8 September 2020

New antimicrobial data and conference presentation

Key highlights

- **New data demonstrates BTX 1801 eliminates methicillin-resistant *Staphylococcus aureus* (*'MRSA'* or *'Golden Staph'*) from human skin explants infected with MRSA**
- **New data also confirms synthetic CBD's novel mechanism of action, where treatment with CBD rapidly disrupts the bacteria's membrane resulting in cell death**
- **The studies provide support for the recently commenced BTX 1801 Phase 2a clinical study, which is on target for completion in 4Q CY2020**
- **Botanix is participating in the 2020 ASX Small & Mid-Cap Virtual Conference and the presentation is attached to this release**

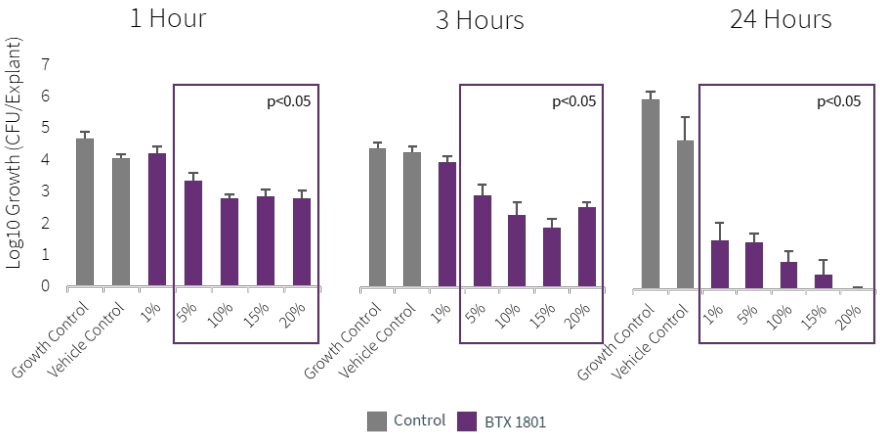
Philadelphia PA and Sydney Australia, 8 September 2020: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to release promising new data which is supportive of its antimicrobial platform and the recently commenced BTX 1801 Phase 2a clinical study. An updated investor presentation is also attached to this release and a video recording of Botanix's presentation at the 2020 ASX Small & Mid-Cap Virtual Conference will be made available on the Company's website: https://botanixpharma.com/invest/

New Data

Botanix recently completed 2 new studies with synthetic cannabidiol and its BTX 1801 formulations. The studies investigated the performance of BTX 1801 in human skin models, as well as further confirming the mechanism of action by which synthetic cannabidiol kills bacteria.

The first study, an *ex vivo* efficacy study ("the Human Skin Study"), demonstrates that BTX 1801 eliminates methicillin-resistant *Staphylococcus aureus* ('*MRSA*' or *'Golden Staph'*) from human skin explants infected with MRSA after 24 hours of treatment in a dose dependent manner. Figure 1 shows complete eradication of MRSA from human skin explants was evident with the high dose cannabidiol (CBD) BTX 1801 ointment, which is the same concentration used in Botanix's Phase 2a clinical study.

Figure 1: Efficacy of different concentrations of CBD in MRSA infected human skin explant

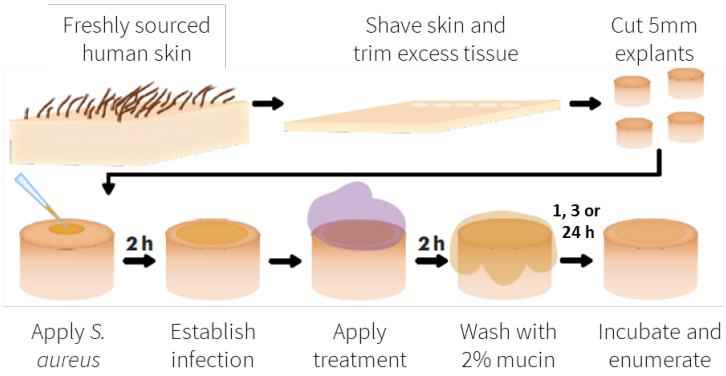


The Human Skin Study showed that by 24 hours all concentrations of CBD in the BTX 1801 ointment resulted in significant reductions ($p < 0.05$) from the growth control. The data from the Human Skin Study supports results previously reported by Botanix using explants from *porcine* skin and further validates the potential for BTX 1801 to decolonise MRSA from human skin in the current clinical study.

The Human Skin study also investigated whether the different concentrations of CBD in the BTX 1801 ointment resulted in any toxic effects on the skin, by measuring the viability of the skin after the 24-hour treatment period compared to the control. There was no evidence of a reduction in viability for any of the concentrations tested compared to the vehicle control. This data reflects studies in minipigs that have confirmed the direct application of BTX 1801 to the nasal passage was safe and well tolerated.

The Human Skin Study was performed by Extherid Biosciences, a leading US-based contract research organisation specialising in predictive models that meaningfully predict clinical conditions and support successful clinical studies. Human skin explants were obtained from patients undergoing abdominoplasty over a 24-hour period. A schematic of the human skin explant model is shown in Figure 2. Human skin prepared in this way maintains its viability for several days post-excision allowing assessments of local toxicity (e.g. signs of irritation) to also be performed.

