botanix PHARMACEUTICALS

ASX/Media Release

30 August 2017

Botanix Pharmaceuticals Preliminary Final Report

Highlights for the year ending 30 June 2017:

- **Transformed single product company into rapidly growing medical dermatology company, with robust product pipeline and multiple commercial opportunities**
- **Rapidly developed BTX 1503 (lead acne treatment product) from formulation testing through to successful completion of Phase 1 clinical study within 12 months**
- **Advanced pipeline products with successful formulation development of BTX 1204 (novel treatment for atopic dermatitis) and completion of a pilot study for BTX 1701 (acne cleanser)**
- **Early stage work undertaken with multiple potential strategic partners, utilising the PermetrexTM technology, which may translate to future licensing or collaboration opportunities**
- **Relisted on ASX in July 2016 after reverse takeover of Bone Medical Limited and raised A$3.5m in oversubscribed offering**
- **Subsequently completed a successful A$7.4m capital raising via a significantly oversubscribed placement to new and existing shareholders**
- **Engaged highly experienced team with substantial track record in FDA approvals and dermatology drug commercialisation**

Philadelphia PA and Sydney Australia, 30 August 2017: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or the "Company") is pleased to release its preliminary final report for the year ending 30 June 2017.

Clinical development

Lead product: BTX 1503 (for moderate to severe acne)

Acne is the most common skin disorder in the US affecting 40 to 50 million Americans and more than 250 million patients worldwide each year. Acne has multiple pathogenic pathways including overproduction of oils, inflammation, and bacterial infection, but currently the only product approved that has an effect on oil production (namely "Accutane" or "Roaccutane"), also carries significant side effects, including the risk of birth defects, lymphoma, and suicide risks. Unlike Accutane or Roaccutane, which are taken as a tablet, BTX 1503 is a topically applied product that offers localised delivery to only those areas on the skin with the disease. This local delivery, combined with the numerous published safety studies on BTX 1503's drug active ("synthetic cannabidiol"), suggests BTX 1503 will have a significantly better side effect profile than Accutane or Roaccutane.

BTX 1503 is targeting the prescription acne market that currently generates more than US$4.5 billion in annual sales. Supporting scientific data suggests that BTX 1503 may inhibit the excessive production of oil in the skin, which is the primary cause of acne, as well as potentially reducing inflammation and bacterial infection.

Botanix has rapidly advanced its lead acne treatment product, BTX 1503 from early formulation development through to successful completion of its first human clinical study for its lead acne treatment product, BTX 1503, in Australia. The open label, Phase 1 study was designed to evaluate the safety, tolerability, and pharmacokinetics (i.e. concentration of drug detected in blood) of BTX 1503, when used in humans. Top line study data clearly demonstrated that BTX 1503 has an excellent safety profile, with little to no skin irritation, and no severe adverse events were recorded.

Data from the Phase 1 study also suggested that the Permetrex™ delivery technology ensures that the majority of the product is delivered across the outer layer of the skin and penetrates the skin tissue, with only small amount of drug being delivered into systemic circulation. The delivery performance of Permetrex™ is a key consideration to allow direct targeting of the relevant organs in the skin (greatly enhancing the probability of successfully treatment), while avoiding excess drug being deposited directly into the blood stream. Generation of this initial clinical data for BTX 1503 is a significant clinical milestone, which has been achieved within 12 months of listing.

Based on the data from this Phase 1 study, Botanix has now initiated a follow-up acne patient pilot study for BTX 1503, which commenced last week. The Phase 1b acne study will enrol up to 20 patients and each patient will receive BTX 1503 treatment over a 4-week period, under close supervision of a dermatologist. Safety assessments, including local skin tolerability to BTX 1503 will be performed throughout the 4-week treatment period. Patients will also be monitored for treatment effects on lesion counts and for improvements in their acne, using an Investigator's Global Assessment ("IGA") of acne severity.

Following completion of this study, Botanix plans to file an Investigational New Drug ("IND") application with the US Food and Drug Administration ("FDA") allowing a multicentre Phase 2 safety and efficacy study for BTX 1503, which is expected to commence in the US in 1H CY2018.

