botanix PHARMACEUTICALS

Update regarding NDA filing for Sofpironium Bromide

26 September 2023

Presenters

VINCE IPPOLITO

Executive Chairman

- COO of Anacor and Medicis; former President Dermavant; more than 17 years at Novartis.
- More than 35 years experience in pharma with 20+ years within dermatology

HOWIE MCKIBBON

Chief Executive Officer

- Former SVP Commercial of Dermavant, Anacor and Medicis
- 20+ years working in dermatology - launched more than 15 brands and managed over 35 dermatology products

DR PATRICIA WALKER

Chief Medical Adviser

- Former President and head R&D Brickell Biotech
- Former CMO/CSO Kythera, Inamed and Allergan Medical responsible for multiple drugs incl. Botox and Tazorac

MATT CALLAHAN

Board Executive Director

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

Dave Clissold

Director

Hyman, Phelps & McNamara

Mr Clissold has broad-based experience advising pharmaceutical, biotechnology, medical device, food, and dietary supplement clients on regulatory and legislative matters at HPM. HPM is the largest dedicated FDA law firm in the United States

Mr Clissold provides guidance throughout the product lifecycle, which includes clinical trials and drug development, advertising and promotion, orphan drug designations, and Hatch-Waxman exclusivity.

Mr Clissold lectures on various FDA topics, including regulation of tobacco products, regulatory obligations in clinical investigations, strategies for developing and marketing drugs and biologics, orphan drugs, and Hatch-Waxman issues. He has presented to the Food and Drug Law Institute and has published papers in *The New England Journal of Medicine*, *The Journal of Pharmacology and Experimental Therapeutics*, *Pharmacology, Biochemistry & Behavior*, and the *Food and Drug Law Journal*.

Announcement today

Botanix receives Letter from FDA identifying one area for clarification relating to patient use instructions

- The **only area** listed in the Letter was **related to the how the patient is instructed to use the product, including the printed Instructions for Use document**
- **No clinical efficacy, safety, pharmacology, non-clinical or manufacturing issues were raised and no additional clinical studies are required by FDA** to support NDA approval
- **No new review issues are anticipated as part of the resubmission review** and the **requested activities can be quickly addressed - approval pathway further de-risked**
- **Botanix will meet with FDA** and undertake the minor activities and plans to **resubmit the NDA by early Q1 CY2024, with a target approval of mid-CY2024**
- The Company is **well funded to complete the resubmission** with an **anticipated delay in launch from 1Q CY2024 of 3-6 months, with no change in large market opportunity**

