



ABN 70 009 109 755

Appendix 4E
PRELIMINARY ANNUAL REPORT
for the year ended 30 June 2023
Comparative year: 30 June 2022

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Botanix Pharmaceuticals Limited

ABN: 26 636 569 634

Appendix 4E – Preliminary Final Report (unaudited)

Results for announcement to the market

For the year ended 30 June 2023

Comparative year: 30 June 2022

Key Information	2023 \$	2022 \$	Change \$	Up / down	%
Revenues from customer sales	102,934	-	102,934	Up	n/a
Loss from ordinary activities after tax attributable to members	(9,153,974)	(13,170,749)	4,016,775	Down	30.5%
Net loss for the period attributable to members	(9,390,667)	(13,358,949)	3,968,282	Down	29.7%
Dividends (distributions)			Amount per security		Franked amount per security
Interim dividend			Nil		- ¢
Final dividend			Nil		- ¢
Previous corresponding period			Nil		- ¢
Record date for determining entitlements to the dividend			N/A		
Net Tangible Assets per share			30 June 2023		30 June 2022
Net tangible asset per ordinary security (cents per share)			0.93		0.50

Brief explanation

Revenues include net royalties received from the Japanese licensee of the Sofpironium Bromide product. Botanix reduced its operating costs during the year by \$4,016,775 and increased its R&D tax incentive refund by \$914,604 resulting in a reduced loss from ordinary activities of \$9,153,974.

Further review of operations is included in the Directors' Report.

Status of audit

The accounts are in the process of being audited.

BOTANIX PHARMACEUTICALS LIMITED
ABN: 70 009 109 755

DIRECTORS' REPORT

Your Directors have pleasure in submitting their report together with the financial statements of the Group consisting of Botanix Pharmaceuticals Limited and the entities it controlled during the period for the financial year ended 30 June 2023, in order to comply with the provisions of the Corporations Act 2001, the Directors report as follows:

Mr Vincent Ippolito	Executive Chairman
Mr Matthew Callahan	Executive director
Dr William Bosch	Non-executive director
Dr Stewart Washer	Non-executive director
Mr Danny Sharp	Non-executive director

PRINCIPAL ACTIVITIES

Botanix Pharmaceuticals Limited (ASX: BOT) is a dermatology company based in Philadelphia and Phoenix (US) which is progressing its lead product Sofpironium Bromide for the treatment of primary axillary hyperhidrosis, through FDA approval which is planned for late Q3 CY2023. Sofpironium Bromide is positioned to be a leading first line and second line therapy and potentially represents a safe and effective new option for patients.

Sofpironium Bromide is the first and only new chemical entity developed to treat “primary axillary hyperhidrosis” – a medical condition which results in excessive underarm sweating. Sofpironium Bromide achieved statistical significance in all primary and secondary endpoints and was found to have a favourable safety profile in Phase 3 pivotal studies and in a 48-week safety study.

RESULTS AND FINANCIAL POSITION

The financial report has been prepared on the going concern basis, which contemplates the continuity of normal business activity, the realisation of assets and the settlement of liabilities in the normal course of business.

The Group has generated a comprehensive loss after tax for the year ended 30 June 2023 of \$9,390,667 (30 June 2022: \$13,358,949). The net loss is attributable primarily to the expenditure in relation to advancing our clinical research and development activities and costs incurred on Sofpironium Bromide. The Group had a net working capital surplus of \$12,093,633 at 30 June 2023 (30 June 2022: \$4,615,560) and experienced net cash outflows from operating activities for the year of \$12,074,064 (30 June 2022: \$11,184,055).

At 30 June 2023, the Group had a cash balance of \$10,250,395 (30 June 2022: \$7,285,653).

The Directors believe that there are sufficient funds to meet the Group’s working capital requirements.

The Directors consider the going concern basis of preparation to be appropriate based on forecast cash flows and have confidence in the Company’s ability to raise additional funds if required.

DIRECTORS' REPORT (CONTINUED)

DIVIDENDS

There were no dividends paid or declared during the year (30 June 2022: Nil).

OPERATING AND FINANCIAL REVIEW AND FUTURE PROSPECTS

OPERATIONAL REVIEW

Overview

The 12 months reporting period ending on 30 June 2023 was a transformative time for the company with the filing for FDA approval of the Company's lead asset, Sofpironium Bromide gel 15% ("Sofpironium Bromide") and the completion of a successful mid-cycle review by the FDA in late 1Q CY2023. Subsequent to the reporting period, Botanix was successful in acquiring the future financial obligations owed to the previous owner of Sofpironium Bromide for US\$8.25 million, a highly value accretive acquisition.

