



# BOT: Kaken 3Q Results, YTD Sales +51% YoY

**BOT.ASX | BOTANIX PHARMACEUTICALS LIMITED | HEALTHCARE | BIOTECHNOLOGY**

PRICE  
**A\$0.185/sh**

TARGET PRICE  
**A\$0.300/sh**  
(UNCHANGED)

RECOMMENDATION  
**SPECULATIVE BUY**  
(UNCHANGED)

ANALYST  
**SETH LIZEE**  
SLIZEE@EUROZHARTLEYS.COM

## Event

BOT's Japanese pharmaceutical partner, Kaken Pharmaceuticals, has released their 3Q FY23 financial results. Link [here](#).

The company reported ¥201 million in 3Q FY23 sales of Sofpironium Bromide (branded as "Ecclock"), taking year-to-date (YTD) sales to ~¥1.6 billion, up +51% YoY. Further, Kaken maintained its FY23 full year sales target of ¥2.1 billion (implying +67% YoY).

## Impact

The success of Sofpironium Bromide in Japan provides a compelling case study of its significant commercial potential. However, it's imperative to note our investment case centres squarely on the US market, and our confidence in BOT's management team to execute – underscored by a successful track record of commercialising 30+ products.

The significant growth in YTD sales (+51% YoY) is highly encouraging, noting we expected the QoQ decrease due to the previously observed seasonality. More importantly, the implied prescription volumes alone and the commercial look through it suggest is significant, as illustrated below.

Based on our analysis, **we estimate Kaken has sold ~163,000 prescriptions year to date**. Moreover, the **FY23 sales target implies +215,000 prescriptions**.

When applied to our estimate of US net pricing (US\$540/month), this **target FY23 full year prescriptions figure implies ~A\$179 million of annual revenues in the United States**.

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 revenues are possible.

We provide the full analysis below.

## Action

**We maintain our Speculative Buy Recommendation and \$0.30/sh Price Target**

The ongoing success of Sofpironium Bromide in Japan, and the commercial look-through implied, is highly encouraging.

We remain confident on BOT securing FDA approval (anticipated late June 2024), noting the complete response letter (CRL) received solely pertained to patient instructions (specifically the instructions paper and product carton wording) — a minor issue in the broader context.

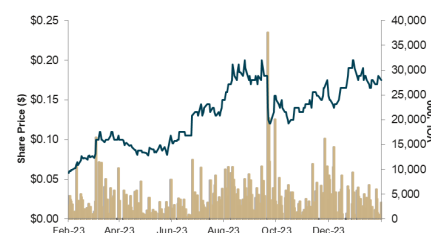
Compared to other ASX-listed cases of CRL's, BOT's appears to be the lowest risk and most manageable. Moreover, the same examples indicate most CRLs eventually secure approval, with precedent of a re-rate following refiling and into approval.

## Catalysts

- FDA Approval - Late June 2024
- Commercial Launch / First US Sales

Share Price	0.185	A\$/sh	
Price Target	0.30	A\$/sh	
Valuation	0.30	A\$/sh	
Shares on issue	1,684	m, dil	-
Market Capitalisation	311.5	A\$m	
Enterprise Value	284.5	A\$m	
Debt	0.0	A\$m	
Cash (Proforma)*	21.8	A\$m	
Unpaid capital	5.3	A\$m	
<i>*Inc R&amp;D, Options</i>			
<b>Key Metrics</b>	<b>24F</b>	<b>25F</b>	<b>26F</b>
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
Norm NPAT (A\$m)	-2.5	3.1	54.6
Gross CF (A\$m)	-1.7	4.1	55.7
Capex (A\$m)	0.0	0.0	0.0
Op. FCF (A\$m)	-3.1	-1.3	37.0
EBITDA Gwth (%)	-0.8	-3.6	12.2
NPAT Gwth (%)	-0.7	-2.2	16.5
Norm EPS (Ac)	-0.2	0.2	3.2
Norm. EPS gwth (%)	-0.8	-2.2	16.5
PER (x)	-111.9	91.5	5.2
EV/EBITDA (x)	-175.8	67.3	5.1
EV/Revenue (x)	84.1	4.6	1.9
Net Cash (A\$m)	19.7	18.6	55.7

