IN-DEPTH RESEARCH NOTE:

Botanix Pharmaceuticals – Speculative Buy

Share Price: A$0.051 | ASX: BOT | 8 May 2017

Botanix Pharmaceuticals (ASX: BOT) is a unique pharmaceutical twist on the current interest in the medicinal cannabis market explosion. Rather than using natural product extracts, BOT is using synthetic cannabidiol to treat serious skin diseases such as acne, psoriasis and atopic dermatitis. We conservatively estimate the Company's global addressable market at greater than US$23bn. Further, post the recent capital raising, we believe the Company's funding position is in a solid position for it to deliver on its short-to-medium clinical trials. In our view, successful data results could see a significant re-rating of the stock which still remains attractively priced in absolute terms relative to its ASX-listed cannabis and pharmaceutical peers (especially when comparing value proposition/investment thesis). In this report, we discuss key investment drivers for BOT and highlight the unique investment proposition BOT offers to investors.

- **Company Overview.** Botanix Pharmaceutical (BOT) is a medical dermatology company, with operations based in Philadelphia, in the United States. The Company is developing prescription treatments using synthetic cannabidiol to treat serious skin diseases such as acne, psoriasis and atopic dermatitis. The Company has also secured the exclusive global rights to use Permetrex delivery technology for all skin diseases. BOT listed on the ASX in July 2016 via the reverse takeover of Bone Medical.

- **Significant market opportunity.** BOT has a significant market opportunity addressing the US$4.5bn acne prescription market. In our view, drug development in dermatology is much quicker and cost effective area to develop drugs compared to cancer and epilepsy, which take many years and hundreds of millions of dollars to develop new products.

- **BOT's leading product could unlock significant value.** BTX 1503 is a formulation of synthetic cannabidiol and other excipients (substance formulated alongside an active ingredient), which comprise the exclusive Permetrex drug delivery system. Synthetic cannabidiol provides an attractive alternative to existing cannabinoid therapies as it permits higher quality, more consistent manufacturing, greater scalability and more straightforward regulatory approval prospects over naturally extracted cannabidiol. The other key advantage of BOT's product is that it is topical (applied directly on skin) rather than orally administered. Management have highlighted the limitation of consuming cannabidiol orally, with around 6% consumed orally becoming available in the blood stream and even less finding its way into the organs in the skin. Hence, the Company has licensed a delivery technology (Permetrex), which effectively delivers pharmaceuticals into and through the skin. Permetrex can potentially deliver approximately 5 times more cannabidiol than traditional approaches.

- **Attractive (cost effective + shorter duration) development timeline.** BOT's development timeline is attractive compared to other early stage biotechnology/pharmaceutical companies: **(1)** shorter duration due to minimal pre-clinical work (i.e. the safety profile of BOT's key component cannabidiol is known); **(2)** straightforward to conduct trials, as the end points (goals) are typically visual assessments); **(3)** require much less investment due to shorter duration and reduced complexity.

- **An experienced management team with a history of achieving FDA approvals.** Botanix is led by an experienced Board and management team, with significant experience in start-ups, product development and biotech industry. This includes 20 plus FDA approved products credited to the broader Botanix leadership team, which we believe is a significant added advantage.

Investment Thesis

We rate BOT as a SPECULATIVE BUY for the following reasons:

- Significant market opportunity, which we estimate to be US$4.5bn in the short term (acne market alone) and greater than US$23bn in the medium term.
- BOT is a pure play on the dermatology market.
- Experienced management team, with significant experience in achieving FDA approvals (20 plus FDA approvals).
- Short-term catalyst (Jun-17) - BOT will need to prove that the formulation developed using cannabidiol does not cause any irritation to the skin and BOT can measure how much of the drug gets into the bloodstream. The data from this study is likely to be released by the end of June 2017.
- Long-term patents provide protection.
- Likely takeover target should initial clinical trials prove successful given the lack of development in the acne space in over 20 years.

Key Risks

We see the following key risks to our investment thesis:

- Initial clinical trials fail to conclusively prove the efficacy of BTX 1503.
- The Company is in very early stages and therefore a highly speculative investment (only suited for investors with a very high risk tolerance).
- Significant liquidity risk.
- Licensing & regulatory risk.
- Competition risk (domestic & global and alternative skin disease treatments).
- Key person risk.

Company Description

Botanix Pharmaceutical (BOT) is a medical dermatology company, with operations based in Randor, Pennsylvania, United States. The Company is developing prescription treatments using synthetic cannabidiol to treat serious skin diseases such as acne, psoriasis and atopic dermatitis. The Company has also secured the exclusive global rights to use Permetrex delivery technology for all skin diseases.

Investment drivers…

Investment driver #1: Pure play on dermatology. To date much of the discussion has been around using cannabis extract to treat epilepsy, chronic pain and arthritis – all of which are complex diseases with long and expensive development pathways.

Investment driver #2: Significant market opportunity, with no new products having been approved for acne in 20 years. BOT is focused on the medical dermatology market, with its key target end-markets being acne, dermatitis psoriasis, atopic dermatitis. We estimate the global opportunity for BOT's products to be greater than US$23bn over the medium term. According to GlobalData, key developed markets globally are expected to experience solid growth rates: pharmacological sales of acne are forecast to grow at a CAGR of +3.9% per annum over a 6-year period; the global atopic dermatitis market is estimated to grow at a CAGR of +7.5% per annum over a 10-year period; and the global psoriasis market is forecast to grow at a CAGR of +7.1% per annum over a 10-year period.

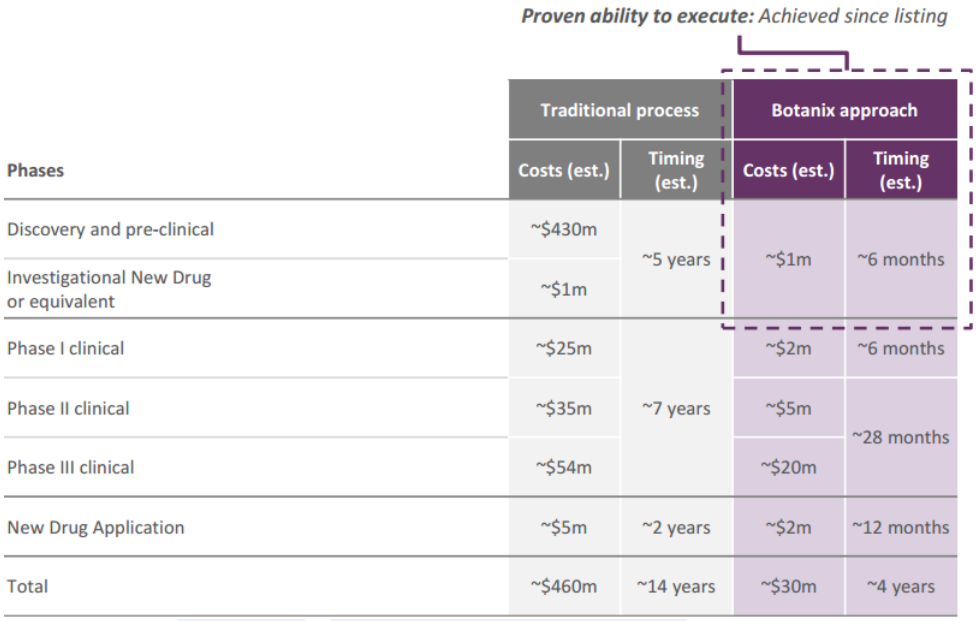
Investment driver #3: BOT's leading product BTX 1503 has significant advantages over competing products. Botanix's first proposed product for the acne market BTX 1503 is a topically applied gel which is likely to have a direct effect on the underlying causes of acne with a benign side effect profile. BTX 1503 is a formulation of synthetic cannabidiol, which is delivered using the Permetrex drug delivery system. It is designed to deliver a consistent dose of cannabidiol to directly impact cutaneous cell growth and differentiation, provide anti-inflammatory effects and regulate sebum production. BOT has opted to go down the path of synthetic drug product rather than trying to extract the target drug from the more than 100 chemicals in the cannabis plant. Besides the challenges of manufacturing a drug (strict regulatory rules / variability in quality / scalability etc), management believes using a synthetic form will also help keep cost of goods much lower than natural extracts. Synthetic cannabidiol provides an attractive alternative to existing cannabinoid therapies as it permits higher quality, more consistent manufacturing, greater scalability and more straightforward regulatory approval prospects over naturally extracted cannabidiol. The other key advantage of BOT's product is that it is topical (applied directly on skin) rather than orally administered. Management have highlighted the limitation of consuming cannabidiol orally, with around 6% consumed orally becoming available in the blood stream and even less finding its way into the organs in the skin. BOT has exclusive use of this technology in all areas of skin disease into perpetuity and is seen by management as a significant competitive advantage as it solves a number of the challenges of delivering cannabidiol efficiently to the targeted area for the treatment of various skin diseases.

