



Bone Medical

ASX / MEDIA RELEASE

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Bone Medical Announces Acquisition of US-based Botanix Pharmaceuticals

- Botanix developing new dermatology products
- \$3m to be raised via issue of 150,000,000 shares at \$0.02 post consolidation
- Rapid path to clinical data within 12 months and funding through to Phase 2 studies.

Bone Medical Limited (ASX:BNE) today announced it has signed an agreement to acquire Botanix Pharmaceuticals Inc., a US-based medical dermatology company. Botanix is developing new prescription products to treat serious skin diseases including acne, psoriasis and atopic dermatitis. Botanix has licensed a novel transdermal drug delivery technology known as Permetrex™, which is designed to deliver pharmaceuticals through the skin more effectively than alternative approaches currently marketed.

Following conclusion of the acquisition, and subject to shareholder approval, the Company will change its name to Botanix Pharmaceuticals Limited.

Botanix's lead product, BTX1503, is a topically applied gel for the treatment of serious acne. BTX1503 utilises a novel pharmaceutical ingredient that recent studies suggest has a novel 4-part mechanism - reducing excessive production of oils, inhibiting over-proliferation of oil producing cells, inhibiting bacteria and providing a novel anti-inflammatory effect.

Botanix has already completed substantial research and preparatory work on the formulation of its lead product (BTX1503) and plans to conduct first human clinical studies in Australia. Botanix views the Australian Therapeutic Goods Administration's (TGA) Clinical Trial Notification (CTN) process as significantly more efficient than the US FDA's Investigational New Drug (IND) process, and believes the Australian process can accelerate the overall development timetable.

Upon completion of the planned offer, Botanix will be funded to complete initial clinical studies over the next 12 months including a pilot study on patients, through to commencement of a planned Phase 2 efficacy study in the United States.

Botanix's products are based on a FDA grade, synthetic form of a molecule known as cannabidiol, which has been manufactured utilising a proprietary and patent protected synthesis process. Various natural extract and other forms of cannabidiol are in late stage clinical trials by numerous other pharmaceutical companies for indications such as epilepsy, pain and arthritis.

“There is a significant unmet patient need for effective dermatological therapies, particularly in the global acne market. There are few new drug products being developed globally and the potential for novel approaches is very attractive,” said Bone Medical Chairman, Mr Robert Towner.

“We see development of BTX1503 through to human clinical trials, and regulatory approval, as relatively rapid, due to the current stage of development of BTX1503, as well as the unique properties of cannabidiol and its established safety profile.”

“There is a growing scientific literature to suggest that cannabidiol has a potential role in treating and preventing skin disease. To date, challenges with the impurity and variability of the drug substance, as well as the challenge of delivering it effectively across the skin, have been limiting. Botanix’s approach of utilising a pure synthetic form of cannabidiol combined with the novel skin delivery technology Permetrex™, are focused on solving both of these challenges.”

The medical dermatology market was valued at over US\$24 billion in global pharmaceutical sales in 2015¹. In 2009, there were an estimated 34 million clinic visits to U.S. dermatologists alone². Acne is one of the most common skin conditions and affects more than 85% of teenagers globally³.

As part of the transaction, Bone Medical will undertake a consolidation of its capital on a one for three and one third basis and plans to raise \$3 million through the issue of 150 million shares at \$0.02 each.

The acquisition of Botanix is subject to mutual due diligence to be completed within 4 weeks of execution of the binding term sheet. Full transaction details have been lodged with the ASX (www.asx.com.au) and also available at <http://bone-ltd.com>

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¹ https://www.visiongain.com/Press_Release/365/The-dermatological-drugs-market-will-reach-24-4-billion-in-2015-shows-visiongain-report

² NAMS CDC fact sheet

³ American Academy of Dermatology. Acne: Who gets and causes. <https://www.aad.org/dermatology-a-to-z/diseases-and-treatments/a---d/acne/who-gets-causes>. Accessed on October 30, 2015.