‘Complete Response Letter’ and ‘End of Review’ meeting

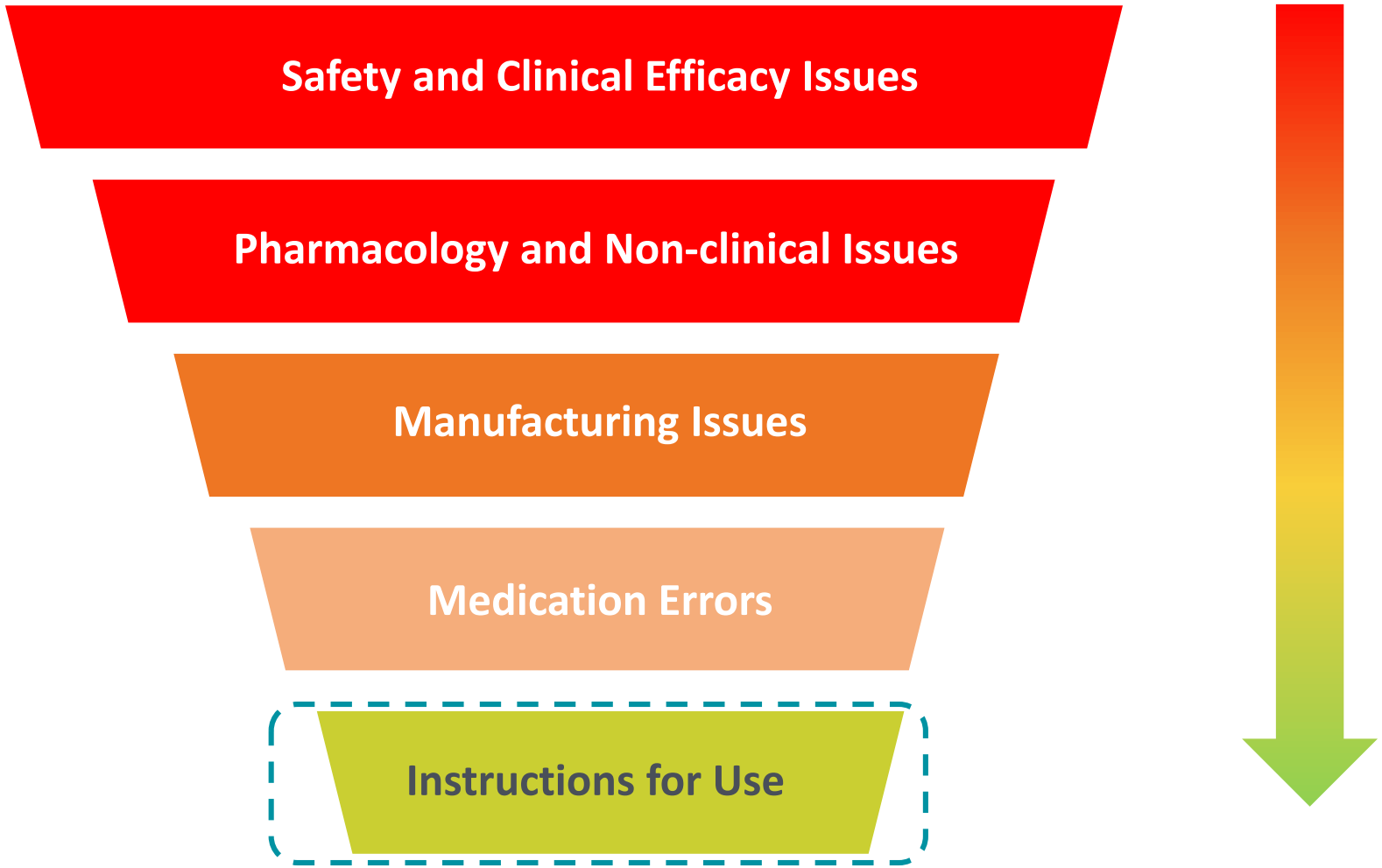
- A Complete Response Letter communicates to a sponsor that the FDA cannot approve the application in its present form and describes any areas that must be addressed before the application can be approved[1]
- The sponsor is not provided with a prior copy of the Complete Response Letter and does not have the opportunity to communicate freely with FDA outside the standard meeting schedule (e.g mid-cycle etc) and the formal meeting request process (e.g Type B meeting – 60 days prior notice)
- FDA regulations do offer an End-of-Review meeting, which is attended by senior FDA personnel and following request, FDA has 30 days to grant and hold that meeting

> (1) *Description of specific deficiencies.* A complete response letter will describe all of the specific deficiencies that the agency has identified in an application or abbreviated application, except as stated in paragraph (a)(3) of this section.
>
> (2) *Complete review of data.* A complete response letter reflects FDA's complete review of the data submitted in an original application or abbreviated application (or, where appropriate, a resubmission) and any amendments that the agency has reviewed. The complete response letter will identify any amendments that the agency has not yet reviewed.