During the reporting period, Botanix continued to progress its pipeline of dermatology products, focused on the treatment of serious skin diseases and new solutions for bacterial infections. In 3Q 2023, the Company reported positive data from its rosacea (BTX 1702) Phase 1/2 clinical study in moderate to severe patients conducted in Australia and New Zealand.

Sofpironium Bromide New Drug Application (NDA) filing

Botanix's lead asset is Sofpironium Bromide, a topically applied gel for the treatment of primary axillary hyperhidrosis (a medical condition which causes excessive underarm sweating). Phase 3 clinical studies have been completed where primary and secondary efficacy endpoints were achieved with a high degree of statistical significance. The Company filed an NDA with the US FDA for the product in September 2022 and approval is planned for late 3Q CY2023.

Statistically significant data and successful studies

Sofpironium Bromide is formulated into a gel that blocks sweating at the point of application, by binding to the receptor and thereby blocking the sweat signal. It is delivered to the underarms using a patented applicator familiar to patients that would have used roll-on antiperspirants, that allows the patient to avoid direct contact with the drug on their hands. The drug is designed to be hydrolyzed by the body as it passes through into the blood stream (rather than traveling around the body and affecting other organs), which potentially helps to minimise the side effects of the drug, compared to other compounds in the class.

Large market opportunity

Sofpironium Bromide has already been approved in Japan by the Japanese equivalent of the FDA and has been successfully commercialised by partner Kaken Pharmaceutical Co., Ltd- (Ecclock® Sofpironium Bromide 5%). Kaken's most recent reported quarterly sales show a significant increase in prescriptions and revenue quarter on quarter and provide a significant indication of the unmet need for new treatments for hyperhidrosis and the potential for the products commercialisation in the US and other international markets.

DIRECTORS' REPORT (CONTINUED)

In the US alone, there are approximately 10 million patients who suffer from primary axillary hyperhidrosis. Approximately 3.7 million of those are already actively seeking treatment.¹

FDA Review of Sofpironium Bromide

Botanix submitted an NDA to the FDA for Sofpironium Bromide in September 2022 following approximately 6 months of work, consolidating the non-clinical and clinical data and preparing the NDA filing.

The Company successfully completed a mid-cycle review of the product in 2Q CY2023. The mid-cycle communication indicated no significant issues had been identified by FDA as a result of its review of product quality, non-clinical or clinical and that there were no major clinical safety issues, no risk management or advisory board requirements.

FDA continues to review the NDA for Sofpironium Bromide and approval is planned for late 3Q CY2023.

Acquisition of the future financial obligations due to Fresh Tracks

Subsequent to the reporting period in June 2023, Botanix announced that it had completed an agreement with Fresh Tracks Therapeutics Inc (Fresh Tracks) to extinguish all of the potential future financial obligations owed to Fresh Tracks under the Asset Purchase Agreement for Sofpironium Bromide. As outlined in Figure 1 below, Botanix was previously obliged to pay Fresh Tracks US\$4M on FDA approval of Sofpironium Bromide, US\$4M if approval is extended to another indication (such as for palmar or plantar hyperhidrosis) and US\$4M for approval in the UK or Europe. The Company was also currently obliged to pay sales milestones of up to US\$160M which commence upon reaching the first US\$75M of Net Sales, as well as to pay royalties ranging from 12% to 20% on Net Sales from initiation of commercial sales.

In exchange for the payment of US\$8.25M to Fresh Tracks, all of these future financial obligations due were extinguished. Given that Botanix was otherwise on target to pay Fresh Tracks US\$4M in September following planned FDA approval of Sofpironium Bromide, the additional US\$4.25m payment amount was viewed by the Company as relatively modest, compared to the significant future potential payments that would be payable to Fresh Tracks as regulatory and sales milestones and royalties on Net Sales of Sofpironium Bromide.

1 Source. 1.Reports and Data, "Hyperhidrosis Treatment Market By Treatment Type, By Disease Type, By End-User, By Regional Outlook, and Segment Forecasts, 2022.