Figure 2: Schematic of Human Skin Explant Model



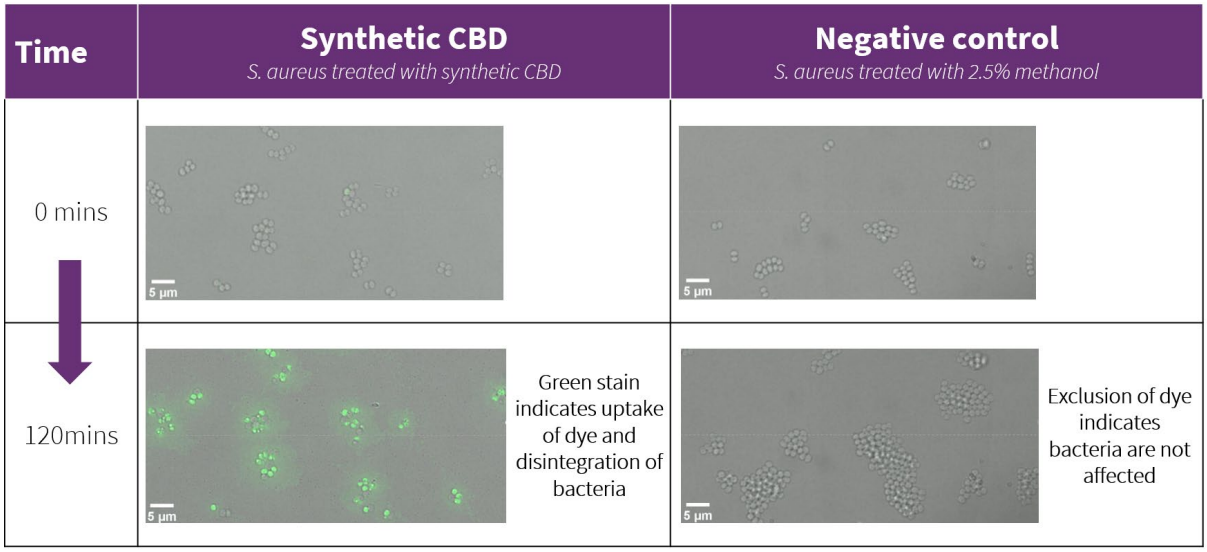
Botanix President and Executive Chairman Vince Ippolito, said: "We are extremely encouraged by this new human explant data for BTX 1801. The results show rapid bactericidal activity of BTX 1801 against MRSA and that the ointment completely eradicates MRSA from clinically relevant human skin explants after 24 hours."

"This builds on previous animal studies conducted by Botanix further validating the potential of BTX 1801. In addition, BTX 1801 is safe when applied nasally in animal safety studies. This gives us great confidence that BTX 1801 will be a valuable treatment option for the prevention of post-surgical infections."

The Company has also recently completed a second study to investigate the novel mechanism of action of synthetic cannabidiol. In this study, Staphylococcus aureus ('*Staph*') was grown at room temperature on an agarose pad containing a green dye (0.25µM SYTOX-Green) over 120 minutes. Images from time-lapsed footage of the study are shown in Figure 3 below.

Figure 3 shows that treatment with synthetic cannabidiol resulted in disruption of the bacterial membrane (allowing the green dye to permeate the cytoplasmic membrane of *Staph*) resulting in cell death and prevention of bacterial growth and multiplication. Conversely, the negative control shows that *without* the presence of CBD, the bacterial membrane remained intact (preventing the dye from crossing the cytoplasmic membrane), allowing the *Staph* to grow and multiply. The time lapse videos will be made available on the Company's website: https://botanixpharma.com/invest/

Figure 3: Time-lapse shows CBD causes rapid permeabilisation of bacterial membrane and cell death



On 12 August 2020, Botanix announced enrolment in the BTX 1801 Phase 2a clinical study, for the prevention of surgical site infections (SSIs) had commenced. The Phase 2a study will test the ability of nasally applied BTX 1801 to eradicate *Staph* and MRSA from the nose of individuals known to carry these bacteria in their nasal cavity.

Nasal carriage of *Staph* and / or *MRSA* greatly increases the risks of serious and life-threatening infections following surgery, due to patients infecting themselves. Nasal decolonisation is a commonly used method for preventing SSIs, but overuse of the widely available antibiotic *Bactroban*^{TM} (also known as *mupirocin*) has led to a significant increase in the development of bacterial resistance to antibiotics.

The BTX 1801 Phase 2a study population is ideal to establish proof of efficacy of BTX 1801, before moving into a pivotal studies involving patients undergoing surgery, for FDA registration. Botanix is targeting study completion in 4Q CY2020. Alongside the clinical study, Botanix has also continued to progress its FDA 'fast-track' status application for BTX 1801. This follows the recent granting of Qualified Infections Disease Product ('QIDP') status for BTX 1801 which provides an additional five years of regulatory exclusivity upon successful FDA approval.

Release authorised by

Vince Ippolito
President and Executive Chairman

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage synthetic cannabinoid company based in Perth (Australia) and Philadelphia (USA) committed to the development of pharmaceutical products that are underpinned by science and supported by well-controlled randomised clinical trials. The Company has two separate cannabinoid development platforms, dermatology and antimicrobial products, both of which leverage the unique anti-inflammatory, immune modulating and antimicrobial properties of cannabinoids, particularly synthetic cannabidiol. Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases.

The Company is developing a pipeline of product candidates that leverages the antimicrobial properties of cannabinoids with first enrolment for BTX 1801 Phase 2a study for the prevention of surgical site infections underway. For the dermatology platform, the Company has confirmed a drug development plan for the BTX 1503 acne program to support registration and plans to progress its Phase 1b rosacea study in the near future.