## Performance



Source: IRESS

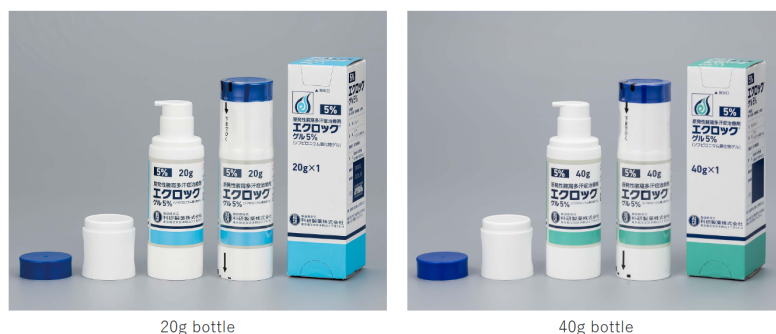
Income Statement				Performance Ratios			
	24F	25F	26F		24F	25F	26F
Net Sales	0.0	60.8	146.0	<b>Growth &amp; Margins</b>			
Royalties	0.9	1.0	1.2	Revenue Growth	-12%	1727%	138%
Other (inc R&D)	2.5	0.0	0.0	EBITDA Growth	-82%	-361%	1220%
<b>Total Revenue</b>	<b>3.4</b>	<b>61.8</b>	<b>147.2</b>	EBIT Growth	-72%	-222%	1652%
(-) COGS (inc. roy)	0.0	-14.6	-33.6	Net Profit Growth	-72%	-222%	1652%
<b>Gross Profit</b>	<b>3.4</b>	<b>47.2</b>	<b>113.6</b>	<b>Margins</b>			
(-) R&D	0.0	0.0	0.0	EBITDA margin	-48%	7%	38%
(-) SG&A	-5.0	-43.0	-57.8	EBIT margin	-75%	5%	37%
<b>EBITDA</b>	<b>-1.6</b>	<b>4.2</b>	<b>55.8</b>	Net profit margin	-75%	5%	37%
(-) D&A	-0.9	-1.1	-1.2	Effective tax rate	0%	0%	0%
<b>EBIT</b>	<b>-2.5</b>	<b>3.1</b>	<b>54.6</b>	<b>Liquidity</b>			
(-) Net finance	0.0	0.0	0.0	Capex/depreciation	0.0	0.0	0.0
(+/-) Other	0.0	0.0	0.0	Current ratio	24.5	4.8	9.6
<b>PBT</b>	<b>-2.5</b>	<b>3.1</b>	<b>54.6</b>	Quick ratio	24.6	3.6	7.6
(-) Tax	0.0	0.0	0.0	Receivable days	60.0	42.5	41.1
<b>NPAT</b>	<b>-2.5</b>	<b>3.1</b>	<b>54.6</b>	Payable days	60.0	60.0	60.0
(+/-) Adj.	0.0	0.0	0.0	<b>Risk Measures</b>			
<b>Norm NPAT</b>	<b>-2.5</b>	<b>3.1</b>	<b>54.6</b>	Dividend Cover	na	na	na
<b>Cash Flow Statement</b>	<b>24F</b>	<b>25F</b>	<b>26F</b>	Payout ratio	0%	0%	0%
<b>NPAT</b>	<b>-2.5</b>	<b>3.1</b>	<b>54.6</b>	Net interest cover	na	na	na
(+) D&A	0.9	1.1	1.2	Net debt/equity	-0.4	-0.4	-0.5
(+) Non-cash expenses	0.0	0.0	0.0	<b>Returns</b>			
(-) Leases	-0.1	-0.1	-0.1	ROIC	-4%	5%	37%
(+/-) Other	0.0	0.0	0.0	ROA	-6%	6%	49%
<b>Gross Cash Flow</b>	<b>-1.7</b>	<b>4.1</b>	<b>55.7</b>	ROE	-6%	6%	53%
(-) Capital expenditure	0.0	0.0	0.0	<b>Share Data/Valuation</b>	<b>24F</b>	<b>25F</b>	<b>26F</b>
(+/-) Working capital	-1.3	-5.4	-18.6	Issued shares	1,541.1	1,541.1	1,541.1
<b>Operating Free Cash Flow</b>	<b>-3.1</b>	<b>-1.3</b>	<b>37.0</b>	Weighted ave shares	1,426.8	1,541.1	1,541.1
(-) Acquisition	-12.1	0.0	0.0	Fully diluted shares	1,684.0	1,684.0	1,684.0