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DIRECTORS' REPORT (CONTINUED)

Financial Obligations to Fresh Tracks	Current Commitment to Fresh Tracks (USD)	After Royalty Buyout Transaction (USD)
Upfront payment to buyout future milestone and royalty payments		\$8.25m
FDA Approval for SB (target September)	\$4m	Nil
Marketing approval for SB in EU or UK	\$4m	Nil
Approval of SB in another indication	\$4m	Nil
Sales Milestones (once Net Sales exceed \$75m - up to \$1.8 billion p.a)	~\$160m	Nil
Royalties on Net Sales	12-20%	Nil*

*Note – Botanix will retain an obligation to the head licensor, Bodor Laboratories, to pay a 5% royalty on Net Sales made by Botanix

Figure 1 – Comparison of financial obligations to Fresh Tracks before and after Transaction

Botanix maintained the Transition Services Agreement with Fresh Tracks that was also entered into in May 2022 and existing royalty of 5% of Net Sales will remain payable to the original inventor of Sofpironium Bromide (Bodor Laboratories).

Preparation for commercialisation of Sofpironium Bromide

In anticipation of the planned approval of Sofpironium Bromide in late 3Q 2023, the Company continues to prepare for the launch of the product with a number of activities focused on market research, payer landscape mapping, as well as product naming and branding, design of the distribution network and creation of a digital strategy for Sofpironium Bromide.

These activities will continue to expand as the planned approval date for Sofpironium Bromide approaches and launch of the product is currently expected early in CY 2024.

Pipeline Clinical Development

During the reporting period, the Company was able to successfully complete its rosacea (BTX 1702) Phase 1/2 clinical study, as announced in Q3 CY2022. The study investigated the safety and tolerability of two different concentrations of BTX 1702 against a vehicle (placebo) in 120 adults over an eight-week treatment period at 16 dermatology sites across Australia and New Zealand. There were no serious adverse events observed during the Study and all arms (vehicle gel, 10% and 20% BTX 1702 gel) were safe and well tolerated. For the exploratory efficacy endpoints, both doses of BTX 1702 showed clinically positive results, with the 10% showing greater results.

Further activities supporting the development of BTX 1702 are currently on hold as the Company prioritizes resources and focus on Sofpironium Bromide, but the Company expects to review the progress of the BTX 1702 and its other development stage pipeline products following launch of Sofpironium Bromide.

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DIRECTORS' REPORT (CONTINUED)

SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

Other than as mentioned in the Review of Operations, no significant changes in the state of affairs of the Consolidated Entity occurred during the financial year.

OPERATIONAL RISKS

There are material risks, inherent in the pharmaceutical industry that, either individually or in combination, may materially and adversely affect the future operating and financial performance and prospects of Botanix and the value of its shares. Some of these risks may be mitigated by Botanix's internal controls and processes but some are outside the control of Botanix, its directors and management. The material risks identified by management are described below:

Clinical development risk

There is an inherent risk in drug development with many product candidates failing to be successfully developed into marketable products. The Company is currently undertaking clinical trials with certain of its products and plans to undertake trials with additional products in its pipeline. Clinical trials have many associated risks which may impact the Company's commercial potential and therefore its future prospects and profitability. Clinical trials may fail to recruit patients, be terminated for safety reasons, or fail to be completed within acceptable timeframes as a result of delay. Clinical trials may reveal product candidates to be unsafe, poorly tolerated or non-effective. Any of these outcomes will likely have a significant adverse effect on the Company, the value of its securities and the future commercial development of its product candidates. Clinical trials might also potentially expose the Company to product liability claims in the event its products in development have unexpected effects on clinical subjects.

Mitigation measures employed by the Company include: ensuring that clinical trials are strongly supported by preclinical safety and efficacy data; careful clinical trial design to minimise the chances of potentially spurious outcomes; use of independent data and safety monitoring boards; engagement of leading contract research organisations to manage the trials and drive recruitment; engagement of well-qualified clinical sites experienced in clinical trial execution and in the relevant therapeutic areas.

Regulatory risks

The research, development, manufacture, marketing and sale of products developed by the Company are subject to extensive regulation by multiple government authorities and institutional bodies in the USA and other jurisdictions. Drug products must undergo a comprehensive and highly regulated development, trial and review process before receiving approval for marketing. The process includes a requirement for approval to conduct clinical trials, and the provision of data relating to the quality, safety and efficacy of the products for their proposed use. There is no guarantee that regulatory approvals to conduct clinical trials and/or to manufacture and market the Company's products will be granted.

DIRECTORS' REPORT (CONTINUED)

If a product is approved, it may also be submitted for cost reimbursement approval to relevant agencies. The availability and timing of that reimbursement approval may have an impact upon the uptake and profitability of products in some jurisdictions. If the Company is unable to secure necessary approvals from regulatory agencies and institutional bodies to undertake its planned trials, market its products and obtain cost reimbursements for its products its future prospects and profitability is likely to be materially and adversely affected.