To learn more please visit: https://www.botanixpharma.com/

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Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate, "expect," "intend," "may," "plan," "predict," "project," "target, "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for is product candidates. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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Unlocking the potential of synthetic cannabinoids

ASX Small & Mid-Cap Conference – 'On-Demand'

Investor Presentation

September 2020

Investment Highlights

Pharma focused

Leading pharmaceutical company leveraging unique properties of synthetic cannabinoids, including cannabidiol (CBD)

Antimicrobial opportunities

Novel antimicrobial platform with positive pre-clinical results that underpin potential to combat antimicrobial resistance

Dermatology opportunities

Targeting key dermatology indications with topical treatments that are safe, well tolerated and validated by clinical efficacy

World-class team

World-class and experienced team with significant cannabinoid, dermatology and antimicrobial drug development expertise

Near-term catalysts

Multiple upcoming key catalysts including Phase 2a antimicrobial study completion, launch of Phase 1b rosacea study and planning for Phase 3 acne study

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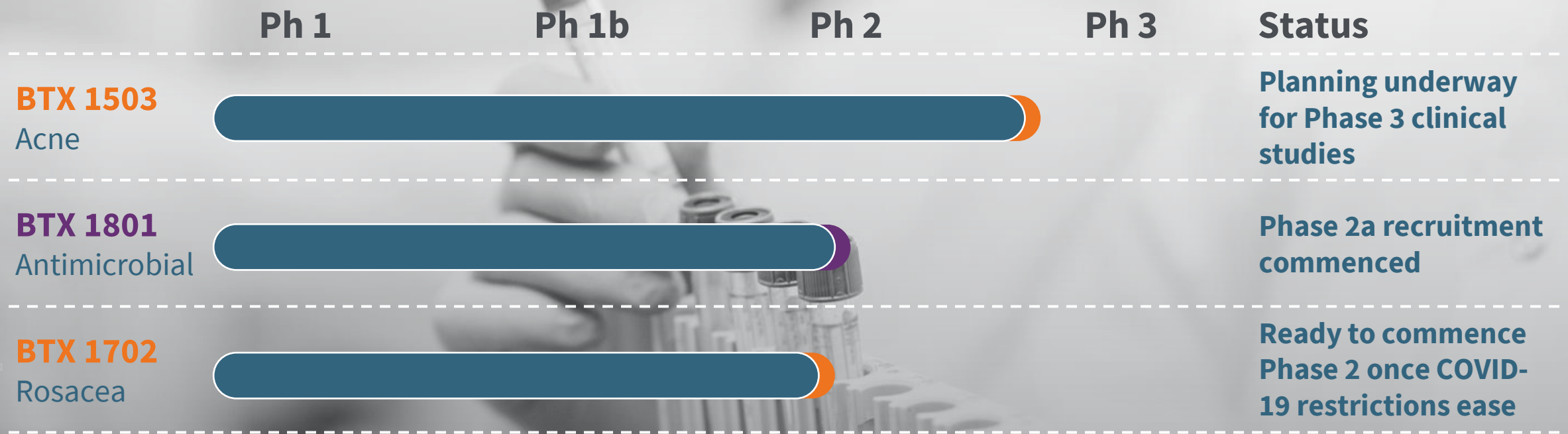
Synthetic Cannabinoids are suited to treat Skin Diseases and Infections

Botanix's studies show synthetic cannabinoids:

- ✓ Safe and well tolerated
- ✓ Broad anti-inflammatory properties relevant to infections
- ✓ Strong and consistent impact on inflammatory lesions
- ✓ Kills *S. aureus* and resistant *S. aureus* (MSRA - "Superbugs")
- ✓ MRSA bacteria do not develop resistance[1]
- ✓ Potential for widespread use across human and animal health

1. See ASX announcement "Antimicrobial Platform Update and Launch of BTX 1801 Study" (13 March 2020)

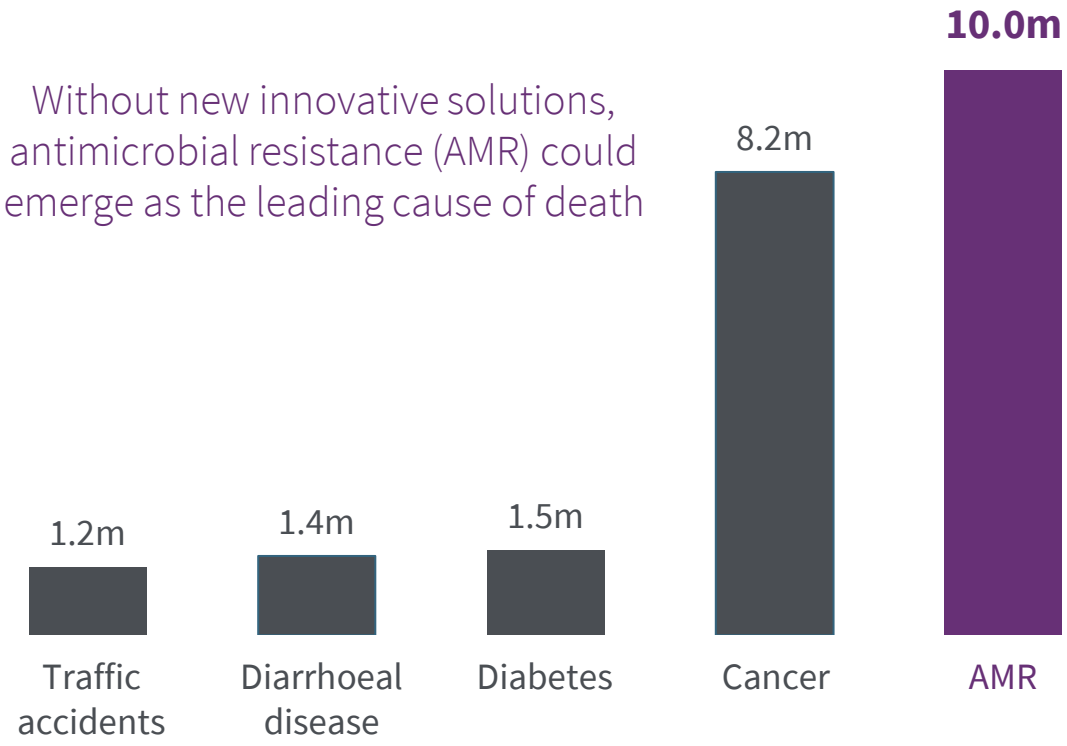
Synthetic Cannabinoids
Advanced Clinical Pipeline



