

31 July 2017

Company Announcements Office Australian Securities Exchange

#### **QUARTERLY REPORT – APPENDIX 4C**

In accordance with ASX Listing Rule 4.7B, Vectus Biosystems Limited (Vectus or the Company) attaches its June 2017 Quarterly Report – Appendix 4C.

#### **Strong Milestones towards Human Trials**

#### Overview

- Rapidly accelerating pharmaceutical company engagement.
- Successful good manufacturing practice (GMP) synthesis of lead compound VB0004 completed. Scale batch demonstrating improved yields and cost efficiency per dose, with only three synthetic steps.
- Investigational New Drug (IND) application enabling toxicology and pharmacokinetic studies for VB0004 continuing to meet all milestones. No adverse events at doses up to 2,000 mg/kg observed in two species. Phase I human clinical trials targeted to commence in early 2018.
- Vectus' attendance at world Biotechnology Innovation Organization's 19 to 22 June 2017 BIO International Convention in San Diego highlighted broad and expanding levels of engagement in the Company's key areas of interest, being cardiovascular disease, pulmonary (lung) fibrosis, non-alcoholic steatohepatitis (NASH) and alcoholic steatohepatitis (ASH) (liver disease).
- Direct discussions with a significant cross-section of global and regional pharmaceutical companies.
- Vectus' CEO and Co-Founder, Dr Karen Duggan's, presentation (by invitation) at the "Fibrosis –
  Insights to Fibrosis Drug Discovery & Development" session at Bioshares Biotech Summit in New
  Zealand was very well received.

#### **Commentary**

#### Lead Candidate VB0004

The quarter saw accelerating progress towards human clinical trials for VB0004. This potentially 'first-inclass' anti-fibrotic has pre-clinically shown to not only slow down damage, but has demonstrated a singular capability to improve normal tissue architecture in diseased organs. Reversing such damage is the ultimate aim of clinicians worldwide.

Central to Vectus' development of VB0004 is the successful, and now completed, initial GMP synthesis. The scale batch production is a major milestone, demonstrating and underpinning the commercial feasibility of Vectus' lead candidate by being manufacturable at large volumes and at a low cost per dose. This is a pivotal step that would enable the commercial production of an orally-dosable small molecule, which is the preferred form of delivery for all pharmaceutical companies that the Company is currently in discussions with.

The U.S. Food and Drug Administration IND application enabling toxicology and pharmacokinetic studies for VB0004 are now in progress, with IND toxicology in-vitro (laboratory) cardiovascular safety studies showing that VB0004 is classified as **low** in terms of HERG inhibition. This critical test predicts the potential of a therapeutic candidate to cause QT prolongation and to cause significant cardiac arrhythmias. This is a further milestone towards the demonstration of human safety and is well regarded as an important attribute by the global pharmaceutical industry.



#### The Classification of "Low" Again Indicates the Extremely-Low Side Effect Profile of VB0004

In-vivo (animal) cardiovascular safety tests are currently in progress and at this stage are consistent with the in-vitro results, with no adverse events at doses up to 2,000 mg/kg observed in two species. Respiratory safety testing has already been completed, with no adverse events observed in rats.

Phase I human clinical trials are targeted to commence in early 2018.

#### **Drug Library and Commercial Activity**

Vectus has a library of over 1,000 compounds, derived from the platform underpinning VB0004, and the various stages of testing are progressing well. These emerging lead compounds address some of the most significant unmet needs in medicine today, and include:

- A32 (liver fibrosis, including NASH and ASH);
- A79 (pulmonary fibrosis, including idiopathic fibrosis, asbestosis and coal dust pneumoconiosis (Black Lung Disease)); and
- P5 (renal fibrosis).

The Company is engaged with a series of global and regional pharmaceutical companies, and is working with expert consultants in the field of both licencing and research and development (R&D) collaboration, with a view to maximising the commercialisation of key pharmaceutical assets in its drug library. In parallel, Vectus is receiving regular enquiries from potential partners as a consequence of the growing awareness of its data set and technical milestones achieved.

This month, Dr Duggan was invited to present at the "Fibrosis – Insights to Fibrosis Drug Discovery & Development" session at the Bioshares Biotech Summit in New Zealand, where she presented detailed data supporting the Company's capability to potentially clinically reverse existing fibrosis whilst demonstrating a potentially desirable toxicological and safety profile, which has generated additional interest in Vectus' emerging therapeutic small molecules.

