

***Biotron***

# **INVESTOR UPDATE**

**ASX:BIT | March 2026**



# FORWARD LOOKING STATEMENT

This presentation may contain forward-looking statements with respect to the financial condition, results and business achievements/performance of Biotron Limited (ACN 086 399 144) and certain of the plans and objectives of its management.

These statements are statements that are not historical facts. Words such as “should”, “expects”, “anticipates”, “estimates”, “believes” or similar expressions, as they relate to Biotron Limited, are intended to identify forward-looking statements.

By their nature, forward-looking statements involve risk and uncertainty because they reflect Biotron’s current expectations and assumptions as to future events and circumstances that may not prove accurate.

There is no guarantee that the expected events, trends or results will actually occur. Any changes in such assumptions or expectations could cause actual results to differ materially from current expectations.

# Biotron's expanded drug portfolio



Dec 2025 acquisition  
Sedarex Ltd with next-  
generation general  
anaesthetic **SedRx**



SedRx provides potential  
fast, low risk  
commercialisation pathway  
to **\$5b+ global market**



Continued, high potential  
antiviral program –  
designing **Phase 1 trial** for  
novel **Hepatitis B** treatment



**Pipeline** addressing other  
high growth neuroscientific  
and anti-viral markets



Targeting **large-scale**  
unmet medical needs with  
near & longer-term  
**commercial outcomes**



**The SedRx  
opportunity:  
commercialising  
a proven, safer  
anaesthetic**

- Biotron aims to re-launch a **reformulated safer general anaesthetic** into global US\$5B pa market with 3.3% CAGR. **Previous formulation had 50% market share** of day care procedures in UK.
- Proven Active Pharmaceutical Ingredient (API), Alfaxalone, used in millions of people & animals.
- Replacing the solubilising agent (CremophorEL) that caused serious allergic reactions with a **safe IP protected formulation** with a widely used solubilising agent (SBECD) already approved by FDA & EMA.
- Formulation & use patents granted worldwide. **Potential fast regulatory pathways to markets.**
- SedRx has **fewer adverse cognition effects vs current anaesthetics**: it stimulates production of neuroprotective brain proteins.
- Potential to become standard of care & improve health economics especially in over-60s.
- **Demographics driving need**: better for older patients, ICUs, brain injured patients due to neurological protection properties & fewer blood pressure effects.



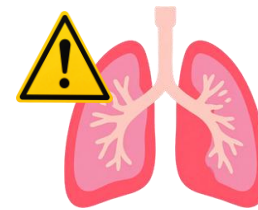
## PROBLEM #1

**Current  
anaesthetics  
may cause harm**



### **Reduce blood pressure**

- 43% of heart attacks during surgery associated with low blood pressure
- 6.8 day increase in hospital stay
- Increases risk of stroke & kidney failure



### **Reduce respiration & airway control**

- Leading cause of malpractice suits
- Low oxygen increases risk of heart attack, severe brain damage & occasionally death



### **Damage brain function**

- Neurone death
- Increased risk of psychological conditions
- Post-operative decline in cognition
- Regulator warning for infants & unborn babies

# Althesin with flawed solubilising agent



PROBLEM #2

**Althesin**  
**allergic**  
**reactions**

Alfaxalone  
API



Althesin held ~50% market share of human day care procedures in EU & UK (Glaxo 1970s-1980s)