Mitigation measures employed by the Company include: engagement of suitably qualified and experienced persons with expertise in the regulation of drug products; regular review of evolving regulatory requirements and analysis of the Company's activities and plans against regulatory expectations in key jurisdictions; and ensuring that the expectations and uncertainties related to regulatory approvals, and the timing of such approvals, are included in business plans.

Manufacturing risk

The Company's development stage and planned commercial products are manufactured by contract manufacturing organisations engaged by Botanix for that purpose. The Company relies on supply relationships with third party organisations and partners for raw materials and other consumables. An inability of these third party organisations to continue to supply the Company in a timely, economical and/or consistent manner could adversely impact on the progress of the Company's development programs and potentially on the financial performance of the Company.

Mitigation measures employed by the Company include: performing rigorous due diligence on suppliers; engaging suppliers with strong track records and sufficient capability to meet the Company's foreseeable needs; and employing a senior manager responsible for managing and monitoring the performance of third parties including suppliers.

Market Risks

The Company is subject to a number of financial risks which arise as a result of its activities. Market risk comprises three types of risk: currency risk, interest rate risk and other price risk.

Currency risk- During the normal course of business the Company enters into contracts with overseas customers or suppliers or consultants that are denominated in foreign currency. As a result of these transactions there is exposure to fluctuations in foreign exchange rates. The principle currency risk faced by the business is the exchange rate between the Australian dollar and the US dollar. The Company holds cash denominated in US dollars and Australian dollars and may have material future expenditure in each of these currencies. Where possible, the Company matches foreign currency income and foreign currency expenditure as a natural hedge, holding foreign currency cash to facilitate this natural hedge. When foreign currency expenditure exceeds foreign currency revenue and foreign currency cash, the Company may consider purchasing foreign currency to meet anticipated requirements under spot and forward contracts.

Interest rate risk - The Company is exposed to changes in market interest rates as the Company holds cash and cash equivalents. The Company mitigates this risk through a series of term deposits structured to provide some certainty of financial returns.

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DIRECTORS' REPORT (CONTINUED)

Liquidity risk - The Company's financial liabilities, comprising trade and other payables and derivatives, are generally repayable within 1 – 3 months. The maturity and availability of financial assets, comprising cash and cash equivalents and trade and other receivables, are monitored and managed to ensure financial liabilities can be repaid when due.

Capital management - The Company monitors capital including share capital, retained earnings and reserves and the cash and cash equivalents presented in the consolidated statement of financial position. The Company has no debt. The key objective of the Company when managing its capital is to safeguard its ability to continue as a going concern, so that the Company can sustain the commercialisation and the future development of the research and development activities being performed by the Company.

DIRECTORS' INTERESTS IN THE SHARES, OPTIONS AND PERFORMANCE RIGHTS OF THE COMPANY

As at the date of this report, the interests of the Directors in ordinary shares, unlisted options and performance rights of the Company were:

Director	Shares		Options		Performance rights	
	Directly	Indirectly	Directly	Indirectly	Directly	Indirectly
Mr Vincent Ippolito	10,801,644	-	12,000,000	-	2,000,000	-
Mr Matthew Callahan	-	74,586,791	-	-	-	1,166,667
Dr William Bosch	18,836,702	-	-	-	500,000	-
Dr Stewart Washer	-	2,170,035	-	5,000,000	-	666,667
Mr Danny Sharp	2,131,313	-	4,000,000	-	666,667	-
Total	31,769,659	76,756,826	16,000,000	5,000,000	3,166,667	1,833,334

EVENTS SINCE THE END OF THE FINANCIAL YEAR

On 21 July 2023, the Company received firm commitments from new and existing institutional and sophisticated investors for 104,166,667 new fully paid ordinary shares at A\$0.12 per share under a placement to raise up to A\$12.5 million in gross proceeds. Proceeds from the placement were primarily used to extinguish the future milestone and royalty payments due to Fresh Track Therapeutics Inc in respect of Sofpironium Bromide, and cover costs associated with finalising FDA review and preparing for commercial launch in the United States.

On 25 August 2023 the Company announced that Dr Howie McKibbin had been appointed as Chief Executive Officer of Botanix, effective 24 August 2023.

Other than the matters above there are no matters or circumstances which have arisen since the end of the year which significantly affect or may significantly affect the operations of the Group, the results of those operations or the state of affairs of the Group in subsequent financial years.