1. 21CFR314.110 – Part 314 – Applications for FDA approval to Market a New Drug

Issues that could be raised in a Complete Response Letter

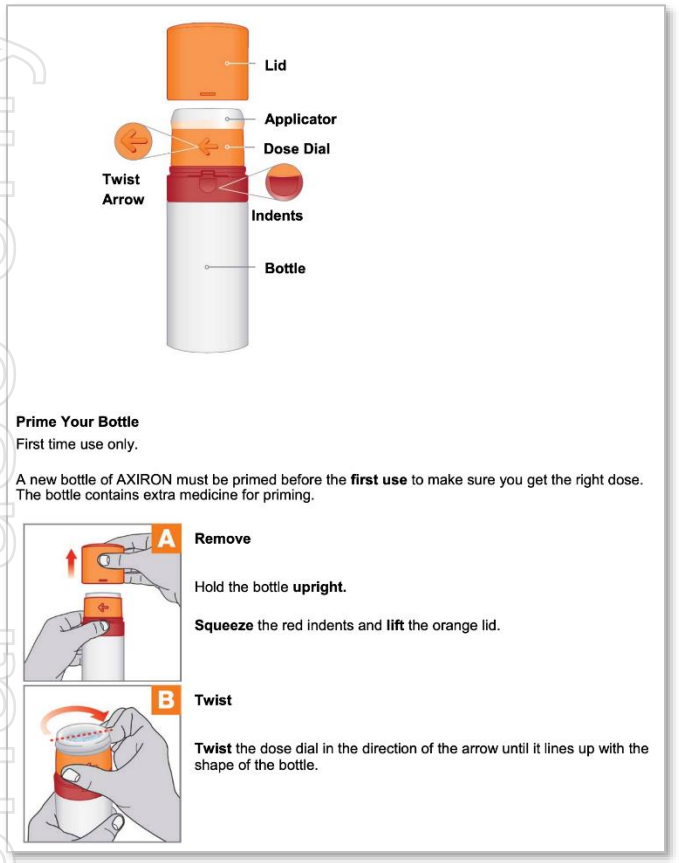
No safety, efficacy, pharmacology, non-clinical or manufacturing issues were raised in the letter for Sofpironium Bromide



Decreasing risk or challenge to overcome issues raised in a Complete Response Letter on resubmission

botanix PHARMACEUTICALS

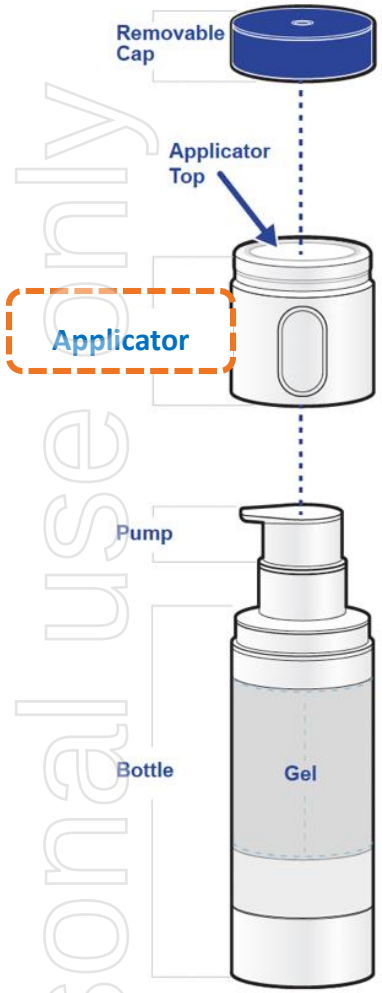
Instructions for Use – why are they needed?