Investment driver #4: An experienced team with a history of achieving FDA approvals. BOT is led by an experienced Board and management team, with significant experience in start-ups, product development and the biotech industry. This includes 20 plus FDA approved products credited to the broader Botanix leadership team, which we believe is a significant added advantage.

Investment driver #5: Attractive (cost effective + shorter duration) development timeline. BOT's development timeline is attractive compared to your traditional pharmaceutical companies: **(1)** shorter duration to minimal pre-clinical work (i.e. the safety profile of BOT's key component cannabidiol is known); **(2)** straightforward to conduct trials, as the end points (goals) are typically visual assessments); **(3)** require

much less investment due to shorter duration and reduced complexity. The diagram below compares the two pathways.

Figure 1: BOT development timeline



Source: Company

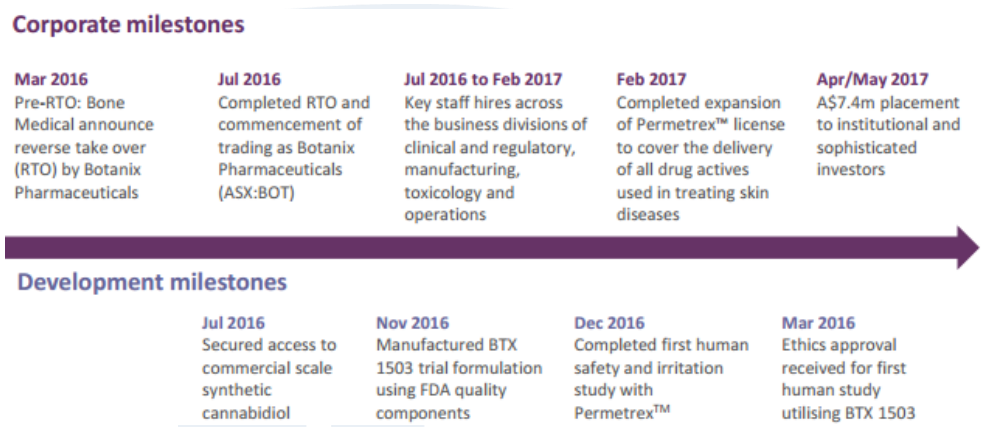
A traditional pharmaceutical company, such as those trying to treat cancer or epilepsy, would have to undertake very long clinical trials and invest significant amount of cash to complete these studies. Additionally, given these types of diseases are life threatening, they are complex and highly scrutinized. Most of BOT's clinical trials are able to be completed within a 4 to 12 weeks timeframe. In our view, this makes BOT (and the dermatology sector in general) a much more attractive proposition. Further, as we highlighted in investment driver #2, the market opportunity is still significant for these companies.

Investment driver #6: Current funding position provides solid runway. BOT's first study will cost approximately A$1.0m and the pilot (second study) will cost between A$1.5 – 2.0m. Phase II study will cost approximately A$7.0m. The funds which the Company raised in July 2016 via the IPO were sufficient to take BOT through Phase Ia and Ib studies in the coming months. The additional money the Company recently raised (A$7.4m) will be used to prepare for the Phase II study and will also be used for synthetic cannabidiol for dermatitis.

Botanix Pharmaceutical (BOT) Overview…

Botanix Pharmaceutical (BOT) is a medical dermatology company, with operations based in Randor, Pennsylvania, United States. The Company is developing prescription treatments using synthetic cannabidiol to treat serious skin diseases such as acne, psoriasis and atopic dermatitis. The Company has also secured the exclusive global rights to use Permetrex delivery technology for all skin diseases. The figure below provides a quick timeline of BOT's corporate and development history.

Figure 2: BOT corporate and development history



Source: Company

Experienced management team…

Botanix is led by an experienced Board and management team, which importantly includes extensive experience and expertise in progressing products through clinical trials and achieving FDA approvals. We note the following key executives:

Graham Griffiths (Chairman) – Mr. Griffiths has over 40 years' corporate experience in technology based companies in a range of roles. Previously he was the Managing Director of ipernica Limited) and is currently Non-Executive Director of Ponterra (ASX: 3DP), iperative and NGIS Australia.

Matthew Callahan (Executive Director) – Mr. Callahan has over 20 years' experience in legal, intellectual property (IP) and investment management. This includes: founding CEO of iCeutica and Churchill Pharmaceuticals; Co-inventor of iCeutica's SoluMatrix Technology; and developed three FDA approved products. He is also currently a Director at Orthocell (ASX: OCC) and Glycan Bioscience LLC.

Dr Bill Bosch (Executive Director) – Dr Bosch has over 20 years' experience in the pharmaceutical industry and was also the co-inventor of iCeutica's SoluMatrix Technology. Further, Dr Bosch's experience includes: developed six FDA approved products; developed four commercial nanotechnology products at Elan Corporation; and co-founder of NanoSystems LLC.

Michael Thurn (Chief Operating Office) – Mr. Thurn's experience is grounded in drug regulation and biopharmaceutical industry, including senior roles in listed and private

companies. He has worked extensively with life science start-ups and is experienced in drug discovery, preclinical and clinical development. Prior to joining BOT, Mr. Thurn held managerial and executive roles at Mimetica, Spinifex Pharmaceuticals and Cytopian and was a toxicology reviewer with the Drug Safety and Evaluation Branch of the Therapeutic Goods Administration.

Industry Overview…

BOT is focused on the medical dermatology market, with its key target end-markets – acne, psoriasis, atopic dermatitis – described in the figure below.