DIRECTORS' REPORT (CONTINUED)

ENVIRONMENTAL REGULATION

The Directors have considered compliance with the National Greenhouse and Energy Reporting Act 2007 which requires entities to report annual greenhouse gas emissions and energy use. For the year ended 30 June 2023, the Directors have assessed that there are no current reporting requirements but may be required to do so in the future.

LIKELY DEVELOPMENTS & EXPECTED RESULTS OF OPERATIONS

Other than as disclosed elsewhere in this report, there are no likely developments in the operations of the Company that were not finalised at the date of this report.

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CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
For the year ended 30 June 2023

	Note	2023 \$	2022 \$
Revenue from continuing operation			
Sales revenue		102,934	-
Total revenue from continuing operations	1	102,934	37,374
Other income			
Interest income		65,958	37,374
Research and Development incentive scheme		3,669,439	2,754,835
		3,735,397	2,792,209
Employee expenses		(1,517,603)	(3,221,580)
Professional Consulting expense	2	(2,682,212)	(1,061,327)
Research expenses		(5,727,498)	(10,292,507)
Depreciation of plant and equipment		(20,535)	(18,433)
Amortisation on Right of Use Asset		(89,899)	(125,066)
Finance expenses		(81,736)	(37,440)
Other expenses	2	(1,340,137)	(887,945)
Foreign exchange gain/(loss)		(11,857)	15,536
Share based payments	11	(1,520,828)	(334,196)
Total expenses		(12,992,305)	(15,962,958)
Loss before income tax expense		(9,153,974)	(13,170,749)
Income tax benefit		-	-
Loss after income tax for the year		(9,153,974)	(13,170,749)
Other Comprehensive income (Loss) for the year:			
Items that may be reclassified subsequently to profit or			
Foreign exchange translation difference		(236,693)	(188,200)
Other Comprehensive income/(loss) for the period, net of		(236,693)	(188,200)
Total Comprehensive Loss for the year attributed to members of Botanix Pharmaceuticals Limited		(9,390,667)	(13,358,949)
Loss per share for the year attributable to members of Botanix Pharmaceuticals Limited			
Basic loss per share (cents)	12	(0.79)	(1.35)
Diluted loss per share (cents)	12	(0.79)	(1.35)

The above Consolidated Statement of Profit or Loss and Other Comprehensive Income should be read in conjunction with the accompanying notes

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CONSOLIDATED STATEMENT OF FINANCIAL POSITION
As at 30 June 2023

	Note	2023 \$	2022 \$
ASSETS			
Current Assets			
Cash & cash equivalents		10,250,395	7,285,653
Inventory	3	3,147,031	3,044,347
Trade and other receivables		489,124	140,824
Prepayments		92,078	30,392
Total Current Assets		13,978,628	10,501,216
Non-current Assets			
Plant and equipment	4	65,376	91,418
Intangible assets	5	10,729,375	3,295,246
Right-of-use asset	6	-	87,847
Other financial assets		62,644	61,706
Total Non-current Assets		10,857,395	3,536,217
Total Assets		24,836,023	14,037,433
LIABILITIES			
Current Liabilities			
Trade and other payables	7	1,733,296	5,667,708
Lease liabilities		-	122,414
Provisions	8	151,700	95,534
Total Current Liabilities		1,884,996	5,885,656
Total Liabilities		1,884,996	5,885,656
Net Assets		22,951,027	8,151,777
EQUITY			
Contributed equity	9	93,489,658	71,475,764
Reserves	10	6,041,423	4,338,786
Foreign currency translation reserve	10	341,878	105,185
Accumulated losses	10	(76,921,932)	(67,767,958)
Total Equity		22,951,027	8,151,777

The above Consolidated Statement of Financial Position should be read in conjunction with the accompanying notes

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CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
For the year ended 30 June 2023

Note	Contributed Equity	Accumulated Losses	Reserves	Translation Reserve	Total
	\$	\$	\$	\$	\$
Balance at 1 July 2022	71,475,764	(67,767,958)	4,338,786	105,185	8,151,777
Total comprehensive loss for the year					
Loss for the year	-	(9,153,974)	-	-	(9,153,974)
Total other comprehensive loss	-	-	-	236,693	236,693
Total comprehensive loss for the year	-	(9,153,974)	-	236,693	(8,917,281)
Transaction with equity holders:					
Ordinary shares issued net of costs	22,013,894	-	181,809	-	22,195,703
Share based payments	-	-	1,520,828	-	1,520,828
Balance at 30 June 2023	93,489,658	(76,921,932)	6,041,423	341,878	22,951,027