Pipeline products: BTX 1204 and BTX 1701

Additionally, during the year Botanix also continued the development of two pipeline products that both utilise the Company's proprietary Permetrex™ delivery technology. The Company plans to advance the first of these products, BTX 1204, a novel clinical treatment for atopic dermatitis which also utilises synthetic cannabidiol as the pharmaceutical active, into first patient studies in 2H CY2017. Given the extensive pre-clinical and human studies completed by Botanix using both Permetrex™ and synthetic cannabidiol for its lead acne product, the Company plans to progress BTX 1204 directly into a Phase 1b study in dermatitis patients in Australia, across several dermatology

sites. Dermatitis is a significant prescription product market with an estimated value of products sold each year exceeding US$4 billion.

The second pipeline product that the Company continued to progress during the quarter was BTX 1701, a development product for the treatment of mild acne. Botanix successfully completed a small patient study at a leading dermatology clinic in the US during 2Q CY2017. Preliminary results demonstrated positive safety outcomes and indicated that the daily application of BTX 1701 reduces oil levels on the skin and removes P. acnes, the bacteria responsible for the development of acne, from the surface of the skin more effectively than a leading facial cleanser product.

BTX 1701 does not utilise synthetic cannabidiol, but instead employs an active which has been used in numerous FDA approved dermatology products, but never for the purpose identified by Botanix. The Company is currently reviewing the commercialisation options for BTX 1701 to choose whether to develop the product through the usual FDA approval process, or as an over-the-counter ("OTC") acne cleanser which would be provided by dermatologists to patients with mild to moderate acne. If developed as an OTC cleanser, the product would not require FDA approval for development and marketing. Botanix plans to commence a further patient study on BTX 1701 in 2H CY2017.

New pipeline products

The inherent flexibility of the Permetrex™ delivery technology and the broad potential of synthetic cannabidiol provides the opportunity for a number of new pipeline products that Botanix is currently investigating outside of acne, psoriasis, and dermatitis. The Company expects at least one of these products to enter early stage formulation development and testing in 2H CY2017 and will be progressed into first clinical studies in early CY2018. Botanix is also reviewing a number of opportunities to deliver existing marketed and approved drugs that have never been delivered topically (through the skin) as pipeline products, given that the development pathway is likely to be more efficient based on the existing safety database that exists for these drugs.

Business development and strategic partnerships (Permetrex™)

The Permetrex™ delivery technology provides further business development and potential revenue generating opportunities for Botanix. The technology has the potential to improve several existing marketed skin products that suffer from poor drug delivery challenges. Further, it also allows for the establishment of collaborative clinical development partnerships with other dermatology companies looking to advance their own compounds using the technology.

Throughout the year Botanix has undertaken several formulation development activities with other dermatology and pharmaceutical companies to utilise the Permetrex™ technology to solve problems that these companies have experienced attempting to deliver drug through the skin to treat various diseases. If the formulation work that Botanix undertakes is viewed as desirable by one or more of these collaborators, then the Company will undertake manufacturing of the new formulation to

enable comparative clinical studies to be conducted to show the benefits of the Permetrex™ approach. Successful clinical outcomes versus the original formulation may then translate into a license opportunity for the Permetrex™ platform, which will deliver upfront payments, milestones, and royalties for Botanix on the collaborator's product.

The Company is also pursuing discussions with a number of potential corporate partners that have expressed interest in Botanix's pipeline products. Opportunities exist to collaborate with these partners to co-fund or license one or more pipeline products in exchange for upfront payments, development, and sales milestones, as well as royalties on eventual sales. This may provide the Company with the option to manage the risk of developing multiple products by itself, while accelerating the development timetable for these assets with larger and well-resourced partners.

Corporate

Botanix relisted on the ASX on 15 July 2016 after a reverse takeover of Bone Medical Limited and successfully raised A$3.5m in an oversubscribed offering at A$0.02 per share, and subsequently completed an oversubscribed placement on 19 May 2017 raising A$7.4m at A$0.055 per share. The recent capital raising placement facilitated the introduction of some well-regarded institutional and family office investors to the share register, and allowed for the accelerated development of the Company's product pipeline. At 30 June 2017, the company had A$5.7m in cash and expects to receive an R&D tax concession return of more than A$1.5m in 4Q CY2017.

Botanix invested approximately A$3.65m on R&D activities, primarily associated with the Phase 1 study for the Company's BTX 1503 acne product and ongoing preparations for the Phase 1b and Phase 2 studies of that product. Botanix's significant investment into clinical product development, rather than administrative overheads highlights a clear focus on prudent cash management.