(-) Milestone payment	0.0	0.0	0.0	Basic EPS	-0.2	0.2	3.5
(+) Placement	24.6	0.0	0.0	YoY change	-76%	-222%	1652%
(+) Disposal	0.0	0.0	0.0	Fully diluted EPS	-0.2	0.2	3.2
(+/-) Other	0.0	0.0	0.0	YoY change	-76%	-222%	1652%
<b>Net Cash Flow</b>	<b>9.4</b>	<b>-1.3</b>	<b>37.0</b>	Fully diluted normalised EPS	-0.2	0.2	3.2
BoP Net Cash / (Debt)	10.2	19.7	18.6	YoY change	-76%	-222%	1652%
(+/-) Net Cash Flow	9.4	-1.3	37.0	Dividend/share	0.0	0.0	0.0
(+/-) Other	0.1	0.1	0.1	Franking	na	na	na
<b>EoP Net Cash / (Debt)</b>	<b>19.7</b>	<b>18.6</b>	<b>55.7</b>	Gross cash flow/share	-0.1	0.3	3.6
<b>Balance Sheet</b>	<b>24F</b>	<b>25F</b>	<b>26F</b>	NBV/share	2.9	3.1	6.7
Cash	19.7	18.6	55.7	NTA/Share	1.5	1.8	5.4
Inventory	3.5	8.5	20.2	<b>Valuation</b>			
Receivables	0.6	7.2	16.6	PER (Basic) (x)	-111.9	91.5	5.2
Other	0.1	0.1	0.1	PER (Fully diluted) (x)	-122.2	100.0	5.7
<b>Current Assets</b>	<b>23.9</b>	<b>34.3</b>	<b>92.5</b>	PER (Fully diluted, normalized) ...	-122.2	100.0	5.7
PP&E	0.0	0.0	0.0	P/CFPS (x)	-163.8	69.5	5.1
Intangible	21.9	20.8	19.7	Price/NBV (x)	6.3	5.9	2.8
ROUA	0.0	0.0	0.0	Price/NTA (x)	12.4	10.5	3.4
Other	0.1	0.1	0.1	Dividend Yield (%)	0.0	0.0	0.0
<b>Non-current Assets</b>	<b>22.1</b>	<b>21.0</b>	<b>19.7</b>	EV/EBITDA (x)	-175.8	67.3	5.1
<b>Total Assets</b>	<b>45.9</b>	<b>55.3</b>	<b>112.3</b>	EV/EBIT (x)	-111.6	91.3	5.2
Payables	0.8	7.1	9.5	EV/Revenue (x)	84.1	4.6	1.9
Lease liabilities	0.0	0.0	0.0				
Provisions	0.2	0.2	0.2				
<b>Current Liabilities</b>	<b>1.0</b>	<b>7.2</b>	<b>9.7</b>				
Lease liabilities	0.0	0.0	0.0				
<b>Non-current liabilities</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>				
<b>Total liabilities</b>	<b>1.0</b>	<b>7.2</b>	<b>9.7</b>				
<b>Net Assets</b>	<b>44.9</b>	<b>48.1</b>	<b>102.6</b>				
Issued Capital	118.1	118.1	118.1				
Reserves	6.4	6.4	6.4				
Retained earnings	-79.5	-76.4	-21.8				
<b>Total equity</b>	<b>45.0</b>	<b>48.1</b>	<b>102.7</b>				

## 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**



Source: Ecclock Website

Kaken has released their 3Q FY23 financial results, link [here](#).