Figure 3: A brief overview of targeted skin conditions

Condition	Description	Symptoms	Patient Profile	Treatment
Acne	A type of skin condition when hair follicles plug with oil and dead skin cells	uninflamed blackheads; pus-filled pimples; red & tender bumps	Teenagers; young adults (under 30)	Over-the-counter creams; cleanser; prescription antibiotics; prescription retinoids (specialist-prescribed)
Psoriasis	A type of skin condition where skin cells build up and form scales and itchy, dry patches. Can also affect nails and joints.	Skin rash (redness, dryness, flakiness, peeling etc); pain in joints	All ages	Coal tar preparations; steroid creams; immunosuppressive drugs; ultraviolet light therapy
Atopic dermatitis (eczema)	A type of inflammation of the skin	Red, itchy, dry rash which can appear anywhere	Typically develops in early childhood & common in people who have a family history	Avoid irritants; moisturisers; steroid and anti-inflammatory creams; oral anti-inflammatory drugs; ultraviolet light therapy

Source: BTIG

It is important to differentiate medical dermatology (treatment of diseases such as those described in the table above) to aesthetics dermatology (treatment related to enhancing a patient's appearances, such as aging etc). Medical dermatology treats conditions which are associated with significant patient morbidity.

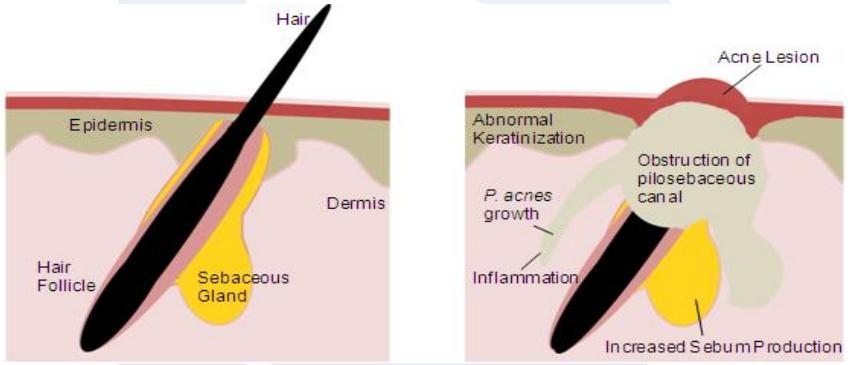
Further, it is also worth noting that BOT is initially targeting the prescription dermatology market, therefore what dermatologists prefer in a treatment is critical to understanding the likely success of BOT's proposed solution. In our discussion with dermatologists, the following key elements were highlighted when considering what to prescribe to patients:

- **Safety (Paramount).** Given the non-life threatening nature of these conditions, there is a particular focus on the safety aspect of the treatment.
- **Delivery method (Important).** Orally delivered is the preferred method of choice, which they believe will maximize patient uptake/compliance.
- **Pricing (Negotiable).** What reimbursements are available on the treatment and overall out-of-pocket cost to the patient is also a consideration. However, in our view, in the event a treatment significantly enhances a patient's quality of life, the associated cost will be a lesser consideration.

Acne Overview…

Acne is the most common skin condition in the United States and it is estimated that 80% of 11 to 30 year olds globally are affected by acne. Acne lesions are caused from an interaction of four primary pathogenic (capable of causing disease) factors: ***(1)*** Excessive production of sebum or lipids by sebaceous glands in the skin; ***(2)*** Hyper-proliferation of sebocytes (highly specialised, sebum-producing epithelial cells) that contribute to clogging of pores through which sebum is normally released to the skin surface; ***(3)*** Colonization of the area in and around the sebaceous gland by bacteria; and ***(4)*** Inflammation, often associated with colonization by bacteria and their breakdown of sebum into irritating breakdown products.

Figure 4: Pathophysiology of acne



Source: Health Plexus

Despite a considerable patient population – estimated at 103.9 million in 2012 across the US and 5 select European countries (UK, France, Germany, Italy, Spain) – the acne market has been overlooked and remained stagnant for the past few decades by big pharmaceutical companies, with no novel drugs entering the arena. Instead, the market has focused on reformulations and/or fixed-dose combination therapies. There are four main prescription pharmaceutical product classes being used today (presented in the figure below).

Figure 5: Current acne treatments

Type	Application	Target	Limitations	Product Examples
Antimicrobials	Topical & oral (severe disease)	Bacterial colonisation & inflammation	Increasing bacterial resistance; declining efficacy	Allergan (Aczone); Valeant (Acanya / Solodyn); Actavis (Doryx)
Retinoids	Topical	Clogging of the pores	Skin irritation; relative modest efficacy	Allergan (Tazorac); Valeant (Retin-A Micro/ Ziana); Stiefel (Fabior / Veltin)
Isotretinoin	Oral	Reduce excess sebum production	Significant systemic toxicity (liver damage / severe birth defects)	Mylan (Amnesteem); Teva (Claravis)
Hormonal therapies	Oral	Reduce excess sebum production by targeting the activity of sex hormones	Systemic side effects - mood disturbance, reduced sexual desire.	Actavis (TriNessa); Pfizer (Aldactone); Bayer (Yaz)

Source: BTIG, Botanix

According to industry experts, the biggest unmet needs in acne include the need for new and innovative products, for improved compliance and for less expensive products relative to existing therapies. According to Physicians, in a survey conducted by GlobalData, inadequate patient compliance is the greatest unmet need for acne. This single factor has hindered the ability for patients to achieve maximum treatment benefit, given the therapeutic options currently available, and resulted in multiple failed treatment attempts.

Acne market opportunity. According to GlobalData, 2012 pharmacological sales of acne total US$2.3bn across six major pharmaceutical markets – US, France, Germany, Italy, Spain and the UK. Unsurprisingly, the US was the largest market (91% or US$2.1bn in sales), with Germany the next largest with estimated sales of US$54.3m. GlobalData forecast the market to grow at a compound annual growth rate (CAGR) of +3.9% per annum over a 6-year period.

Figure 6: 2012 Acne market US$2.3bn

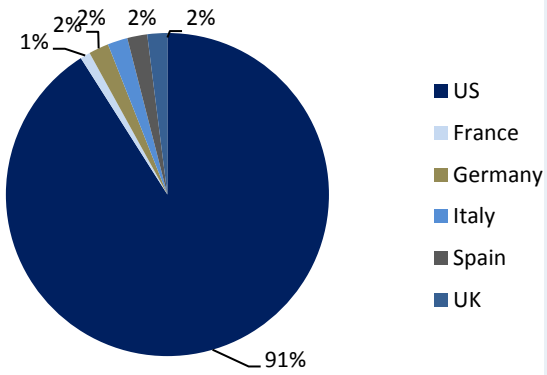
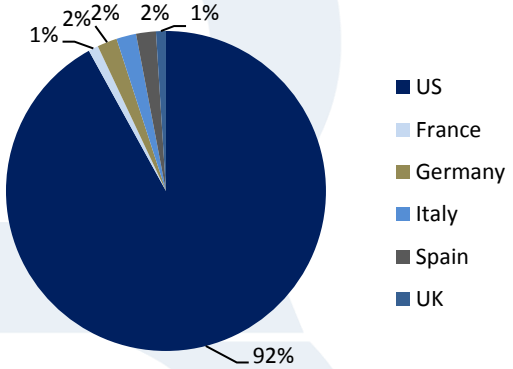


Figure 7: 2018E Acne market US$2.9bn



Source: GlobalData

Acne deal history. The data below shows recent deal activity in the acne space.