Forecast expenditure for the coming quarter is estimated to be A$2.2m with approximately $2.0m planned to be spent on further clinical development associated with the BTX 1503, BTX 1204 and BTX 1701. Successful completion of the BTX 1503 Phase 1b study will represent a significant milestone, acting to further de-risk the Company's overall clinical program. Patient studies for both BTX 1204 and BTX 1701 will likewise provide important validation of the potential for these new therapies and represent significant value inflection points for the Company.

Botanix has established a strong board led by Chairman Mr Graham Griffiths, along with Executive Directors Matt Callahan and Dr Bill Bosch, as well as Mr Rob Towner who all have a proven record in building and developing successful pharmaceutical businesses. In the last 12 months, the Botanix team has been boosted by the engagement of a number of very experienced staff members with significant dermatology experience including Dr Michael Thurn (COO) and Mark Davis (VP of Clinical Regulatory Affairs). Combination of the Board, executive management and a world class scientific advisory board led by Professor James Leyden and Professor Diane Thiboutot, Botanix is now very well placed to rapidly develop and commercialise its pipeline of dermatology clinical products, as

well as engage partners and collaborators in transactions around the Permetrex™ skin delivery technology.

About Botanix Pharmaceuticals

Botanix Pharmaceuticals is a clinical stage medical dermatology company, which is dedicated to developing next generation therapeutics for the treatment of serious skin diseases. Our mission is to improve the lives of patients battling acne, psoriasis, and atopic dermatitis, by providing new treatment options for conditions that currently are inadequately addressed, or are treated with therapeutics that are burdened with side effects profiles. Botanix is harnessing the untapped potential of a synthetic active pharmaceutical ingredient, known as cannabidiol, which has a well-established safety profile. Botanix has successfully completed its first-in-man studies with its lead acne product (BTX 1503) and has recently commenced a follow-on clinical trial in acne patients for the product which is planned to complete in December 2017. The Company has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases and plans to progress the development of BTX 1503 for acne and its pipeline of other Permetrex™ enabled products alone, or in collaboration with partners.
For more information on Botanix, please visit www.botanixpharma.com or follow us on Twitter @Botanixpharma.

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Appendix 4E
Preliminary final report

Name of entity

Botanix Pharmaceuticals Limited

ABN or equivalent company reference

70 009 109 755

Financial year ended ('current period')

30 June 2017

For announcement to the market

				$AUD
Revenues from continuing operations	Up	-	to	46,501
Loss from ordinary activities after tax attributable to members	Up	179%	to	(4,773,098)
Net loss for the period attributable to members	Up	179%	to	(4,773,098)

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	**30 June 2017**	**30 June 2016**
Net tangible asset backing per ordinary security (cents per share)	1.0	0.8

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

Management Discussion and Analysis

Provided as a covering announcement to this preliminary final report

Consolidated Statement Profit or Loss and Other Comprehensive Income

For the year ended 30 June 2017

	Notes	for the year ended 30 June 2017 $	for the period 13 August 2015 to 30 June 2016 $
Operating revenue	**3**	**46,501**	**-**
Operating expenses	**3**	(4,819,599)	(1,708,377)
Loss from continuing operations before income tax		**(4,773,098)**	**(1,708,377)**
Income tax benefit		-	-
Net loss attributable to members of Botanix Pharmaceuticals Limited		**(4,773,098)**	**(1,708,377)**

Earnings per share	for the year ended 30 June 2017 Cents	for the period 13 August 2015 to 30 June 2016 Cents
Basic earnings/(loss) per share from continuing operations	(1.10)[1]	(1.08)[1]
Diluted earnings/(loss) per share from continuing operations	(1.10)[1]	(1.08)[1]

[1] Based on a weighted average number of shares totalling 434,195,513 (ordinary shares) as at 30 June 2017 (2016: 157,746,253 ordinary shares). The Company currently has 543,111,296 ordinary shares on issue.