Note	Contributed Equity	Accumulated Losses	Reserves	Translation Reserve	Total
	\$	\$	\$	\$	\$
Balance at 1 July 2021	71,475,764	(54,597,209)	4,004,590	(83,015)	20,800,130
Total comprehensive loss for the year					
Loss for the year	-	(13,170,749)	-	-	(13,170,749)
Total other comprehensive loss	-	-	-	188,200	188,200
Total comprehensive loss for the year	-	(13,170,749)	-	188,200	(12,982,549)
Transaction with equity holders:					
Ordinary shares issued net of costs	-	-	-	-	-
Share based payments	-	-	334,196	-	334,196
Balance at 30 June 2022	71,475,764	(67,767,958)	4,338,786	105,185	8,151,777

The above Consolidated Statement of Changes in Equity should be read in conjunction with the accompanying notes.

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CONSOLIDATED STATEMENT OF CASH FLOWS
For the year ended 30 June 2023

	Note	2023 \$	2022 \$
CASHFLOWS FROM OPERATING ACTIVITIES			
Interest received		65,215	37,374
Receipts from customers		518,398	-
R&D tax concession received		3,669,439	2,754,835
Payments to suppliers and employees		(16,247,096)	(13,938,824)
Finance costs		(80,020)	(37,440)
Net cash used in operating activities		(12,074,064)	(11,184,055)
CASHFLOWS FROM INVESTING ACTIVITIES			
Payment for property, plant and equipment		(7,572)	(7,208)
Payment for intangibles		(7,046,149)	(2,914,662)
Net cash used in investing activities		(7,053,721)	(2,921,870)
CASHFLOWS FROM FINANCING ACTIVITIES			
Repayment of lease liability		(122,414)	(152,412)
Proceeds from issue of shares		23,590,350	-
Transaction costs paid from the issue of shares		(1,438,359)	-
Repayment of borrowings		(1,849,236)	-
Proceeds from loan		1,849,237	-
Net cash used in by financing activities		22,029,578	(152,412)
Net (decrease)/increase in cash held		2,901,793	(14,258,337)
Cash and cash equivalents at beginning of financial year		7,285,653	21,554,906
Foreign exchange adjustment		62,949	(10,916)
Cash and cash equivalents at end of financial year		10,250,395	7,285,653

The above Consolidated Statement of Cash Flows should be read in conjunction with the accompanying notes.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: SALES REVENUE AND OTHER INCOME

	2023	2022
	\$	\$
Royalty fees received	914,973	-
Royalty fees paid	(812,039)	-
Sales revenue	<u>102,934</u>	<u>-</u>

NOTE 2: OTHER EXPENSES

Loss before Income Tax includes the following specific expenses:

	2023	2022
	\$	\$
Corporate advisors	536,711	305,479
Corporate investor advisory	152,769	323,227
Legal fees	859,547	176,146
Other professional fees	1,133,185	256,475
Professional consulting expense	<u>2,682,212</u>	<u>1,061,327</u>
Insurance	193,772	227,455
Travel	306,983	112,491
Milestone payment	445,648	-
Other operating costs	393,734	547,999
Other expenses	<u>1,340,137</u>	<u>887,945</u>

NOTE 3: INVENTORY

	2023	2022
	\$	\$
Sofpironium Bromide	2,703,579	2,600,895
Packaging	443,452	443,452
Total inventory	<u>3,147,031</u>	<u>3,044,347</u>

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NOTE 4: PROPERTY, PLANT AND EQUIPMENT

	2023	2022
	\$	\$
Opening balance	91,418	76,392
Acquisition of computer equipment	-	7,208
Acquisition of other assets	-	20,264
Less: depreciation	(20,535)	(18,433)
Less: adjustment for foreign exchange differences	(5,507)	5,987
	65,376	91,418

NOTE 5: INTANGIBLE ASSETS

	2023	2022
	\$	\$
At cost	10,729,375	3,295,246
	10,729,375	3,295,246

	2023	2022
	\$	\$
Sofpironium Bromide Licences		
Opening balance	3,295,246	-
Acquisition Sofpironium Bromide Licences	-	3,295,246
Development costs	7,434,129	-
	10,729,375	3,295,246

	Acquisition costs	Development costs	Total
	\$	\$	\$
Balance at 1 July 2022	3,295,246	-	3,295,246
Additions ⁽¹⁾	3,560,009	-	3,560,009
Additions from internal development	-	3,874,120	3,874,120
Balance at 30 June 2023	6,855,255	3,874,120	10,729,375

⁽¹⁾ As part of the acquisition of Sofpironium Bromide, the Company paid US\$2m based on a positive "Day-74 letter" being received from the FDA after NDA filing being resolution of an uncertain event in the variable consideration as disclosed at 30 June 2022.

