Appendix 4E

Preliminary Final report

Name of entity

Botanix Pharmaceuticals Limited

ABN

70 009 109 755

Financial year ended ('current period')

30 June 2022

('comparative period')

30 June 2021

For announcement to the market

				$AUD
Other income from continuing operations	Down	67%	to	37,374
Loss from ordinary activities after tax attributable to members	Up	295%	to	(13,170,749)
Net loss for the period attributable to members	Up	281%	to	(12,982,549)

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, (in the case of a trust, distribution)	N/A	

Net Tangible Assets per share	**2022**	2021
Net tangible asset backing per ordinary security (cents per share)	0.50	2.14

The above results should be read in conjunction with the notes and commentary contained in the Annual Report lodged with this report.

Compliance statement

1 This report has been prepared in accordance with AASB Standards, other AASB authoritative pronouncements and Urgent Issues Group Consensus Views or other standards acceptable to ASX.

2 This report, and the +accounts upon which the report is based (if separate), use the same accounting policies.

3 This report does give a true and fair view of the matters disclosed.

4 This report is based on +accounts to which one of the following applies.

(Tick one)

☐	The +accounts have been audited.	☐	The +accounts have been subject to review.
☑	The +accounts are in the process of being audited or subject to review.	☐	The +accounts have *not* yet been audited or reviewed.

Date: 31 August 2022

Name of authorised officer authorising lodgement:

Vincent Ippolito
Executive Chairman/President

Review of operations and results

Overview

The 12 months reporting period ending on 30 June 2022 (FY22) has been a transformative period for the company with the acquisition of the late-stage dermatology asset, Sofpironium Bromide gel 15% ("Sofpironium Bromide"). Positive data from pivotal phase 3 clinical studies have been incorporated in a New Drug Application (NDA) which is being readied this quarter to be submitted to the FDA for approval in the United States. This acquisition transitions Botanix from being an early stage drug development company, reliant on the success of multiple clinical studies being conducted on its pipeline, to a commercial stage company preparing to launch its first dermatology product and to generate revenue. From a risk and value perspective, the Directors believe this positions the company for significant growth and value inflection over the coming 12-14 months as FDA approval is pursued and commercialisation of Sofpironium Bromide begins.

During the reporting period, Botanix also has continued to progress its pipeline of dermatology products, focused on the treatment of serious skin diseases and new solutions for bacterial infections. Botanix's dermatology pipeline is well advanced, with rosacea (BTX 1702) Phase 1/2 clinical study and the canine dermatitis pilot study (BTX 1204A) fully enrolled and on target for completion in Q3 2022. The Company's antimicrobial platform has also made significant progress, with the submission of ethics approval for the planned Phase 2 study and the successful receipt of Qualified Infectious Disease Product (QIDP) designation from the FDA which potentially provides an extra 5 years of regulatory exclusivity on approval to BTX 1801 and enables much smaller and more focused clinical trials to be conducted for FDA approval.

Sofprionium Bromide New Drug Approval (NDA) filing with FDA for 3Q CY 2022

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 is in the final stages of preparing a New Drug Application (NDA) which is expected to be submitted to the FDA in 3Q CY2022.

Statistically significant data and successful studies

In May 2022, Botanix acquired the rights for a novel product called Sofpironium Bromide, the first and only chemical entity developed to treat excessive underarm sweating ("primary axillary hyperhidrosis").

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 similar to a roll on commonly used in anti perspirants, that allows the patient to avoid direct contact with the drug on their hands. The drug is designed to be metabolised by the body as it passes through into the blood stream (rather than traveling around the body and affecting other organs), which helps to minimize the side effects of the drug compared to other compounds in the class.

Positive results from Phase 3 clinical studies have been completed with approximately 85% of patients using the gel experiencing a clinically meaningful improvement in their condition. More than 700 patients were enrolled in the two Phase 3 studies and approximately 300 patients participated in a

separate 48-week safety study of Sofpironium Bromide. There were no treatment related serious adverse events in any of the studies and adverse events were transient and mild to moderate in nature. Based on these studies, the Company believes that Sofpironium Bromide has the potential to be the best in class treatment for axillary hyperhidrosis, as existing therapies are less than ideal, either because of the lack of efficacy, an unfavourable side effect profile, the risk of drug exposure, or pain from invasive injection procedures or severing of the nerves through surgery.

