



CEO AGM 2022 Presentation

Julie Phillips | CEO and Director, BioDiem Ltd





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FY2022 Highlights





Income from royalties,
milestone and
consulting fee
payments totalling
\$403,184



Changchun BCHT
Biotech Co extension
of licenced
territories; Serum
Institute approval of
quadrivalent LAIV



Board changes
with retirement of
Mr Hugh Morgan
AC and addition of
Mr Damien
Hannes as
chairman



Company strategy refocus: to establish
Australian smallscale manufacturing
facility for clinical
trial supplies



Changchun BCHT Biotechnology Co







Article

Safety and Viral Shedding of Live Attenuated Influenza Vaccine (LAIV) in Chinese Healthy Juveniles and Adults: A Phase I Randomized, Double-Blind, Placebo-Controlled Study

Li Li ¹, Nianmin Shi ², Na Xu ³, Haibin Wang ¹, Hui Zhao ⁴, Haidong Xu ⁵, Dawei Liu ³, Zheng Zhang ¹, Shuping Li 1, Junnan Zhang 1, Chunhui Guo 6, Jinglei Huo 7, Menghan Zhao 5, Fengji Luo 8, Liqing Yang 1, Yunhua Bai ¹, Qiang Lu ⁸, Yusong Zhang ¹, Yi Zhong ¹ and Wenhui Gao ^{1,*}

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- Changchun BCHT Biotechnology Co., No. 138 Zhuoyue St., Gaoxin District, Changchun 130012, China
- National Institutes for Food and Drug Control, No. 31, Huatuo Avenue, Daxing Biomedical Complex, Daxing District, Beijing 102600, China
- Jinsong Community Health Service Center, No. 501, Jinsong St., Chaoyang District, Beijing 100020, China
- Baotou Medical College, No. 31 Jianshe Rd., Donghe District, Baotou 014000, China
- Xianghevuan Community Health Service Center, No. 15 Liufang St., Chaoyang District, Beijing 100020, China
- Beijing Institute of Biological Products, No. 13, South East Third Ring Rd., Chaoyang District, Beijing 100021, China
- Correspondence: cyqwjwcdcgwh@bjchy.gov.cn



Influenza Vaccine Manufacturers (2021) Bio Diem

Manufacturer	Type of Vaccine	Inoculation Method	Specification (mL)	User Group	Dose of Vaccination	Time to Market
Fosun Pharmaceutical	Trivalent split	Intramuscular	0.25/0.5	6M-3Y/>3Y	2/1	2005
Sanofi China	Trivalent split	Intramuscular	0.25/0.5	6M-3Y/>3Y	2/1	2013
Adimmune Corporation	Trivalent split	Intramuscular	0.25/0.5	6M-3Y/>3Y	2/1	2015
Zhongyianke Biotech. Co., Ltd.	Trivalent subunit	Intramuscular	0.5	3Y	1	2010
Changchun BCHT Biotechnology Co.	Trivalent attenuated (nasal spray)	Spray	0.2	3–17Y	1	2020
Hualan Biological Engineering, Inc.	Trivalent split Tetravalent split	Intramuscular	0.25/0.5 0.5	6M-3Y/>3Y >3Y	2/1 1	2011/2008 2018
Sinovac Biotech Ltd.	Trivalent split Tetravalent split	Intramuscular	0.25/0.5 0.5	6M-3Y/>3Y >3Y	2/1 1	2005 2020
Changchun Institute of Biological Products Co., Ltd.	Trivalent split Tetravalent split	Intramuscular	0.25/0.5 0.5	6M-3Y/>3Y >3Y	2/1 1	2007/2004 2020
Shanghai Institute of Biological Products Co., Ltd.	Trivalent split Tetravalent split	Intramuscular	0.25/0.5 0.5	6M-3Y/>3Y >3Y	2/1 1	2004/2001 2021
GDK Biotechnology Co., Ltd.	Tetravalent split	Intramuscular	0.5	>3Y	1	2019
Wuhan Institute of Biological Products Co., Ltd.	Tetravalent split	Intramuscular	0.5	>3Y	1	2020













Central Drugs Standard Control Organization

Directorate General of Health Services Ministry of Health & Family Welfare Government of India



<u>Details of manufacturing permissions of Human Vaccines approved by CDSCO (2009 to 2022)</u>

Year: 2021

		I		
24.	M/s Serum Institute of India	Influenza Vaccine (Human, Live	For active Immunization against influenza	MF/BIO/21/000139
	Pvt. Ltd. 212/2, Off Soli	Attenuated) I.P., Quadrivalent	disease caused by two influenza A	Dated 30-Dec-2021
	Poonawalla Road,		subtype viruses and two influenza Type B	
	Hadapsar, Pune, Maharashtra		viruses in the age group of 2 years and	
	(India)- 411028		above.	



https://cdsco.gov.in



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



FY22 Highlights



\$250,000 placement in Sep 2021;\$162,431 raised from option exercise;\$87,569 raised from placement post-year end



re-focus: to
establish Australian
small-scale
manufacturing
facility for clinical
trial supplies



Three grant
applications
lodged to support
new strategy
(partners
Formulytica Pty Ltd;
University of
Western Australia)



Board change: Mr
Hugh Morgan AC
and Mr Peter
Snowball retire from
the board; Mr
Damien
Hannes(chairman of
BioDiem Ltd) joins
as a non-executive
director







EOI lodged 18 Mar 2021

- New site owner announced & discussions opened (June '21) to create a life sciences precinct
- Discussions
 undertaken with
 governments,
 industry groups,
 local and
 international
 companies,
 universities, the site
 owner and others
 to develop a
 business plan for
 the site.