The company reported ¥201 million in 3Q FY23 sales of Sofpironium Bromide (branded as "Ecclock"), taking year-to-date (YTD) sales to ~¥1.6 billion, up +51% YoY. Further, Kaken maintained its FY23 full year sales target of ¥2.1 billion (implying +67% YoY).

**Figure 2: Kaken Segment Breakdown**

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

(amounts are rounded down to the nearest million Yen)

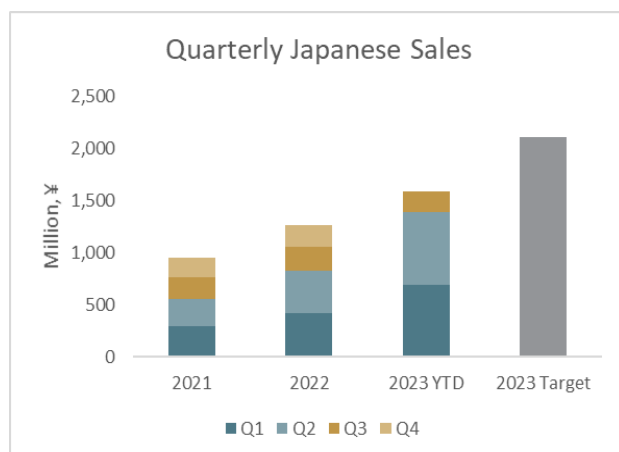
	FY2022 3Q	FY2022	FY2023 3Q	Change (%)	Plan FY2023	Change (%)
Onychomycosis treatment Clenafin	14,444	17,985	13,821	95.7%	17,700	98.4%
Anti-osteoarthritis agent Artz	13,159	17,062	13,845	105.2%	18,100	106.1%
Post-operative anti-adhesive Seprafilm	6,095	7,790	5,479	89.9%	7,000	89.9%
Wound-healing agent Fibblast	2,075	2,759	2,008	96.8%	2,700	97.9%
Primary axillary hyperhidrosis treatment Ecclock	1,049	1,257	1,588	151.4%	2,100	167.1%
Periodontal regenerative agent Regroth	670	891	670	100.1%	900	101.0%
Lumber disc herniation treatment Hernicore	303	392	291	96.3%	400	102.0%
Generic products (total)	6,375	8,201	6,200	97.3%	7,900	96.3%

Source: Kaken quarterly report

note: quarterly figures are quoted as year-to-date figures and growth figures are quoted relative to 100% baseline and are based on the 'quarterly; figure comparison.

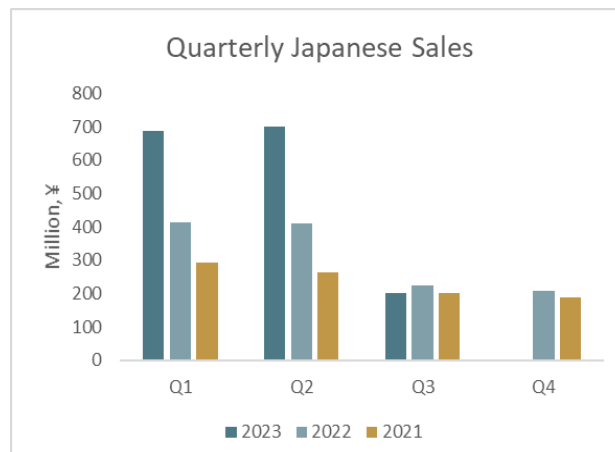
We have compiled the quarterly Japanese sales data for Sofpironium Bromide below.

**Figure 3: ECCLOCK Sales**



Source: Kaken quarterly report, EH analysis, \*YTD: year-to-date

**Figure 4: ECCLOCK Sales**



Source: Kaken quarterly report, EH analysis

The significant growth in YTD sales (+51% YoY) is highly encouraging, noting we expected the QoQ decrease due to previously observed seasonality.