Antimicrobial Resistance is a Fast-Growing Problem

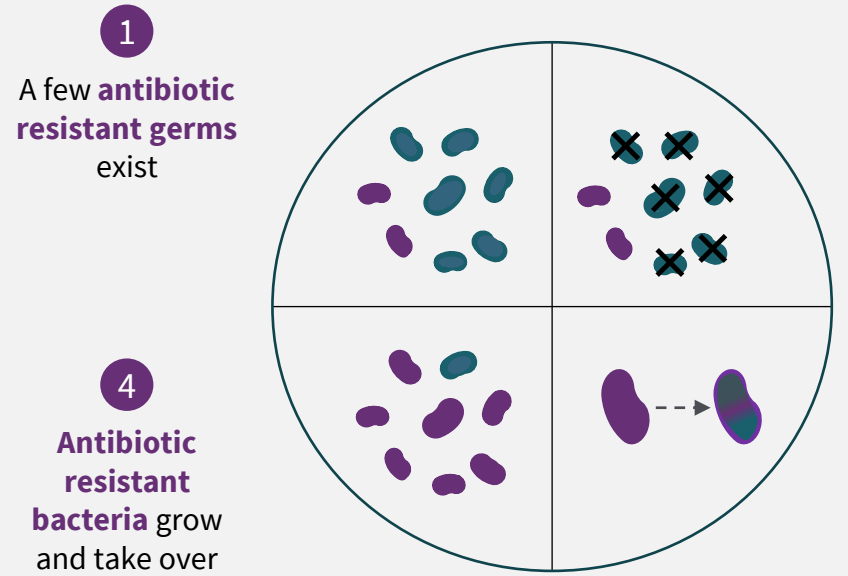
Global forecast deaths by 2050[1] (p.a.)

Without new innovative solutions, antimicrobial resistance (AMR) could emerge as the leading cause of death



How does AMR develop?

- Exposure to antibiotics leaves only drug-resistant bacteria
- Repeat exposure builds resistance and limits drug efficacy
- "Superbugs" emerge increasing morbidity and mortality

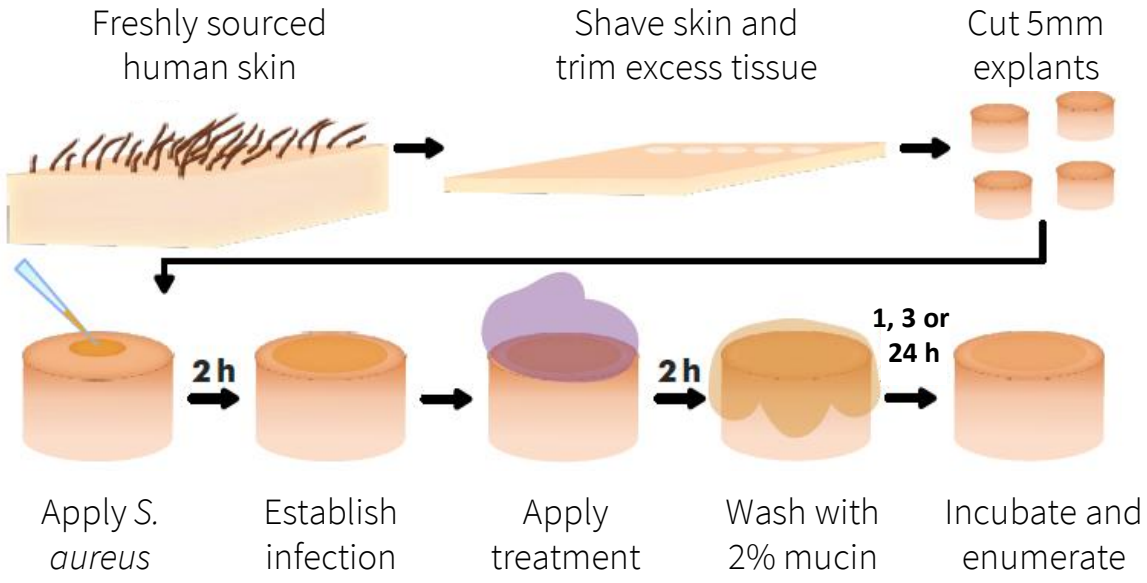


1. Tackling Drug Resistant Infections Globally Final Report and Recommendations (2016), The Review on Antimicrobial Resistance

Encouraging new pre-clinical data

Human explant data demonstrates BTX 1801 eliminates MRSA from infected human skin

Human Skin Explant Model



Efficacy of different concentrations of BTX 1801 in MRSA infected human skin explants

Complete eradication of MRSA from human skin explants was evident with the high dose BTX 1801 to be used in the Phase 2a clinical study