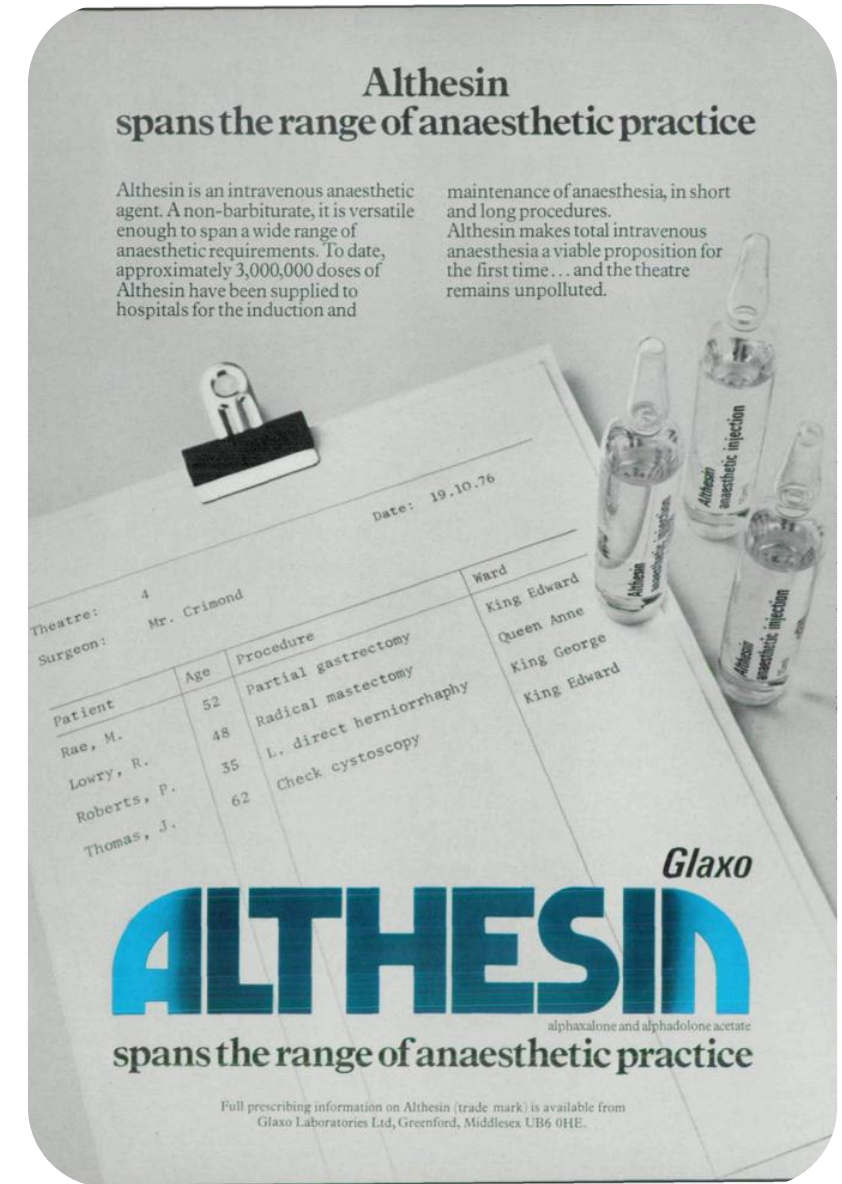


CremophorEL  
Solubilising Agent



CremophorEL caused some patients to develop severe allergic reactions (anaphylaxis)

Glaxo withdrew voluntarily



*Althesin: 3 million doses administered (at March 1977)*



SOLUTION

**SedRx**

**a safer validated  
anaesthetic**

- Patented, improved reformulation of a proven Alfaxalone general anaesthetic used in Europe for 14 years
- Fixed side effects from previous version's solubilising agent
- Optimised for critical care, elderly, pediatric & brain-injured patients