Figure 8: Acne – Number of deals

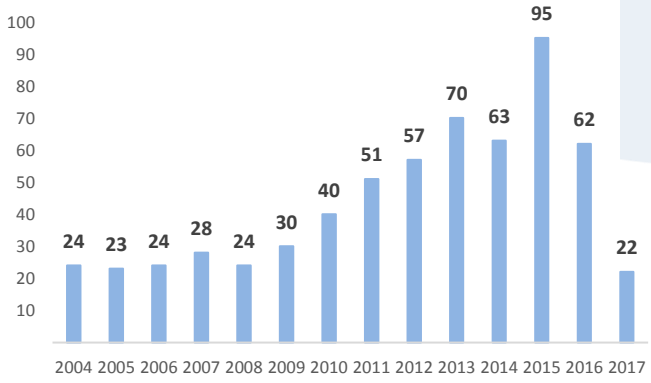
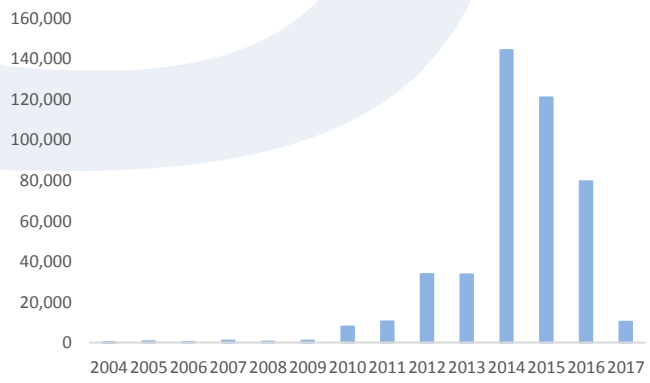


Figure 9: Acne – total value of deals per year (USD million)



Source: GlobalData

Acne clinical trials data. The data below shows the clinical trials by phase and the major sponsors of these trials.

Figure 10: Acne – Clinical trials by phase

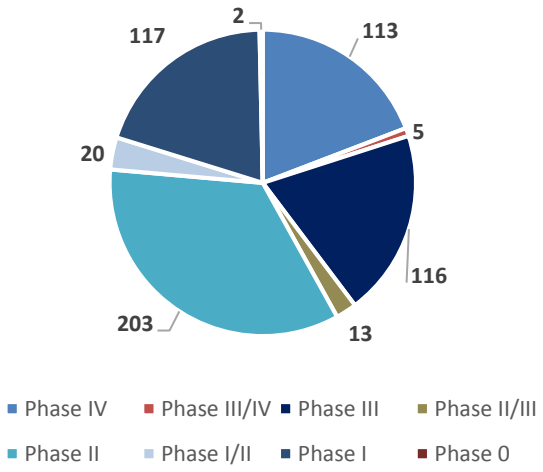
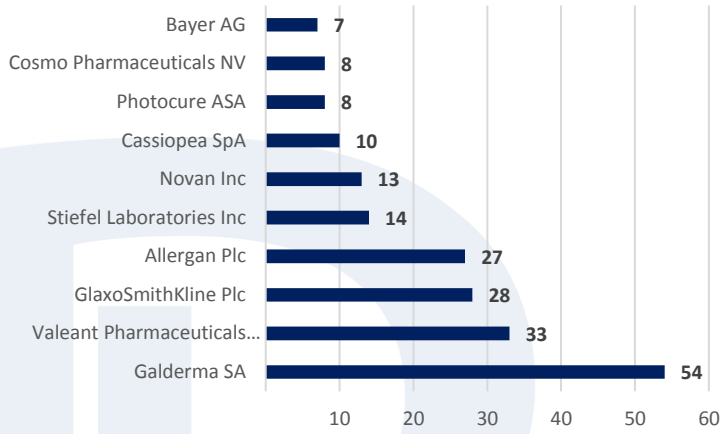


Figure 11: Acne – Clinical trials by top 10 sponsors



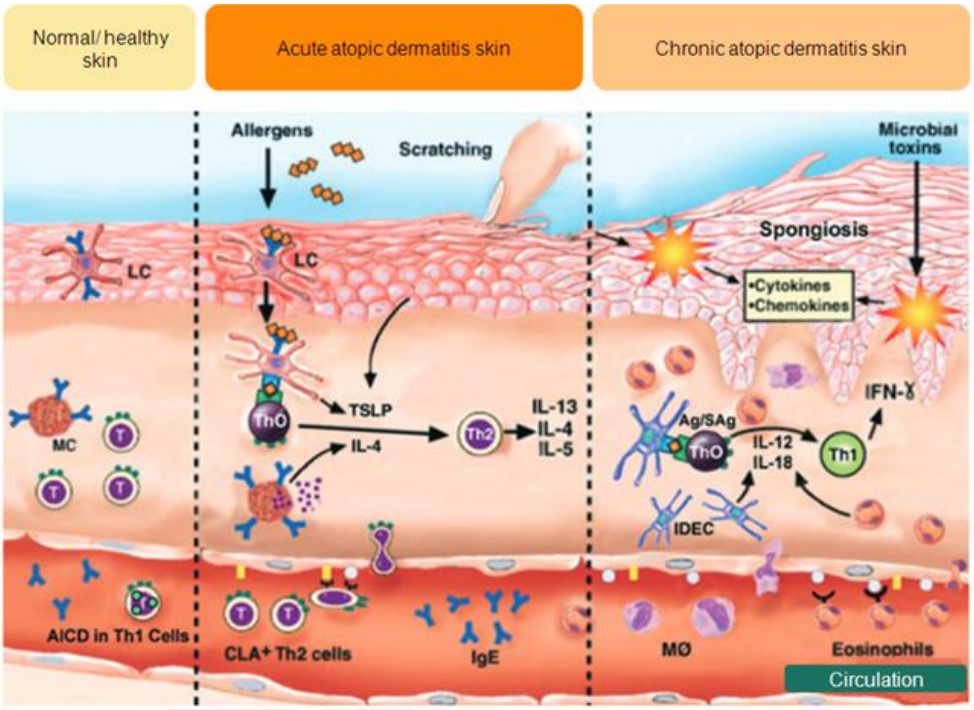
Source: GlobalData

Atopic Dermatitis (Eczema) Overview…

Atopic dermatitis is an inflammatory skin disease caused by a number of factors including environmental, immunologic, genetic and pharmacologic. Also referred to as eczema, the condition is described as an uncomfortable sensation leading to increased desire to scratch the affected area, causing redness, scaling and loss of skin surface. Recent studies suggest the primary defects in the epidermal structure, particularly formation of the stratum corneum (outer layer of the skin), play a key role in driving the pathogenesis of atopic dermatitis. The key effect of these epidermal impairments is a reduced ability for atopic skin to self-repair, leading to extended signaling of repair and inflammatory cascades. These signals in turn trigger further impairment of skin functions, which results in chronic activation of immune cells, and which eventually presents as atopic dermatitis and related conditions.