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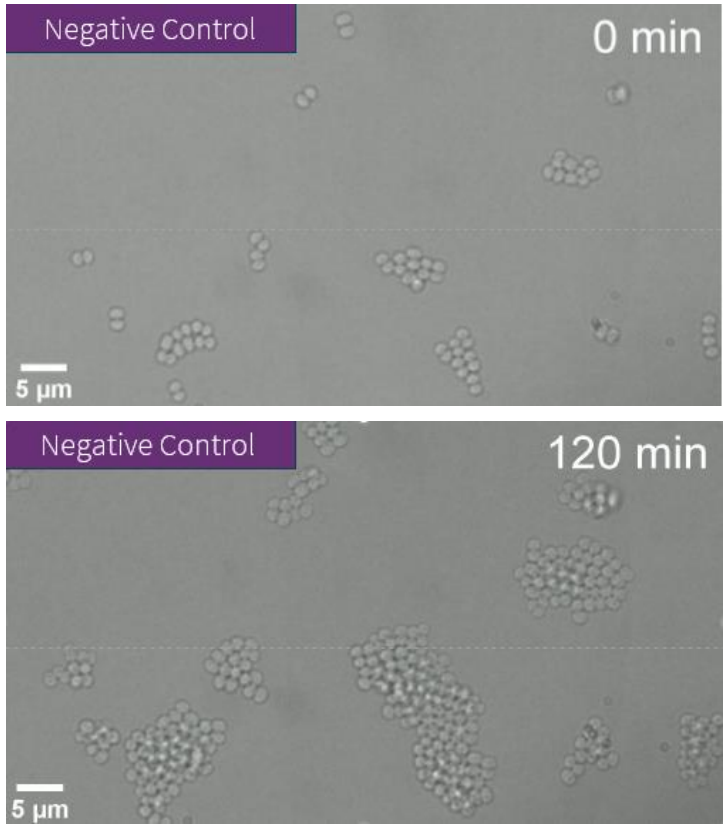
Novel Mechanism of Action Confirmed

The time-lapse shows CBD causes rapid permeabilization of the bacterial membrane and cell death

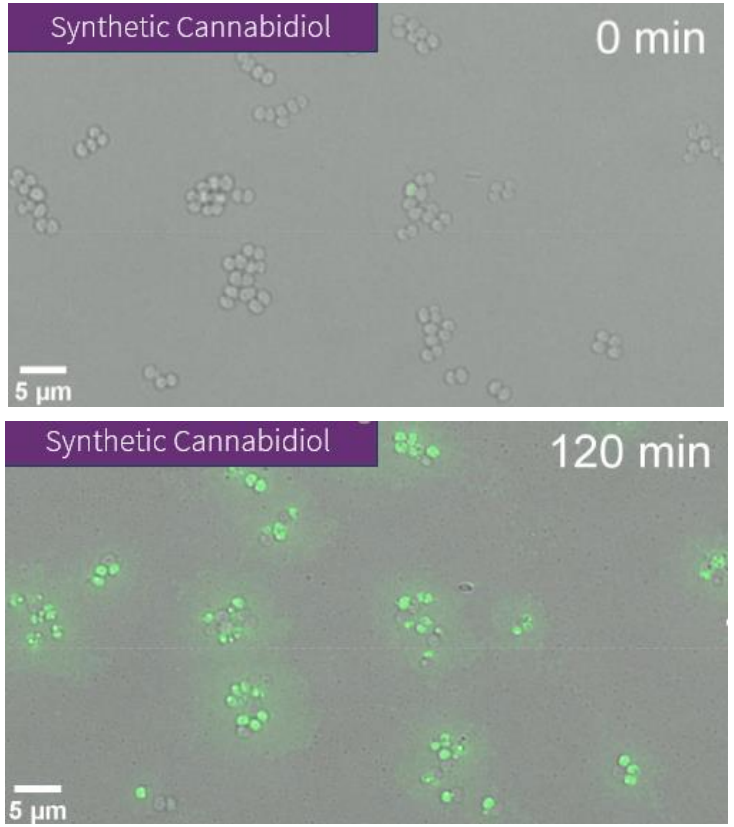
S.aureus treated with 2.5% methanol (negative control)[1]



Staph bacteria treated with negative control

Bacteria are not affected over 120 mins

S.aureus treated with synthetic cannabidiol[1]



Staph bacteria treated with synthetic CBD

Green staining indicates uptake of dye and disintegration of bacteria

1. *S. aureus* grown at room temperature on an agarose pad containing 0.25µM SYTOX-Green. Phase images were collected every five minutes for 120 minutes

Surgical Site Infections (SSI) Indication: Significant Demand From Key Stakeholders

- ✓ SSIs are considered the **most frequent complication in surgical patients**[1]
- ✓ **Prevention of SSIs** reduces patient **mortality and morbidity**
- ✓ SSIs constitute a **financial burden on patients** and **negatively impact on patient quality of life**
- ✓ SSIs significantly increase a **patients time spent in the hospital by 3-20 days**[2]

- ✓ Preventing a single case of **SSI due to MRSA can save hospitals as much as US$60,000**[3]
- ✓ Hospitals recording **resistance rates of up to 95%**[4] creating **demand for new antibiotics** while some hospitals **have halted use of mupirocin**
- ✓ US hospitals with high MRSA infection **face financial penalties and reputational damage**

- ✓ Costs of SSI are up to **$10 billion annually**[5] and represent a significant **burden to the economy and health care systems**
- ✓ Demand for solutions that **reduces overuse of antibiotics** and slow the **spread of AMR**
- ✓ Avoiding complex infections **reduces repeat doctor visits**

