



DEVELOPING COMMERCIAL OUTCOMES

CEO Presentation

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FY2021 Highlights



Income from royalties
and milestone
payments totalling
\$736,003



Changchun BCHO Biotech
Co launch of “Influenza
Vaccine, Live, Nasal,
Freeze-Dried” in August
2020



Board changes with
retirement of Prof. Li
and new director Mr
Fergus Mak

BCHT LAIV vaccine launch

BioDiem

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"This is the first needle-free, intranasal and homebred influenza vaccine launched in China. I hope that with its effectiveness and acceptability, the vaccine will help prevent more people getting influenza infection giving them a healthier life, especially under the current circumstance of the COVID-19 pandemic."

Dr. Kong Wei

CEO of Changchun BCHT Biotechnology Co., China

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BCHT LAIV Influenza Vaccine



Changchun BCHT Biotechnology Co (China)



- 2012: BioDiem signs licence with BCHT
- 2018: BCHT lodges marketing application with National Medical Products Administration (Chinese FDA)
- 2020: Regulatory approval (Feb 20) & vaccine product launch (Aug 20)
- 2020-2021 : BioDiem receives royalty payment on year sales



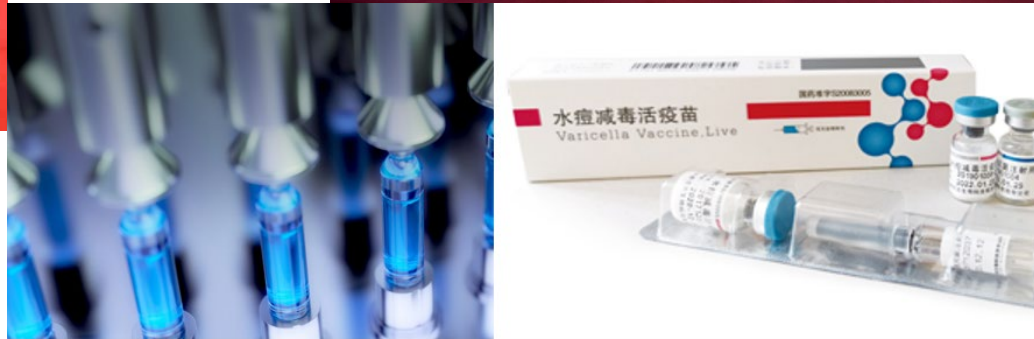
Changchun BCHT Biotechnology Co

BioDiem



BCHT milestone

BioDiem



Changchun BCHT Biotechnology's share price surged 226% from debut to RMB 118.50 per share