De-risked asset and large market opportunity

Sofpironium Bromide is a de-risked asset as the drug has already been approved in Japan by the Japanese equivalent of the FDA and was recently launched by Botanix's 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.

In the US alone, there are approximately 7.3 million subjects who suffer from severe primary axillary hyperhidrosis which is the patient population in which the successful Phase 3 studies were conducted. Of those subjects, approximately 3.7 million subjects are actively seeking treatment. Even assuming a modest 1% penetration of this population at the current price of competitive treatments (ie approximately US$7,200 per annum), this provides a market opportunity of more than US$280 million per annum for Sofpironium Bromide.[1]

Filing for FDA approval

Botanix is currently working to complete the final parts of the NDA submission which is now expected to be submitted to the FDA in 3Q CY2022 (having accelerated that submission from 2H CY 2022), with an anticipated approval in 2023 (assuming the standard 12-month review cycle).

Pipeline Clinical Development

The Company's product pipeline also includes Phase 1b and 2 dermatology and antimicrobial programs which leverage the Company's novel skin delivery technology (Permetrex™), along with the unique anti-inflammatory and antimicrobial properties of synthetic cannabidiol (CBD).

BTX 1702: Phase 2 study for Papulopustular Rosacea

Recently, Botanix announced that the rosacea (BTX 1702) Phase 1/2 clinical study is now fully enrolled and on track for completion in Q3 CY2022. The study is investigating 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. The study also aims to examine the change in inflammatory lesion counts from baseline at days 15, 29 and 57, the proportion of patients with Investigator's Global Assessment (IGA) treatment success, the change in Clinician's Erythema Assessment (CEA) scale as well as a number of other imaging and patient reported outcomes.

The study has been designed to enable increased data capture and to provide additional insights to support Botanix's broader dermatology platform. This includes use of advanced Canfield imaging technology in all sites to support clinical assessment and improve patient tracking, as well as

[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.

centralised review of each clinical investigator's ratings for patient inclusion and some endpoint assessments. This study is strategically important for the Company's wider clinical development as it will provide some endpoint assessments for quality control and consistency. Data readout will follow the completion of the study in 3Q CY2022.

BTX 1204A: Canine atopic dermatitis

Botanix also announced on 7 July 2022 that the canine dermatitis (BTX 1204A) pilot study is now fully enrolled and on track for completion in Q3 CY2022.

Following promising data from a pilot study in canines completed in CY2021 over a 28-day period, Botanix launched its larger BTX 1204A proof of concept study in late 2021, with receipt of ethics approval and the initiation of sites across Australia and New Zealand.

Given the similarity in disease between humans and canines, further positive outcomes of this study will support progress towards a late-stage Phase 2b clinical study in humans. Additionally, successful results have the potential to broaden licensing and partnering opportunities in the canine dermatitis application, facilitating product development and commercialisation.

BTX 1801 for bacterial infections

In April 2022, Botanix announced that the United States Food and Drug Administration (FDA) Office of Antimicrobial Products has granted Qualified Infectious Disease Product (QIDP) status for the Botanix novel cannabidiol antibacterial product, BTX 1801.

Previously the FDA had granted QIDP designation for BTX 1801 specifically for the prevention of post-surgical infections. This new status covers the usage of BTX 1801 for the "reduction of risk of S. aureus bloodstream infections in colonised patients on central venous catheter-dependent hemodialysis" and is the first designation ever granted for nasal decolonisation agent for patients suffering from hemodialysis.

On top of the standard regulatory exclusivity that comes with FDA approval of a New Drug Application (NDA), the most significant incentive afforded to products with QIDP status is an additional 5 years of regulatory exclusivity, and during this period generics must not enter the market.

During FY2022, Botanix presented at the 32nd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), which took place in in Lisbon, Portugal on 23–26 April 2022. This prestigious event is attended by renowned experts from across the globe in the areas of infectious diseases, infection control and clinical microbiology providing widespread exposure and significant potential future commercial opportunities for the Company's pioneering products. The Company guaranteed two presentations, with the following topics 'The Antimicrobial profile of BTX-1801: a new synthetic cannabidiol active against Gram-positive bacteria associated with serious infections' and 'The Bactericidal activity of BTX 1801: a synthetic cannabidiol with potent activity versus Staphylococcus aureus' which were well received.