At the global BIO International Convention in San Diego held in June 2017, the Company was further recognised as the 2016 winner of the Medtech and Pharma category of the Australian Technologies Competition. This award notes that of the 39 entrants in the category, Vectus had the "greatest potential to have a global impact" and supported a high profile for the Company at that event.

#### Patent Library

Further pivotal milestones were achieved during the quarter, with Vectus receiving notification of either grant, or intention to grant, further key patents underpinning the Company's global intellectual property position deriving from its drug library of 1,000 compounds. In particular, patents covering VB0004 have been granted in South Korea and Singapore, have been allowed to proceed to grant in Europe and have been accepted in the Philippines. Further, the patent that encompasses the VB0004 library has been granted in Australia and in the USA, with a 'proceed to grant' decision being issued in South Africa.

The Patent Cooperation Treaty (PCT) for VB4-A79 (lung) and associated compounds compositions, and methods of use for treatment of pulmonary fibrosis, have been lodged with a view to protecting this important discovery via an additional patent family.

#### Accugen

Accugen was developed internally by Vectus to address a well-known inadequacy in quantifying changes in DNA across a broad range of applications. Accucal, the core product, is unique in that it is targeted to eliminate variability and inaccuracy in the current methodology of using housekeeping genes. These housekeeper genes are currently widely used, yet are time consuming and costly, and are a potentially inaccurate method of calibrating the results from quantitative polymerase chain reaction (qPCR) analysis.



The Company's technology is based on a consumable and related software product, with broad applicability for a wide range of machines in the world market.

Vectus is now moving into early commercial production of Accucal, and is evaluating, both regionally and globally, the preferred path to market for this disruptive technology platform. The market opportunity for the Accugen system is over 100,000 laboratories, and whilst this market is inherently conservative when adopting new technology, Accucal offers the potential for both increased accuracy and cost savings.

#### <u>Finance</u>

The Company is currently taking steps to support the funding of its future R&D and product commercialisation work. Vectus is in dialogue with a number of brokers and institutional fund managers regarding its future capital requirements. In addition, the Company is entitled to an R&D cash-back taxation refund based on activities for the 2016-17 financial year, which have been approved by AusIndustry, and the refund of approximately \$1.3 million is expected to be received in the current half of the 2017-18 financial year. In parallel, Vectus is actively engaged in discussions regarding collaboration agreements with pharmaceutical companies to help jointly fund the advancement of its key programmes.

The Company is currently finalising an agreement with an international consulting firm that specialises in non-dilutive fundraising, particularly grant funding. This firm has advised Vectus that the Company's core programmes may be well be suited to achieving success in grant applications and that it will be commencing its efforts on behalf of Vectus in August 2017.

#### Summary

The Company continues to demonstrate increasing momentum towards the clinic for its lead candidate, VB0004, together with additional small molecule drug candidates progressing in a meaningful fashion. Vectus is now moving into a phase that represents an opportunity for increasing shareholder value. Industry statistics demonstrate that the pre-clinical phase that Vectus has now achieved, and running through to early human trials, are an increasingly-common inflection point for commercial relationships.

#### **Vectus Biosystems Limited**

#### Karen Duggan

Chief Executive Officer and Executive Director

#### **About Vectus Biosystems Limited**

Vectus Biosystems Limited (Vectus or the Company) is developing a treatment for fibrosis and high blood pressure, which includes the treatment for three of the largest diseases in the fibrotic market, namely heart, kidney and liver disease. Vectus successfully completed its Initial Public Offering (IPO) on the Australian Securities Exchange (ASX:VBS) and commenced trading on ASX on 23 February 2016, after raising A\$5.1 million. Funds from the IPO are being used to develop the Company's lead compound VB0004, which aims to treat the hardening of functional tissue and high blood pressure. Vectus has conducted a range of successful pre-clinical trials, which have shown that VB0004 slows down the advances of fibrosis, potentially repairs damaged cell tissue and reduces high blood pressure. VB0004 is now progressing through a number of important milestones, including pharmaceutical scale-up and additional toxicity studies. Successful results are providing the Company with a clear path to Human Phase I and IIa Clinical Trials. Vectus' strategy is to develop and perform early validation of its drug candidates to the point where they may become commercially attractive to potential pharmaceutical partners.