China 'flu season

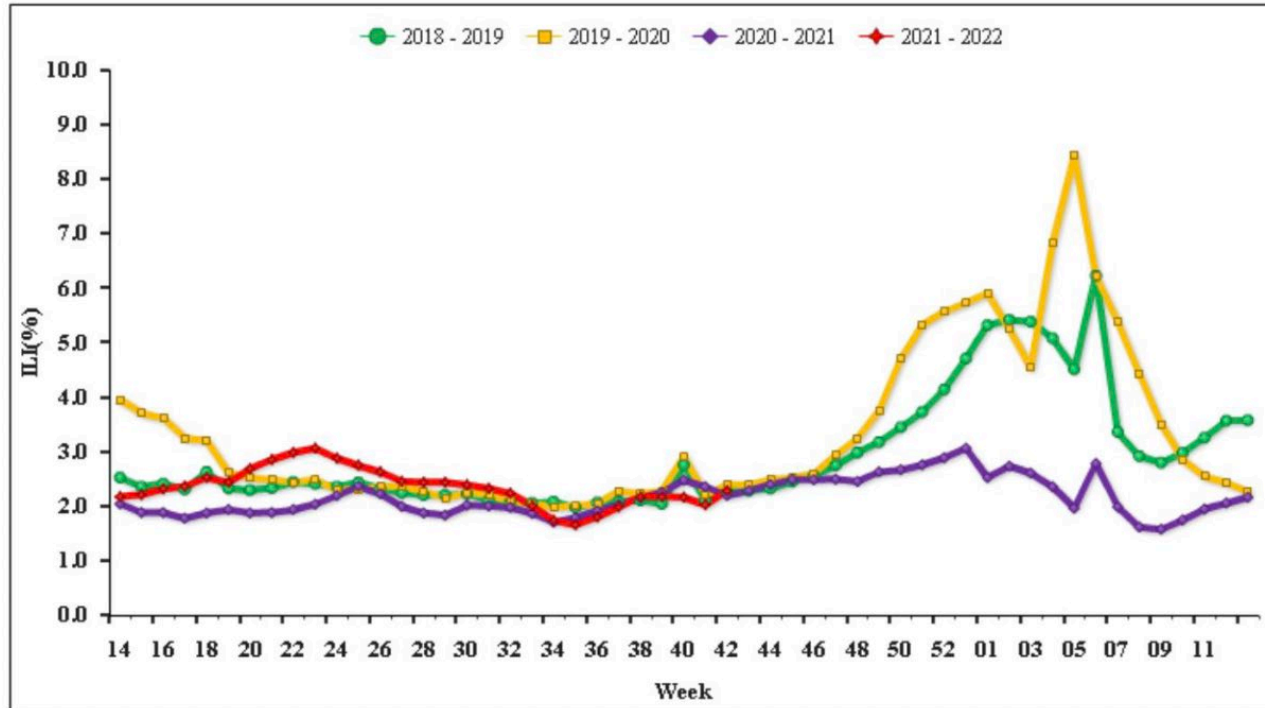


Figure 2: Percentage of visits for ILI at sentinel hospitals in Northern China, 2018-2021

([Source](#): China National Influenza Center)

Bird 'flu - China



October 26, 2021
6:50 PM AEDT
Last Updated a month ago

Environment

Rise in human bird flu cases in China shows risk of fast-changing variants: experts

By Dominique Patton

4 minute read

<https://www.reuters.com/business/environment/rise-human-bird-flu-cases-china-shows-risk-fast-changing-variants-health-experts-2021-10-26/>



An Australian biotechnology company focused on growing Australia's vaccine and pharmaceutical development and manufacturing capability

FY21 Highlights



BDM-I results:
additional information
about blood and tissue
levels of BDM-I



\$25,287: from
R&D tax
incentive



**Company
strategy review:**
EOI lodged for the
pharmaceutical
manufacturing site
at Boronia, Victoria



\$250,000
placement
(post year-
end)



**Board
change:** Ken
Windle
assumes
chairman role
(post year-end)

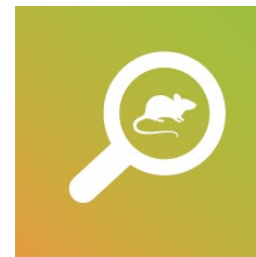
BDM-I Results

Maximum tolerated dose study (mouse)

Oral versus intravenous administration of BDM-I

- Single doses up to 1mg/kg intravenously (maximum tested)
- Single doses up to 100mg/kg by mouth (maximum tested)

Well tolerated and no mortality



Tolerability and PK studies (mouse)

Intravenous (iv) vs intraperitoneal (ip) administration of BDM-I

BDM-I 32mg/kg v 16mg/kg

- 16mg/kg was tolerated well by iv and ip
- 32mg/kg showed signs of toxicity

Intraperitoneal (ip) vs oral (po) administration of BDM-I

BDM-I 16mg/kg v 8mg/kg single dose

Blood and lung tissue BDM-I concentration measurements

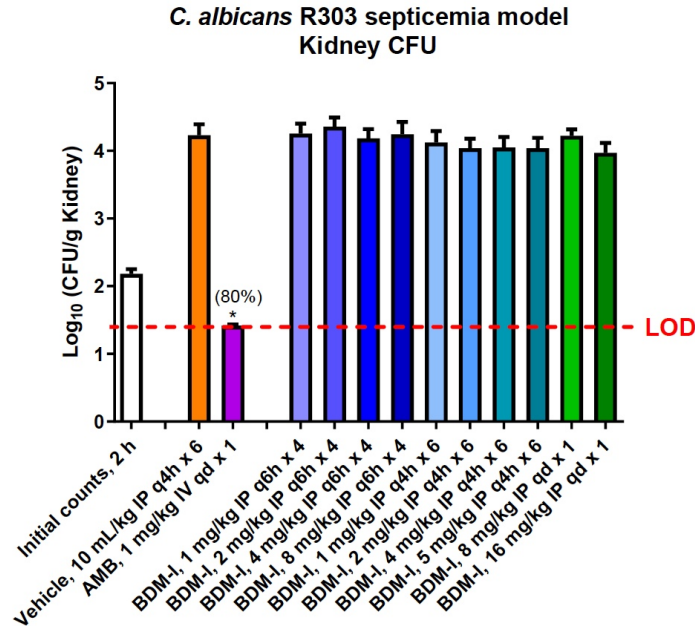
16mg/kg ip and 8mg/kg ip gave similar blood concentrations