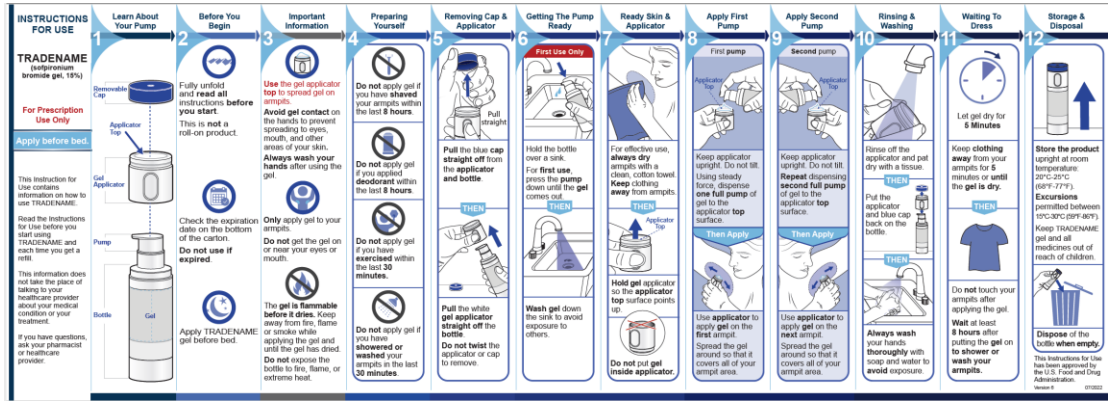


Example – Axiron® Instructions For Use

- Sofpironium Bromide gel, 15% is a ”combination product” in that it combines a drug (Sofpironium Bromide), with a dispenser pump and applicator, that is used to apply the drug
- Instructions For Use generally contain step-by-step written and visual instructions For Use, set out in a patient-friendly manner
- Instructions For Use generally go through multiple drafting iterations, informed by human factors validation studies, where volunteers read and follow the Instructions, to check whether they can correctly apply the drug in accordance with those Instructions
- FDA carefully reviews the Instructions for Use as part of its label review during the NDA review, to ensure that those Instructions support the safe and effective use of the drug (and avoids excess dosing, secondary exposures etc)

What does FDA want now?