According to the National Eczema Association (US), an estimated 31.6 million people in the US have symptoms of eczema or eczematous conditions. The National Eczema Association also estimates that the worldwide prevalence of atopic dermatitis in infants and children is approximately 10 – 18%.

Figure 12: Pathophysiology of atopic dermatitis



Source: GlobalData, adapted from Akdis et al 2006

Atopic dermatitis market opportunity. According to GlobalData, in 2014 the estimated global atopic dermatitis market reached US$3.6bn across seven major markets – US, UK, France, Italy, Spain, Germany and Japan. The US market was the largest market, making up 58.1% or US$2.1bn in sales across the seven major markets. GlobalData forecast the market to grow at a compound annual growth rate (CAGR) of 7.5% per annum over a 10-year period.

Figure 13: 2014 Atopic Dermatitis market US$3.6bn

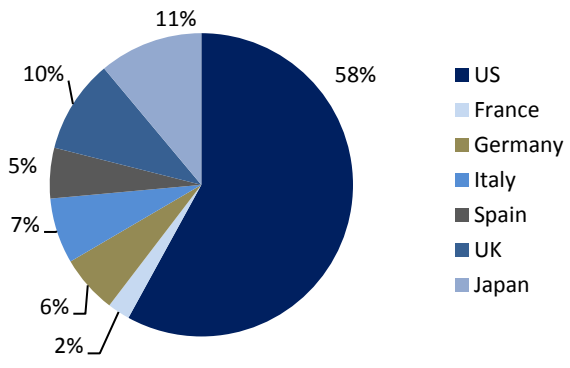
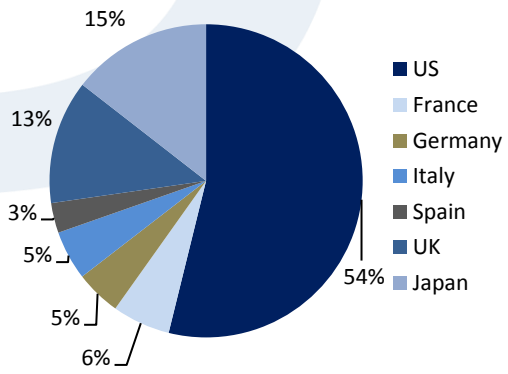


Figure 14: 2024E Atopic Dermatitis market US$7.3bn



Source: GlobalData

Atopic dermatitis deal history. The data below shows recent deal activity in the dermatitis space.

Figure 15: Atopic dermatitis – Number of deals

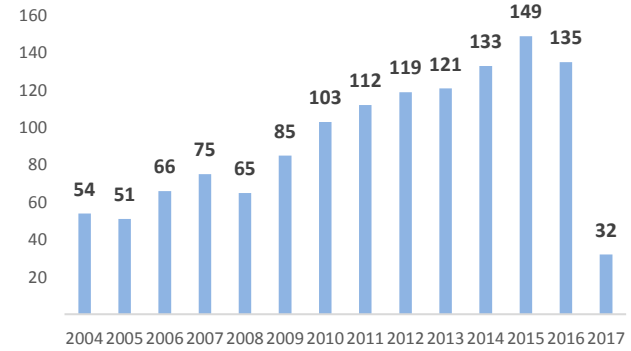
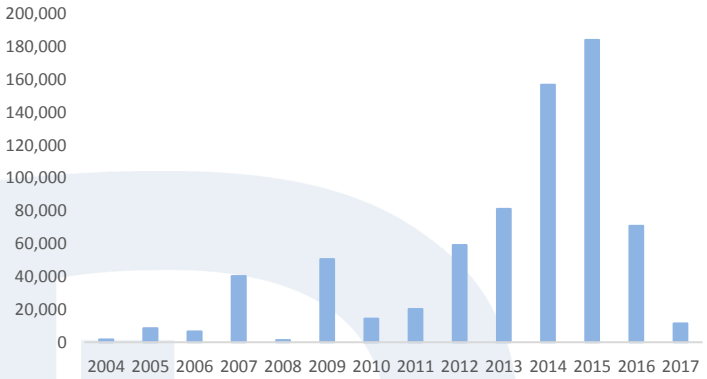


Figure 16: Atopic dermatitis – total value of deals per year (USD million)



Source: GlobalData

Atopic dermatitis clinical trials data. The data below shows the clinical trials by phase and the major sponsors of these trials.

Figure 17: Atopic dermatitis – Clinical trials by phase

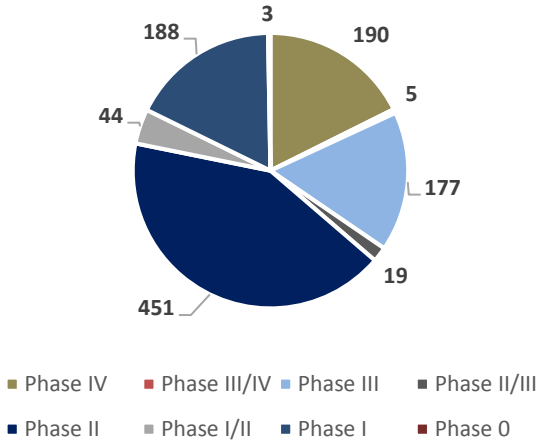
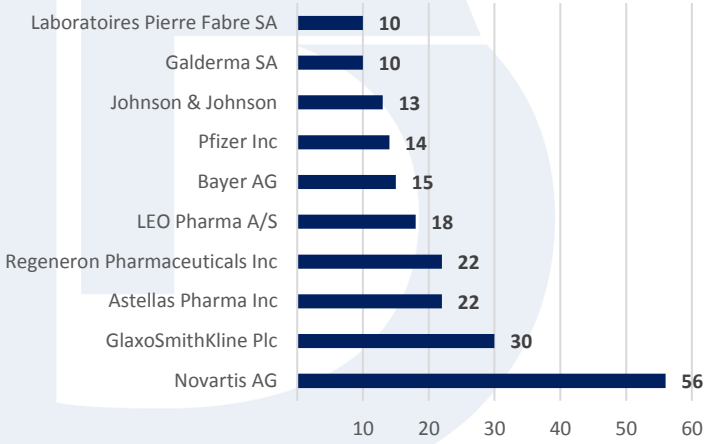


Figure 18: Atopic dermatitis – Clinical trials by top 10 sponsors

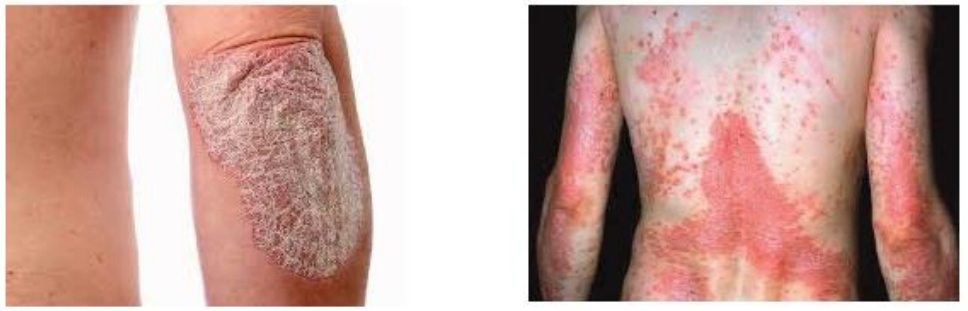


Source: GlobalData

Psoriasis Overview…

Psoriasis is a chronic, complex and immune-mediated disease that requires long-term treatment. Dysregulation of the immune system is thought to be a critical factor in the pathophysiology of this condition. Approximately 80% of psoriasis patients have plaque psoriasis. These patients typically have symmetrically distributed plaques of thickened, inflamed red skin, covered with slivery scales located on portions of the body including the elbows, knees, scalp or back.