	Acquisition costs	Development costs	Total
	\$	\$	\$
Balance at 1 July 2021	-	-	-
Additions	3,295,246	-	3,295,246
Additions from internal development	-	-	-
Balance at 30 June 2022	3,295,246	-	3,295,246

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NOTE 6: RIGHT-OF USE LEASE ASSETS

	2023	2022
	Premises	Premises
	\$	\$
Carrying value		
Cost	431,899	431,899
Accumulated depreciation	(454,050)	(337,019)
Foreign exchange adjustment	22,151	(7,033)
Carrying value as at 30 June	-	87,847
Reconciliation		
	2023	2022
	Premises	Premises
	\$	\$
Opening Balance	87,847	201,243
Additions	-	-
Depreciation expense	(89,899)	(125,066)
Foreign exchange adjustment	2,052	11,670
Closing Balance	-	87,847

NOTE 7: CURRENT LIABILITIES – TRADE AND OTHER PAYABLES

	2023	2022
	\$	\$
Current:		
Trade payables ¹	1,390,702	4,681,837
Sundry payables & accrued expenses	342,594	985,871
	1,733,296	5,667,708

¹Trade payables are non-interest bearing and are normally settled on 30-day terms.

NOTE 8: CURRENT LIABILITIES – PROVISIONS

	2023	2022
	\$	\$
Annual leave provision	151,700	95,534
	151,700	95,534

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NOTE 9: CONTRIBUTED EQUITY

(a) Issued and Paid Up Capital

	2023	2023	2022	2022
	Number	\$	Number	\$
Fully paid ordinary shares	1,312,460,376	93,489,658	973,142,074	71,475,764

(b) Movements in fully paid shares on issue

	Number	\$
Balance as at 1 July 2022	973,142,074	71,475,764
Exercise of options	6,091,310	-
Placement	106,060,609	7,000,000
Placement	79,365,080	5,000,000
Share purchase plan	15,246,240	960,513
Shares issued to Directors	7,575,755	500,000
Exercise of options	1,701,532	127,683
Placement	111,111,111	10,000,000
Exercise of performance rights	12,166,665	-
Less: transaction costs	-	(1,574,302)
Balance as at 30 June 2023	1,312,460,376	93,489,658
Balance as at 1 July 2021	973,142,074	71,475,764
Exercise of options	-	-
Balance as at 30 June 2022	973,142,074	71,475,764

(c) Issued Options

	Number
Unlisted Options	111,111,761

(d) Movements in options on issue

Balance as at 1 July 2022	70,153,639
Add: Options issued	76,530,464
Less: Exercise of Options	(32,572,342)
Less: Expiry and cancellation of Options	(3,000,000)
Balance as at 30 June 2023	111,111,761

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NOTE 10: RESERVES & ACCUMULATED LOSSES

	2023	2022
	\$	\$
Share based payments reserve	6,041,423	4,338,786
	6,041,423	4,338,786
Share based payments reserve		
Balance at beginning of year	4,338,786	4,004,590
Share based expense	1,520,828	334,196
Issue of options (cost of raising equity)	181,809	-
Balance at end of year	6,041,423	4,338,786
Foreign currency translation reserve		
Balance at beginning of year	105,185	(83,015)
Effect for foreign currency translation during the year	236,693	188,200
Balance at end of year	341,878	105,185
Accumulated Losses		
	2023	2022
	\$	\$
Movements in accumulated losses were as follows:		
Balance at beginning of year	(67,767,958)	(54,597,209)
Net loss for the year – continuing operations	(9,153,974)	(13,170,749)
Balance at end of year	(76,921,932)	(67,767,958)

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NOTE 11: SHARE BASED PAYMENTS

Employee Securities Incentive Plan (“ESIP”)

The ESIP was originally approved by shareholders on 14 June 2016 and re-approved on 19 November 2018 and 26 October 2021. In accordance with the provisions of the ESIP, Directors, employees and consultants may be granted options to purchase ordinary shares at an exercise price determined by the Board with regard to the market value of the shares when it resolves to offer the options. The options may only be granted to eligible participants after the Board considers the person’s seniority, position, length of service, potential contribution and any other matters which the Board considers relevant.