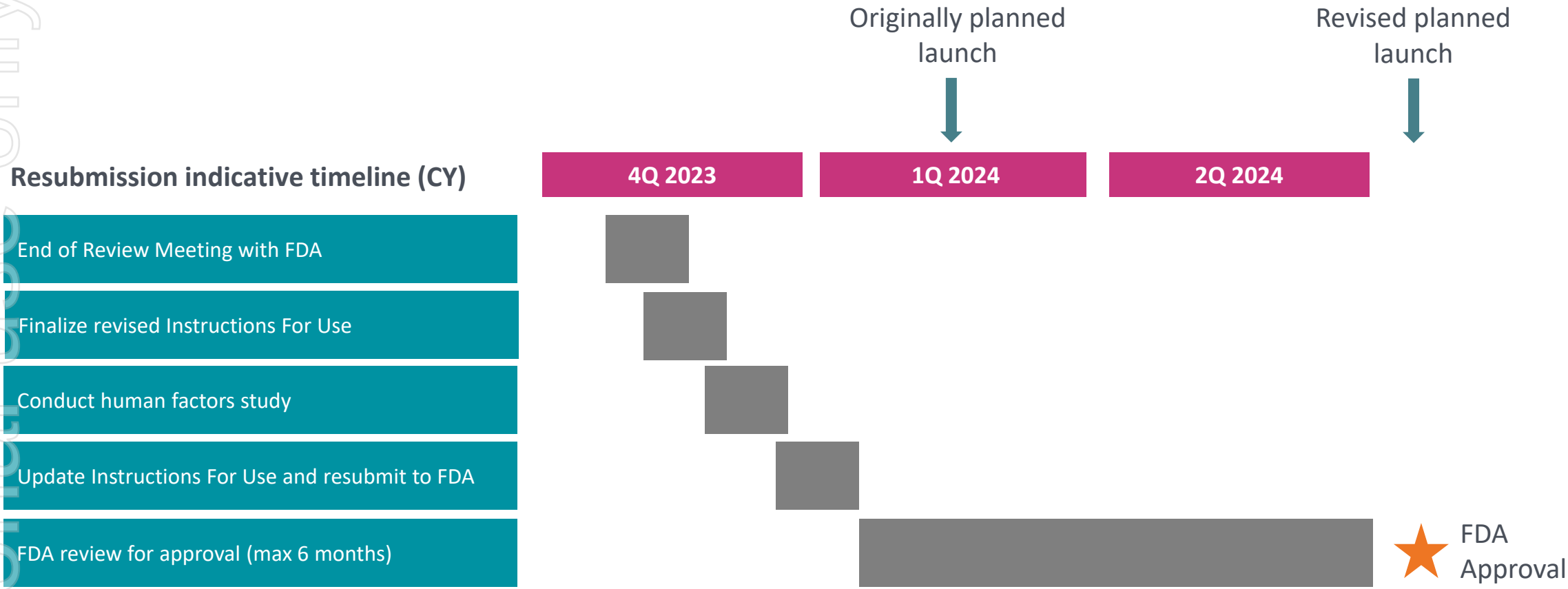


1. Label gel applicator with “applicator”
2. Reformat the Instructions For Use so that it does not fold and “revise” the Instructions to further simplify the guidance for application
3. Place the statement “wash hands with soap and water immediately after use” on the outside of the carton and on the bottle prominently
4. Conduct another human factors validation study to demonstrate the revised Instructions For Use are capable of being followed to be able to apply Sofpironium Bromide gel safely and effectively

botanix PHARMACEUTICALS

How long will this take - planned timeline

Rapid engagement with FDA, followed by short human factors validation study and resubmission - with a 6-month review clock



botanix PHARMACEUTICALS

Impact on the commercial opportunity for Sofpironium Bromide?

Minimal delay in commercialisation and no impact on market opportunity

- Given commercialization was planned to commence in 1Q CY2024, the **delay caused by the resubmission is likely to be only 3-6 months**
- **No clinical efficacy, safety, pharmacology, non-clinical, or manufacturing issues were raised and no additional clinical studies are required by FDA -** NDA approval pathway de-risked
- **Large market targeting the ~3.7 million patients** currently in the doctor's office seeking therapies to treat their condition and the **~6.3 million patients seeking solutions** online
- Revised approval timetable allows for the **potential to also launch the digital and telemedicine platform following expected approval in mid-CY2024**
- **Botanix is funded to reach the new approval date** and will adjust operating costs and commercial spend to ensure runway extends appropriately

Important Notice & Disclaimer

1. Summary information

This presentation has been prepared by Botanix Pharmaceuticals Ltd ("Botanix") and contains summary information about Botanix and the business conducted by it which is current as at the date of this presentation ("Presentation") (unless otherwise indicated).

The information in this Presentation is general in nature and does not purport to be accurate nor complete, nor does it contain all of the information that an investor may require in evaluating a possible investment in Botanix, nor does it contain all the information which would be required in a disclosure document or prospectus prepared in accordance with the requirements of the Corporations Act 2001 (Cth). It has been prepared by Botanix with due care but no representation or warranty, express or implied, is provided in relation to the accuracy, reliability, fairness or completeness of the information, opinions or conclusions in this Presentation by Botanix or any other party.

The information in this Presentation remains subject to change without notice. Reliance should not be placed on information or opinions contained in this Presentation, and Botanix does not have any obligation to finalise, correct or update the content of this Presentation. Certain data used in this Presentation has been obtained from research, surveys or studies conducted by third parties, including industry or general publications.

To the maximum extent permitted by law, Botanix is not responsible for updating, nor undertakes to update, this Presentation. It should be read in conjunction with Botanix's other periodic and continuous disclosure announcements lodged with the ASX, which are available at www2.asx.com.au or at https://botanixpharma.com/category/asx-releases/.

2. Not an offer

Neither this Presentation nor any of its contents will form the basis of any understanding, proposal, offer, invitation, contract or commitment.

3. Industry data

Certain market and industry data used in connection with or referenced in this Presentation has been obtained from public filings, research, surveys or studies made or conducted by third parties, including as published in industry-specific or general publications. Neither Botanix nor its advisers, or their respective representatives, have independently verified any such market or industry data.