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 5: Japanese Sofpironium Bromide Sales**

Japanese Sofpironium Bromide Sales		FY20a	FY21a	FY22a	FY23YTD	FY23 Target	FY20-23 %CAGR
ECCLOCK Gel Revenues	¥ million	170	950	1,257	1,588	2,100	131%
(/) Japanese Pricing	¥/month	9,748	9,748	9,748	9,748	9,748	
Implied Prescriptions	#*/pa	17,439	97,456	128,950	162,905	215,429	

Source: Kaken quarterly report, EH analysis, \*equivalent to 1 months' supply

We estimate Kaken has sold ~163,000 prescriptions year to date, with their FY23 sales target implying +215,000 prescriptions for the year.

Applying an equivalent USA pricing we can extrapolate the revenues generated by this volume of prescriptions in the United States (Figure 6).

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 6: Est. Equivalent US Revenues**

Equivalent U.S. Revenues		FY20a	FY21a	FY22a	FY23YTD	FY23 Target	FY20-23 %CAGR
Indicative Japanese Scripts	#/pa*	17,439	97,456	128,950	162,905	215,429	131%
(x) US Pricing	US\$/unit*	540	540	540	540	540	
Equivalent US Revenues	US\$m	9.4	52.6	69.6	88.0	116.3	
Equivalent US Revenues**	A\$m	14.5	81.0	107.1	135.3	179.0	

Source: EH analysis, \*equivalent to 1 months' supply, \*\*0.65 AUD/USD

Indicatively, this implies Sofpironium Bromide could do +A\$135 million of annual revenues in the United States based just on our estimate of Kaken's year to date prescription volumes, and circa A\$179 million based on its FY23 target.

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 Review

We remain confident on BOT securing FDA approval – this remains on track for late June 2024.

BOT's complete response letter (CRL) solely pertained to patient instructions (specifically the instructions paper and product carton wording) — a minor issue in the broader context.

ASX-listed instances of CRL's aren't that all uncommon (Figure 7), with some observations:

- Out of the drugs listed below, we note most were eventually approved despite receiving a complete response letter (or multiple letters), with only one withdrawn.
- Moreover, it's clear the deficiencies listed in these other examples are much more significant than BOT's. We would go further to say BOT has one of the most manageable and low risk CRL's out of all of these comparisons.

**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

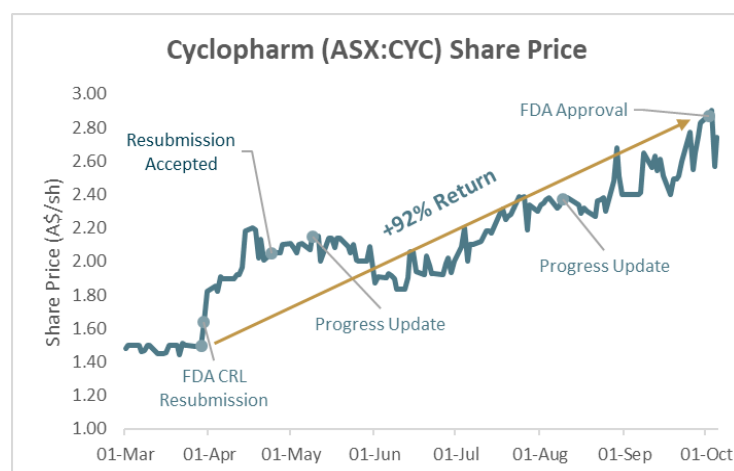
Source: Company announcements, EH analysis

\*Non exhaustive, as only lists first instance of CRL, noting some of the applications received multiple CRL's

The most recent example of a CRL being approved is Cyclopharm (ASX: CYC), which received FDA approval for its 'Technegas' product in early October 2023. 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, EH analysis

## Forecasts

The table below illustrates a summary of our US Sofpironium Bromide forecasts.