Figure 19: Psoriasis symptoms



Source: Botanix

The American Academy of Dermatology estimates that prevalence of psoriasis in the US was approximately 7.5 million people, and 1.5 million adults are estimated to have moderate to severe psoriasis.

Psoriasis market opportunity. According to GlobalData, in 2014 the estimated global psoriasis market reached US$6.6bn sales across eight major markets – US, UK, France, Italy, Spain, Germany, India and Japan. The US market was the largest market, making up 65.3% or US$4.3bn in sales across the eight major markets. GlobalData forecast the market to grow at a compound annual growth rate (CAGR) of 7.1% per annum over a 10-year period.

Figure 20: 2014 Psoriasis market US$6.6bn

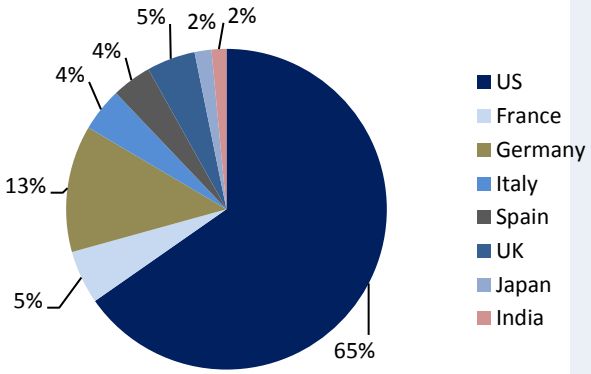
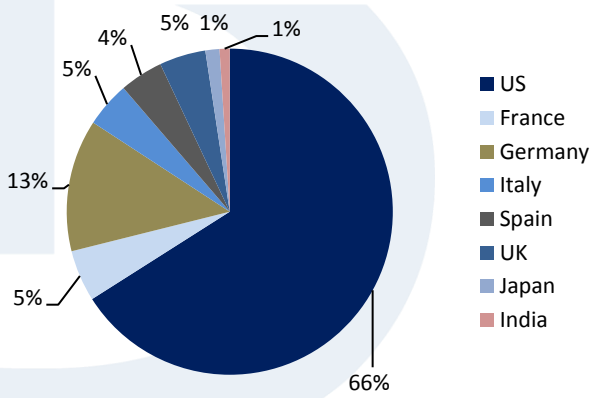


Figure 21: 2024E Psoriasis market US$13.1bn



Source: GlobalData

Psoriasis deal history. The data below shows recent deal activity in the psoriasis space.

Figure 22: Psoriasis – Number of deals

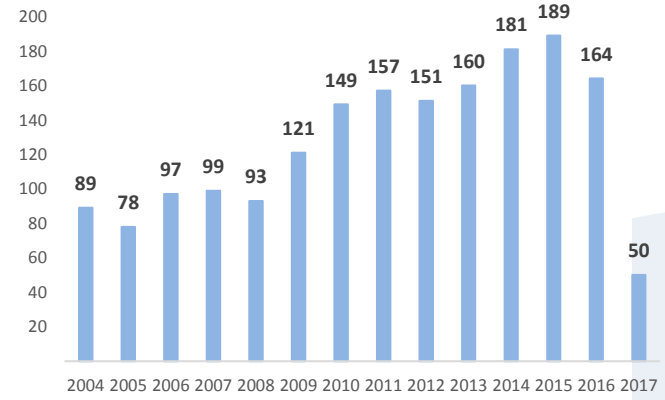
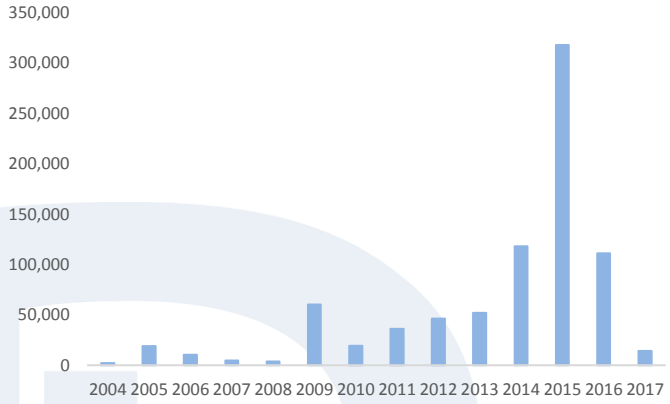


Figure 23: Psoriasis – total value of deals per year (USD million)



Source: GlobalData

Psoriasis clinical trials data. The data below shows the clinical trials by phase and the major sponsors of these trials.

Figure 24: Psoriasis – Clinical trials by phase

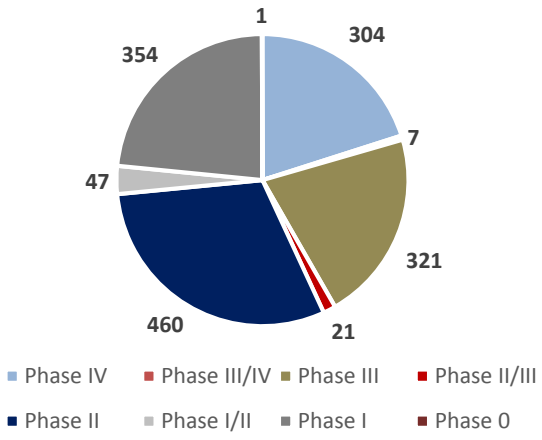
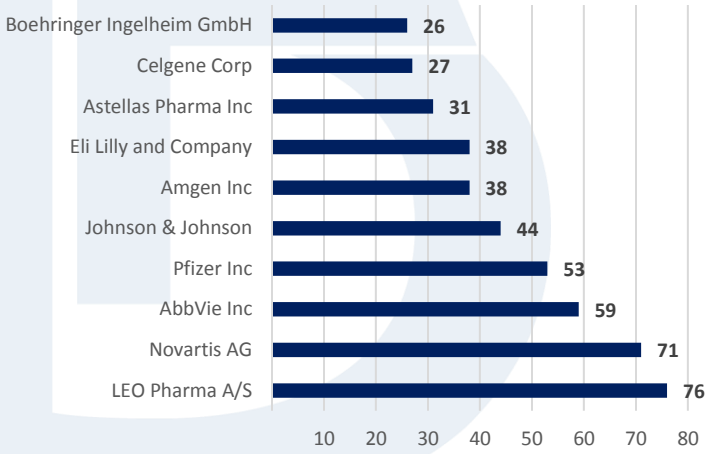