4. Financial data

All dollar values are in United States dollars ($ or US$) unless otherwise stated. Amounts, totals and change percentages are calculated on whole numbers and not the rounded amounts presented.

5. Forward-looking statements and forecasts

This Presentation contains certain "forward-looking statements" and comments about future matters. Forward-looking statements can generally be identified by the use of forward-looking words such as, "expect", "anticipate", "likely", "intend", "should", "could", "may", "predict", "plan", "propose", "will", "believe", "forecast", "estimate", "target" "outlook", "guidance" and other similar expressions and include, but are not limited to, plans and prospects for the Company, the Company's strategy, future operations, the expected timing and/or results of regulatory approvals and prospects of commercialising product candidates or research collaborations with its partners, including in Japan, the outcome and effects of Sofpironium Bromide and the market for Sofpironium Bromide. Indications of, and guidance or outlook on, future earnings or financial position or performance are also forward-looking statements. You are cautioned not to place undue reliance on forward-looking statements. Any such statements, opinions and estimates in this Presentation speak only as of the date hereof, are preliminary views and are based on assumptions and contingencies subject to change without notice, as are statements about market and industry trends, projections, guidance and estimates. Forward-looking statements are provided as a general guide only. The forward-looking statements contained in this Presentation are not indications, guarantees or predictions of future performance and involve known and unknown risks and uncertainties and other factors, many of which are beyond the control of Botanix, and may involve significant elements of subjective judgement and assumptions as to future events which may or may not be correct.

Any such forward looking statements are also based on assumptions and contingencies which are subject to change and which may ultimately prove to be materially incorrect, as are statements about market and industry trends, which are based on interpretations of current market conditions. Investors should consider the forward looking statements contained in this Presentation in light of those disclosures and not place undue reliance on such statements (particularly in light of the current economic climate and significant volatility, uncertainty and disruption caused by the COVID-19 pandemic). The forward looking statements in this Presentation are not guarantees or predictions of future performance and may involve significant elements of subjective judgment, assumptions as to future events that may not be correct, known and unknown risks, uncertainties and other factors, many of which are outside the control of Botanix.

Except as required by law or regulation, Botanix undertakes no obligation to finalise, check, supplement, revise or update forward-looking statements or to publish prospective financial information in the future, regardless of whether new information, future events or results or other factors affect the information contained in this Presentation.

6. No liability

The information contained in this document has been prepared in good faith by Botanix. Neither Botanix, nor any of its advisers or any of their respective affiliates, related bodies corporate, directors, officers, partners, advisers, employees and agents have authorised, permitted or caused the issue, lodgement, submission, dispatch or provision of this Presentation in a final form and none of them makes or purports to make any binding statement in this Presentation and there is no statement in this Presentation which is based on any statement by them.

To the maximum extent permitted by law, Botanix and its advisers, affiliates, related bodies corporate, directors, officers, partners, employees and agents:

expressly disclaims any and all liability, including, without limitation, any liability arising out of fault or negligence, for any loss arising from the use of or reliance on information contained in this document including representations or warranties or in relation to the accuracy or completeness of the information, statements, opinions, forecasts, reports or other matters, express or implied, contained in, arising out of or derived from, or for omissions from, this document including, without limitation, any estimates or projections and any other financial information derived therefrom, whether by way of negligence or otherwise; and

expressly exclude and disclaim all liabilities in respect of, make no representations regarding, any part of this Presentation and make no representation or warranty as to the currency, accuracy, adequacy, reliability or completeness or fairness of any statements, estimates, options, conclusions or other information contained in this Presentation.

Operations:
3602 Horizon Drive, Suite 160
King of Prussia PA 19406

Corporate Office:
Level 1, 50 Angove Street North
Perth W. Australia 6006

Authorised for release by Vince Ippolito, Executive Chairman

Botanix Pharmaceuticals Limited