Submission of grant applications





Company focus CY22: Perth site

- Perth manufacturing site
- WA visit potential facility sites, UWA, WA government (May 2022)
- Medical Research Future Fund (MRFF): mRNA Clinical Trial Enabling Infrastructure grant
 - Professor Archa Fox (University of Western Australia) contacted
 - Western Australian (WA) government contacted
 - Grant application finalized and submitted 15 Jul 2022
- Medical Research Future Fund (MRFF): National Critical Research Infrastructure grant
 - Grant application finalized and submitted 7 Sep 2022
- Western Australian Investment Attraction Fund EOI submitted (May 2022)
 - Invited to submit final application (Aug 2022)
 - Full application finalized and submitted (Oct 2022)

Results awaited.





Project Overview

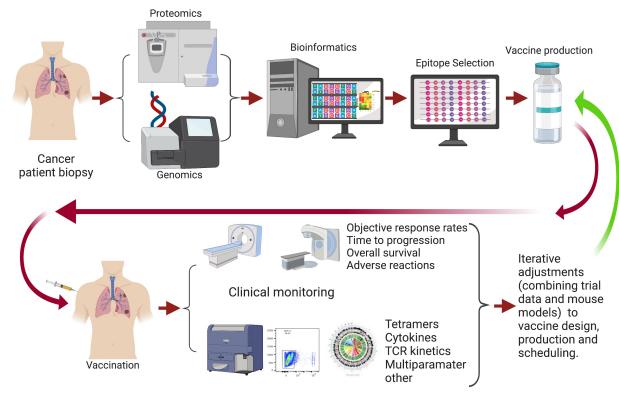
- Small scale pharmaceutical manufacturing facility
- Fee-for-service operation
 - Manufacture to meet relevant global regulatory standards
- Focus on personalised/precision medicine
- Novel mRNA lung cancer vaccine candidate development with partners UWA and Formulytica Pty Ltd







mRNA vaccine targeting lung cancer

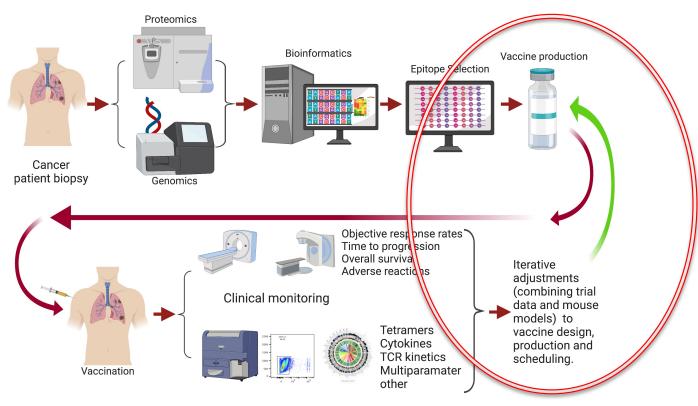


Immunological monitoring



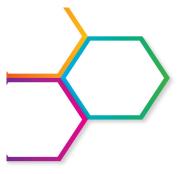


mRNA vaccine targeting lung cancer

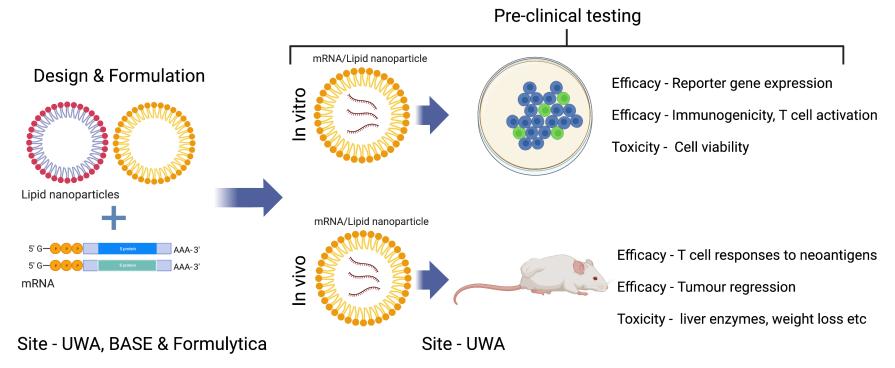


Immunological monitoring





Vaccine development





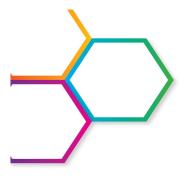


Lead candidate production for clinical testing









Outlook for FY23

- Grant funding
- Partnership with Formulytica Pty Ltd
- Capital raise for balance of funding (as required)
- Execute plan to establish small scale manufacturing capability for sterile liquid products including vaccines.









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