**Neuro protection**



**Improved cardiovascular &  
cognition support**

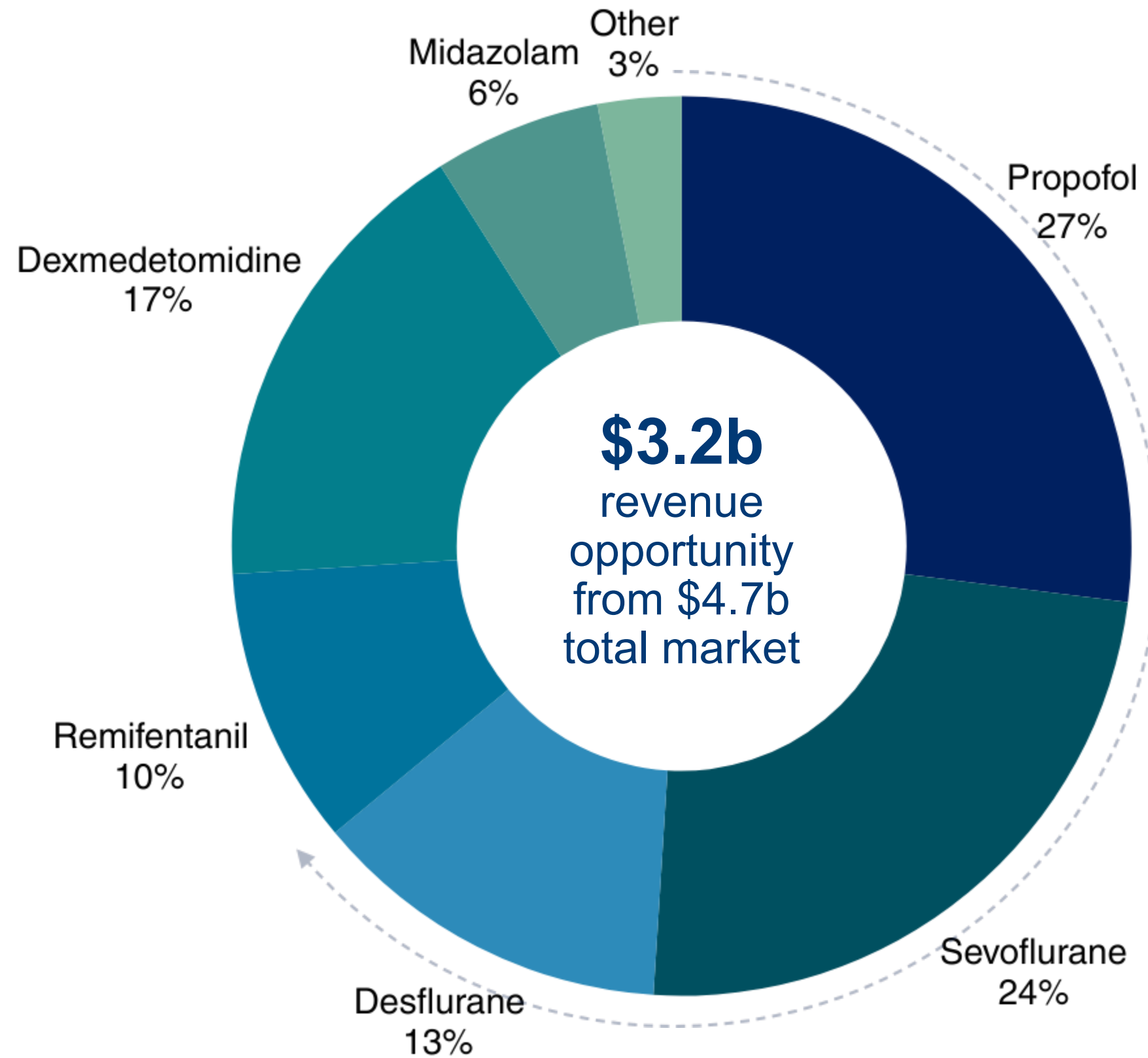


**No stinging upon administration**



**Reduced patient recovery times —  
increasing patient throughput &  
decreasing costs**

# Growing market for general anaesthetics



**Propofol, Sevoflurane & Desflurane are 64% of the market, growing ~4% pa**

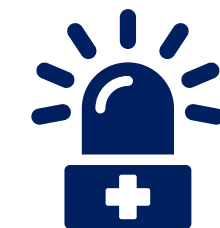
## Demand is driven by:



Ageing population




More knee, hip, cardiac procedures increasing



Increasing ICU admissions where propofol has 60% market share

# SedRx designed to be the ideal anaesthetic

	SedRx	Propofol	Fluranes
Rapid sleep onset	✓	✓	✓
Fast wakeup	✓	✓	✓
Improved CVS safety	✓	✗	✗
Breathing safety	✓	✗	✗
Less damage to brain	✓	✗	✗
Infection safety	✓	✗	n/a
No FDA black box warning	none expected	✗	n/a
Occupational health & safety or environmental pollution risks	✓	✗ <sup>1</sup>	✗ <sup>2</sup>

- Improved clinical outcomes 
- Easier & cheaper to manufacture
- Less chance of contamination
- Black box warning unlikely

### NOTES

**1** Propofol has both acute & chronic aquatic toxicity, & does not readily degrade

**2** Banning of fluranes has begun due to its negative impact on the environment

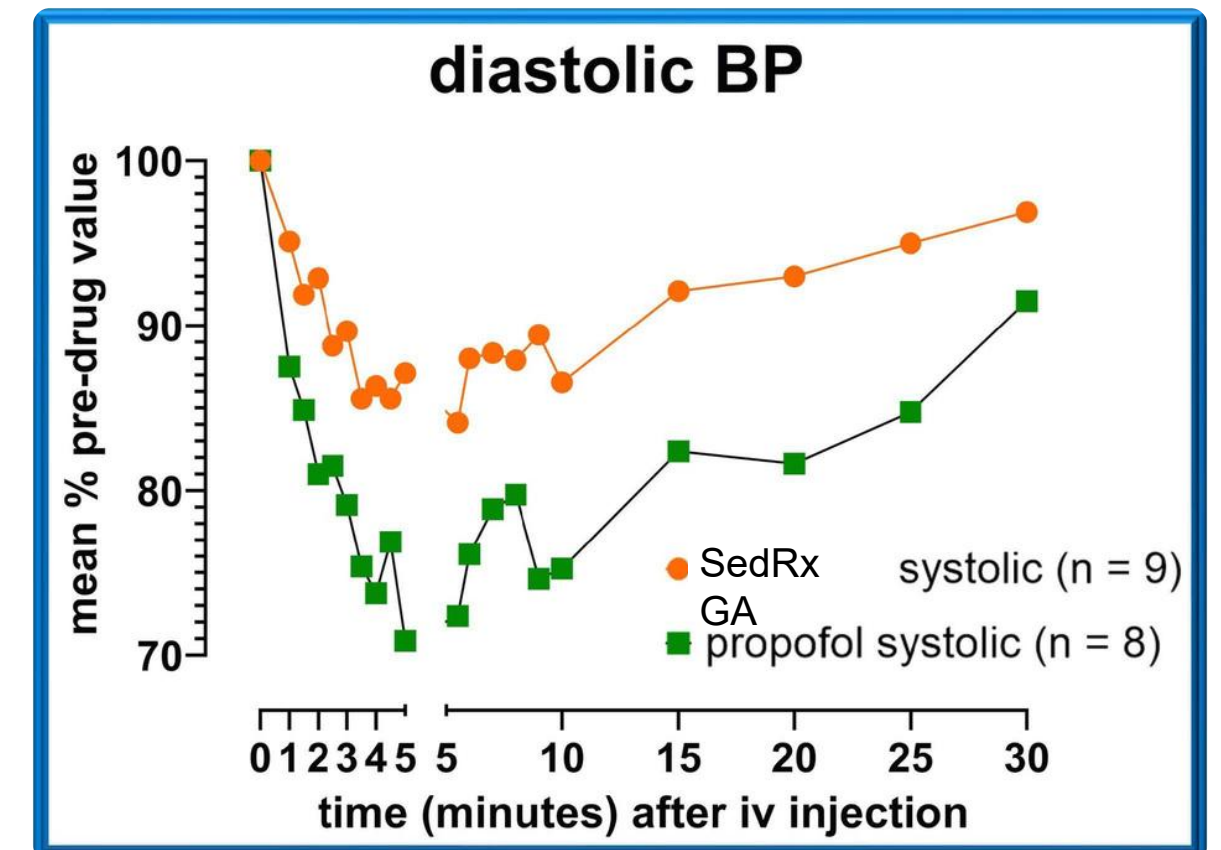
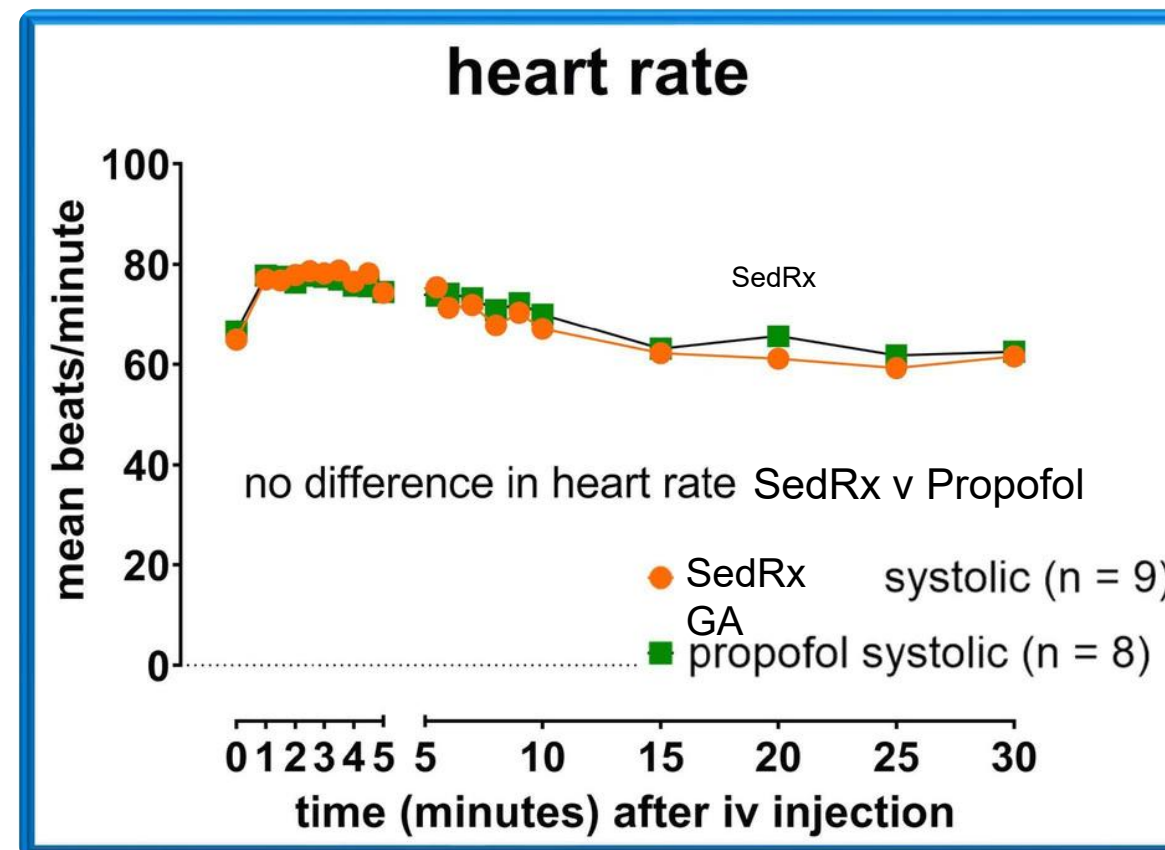
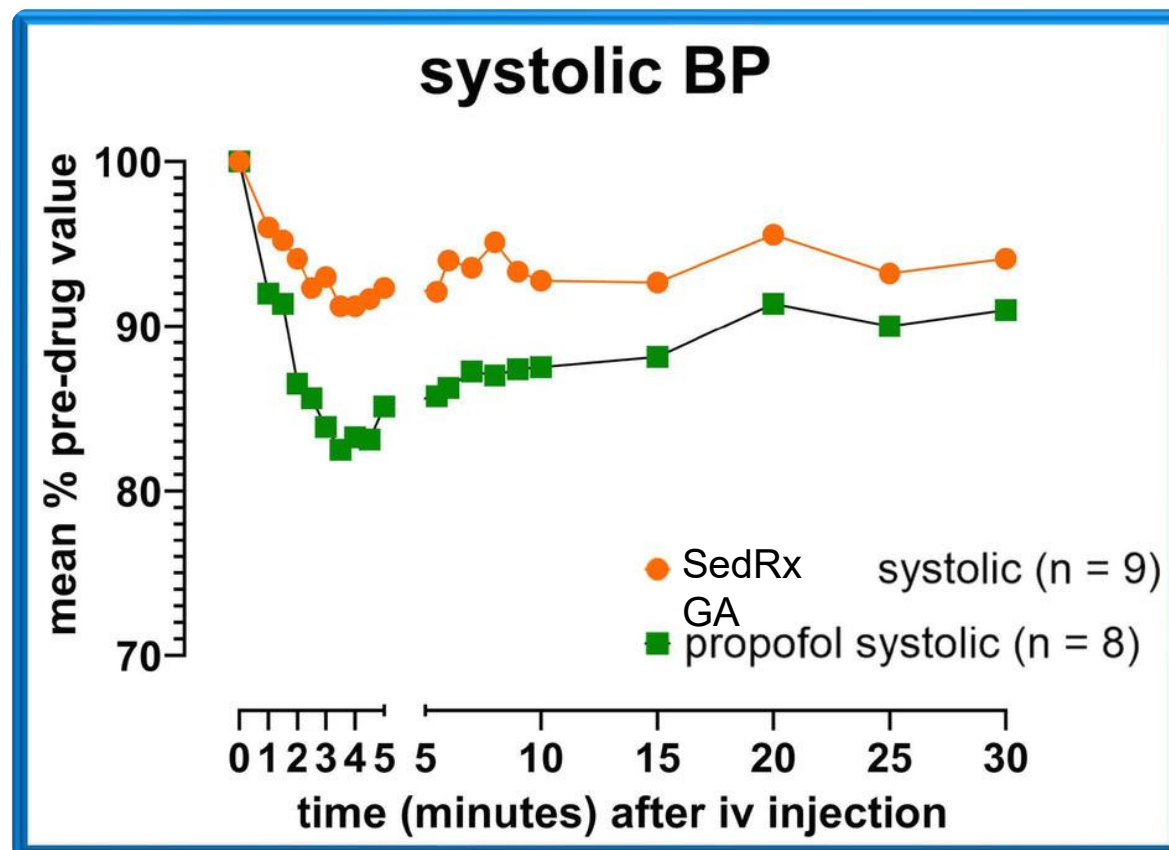
# Path to market: completed Phase 1 clinical trial, Successful cardiovascular results: effective & safer than propofol