1. B. Braun. Surgical Site Infections – Risk Prevention by Surgical Gloving. (accessed Aug. 2016); 2. WHO. Hand Hygiene and the Surgical Patient Journey. (accessed Aug. 2016); 3. UN General Assembly High-Level Meeting on Antimicrobial Resistance in New York City – Fall 2018; 4. Preventing Surgical-Site Infections in Nasal Carriers of Staphylococcus aureus Jan 2010, Bode et al N Engl J Med 2010; 362:9-17; 5. Centers for Disease Control and Prevention. (CDC). Surgical Site Infection (SSI) Toolkit

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BTX 1801: Clinical Development Strategy

Study update

- ✓ Recruitment of Phase 2a study has commenced and will be conducted wholly in Western Australia
- ❖ Study evaluates safety and local tolerability of 2 formulations to decolonise *Staph / MRSA* from the nose of healthy adults
- ❖ Phase 2a study supports rapid progression into a pivotal clinical study for FDA registration
- ❖ Target study completion in 4Q CY20
- ❖ Continue to progress FDA 'fast-track' status application for BTX 1801 following grant of QIDP designation recently

Study design

- ❖ Double-blind, vehicle-controlled Phase 2a clinical study
- ❖ 4 dose groups: ~60 healthy volunteers:
  - BTX 1801 Formulation A: 20 healthy volunteers
  - BTX 1801 Formulation B: 20 healthy volunteers
  - Vehicle A: 10 healthy volunteers
  - Vehicle B: 10 healthy volunteers
- ❖ Sites: single Australian site
- ❖ Patients: adults: 18 years and older with positive nasal SA
- ❖ Treatment: twice daily treatment for a 5-day period
- ❖ Primary endpoints: safety and local tolerability, proportion of volunteers carrying *Staph/MRSA* at Day 12

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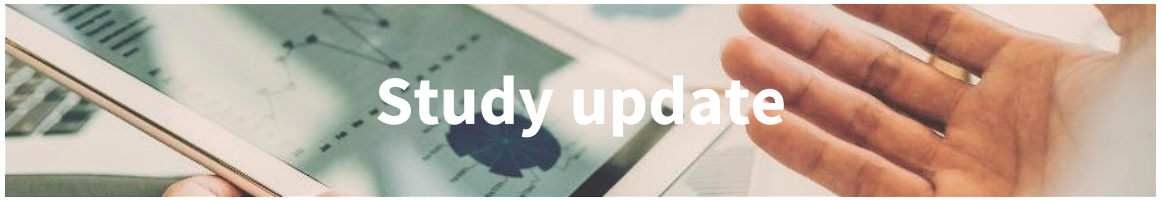
BTX 1503: Successful End-of-Phase 2 FDA Meeting

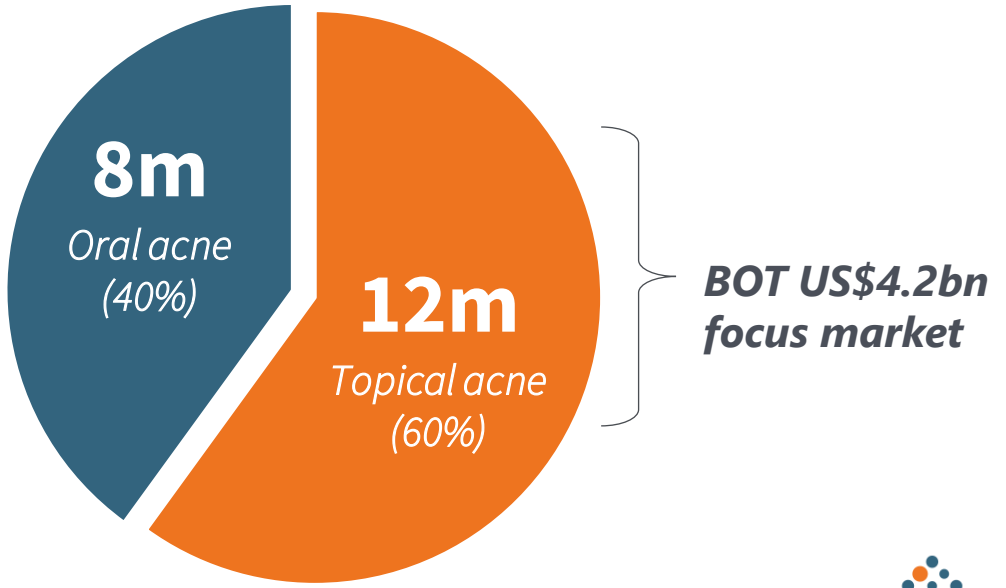


Study update

- ✓ End of Phase 2 meeting with FDA successfully completed
- ✓ FDA highlighted excellent safety profile of BTX 1503, and allowed several waivers for studies that are typically required for dermatology drug registration
- ✓ Co-primary efficacy endpoints[1] agreed for Phase 3 studies
- ✓ Confirmed drug development plan to support registration of BTX 1503 for treatment of moderate and severe acne
- ❖ Planning underway for Phase 3 clinical studies to be informed by completion of BTX 1702 Phase 2 study and lifting of COVID-19 restrictions

Sizable acne prescription market

The global acne market expected to reach **US$7bn** by 2024



1. Co-primary efficacy endpoints: (1) Absolute change from baseline in inflammatory and absolute change from baseline in non-inflammatory lesion at Week 12; (2) Proportion of patients with an Investigators Global Assessment (IGA) of "clear" or "almost clear" and at least a 2-grade improvement in IGA from baseline at Week 12