Consolidated Statement of Financial Position

As at 30 June 2017

	Notes	as at 30 June 2017 $	as at 30 June 2016 $
Current assets			
Cash and cash equivalents	**1**	5,720,514	3,651,986
Receivables		186,909	44,754
Total current assets		**5,907,423**	**3,696,740**
Total assets		**5,907,423**	**3,696,740**
Current liabilities			
Trade and other payables		470,600	515,826
Total current liabilities		**470,600**	**515,826**
Total liabilities		**470,600**	**515,826**
Net Assets		**5,436,823**	**3,180,914**
Equity			
Issued capital	**5**	11,631,844	4,716,525
Share based payment reserve		267,387	166,410
Foreign currency translation reserve		19,067	6,356
Accumulated losses		(6,481,475)	(1,708,377)
Total equity		**5,436,823**	**3,180,914**

Consolidated Statement of Cash Flows

For the year ended 30 June 2017

	Notes	for the year ended 30 June 2017 $	for the period 13 August 2015 to 30 June 2016 $
Cash flows from operating activities			
Payments to suppliers & employees		(1,120,827)	(6,688)
Research and development		(3,550,312)	-
Finance costs		(3,225)	
Interest received		31,277	-
Net cash flows (used) in operating activities		**(4,643,087)**	**(6,688)**
Cash flows from investing activities			
Cash acquired on acquisition		-	404,034
Net cash from investing activities		**-**	**404,034**
Cash flows from financing activities			
Proceeds from issue of shares and options		7,453,031	3,434,000
Share issue costs		(562,909)	(179,360)
Repayment of borrowings		(181,667)	-
Net cash flows from financing activities		**6,708,455**	**3,254,640**
Net increase in cash held		2,068,528	3,651,986
Cash and cash equivalents at beginning of period		3,651,986	-
Cash and cash equivalents at end of period	**1**	**5,720,514**	**3,651,986**

Consolidated Statement of Changes in Equity

For the year ended 30 June 2017

	Issued Capital $	Share based payment reserve $	Translation reserve $	Accumulated losses $	Total equity $
At 13 August 2016					
Issue of shares, net of costs	4,716,525	-	-	-	4,716,525
Share based payment reserve	-	166,410	-	-	166,410
Foreign currency reserve	-	-	6,356	-	6,356
Loss for year	-	-		(1,708,377)	(1,708,377)
As 30 June 2016	**4,716,525**	**166,410**	**6,356**	**(1,708,377)**	**3,180,914**
Issue of shares, net of costs	6,915,319	-	-	-	6,915,319
Share based payment reserve	-	100,977	-	-	100,977
Foreign translation reserve	-	-	12,711	-	12,711
Loss for year	-	-		(4,773,098)	(4,773,098)
At 30 June 2017	**11,631,844**	**267,387**	**19,067**	**(6,481,475)**	**5,436,823**

Notes to and forming part of the financial statements

For the year ended 30 June 2017

1. Reconciliation of cash

Reconciliation of cash at the end of the period (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows:	**As at 30 June 2017 $**	**As at 30 June 2016 $**
Cash at bank	5,720,514	3,651,986
Total cash at end of period	**5,720,514**	**3,651,986**

2. Non-cash financing and investing activities

There were no non cash financing and investing activities for the year ended 30 June 2017.

3. Revenue and expenses

	for the year ended 30 June 2017 $	**for the period 13 August 2015 to 30 June 2016 $**
Operating revenue		
Finance revenue - interest received	46,501	-
Total operating revenue	46,501	-
Operating expenses		
Employee costs	379,899	-
Administrative and corporate expenses	674,754	308,401
Finance expense	3,225	484
Listing expenses	-	1,399,492
Research and development	3,650,526	-
Foreign exchange losses	10,218	-
Share based payments	100,977	-
Total operating expenses	4,819,599	1,708,377

4. Dividends paid and proposed

No dividends have been paid or proposed during the year.

5. Issued capital

	for the year ended 30 June 2017 $	for the year ended 30 June 2016 $
Ordinary shares (net of issue costs)	11,631,844	4,716,525

	Number of shares	$
At 30 June 2016	405,514,770	4,716,525
At 30 June 2017	543,111,296	11,631,844

6. Group structure

Companies within the Botanix Pharmaceuticals Group (all wholly owned) carry out designated activities:

- Botanix Pharmaceuticals Limited
- Botanix Pharmaceuticals Inc.
- Bone Limited

7. Events after the reporting period.

No matters or circumstances have arisen since the end of the financial year which significantly affected or may significantly affect the operations of the Company, the results of those operations or the state of affairs of the Company in future financial years.

8. Annual meeting

(Preliminary final report only)

The annual meeting will be held as follows:

Place	TBA
Date	On or before 30 November 2017
Time	TBA
Approximate date the annual report will be available	On or before 30 October 2017

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.

Sign here: Date: 30 August 2017

(Company Secretary)

Print name: Simon Robertson