Botanix has submitted an application for ethics approval for the planned Phase 2 study and plans to initiate the study in 2H CY2022.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended 30 June 2022

	2022 $	2021 $
Revenue from continuing operation		
Interest income	37,374	103,788
Cashflow boost	-	10,250
Total revenue from continuing operations	**37,374**	**114,038**
Other income		
Research and Development incentive scheme	**2,754,835**	**6,876,948**
Employee expenses	(3,221,580)	(1,675,119)
Finance expenses	(37,440)	(55,941)
Other expenses	(775,454)	(410,576)
Depreciation of plant and equipment	(18,433)	(16,425)
Professional Consulting expense	(1,061,327)	(918,940)
Travel expense	(112,491)	(28,631)
Research expenses	(10,292,507)	(6,571,399)
Foreign exchange gain/(loss)	15,536	(1,770)
Amortisation on Right of Use Asset	(125,066)	(77,799)
Share based payments	(334,196)	(568,387)
Total expenses	**(15,962,958)**	**(10,324,987)**
Loss before income tax expense	**(13,170,749)**	**(3,334,001)**
Income tax benefit	-	-
Loss after income tax for the year	**(13,170,749)**	**(3,334,001)**
Other Comprehensive income (Loss) for the year:		
Items that may be reclassified subsequently to profit or loss:		
Foreign exchange translation difference	188,200	(71,014)
Other Comprehensive income/(loss) for the period, net of tax	188,200	(71,014)
Total Comprehensive Loss for the year attributed to members of Botanix Pharmaceuticals Limited	**(12,982,549)**	**(3,405,015)**
Loss per share for the year attributable to members of Botanix Pharmaceuticals Limited		
Basic loss per share (cents)	**(1.35)**	(0.34)
Diluted loss per share (cents)	**(1.35)**	(0.34)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at 30 June 2022

	2022 $	2021 $
ASSETS		
Current Assets		
Cash & cash equivalents	7,285,653	21,554,906
Inventory	3,044,347	-
Trade and other receivables	140,824	45,387
Prepayments	30,392	9,921
Total Current Assets	**10,501,216**	**21,610,214**
Non-current Assets		
Plant and equipment	91,418	76,392
Intangible assets	3,295,246	-
Right-of-use asset	87,847	201,243
Other financial assets	61,706	62,371
Total Non-current Assets	**3,536,217**	**340,006**
Total Assets	**14,037,433**	**21,950,220**
LIABILITIES		
Current Liabilities		
Trade and other payables	5,667,708	804,881
Lease liabilities	122,414	147,146
Provisions	95,534	85,891
Total Current Liabilities	**5,885,656**	**1,037,918**
Non-Current Liabilities		
Lease liabilities	-	112,172
Total Non-Current Liabilities	**-**	**112,172**
Total Liabilities	**5,885,656**	**1,150,090**
Net Assets	**8,151,777**	**20,800,130**
EQUITY		
Contributed equity	71,475,764	71,475,764
Reserves	4,338,786	4,004,590
Foreign currency translation reserve	105,185	(83,015)
Accumulated losses	(67,767,958)	(54,597,209)
Total Equity	**8,151,777**	**20,800,130**

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the year ended 30 June 2022

	Note	Contributed Equity $	Accumulated Losses $	$	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 profit		-	-	-	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	14	-	-	-	-	-
Share based payments	16	-	-	334,196	-	334,196
Balance at 30 June 2022		**71,475,764**	**(67,767,958)**	**4,338,786**	**105,185**	**8,151,777**

	Note	Contributed Equity $	Accumulated Losses $	$	Translation Reserve $	Total $
Balance at 1 July 2020		**71,414,355**	**(51,263,208)**	**3,497,612**	**(12,001)**	**23,636,758**
Total comprehensive loss for the year						
Loss for the year		-	(3,334,001)	-	-	(3,334,001)
Total other comprehensive loss		-	-	-	(71,014)	(71,014)
Total comprehensive loss for the year		-	(3,334,001)	-	(71,014)	(3,405,015)
Transaction with equity holders:						
Ordinary shares issued net of costs		61,409	-	(61,409)	-	-
Share based payments		-	-	568,387	-	568,387
Balance at 30 June 2021		**71,475,764**	**(54,597,209)**	**4,004,590**	**(83,015)**	**20,800,130**