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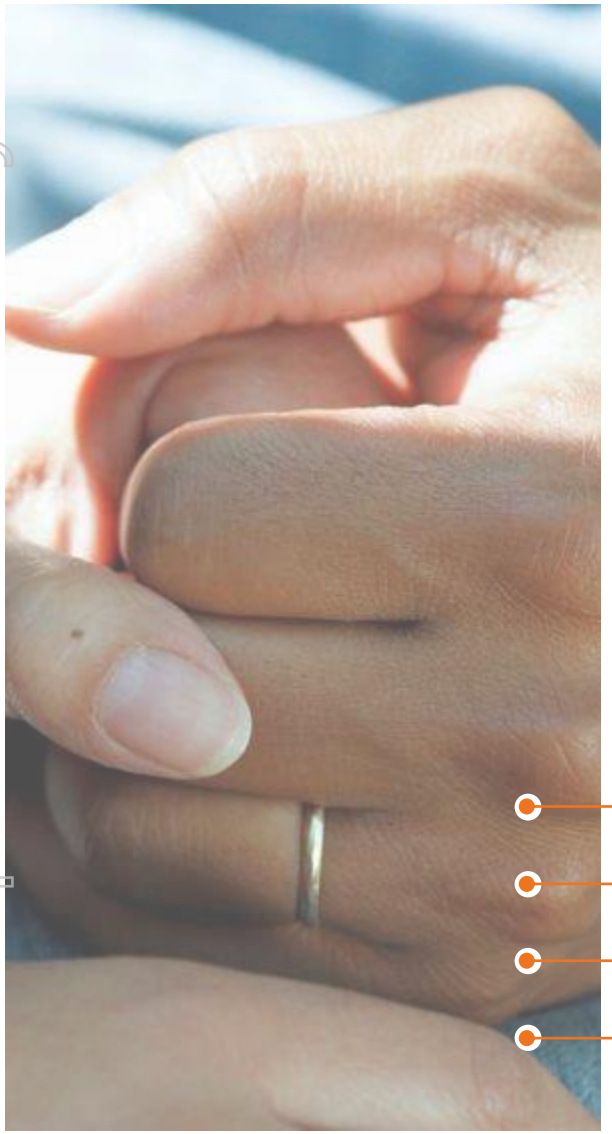
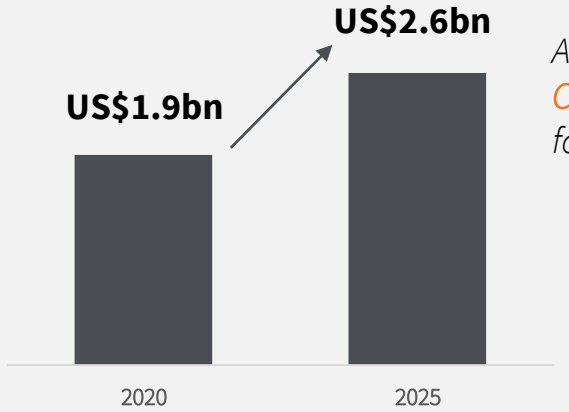


BTX 1702: Impact of Rosacea and Significant Market Opportunity

- Papulopustular rosacea is a **chronic skin disease** characterised by **redness (inflammation) and acne-like-break-outs**[1]

- Patients diagnosed with Rosacea tend to have higher incidences[2] of:
  - Depression
  - Social anxiety
  - Embarrassment
  - Decreased quality of life

A rapidly growing market
Rosacea market projected to grow to US$2.6bn by 2025[3]

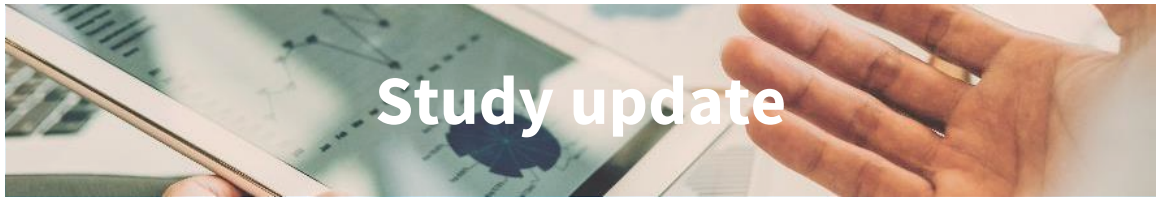


Anticipated to register CAGR of ~6.8%[3] over the forecast period

- Affects ~5.5% of the global population[4], ~430m individuals
- 85% of patients are over 30 years old[5]
- There are currently over 16m Americans affected[6] by the illness, with ~5m medical treatment prescriptions[7] in the US alone

1. Blount BW, Pelletier AL. Am Fam Physician. 2002;66:435-440., 2. Moustafa F. J Am Acad Dermatol. 2014;71:973-980, 3. Grandview Research. www.Grandview research.com, 4. Gether L, et al. Br J Dermatol. 2018;179:282-289, 5. Aimee Two, et al, JAAD, Volume 72, Issue 5, May 2015, 6. National Rosacea Society. www.rosacea.org, 7. Symphony Health Solutions, PHAST

BTX 1702: Rosacea Study Primed to Kick Off



Study update

- ✓ BTX 1702 ethics approval received
- ✓ Study preparations underway to ensure enrolment can process safely and efficiently when ready
- ❖ Phase 1b clinical study poised to commence recruitment once travel and clinical study conduct restrictions are eased across Australia and New Zealand
- ❖ This will enable study enrolment to commence and continue in a timely and consistent fashion
- ❖ Botanix continues to actively monitor the situation and will initiate the BTX 1702 study as soon as practicable