Less CVS depression at equivalent depth of anaesthesia



No compensatory heart rate change to explain the difference



Monagle et al. Anesth Analg 2015 121 (4) 914-92

# Path to market: Successful Phase 2A (pilot Phase 3) clinical trial completed



Alfaxalone anaesthesia delivers better recovery of cognition & preservation of brain derived neurotrophic factor compared with propofol & sevofluran

Filling in Digit Symbol Substitution test  
40 mins after anaesthesia

PROPOFOL



Propofol subjects: impaired cognition

ALFAXALONE



Alfaxalone-treated subjects = normal controls

# Path to market: EUROPE — Accelerated regulatory pathway

European Medicines Agency (EMA) — pathway to near term revenue

- Potentially no Phase 3 trial required
- Althesin was approved in UK with up to 50% share in day care market (also approved in France, Germany & Netherlands)
- No new entrants with the safety & efficacy profile of Althesin
- SedRx replaces CremophorEL with SBECD used in many other drug formulations

## Regulatory consultants:

(EU) Member states where licences previously existed & which could potentially support... an abridged licence application.

*Biotron is currently working with an international regulatory consultancy group to make a submission to the Scientific Committee of the EMA to clarify regulatory pathway in EU/UK markets. Response expected July 2026.*

\$863m EU market opportunity	
Peak market penetration	Valuation (USD)
15%	51m
25%	67m
35%	156m
45%	267m

*Clinical uptake to be driven by improved clinical outcomes & reduced risk to insurance companies & hospitals*

# Path to market:

## USA — Regulatory pathway

### Dialogue with US Food and Drug Administration (FDA)

- Successfully completed pre-clinical trial, Phase 1 trial & pilot Phase 3 (2a) trial comparing SedRx to propofol & sevoflurane, the current leading general anaesthetics
- Across a range of indicators SedRx was the better anaesthetic

#### Pre-IND meeting with FDA:

Does the agency think a route to NDA using form 505b(2) is appropriate and possible?

#### FDA Response:

Yes, the 505(b)(2) pathway referencing the published literature to support safety and efficacy is an appropriate pathway.

— Official FDA Minutes

**While currently focused on the EMA submission, Biotron is exploring options for progressing a path to approval in the USA.**

### US\$3.2b US revenue opportunity

Peak market penetration	Valuation (USD)
15%	274m
25%	441m
35%	607m
45%	772m

*Clinical uptake to be driven by improved clinical outcomes & reduced risk to insurance companies & hospitals*

# 2026 Sedarex Milestones

(per Nov 2025 Prospectus)

Biotron's acquisition of Sedarex includes **two key performance-based milestones** targeted for delivery in 2026



## 1 European Regulatory Pathway Guidance (by 31 July 2026)

Sedarex to receive formal guidance on the European regulatory pathway for the Sedarex general anaesthetic

**IN PROGRESS & ON SCHEDULE**

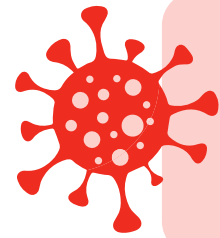
## 2 New Indication Proof-of-Concept (by December 2026)

Sedarex to demonstrate efficacy of a new SedRx formulation in an animal disease model for a new indication — to be achieved by the earlier of **9 months** from product availability for animal trial or **December 2026**

**IN PROGRESS & ON SCHEDULE**

# BIT-HBV001: Hepatitis B virus (HBV) program

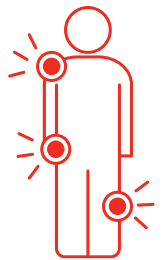
## CURRENT ISSUES



Existing drugs treat HBV, but don't eradicate the virus



>2 billion people have been infected with HBV



WHO estimates >250m chronically infected



Global market estimate US\$4.6B

## BIT-HBV001



Novel compounds with differentiated mode of action (structures undisclosed)



Good activity against HBV in pre-clinical studies



Reduced levels of cccDNA & key viral markers



No toxicity in preliminary animal studies



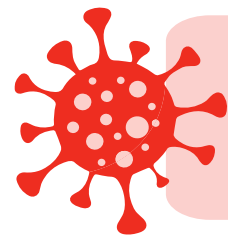
Planning Phase 1 safety trial



Further develop through partnerships, eg with other anti-HBV agents

# BIT-HBV001: Latest data supports ongoing development for “functional cure” HBV therapy

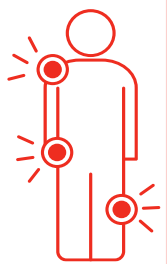
## Hepatitis Delta(HDV)