CONSOLIDATED STATEMENT OF CASH FLOWS

For the year ended 30 June 2022

	2022	2021
	$	$
CASHFLOWS FROM OPERATING ACTIVITIES		
Interest received	37,374	103,788
Cashflow boost received	-	10,250
R&D tax concession received	2,754,835	6,876,948
Payments to suppliers and employees	(13,938,825)	(9,903,068)
Finance costs	(37,440)	(55,941)
Net cash used in operating activities	**(11,184,056)**	**(2,968,023)**
CASHFLOWS FROM INVESTING ACTIVITIES		
Payment for property, plant and equipment	(7,208)	(8,281)
Payment for Intangibles	(2,914,662)	-
Net cash used in investing activities	**(2,921,870)**	**(8,281)**
CASHFLOWS FROM FINANCING ACTIVITIES		
Repayment of lease liability	(152,412)	(125,502)
Net cash used in by financing activities	**(152,412)**	**(125,502)**
Net (decrease)/increase in cash held	(14,258,337)	(3,101,806)
Cash and cash equivalents at beginning of financial year	21,554,906	24,645,185
Foreign exchange adjustment	(10,916)	11,527
Cash and cash equivalents at end of financial year	**7,285,653**	**21,554,906**

Incorporation of subsidiary and acquisition of Sofpironium Bromide

During the year Botanix SB INC was incorporated as a wholly owned subsidiary of the Company to acquire a 100% interest Sofpironium Bromide gel 15%.

On 4 May 2022 the Company announced that it had acquired a 100% interest Sofpironium Bromide gel 15% (SB), a dermatology asset developed to treat "primary axillary hyperhidrosis" – a medical condition which results in excessive underarm sweating.

Consideration

Consideration paid or payable for the acquisition is as follows:

Initial Consideration:

	S
Initial payment for assets	4,355,401
Reimbursement for Sofpironium Bromide	673,033
Agreed costs reimbursed	947,872
Legal fees	364,207
Total	**6,339,593**

Contingent consideration and other payments

The acquisition also includes contingent consideration and payments, for which no amounts have been recognised in the financial statements as follows:

- US$2M if a positive "Day-74 letter" is received from FDA after NDA filing (which letter notifies the applicant if any deficiencies in the NDA filing are identified by FDA during the initial review phase);
- If FDA approval is received before 30 September 2023 Botanix will pay US$4M, which is reduced down to zero, if the NDA is approved after 17 February 2024;
- Botanix will pay a milestone payment of US$4M if marketing approval is received from an international regulatory authority in the European Union/United Kingdom;
- Botanix will pay a milestone payment of US$4M for marketing approval is received for a new indication, from an international regulatory authority in the USA or European Union/United Kingdom;
- Botanix will pay one-time sales milestone payments once Net Sales exceed US$75 million for the first time in a year. Such milestones are payable on incremental annual Net Sales amounts and are capped at US$160 million. Botanix would only pay this aggregate of milestones, if Net Sales to Botanix amounted to more than US$1.8 billion, which is contingent upon sales performance of the product and is not guaranteed;[2] and
- Botanix will also pay royalties that in the aggregate start at 12% and rise to 20%, above $500M of annual Net Sales.

The fair value of the consideration paid and allocation to net identifiable assets is as follows:

	$
Fair value of consideration paid:	
Cash	6,339,593
Fair value of net identifiable assets acquired:	
Inventory	3,044,347
Intangible assets	3,295,246
	6,339,593

Clinical Trials Expenditure

The Company's expenditure in respect of clinical studies increased during the year as subject recruitment peaked and then was completed before the end of the year. As both BTX 1702 and BTX1204A studies are on schedule to complete in 3Q CY2022, expenditure on clinical trials will reduce accordingly. New expenditure on clinical trials will only occur as the Company initiates new studies.

Subsequent event - Financing

Subsequent to the end of the year the Company secured and drew down a $1.85m drawdown facility provided by Radium Capital secured against its expected R&D refund.