

**ASX/Media Release**

**27 June 2017**

**12 month operational review highlights significant progress**

Philadelphia PA and Sydney Australia, 27 June 2017: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, “Botanix” or the “Company”) is pleased to release a 12 month operational review, enclosed with this announcement. The review tracks Botanix’s significant progress across all key operational aspects of the company, including executive management, intellectual property, business and product development, as well as significant progress in the development of new product opportunities - all within the first 12 months of listing. This strong progress supported the April placement to new and existing institutional and sophisticated investors, that raised A\$7.4 million.

**TARGET MILESTONES ACHIEVED WITHIN THE FIRST 12 MONTHS OF LISTING**

- Appoint experienced industry leaders for team positions
- Formalisation of world-class Scientific Advisory Board
- Secure synthetic source of drug substance for BTX 1503
- Completion of GMP Manufacturing and testing for BTX 1503
- Filing TGA, DEA and/or Customs licenses for BTX 1503
- Pipeline development progress – psoriasis and atopic dermatitis
- New product addition to pipeline (based on Permetrex™ delivery platform)
- Commencement and then completion of first human trials of BTX 1503
- Conference presentation/attendances
- Collaborative research arrangements

Matthew Callahan, Executive Director, commented, “We are pleased with our strong operational performance, and demonstrated ability to deliver on our milestones over the last year. Our significant achievements have Botanix well positioned to rapidly progress our lead acne product, and further develop and commercialise our wider product portfolio.”

**About Botanix Pharmaceuticals**

Botanix Pharmaceuticals 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 is preparing for the first human trials with synthetic cannabidiol utilising a proprietary drug delivery system (Permetrex™) for direct

skin delivery of the therapy and plans to progress the development of its pipeline of other Permetrex™ enabled products alone, or in collaboration with partners.

For more information on Botanix, please visit [www.botanixpharma.com](http://www.botanixpharma.com) or follow us on Twitter @Botanixpharma.

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# botanix

PHARMACEUTICALS

RESTORING HEALTHY SKIN

12 month operational review  
July 2017



# Target milestones for first 12 months

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Botanix has successfully delivered on its target milestones within its first year of listing

**Secure synthetic source of drug substance for BTX 1503**



**Completion of GMP Manufacturing and testing for BTX 1503**



**Filing TGA, DEA and/or Customs licenses for BTX 1503**



**Commencement and then completion of first human trials of BTX 1503**



**Pipeline development progress – psoriasis and atopic dermatitis**



**New product addition to pipeline (based on Permetrex™ platform)**



**Collaborative research arrangements**



**Appoint experienced industry leaders for team positions**



**Formalisation of world-class Scientific Advisory Board**



**Conference attendance and presentations**





# Details of BTX 1503 milestones achieved

Completed initial manufacturing and testing; obtained key export licenses and approvals, commenced first human clinical trials for BTX 1503 with Phase 1a results due

## Secure drug substance supply and completion of GMP manufacturing and testing

- Manufacturing and initial testing of BTX 1503 formulation **completed within 5 months of listing**
- Commercial-scale supply of synthetic cannabidiol secured
- BTX 1503 clinical trial material manufactured by US partner
- Testing and stability work completed in time for first Phase 1a study

## Filing TGA, DEA and/or Customs licenses

- Key export and import licenses and approvals **obtained within 8 months of listing**
- US DEA approved export license and Australian Office of Drug Control approved import of synthetic cannabidiol for Botanix's planned clinical studies

## Commencement and completion of first human trial (BTX 1503)

- Successfully obtained ethics approval for Phase 1a human studies **within 9 months of initiating the BTX 1503 program**
- Commenced Phase 1a safety, tolerability and pharmacokinetics (amount of drug in blood) study for BTX 1503 in May 2017
- Data from Phase 1a study due by end June 2017 **(within 12 months of listing)**



# Development pipeline milestones achieved

Further expansion and development of the Botanix's product pipeline and growing industry acceptance of the advantages of the Permetrex™ delivery technology

## Pipeline development progress (psoriasis and atopic dermatitis)

- Successful expansion of license and filing of 5 new patent applications (covering products for psoriasis and atopic dermatitis) for Permetrex™ technology **within 7 months of listing**
- Permatrex™ license expanded to encompass all active drugs being used to treat skin diseases (not just cannabinoids)
- New formulations for psoriasis and atopic dermatitis created

## New product addition to pipeline (based on Permetrex™)

- Achieved positive data from first human clinical trials of Permetrex™ in humans proving safety of the delivery system
- Added a new over-the-counter (OTC) facial cleanser product, BTX 1701 (based on the Permetrex™ technology), to the Botanix product pipeline
- Completed positive pilot study in humans of new BTX 1701 (OTC facial cleanser product based on Permetrex™ technology) **within first 11 months of listing**

## Collaborative research arrangements

- Concerted business development effort has resulted in **multiple engagements by third parties to use the Permetrex™ delivery technology**
- Permetrex™ delivery technology usage to **solve formulation problems**
- Currently undertaking early stage project with unnamed partner



# Key corporate milestones achieved

Appointed several experienced team members and remain focused on increasing Botanix's profile with complementary market awareness activities

## Appointment of experienced industry leaders

- Highly seasoned team assembled with decades of dermatology industry experience
- Dr Michael Thurn: operations (>20 years experience)
- Mark Davis: clinical and regulatory (>35 years experience with 19 FDA approvals)
- Steve Newhard: manufacturing and packaging (>30 years experience)
- Phil Johns: toxicology (>35 years experience)
- Formed world-class Scientific Advisory Board

## Conference attendance and presentations

- AusBiotech 2016
- Australian Microcap Investment Conference 2016
- JP Morgan Healthcare Conference 2017
- American Academy of Dermatology Annual Meeting 2017
- Shaw and Partners Investor Seminar 2017
- Bioshares Biotech Summit 2017 (upcoming)



# Upcoming milestones for next 12 months

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Positioning Botanix for significant value inflection points in the near and medium term

**Phase 1a data for BTX 1503**

**Ethics approval for Phase 1b acne patient pilot study for BTX 1503**

**Completion of Phase 1b acne patient trial for BTX 1503**

**Pre-IND meeting and IND filing in anticipation of US Phase 2 studies for BTX 1503**

**Collaboration agreement for use of Permetrex™ delivery platform**

**New products for pipeline using Permetrex™ delivery platform**

**Progression on development of BTX 1701 facial cleanser for mild acne/oily skin**

**Progression on development of BTX 1204 for atopic dermatitis**

**Initial data on use of synthetic cannabidiol for new indication**

**Conference attendance and presentation**





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