Lung tissue concentrations were too low to measure

Blood concentrations after oral administration were too low to measure

No signs of toxicity

C. albicans neutropenic mouse study



The highest blood concentration reading was 800ng/mL or 0.8 microgram/mL (which less than MIC of organism being 4 microgram/mL)

Review of previous “Outlook FY21”

1) BDM-I

High insolubility of BDM-I/formulation

- Other animal models: *Candida glabrata* or other with lower MICs

“BDM-I” analogues

- Glycosylated derivatives (now manufactured and ready for testing)
- ARC Antimicrobial Research Hub to Combat Antimicrobial Resistance

Alternatives to systemic administration

- Topical
- Oral

2) New antimicrobial projects

New Australian and international research projects

Active identification of existing projects with world-class researchers

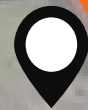
- antifungals

Opportunities in manufacturing (1)

- Modern Manufacturing Initiative (\$1.3b) federal govt.
- COVID-19 pandemic critical medicines shortages
- COVID-19 vaccine manufacturing interest
- GSK Boronia manufacturing site sale
 - Site capability for “fill and finish” of vaccines
 - Limited Australian capability for “fill and finish”
 - EOI lodged 18 Mar 2021
 - Site owner announced & seeking Opal discussion (June ‘21)

Opportunities in manufacturing (2)

- Formulytica Pty Ltd
- Sale agreement executed
- Capital raising commenced and IM issued
- Boronia site develops led to withdrawal of capital raising and return of funds
- Opportunity to be re-cast in light of Boronia site.



2025 Growth Vision – Boronia Biotech Precinct

*- full onshore development and
manufacture capability*

Population scale products portfolio

- Local market and export
- Vaccine portfolio: manufacture/fill & finish
- Inhalation products
- Essential sterile pharmaceutical products
- Other dosage forms





AUSTRALIA SEEKS



Population scale:

- Sovereign manufacturing capability for secure supply chain & rapid response for pandemics/bioterrorism events.
- Ability to use bulk vaccine and locally fill and finish for local/regional supply
- Flexibility to meet changing demand, at scale.

Research scale:

- Scale up capability to produce stability and clinical batches to support biotech and research institutes in Australia

GMP facilities

- Support all stages of development
- Expertise in the industrialization of products

Industry/university/MRI collaboration to harness and grow innovative ideas and train a new workforce

BORONIA SITE PROVIDES



- Large manufacturing site with critical infrastructure
- TGA licence for filling sterile injectables and vaccines
- Highly skilled & trained and experienced work force
- Highrise warehouse & 2-8°C/ 70 pallet storage facility designed for population-scale vaccine distribution
- 11 filling machines with unique Blow-Fill-Seal technology, which is at the heart of the Apiject device
- Extensive chemistry & microbiology labs; stability rooms to support product development & production
- Onsite learning centre for training and internships
- Proposed additions include PC3 labs, extra clean rooms



Boronia Employment ECOSystem

300+ skilled manufacturing workers & scientists

Key linkages to:

- CSIRO/universities/government
- Industry-led projects
- Internships/training for STEM graduates
- Estimated 3x number employed to support site
- Engineers, couriers, support services, etc
- SME's



300+ skilled
workers

900+ support
workers

Outlook for FY22

- Continued royalty stream from LAIV sales
- Exploration of commercial opportunities and to increase liquidity for shareholders
- Support Opal's vision to develop a revenue-generating **manufacturing business and its potential to IPO in FY23.**