYC), which recently received FDA approval for its 'Technegas' product in early october of this year. CYC originally received a CRL in June 2021.

From refiling to FDA approval, the CYC share price nearly doubled (Figure 8).

Figure 8: Cyclopharm (CYC) Share Price



Source: IRESS, EHL analysis

Furthermore, it is very clear the deficiencies listed in these other ASX-listed 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.

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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.

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Botanix Pharmaceuticals Limited (BOT.ASX) | Price A$0.150 | Target price A$0.310 | Recommendation Speculative Buy;

Price, target price and rating as at 17 November 2023 (not covered)*

Additional disclosures

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