Study design

- ❖ **Four dose groups, ~120 patients:**
  - BTX 1702 Formulation A - twice daily: 30 patients
  - BTX 1702 Formulation B - twice daily: 30 patients
  - Vehicle A - twice daily: 30 patients
  - Vehicle B - twice daily: 30 patients
- ❖ **Sites:** ~6 dermatology sites across Australia
- ❖ **Patients:** adults (18+ years) with moderate to severe papulopustular rosacea
- ❖ **Treatment period:** 6 weeks
- ❖ **Assessment:** facial photos with Canfield imaging

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World-Class Team

Board

Vince Ippolito

President and Executive Chairman

- COO of Anacor and Medicis with 17 years at Novartis
- More than 30 years experience in pharma with 20+ years within dermatology

Matt Callahan

Executive Director

- Serial founder and ex-investment director of two venture capital firms in life sciences
- Developed 4 products through FDA approval and launch

Dr Michael Thurn

Executive Director

- Previous MD of Spinifex Pharmaceuticals which sold to Novartis for A$700m
- Extensive start up life sciences experience in dermatology

Dr Stewart Washer

Director

- Currently a board member of Orthocell, Zelda Therapeutics and Cynata Therapeutics
- 20+ years of experience in medical tech, biotech and agrifood

Dr Bill Bosch

Executive Director

- 20+ years of experience in the pharma industry
- Former CSO of iCeutica Inc. and
- Co-inventor of SoluMatrix™, a drug delivery technology and NanoCrystal® Technology

Advisors

Dr Ron Dolle

CMC and Medicinal Chemistry

- Accomplished drug discovery executive with a record of innovation and success, team leadership, candidate selection, preclinical development, and registration

Dr Joyce Rico

MD, MBA, FAAD

- Recently CMO for Novan Pharmaceuticals
- Experience as Board Member for the Society of Investigative Dermatology, VP Medical Affairs at Astellas and faculty member at Duke, NYU and Northwestern

Dr Ira Lawrence

MD, FACP

- 30+ years of senior level leadership experience within the global pharmaceutical and medical device industries
- Currently serves as a senior-level consultant, with numerous clients worldwide

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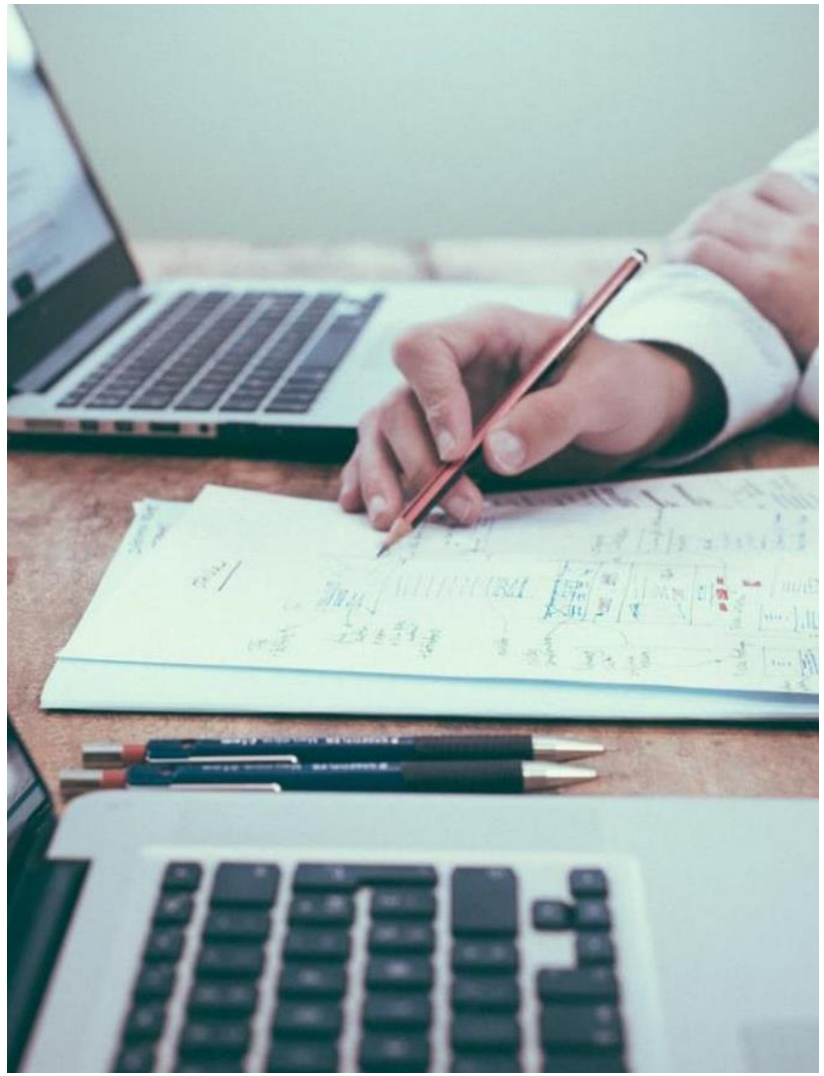
Executing on Key Near-Term Milestones

- **Antimicrobial: BTX 1801 Phase 2a study completion**
  Targeting completion of the study in 4Q CY2020 – December 2020

- **Acne: BTX 1503 planning for Phase 3 clinical studies**
  Timetable for progression of Phase 3 is pending the completion of BTX 1702 Phase 2 clinical study

- **Rosacea: BTX 1702 phase 2 recruitment**
  Currently on hold - recruitment to recommence when COVID-19 travel restrictions ease

Strong cash position - A$24.6m
As at 30 June 2020



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