**Figure 9: US Sofpironium Bromide (SB) Forecasts**

US SB Forecasts	Units	FY2025	FY2026	FY2027	FY2028	FY2029	FY2030	FY2031	FY2032	FY2033
<b>Prescriptions Sold</b>	<b>'000s</b>	<b>72.0</b>	<b>168.0</b>	<b>228.0</b>	<b>276.0</b>	<b>312.0</b>	<b>348.0</b>	<b>384.0</b>	<b>420.0</b>	<b>456.0</b>
Implied Patients Treated	'000s	6.0	14.0	19.0	23.0	26.0	29.0	32.0	35.0	38.0
... Market penetration	%	0.2%	0.4%	0.5%	0.6%	0.7%	0.8%	0.9%	0.9%	1.0%
... Growth	%		133%	36%	21%	13%	12%	10%	9%	9%
Wholesale Pricing (WAC)	US\$/script	720	742	764	787	810	835	860	886	912
...Price escalation	%		3%	3%	3%	3%	3%	3%	3%	3%
Net pricing (net)	US\$/script	540	556	573	590	608	626	645	664	684
...Gross-to-net	%	25%	25%	25%	25%	25%	25%	25%	25%	25%
<b>Net Sales</b>	<b>US\$m</b>	<b>38.9</b>	<b>93.4</b>	<b>130.6</b>	<b>162.9</b>	<b>189.6</b>	<b>217.9</b>	<b>247.6</b>	<b>278.9</b>	<b>311.9</b>
<b>(-) COGS</b>	<b>US\$m</b>	<b>-7.4</b>	<b>-16.8</b>	<b>-22.2</b>	<b>-26.1</b>	<b>-28.4</b>	<b>-32.7</b>	<b>-37.1</b>	<b>-41.8</b>	<b>-46.8</b>
<b>Gross Profit</b>	<b>US\$m</b>	<b>31.5</b>	<b>76.6</b>	<b>108.4</b>	<b>136.8</b>	<b>161.2</b>	<b>185.2</b>	<b>210.5</b>	<b>237.1</b>	<b>265.1</b>
...Gross Margin	%	81%	82%	83%	84%	85%	85%	85%	85%	85%
<b>(-) SG&amp;A</b>	<b>US\$m</b>	<b>-27.5</b>	<b>-37.0</b>	<b>-39.2</b>	<b>-44.8</b>	<b>-47.4</b>	<b>-49.0</b>	<b>-49.5</b>	<b>-55.8</b>	<b>-62.4</b>
...as % of Net sales	%	71%	40%	30%	28%	25%	23%	20%	20%	20%
<b>(-) Royalty</b>	<b>US\$m</b>	<b>-1.9</b>	<b>-4.7</b>	<b>-6.5</b>	<b>-8.1</b>	<b>-9.5</b>	<b>-10.9</b>	<b>-12.4</b>	<b>-13.9</b>	<b>-15.6</b>
...as % of Net sales	%	5%	5%	5%	5%	5%	5%	5%	5%	5%
<b>Operating Income</b>	<b>US\$m</b>	<b>2.0</b>	<b>35.0</b>	<b>62.7</b>	<b>83.9</b>	<b>104.3</b>	<b>125.3</b>	<b>148.6</b>	<b>167.4</b>	<b>187.2</b>

Source: EH estimates

\*based on 12 scripts/pa

\*\*based on 3.7m target patient population

## Personal disclosures

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.

Botanix Pharmaceuticals Limited (BOT.ASX) | Price A\$0.185 | Target price A\$0.300 | Recommendation Speculative Buy;

*Price, target price and rating as at 08 February 2024 (\* not covered)*

## Additional disclosures

The analyst declares that they have a beneficial interest in: Botanix Pharmaceuticals Limited (BOT.ASX)

Euroz Hartleys declares that it has provided corporate advice during the last year and has received a fee for these services from: Botanix Pharmaceuticals Limited (BOT.ASX)

Euroz Hartleys declares that it has acted as underwriter to, and/or arranged an equity issue in, and/or been engaged in a capital raising during the last year. Euroz Hartleys has received a fee for these services from: Botanix Pharmaceuticals Limited (BOT.ASX)

Euroz Hartleys has received an allocation of shares and/or options as part of our fee for the provision of Corporate services. These holdings are maintained in our Nominee company, and may present a potential benefit to Euroz Hartleys when sold for: Botanix Pharmaceuticals Limited (BOT.ASX)

## Other disclosures, disclaimers and certificates

### 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.

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) 9268 2888. 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.

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.