Each share option converts into one ordinary share of the Company on exercise. No amounts are paid or payable to the Company by the recipient on receipt of the option. The options carry neither rights to dividends nor voting rights. Options may be exercised at any time from the date of vesting to the date of expiry. The number of options granted are determined by the Board.

Options on issue at 30 June 2023

Description	2023 Number	Weighted Average Exercise Price	2022 Number	Weighted Average Exercise Price
Options				
Opening balance	70,153,639	0.10	50,320,307	0.113
Issued during the period for remuneration	5,000,000	0.102	25,000,000	0.082
Issued during the period to consultants	8,500,000	0.078	-	-
Issued during the period as transaction costs from the issue of shares	10,000,000	0.094	-	-
Exercised during the period ²	(31,153,639)	(0.051)	-	-
Expired and cancelled during the period	(3,000,000)	(0.115)	(5,166,668)	0.127
Balance at 30 June 2023	59,500,000	0.116	70,153,639	0.10

The weighted average exercise period is 1.39 years (2022:1.00 years).

Performance Rights on issue at 30 June 2023

Description	2023 Number	Weighted Average Exercise Price	2022 Number	Weighted Average Exercise Price
Performance Rights				
Opening balance	-	-	-	-
Issued during the period for remuneration	19,000,000	0.00	-	-
Exercised during the period	(12,166,665)	(0.00)	-	-
Balance at 30 June 2023	6,833,335	0.00	-	-

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NOTE 11: SHARE BASED PAYMENTS (CONTINUED)

Total expenses arising from share-based payment transactions recognised during the year were as follows:

	2023	2022
	\$	\$
Share options	542,362	334,196
Performance rights	978,466	-
Total Value of Share Based Payments expense	1,520,828	334,196

8.5 million Options (valued at \$0.0358 per option) were issued to Consultants on 14 March 2023, vesting 33.33% at 6, 12 and 24 months respectively from the issue date. Unvested options will expire if contractors cease to be engaged by the Group. \$111,016 has been recorded as an expense in the 2023 year for the issue of these options.

The Options were valued using Black Scholes with the below assumptions:

	Unlisted options
Number of options in series	8,500,000
Grant date share price	14 March 2023
Exercise price	\$0.078
Expected volatility	65.0%
Option life	3 years
Dividend yield	0.0
Interest rate	3.22%

2.45 million Options (valued at \$0.0408 per option) were issued to Employees on 8 June 2023, vesting 33.33% at 6, 12 and 24 months respectively from the issue date. Unvested options will expire if employees cease to be employed by the Group. \$26,307 has been recorded as an expense in the 2023 year for the issue of these options.

The Options were valued using Black Scholes with the below assumptions:

	Unlisted options
Number of options in series	2,450,000
Grant date share price	Note 1
Exercise price	\$0.105
Expected volatility	65.0%
Option life	3 years
Dividend yield	0.0
Interest rate	3.22%

Note 1: the options have not been issued as at 30 June 2023 but were approved prior to 30 June 2023.

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NOTE 11: SHARE BASED PAYMENTS (CONTINUED)

13 million performance rights (valued at \$0.063 per right) were granted to Directors on 21 November 2022 upon shareholder approval. One third of these rights vest on receipt of the Day 74 letter; one third on mid-cycle review (both vesting conditions satisfied) and one third on FDA approval. \$693,000 has been recorded as an expense in the 2023 year for the issue of these performance rights.

The performance rights were valued with reference to the share price on grant date (\$0.063).

6 million performance rights (valued at \$0.057 per right) were granted to Key Management Personnel on 29 December 2022. One third of these rights vest on receipt of the Day 74 letter; one third on mid-cycle review (both vesting conditions satisfied) and one third on FDA approval. \$285,466 has been recorded as an expense in the 2023 year for the issue of these performance rights.

The performance rights were valued with reference to the share price on grant date (\$0.057).

NOTE 12: LOSS PER SHARE

	2023	2022
	\$	\$
Continuing operations		
Basic loss per share – cents	(0.79)	(1.35)
Diluted loss per share – cents	(0.79)	(1.35)
Loss used in the calculation of basic and diluted loss per share	(9,153,974)	(13,170,749)
	No	No
Weighted average number of ordinary shares outstanding during the year used in calculation of basic loss per share	1,153,951,540	973,142,074
Weighted average number of ordinary shares outstanding during the year used in calculation of diluted loss per share	1,153,951,540	973,142,074

Options outstanding during the year have not been taken into account in the calculation of the weighted average number of ordinary shares as they are not considered dilutive.

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