Figure 25: Psoriasis – Clinical trials by top 10 sponsors

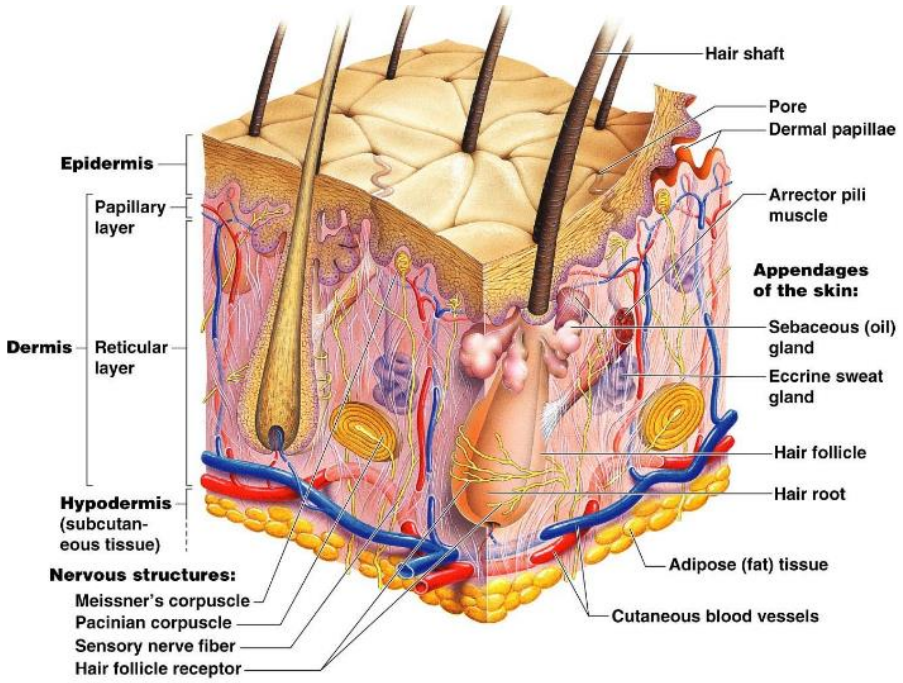


Source: GlobalData

BOT's products…

Botanix Pharmaceuticals' products under development are focused on modulating the body's 'endocannabinoid system' of receptors which regulates skin function, growth and renewal.

Figure 26: Skin structure



Source: Pearson Education 2009

Humans naturally synthesize chemical compounds - endocannabinoids – that activate the same receptors as THC (delta-9-tetrahydrocannabinol) which is the active component of marijuana (cannabis sativa). It is understood that cannabidiol may play a significant role in normalizing unwanted skin growth, reducing excessive production of oils and reducing inflammation and infection, amongst other functions. BOT has explored whether endocannabinoid modulating drugs (such as synthetic cannabidiol) can be exploited in the management of common skin disorders such as acne, psoriasis and atopic dermatitis.

Synthetic cannabidiol. BOT's products under development all use an active pharmaceutical ingredient ***2-[(1R, 6R)-6-isopropenyl-3-methylcyclohex-2-en-1-yl]-5-pentylbenzene-1, 3-diol***. This chemical is a GMP (Good Manufacturing Practice) manufactured synthetic analogue of a naturally derived compound, known as cannabidiol. Cannabidiol is a member of a broader family of compounds known as cannabinoids, which in turn, are a class of compounds originally derived from the cannabis sativa plant. Synthetic cannabidiol is not psychoactive and it is understood that cannabidiol may successfully treat epilepsy, arthritis and chronic pain.

Why use synthetic form? Besides the challenges of manufacturing a drug (strict regulatory rules / variability in quality / scalability etc), management believes using a synthetic form will also help keep cost of goods low (fewer required). Additionally,

extraction processes often involve high temperatures and dangerous chemicals, which may remain in the final drug substance mixture that is used in a final pharmaceutical product. The Company has identified a proprietary GMP quality synthetic form of cannabidiol for use in its clinical development programs. Synthetic cannabidiol provides an attractive alternative to existing cannabinoid therapies as it permits higher quality, more consistent manufacturing, greater scalability and more straightforward regulatory approval prospects over naturally extracted cannabidiol.

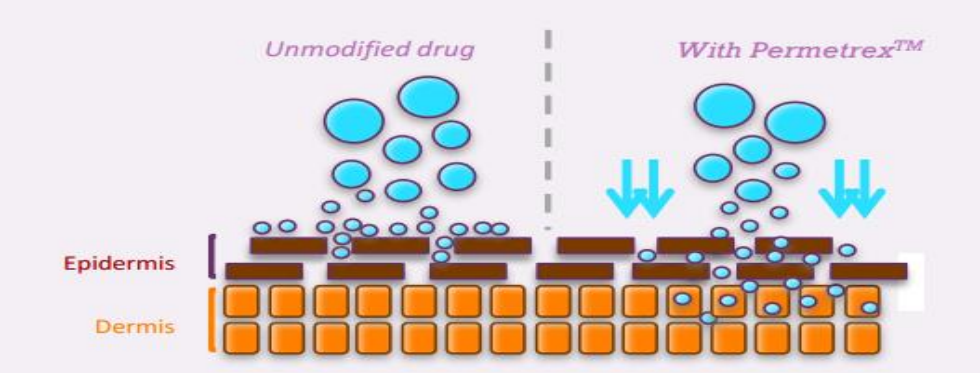
Figure 27: Advantages of synthetic cannabidiol

Synthetic cannabidiol	Naturally extracted cannabidiol
1 chemical	100+ chemicals
100% pure	Multiple impurities
Scaled up to ~50kg	Scaled up to ~1kg
Material registered with FDA	Not registered with FDA
No additional compliance required	Must comply with FDA's "Botanical Drug Development Guidance for Industry"

Source: Botanix

Permetrex delivery technology. Management have highlighted the limitation of consuming cannabidiol orally, with around 6% consumed orally becoming available in the blood stream and even less finding its way into the organs in the skin. Hence, the Company has developed a delivery technology with a partner – Dr Cooper – called Permetrex, which effectively delivers pharmaceuticals into and through the skin. Management believes Permetrex can ensure approximately 70% of the cannabidiol makes it into the blood stream. It achieves this by generating substantial kinetic energy when applied to the skin (i.e. it is very volatile and it evaporates at a very high speed), which in turn drives the rapid delivery of active pharmaceutical ingredients into the skin. BOT has exclusive use of this technology in all areas of skin disease into perpetuity and is seen by management as a significant competitive advantage as it solves a number of the challenges of delivering cannabidiol efficiently to the targeted area for the treatment of various skin diseases.

Figure 28: Botanix solution - Permetrex



Source: Botanix

BOT's most advanced product – BTX 1503. BOT's first proposed product for the acne market BTX 1503 is a gel for the treatment of acne. BTX 1503 is a formulation of synthetic cannabidiol and other chemicals, which comprise the Permetrex drug delivery system. It is designed to deliver a consistent dose of cannabidiol to directly impact cutaneous cell growth and differentiation, provide anti-inflammatory effects and regulate sebum production. It is considered that cannabidiol: **(1)** normalizes excessive lipid synthesis of human sebocytes (the cells from the oil producing sebaceous glands in the skin which disintegrates and release their oil content); **(2)** decreases proliferation (but not the viability) of these human sebocytes; **(3)** exerts universal anti-inflammatory actions; and **(4)** may have anti-bacterial effects.