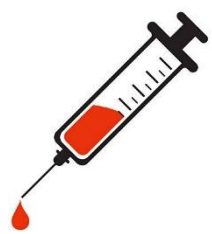
HDV only infects people infected with HBV



12-60 million infected with HDV worldwide



HDV/HBV co-infected are at a much greater risk of the most severe form of viral hepatitis, with rapid progression to cirrhosis, liver failure, or hepatocellular carcinoma



Limited treatment options

## BIT-HBV001



Recent data showed BIT-HBV001 reduces levels of Hepatitis Delta Virus (HDV) proteins by ~85% in cells co-infected with HBV and HDV



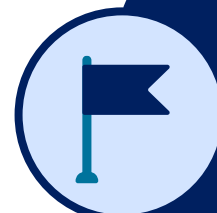
Opens up new treatment pathways for serious HBV infection in a hard-to-treat population with limited treatment options

# Financial summary



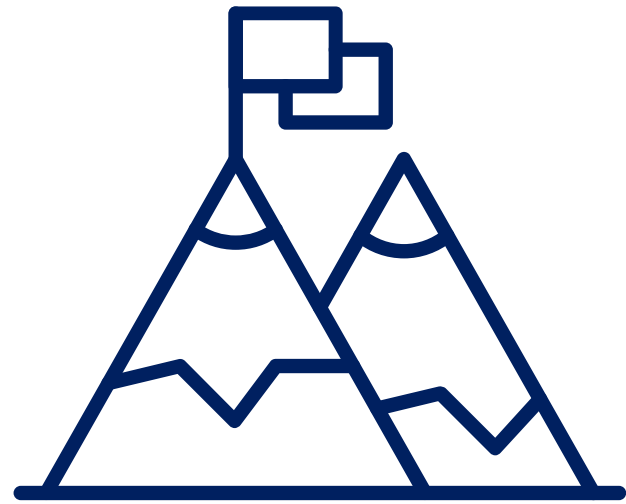
## Strong Financial Foundation & Capital Position (As of 31 Dec 2025)

- **Cash Reserves:** ended quarter with **\$1.64m** cash & cash equivalents (excludes shortfall monies received in Jan 2026)
- **Successful Capital Raising:** completed a **\$2.5m capital raising** program, including a \$1m two-tranche placement & \$645,861 entitlement offer in late 2025, with shortfall of \$878,000 filled in early 2026
- **Operational Runway:** funds expected to support planned Sedarex programs as set out in Prospectus of Nov 25, providing a solid platform for upcoming milestones throughout 2026



## Corporate Milestones & Commercialisation

- **Expert Leadership:** strengthened board with the appointment of **Dr Paul Kasian** as Non-Exec Director
- **Global Reach:** Continuing engagement with potential partners across all programs
- **Disciplined R&D:** Focused on delivering key value-adding short-term milestones for Sedarex and Biotron programs throughout 2026



# Outlook for 2026

## Key Program Milestones

SedRx	Hepatitis B Virus (HBV)
Receiving guidance on the European regulatory pathway for the SedRx general anaesthetic by 31 July 2026	Complete pre-clinical studies to demonstrate suitability of BIT-HBV001 for progression to formal toxicology and safety studies (2H26)
Demonstrating efficacy of a new formulation of SedRx in an animal disease model <u>for a new indication</u> by Dec 2026	Scale up, process development & manufacture of quantities of drug for first-in-human safety study (2H26)

# Summary

- SedRx opens up significant development and commercial opportunities for Biotron
  - **Positions Biotron with a clear commercialisation pathway in multi-billion dollar markets**
- SedRx has significant safety & cognitive advantages over current standard general anaesthetics
- Improves patient outcomes & economies for hospitals & insurers
- Patented, de-risked asset with good existing clinical data
- Pursuing fast track regulatory pathways
- Additional indications for SedRx in the pipeline addressing other high growth neuroscientific markets
- On-going development of anti-viral pipeline with 2026 focus on Hepatitis B program

# *Biotron*

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