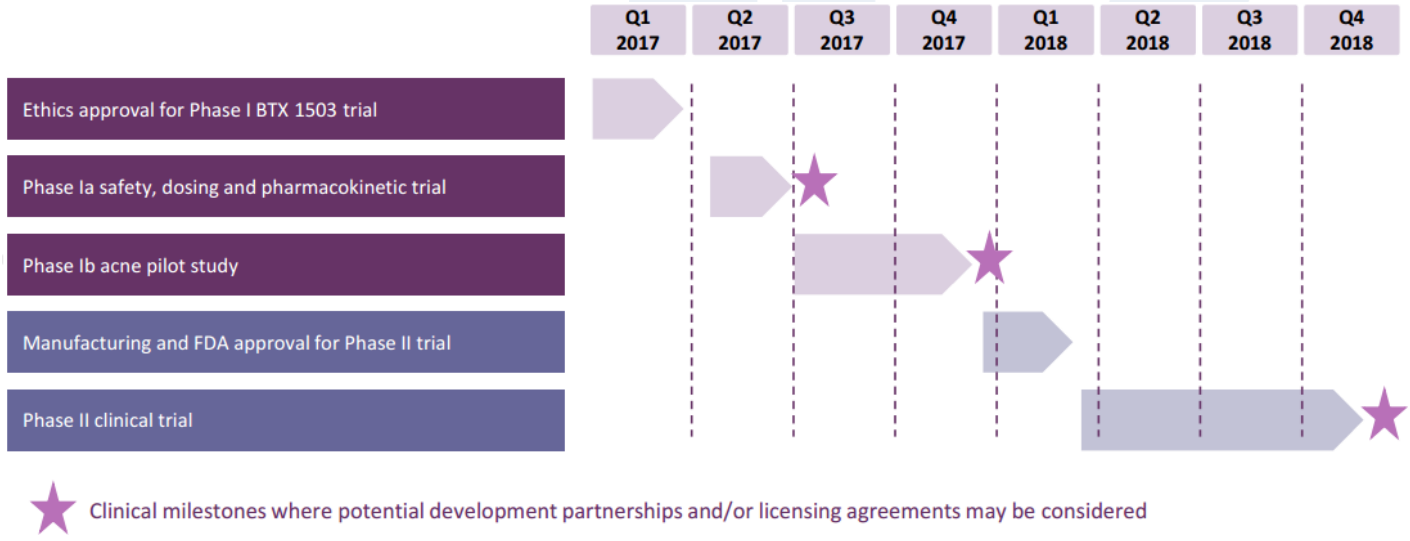
Figure 29: BTX 1503 market positioning

Method of action	BTX 1503	Clindamycin	Tretinoin	Adapalene	Minocycline	Erythromycin	Accutane
Reduces excessive sebum (skin oil) production	✓						✓
Anti-inflammatory	✓		✓	✓			✓
Anti-bacterial	✓	✓			✓	✓	✓
Topical (applied to a specific area of the body)	✓		✓	✓			
Minimal side effects	✓		✓	✓		✓	
Patent protected (not a generic product)	✓						

Source: Botanix

BOT has already completed its first human study of Permetrex, which successfully showed that the delivery technology did not result in any safety or irritation issues. The Company is moving into its Phase Ia and Phase Ib clinical trials for BTX 1503, for which it is fully funded.

Figure 30: BTX 1503 indicative clinical timeline



Source: Botanix

In its first study, BOT will need to prove that the formulation developed using cannabidiol does not cause any irritation to the skin and BOT can measure how much of the drug gets into the bloodstream. This study is about 4 weeks in duration. The data from this study is likely to be released by the end of June 2017.

The second study, once the data from the first study is released, is conducting a pilot study with acne patients. In this study, patients will be treated by the gel over a period of time and the end-point (i.e. goal) of the trial will be to measure the reduction in the patients' acne. The clinical trial is very simple, which essentially entails taking a photo of the patient's affected skin area prior to using BOT treatment (i.e. count number of pimples on day 1) and then several time point shots to the final date (i.e. count number of pimples after 4 weeks). The pilot will have 16-20 patients and will be conducted over a 4 week trial period.

The results from this study should give the Company confidence to move into Phase II. The study will be conducted in the US and other jurisdictions where the Company intends on getting FDA approval in the first instance. This comes as no surprise as the US market comprises more than 75% of the world's drug market by value. The Phase II study will be a multi site study spread across different dermatology sites. The treatment period for this study will go for 12 weeks (up from 4 weeks in the Phase 1b acne patient pilot study) and will include approximately 250 patients.

Competitive landscape. Zynerba is BOT's closest peer, given Zynerba is also focused on utilizing synthetic cannabidiol in its treatment. Zynerba recently completed its Phase I study of ZYN002 CBD Gel and is preparing for Phase II. Zynerba has a market capitalisation of approximately US$240 million and is listed on NASDAQ. Within the dermatology space, Dermira is the closest competitor (with a market capitalization of US$1.4 billion), however Dermira's approach to acne treatment is quite different. Given the lack of development in the acne space, positive announcements of successful completion of Phase studies or data results have led to significant re-rating of stock prices.

Funding position. BOT's first study will cost approximately A$1.0m and the pilot (second study) will cost between A$1.5 – 2.0m. Phase II study will cost about A$7.0m. The funds which the Company raised last July through the IPO process was sufficient to take BOT through Phase 1a and 1b studies in the coming months. The additional money the Company recently raised (A$7.0m) will be used to prepare for the Phase II study and will also be used for synthetic cannabidiol for dermatitis. Given the Company would have already done the clinical trials to prove the safety aspect of their treatment, they will not have to repeat these with dermatitis. This means the Company can go straight into Phase Ib pilot study for dermatitis. Once the Company has the results from its Phase 1a studies it can start preparing for its dermatitis study to see if it works in dermatitis patients.

Key risks…

The key risks to an investment in BOT include, but not limited to:

- **Dilution risk.** While the Company has enough funding in place to take it through its near-term clinical trials and studies, it is highly likely the Company will need to raise cash again via capital raisings in order to fund future development plans. Presumably with clinical success, these raising will occur at a premium to the current price.

- **Significant liquidity risk.** The stock is likely to be lowly traded, especially during the period where a large portion of the issued capital is locked up for a period of time in escrow.

- **Early stage company with an unproven treatment.** BOT is an early stage company with an unproven treatment. There is no guarantee BOT's treatment will be successful during clinical trials and even if successful will achieve the necessary regulatory approvals to distribute its product.

- **Clinical trials risk.** Initial clinical trials may fail to conclusively prove the efficacy of BTX 1503.

- **Licensing & regulatory risk.** The Company does not get the necessary approvals to conduct its clinical trials from cannabis or cannabis extracts. Additionally, the Company's Permetrex licence agreement is exclusive and any breach of this agreement could adversely impact the Company's ability to commercialise this product.

- **Competitive risk.** Increased competition from an existing or new innovative product.

- **Healthcare insurers and reimbursement risks.** Australian or/and foreign may fail to approve Botanix's products for reimbursement purposes for therapeutic products. This could significantly impact BOT's ability to compete in the market place.

- **Doctors risk.** Failure of the medical industry to recognize BOT's product as credible treatment for acne, psoriasis and atopic dermatitis.

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