The Company has also developed technology aimed at improving the speed and accuracy of measuring the amount of DNA and RNA in samples tested in laboratories. The technology, called Accugen, is owned by Vectus' wholly-owned subsidiary Accugen Pty Limited. The technology offers a time, cost and accuracy benefit compared to currently-available systems. The Company's current stage of investment in Accugen is a commercialisation programme that may include direct sales, distribution partnerships and licensing opportunities.



## **Appendix 4C**

### **Quarterly report for entities subject to Listing Rule 4.7B**

Name of entity

## **Vectus Biosystems Limited**

ABN

Quarter ended ("current quarter")

54 117 526 137

30 June 2017

#### **Consolidated statement of cash flows**

1 Cash flows from operating activities	Current	Year to date
	quarter	(12 months)
	\$A'000	\$A'000
1.1 Receipts from customers	6	6
1.2 Payments for		
(a) patent and research expenses	(729)	(2,643)
(b) staff costs and directors' fees	(253)	(1,158)
(c) occupancy cost	(85)	(341)
(d) corporate overheads	(118)	(481)
(e) legal and professional fees	(61)	(388)
(f) other operating costs, including working capital	(16)	(13)
1.3 Dividends received	-	-
1.4 Interest and other items of a similar nature received	6	90
1.5 Interest and other costs of finance paid	-	(5)
1.6 Income tax refund received (including R&D Tax Offset)	18	1,024
1.7 Government grants and tax incentives	-	-
1.8 Others (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(1,233)	(3,910)

	Current quarter \$A'000	Year to date (12 months) \$A'000
2 Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	_	(28)
(b) businesses (item 10)	_	(23)
(c) investments	_	_
(d) intellectual property	_	_
(e) other non-current assets	_	_
2.2 Proceeds from disposal of:		
(a) property, plant and equipment	_	_
(b) businesses (item 10)	_	_
(c) investments	_	_
(d) intellectual property	_	_
(e) other non-current assets	_	_
2.3 Loans to other entities	_	_
2.4 Dividends received (see note 3)	_	_
2.5 Other (provide details if material)	_	_
2.6 Net cash from / (used in) investing activities	_	(28)
2.0 Net cash from / (used iii) investing activities		(20)
3 Cash flows from financing activities	I	
3.1 Proceeds from issue of shares	_	_
3.2 Proceeds from issue of convertible notes		_
3.3 Proceeds from exercise of share options	_	_
3.4 Transaction costs related to issues of shares,		
convertible notes or options	_	_
3.5 Proceeds from borrowings		_
3.6 Repayment of borrowings		
3.7 Transaction costs related to loans and borrowings	_	_
3.8 Dividends paid	_	_
3.9 Other (provide details if material)	_	_
3.10 Net cash from / (used in) financing activities		
3.10 Net cash from / (used iii) illianoing activities		
4 Net increase / (decrease) in cash and cash		
equivalents for the period		
4.1 Cash and cash equivalents at beginning of quarter/year	1,750	4,455
4.2 Net cash from / (used in) operating activities	(1,233)	(3,910)
(item 1.9 above)		
4.3 Net cash from / (used in) investing activities	-	(28)
(item 2.6 above)		
4.4 Net cash from / (used in) financing activities	-	-
(item 3.10 above)		
4.5 Effect of movement in exchange rates on cash held	-	-
4.6 Cash and cash equivalents at end of quarter	517	517

5 Reconciliation of cash and cash equivalents	
at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the	Current quarter
accounts	\$A'000
5.1 Cash on hand and at bank	517
5.2 Term Deposits	-
5.3 Bank overdrafts	-
5.4 Other (provide details)	-
5.5 Cash and cash equivalents at end of quarter (item 4.6)	517
6 Payments to directors of the entity and their associates	Current quarter \$A'000
6.1 Aggregate amount of payments to these parties included in item 1.2	88
6.2 Aggregate amount of loans to these parties included in item 2.3	-
6.3 Explanation necessary for an understanding of these transa	actions
Salaries paid to Karen Duggan, Executive Director and Chief Executive Officer	36
Directors' fees paid to Non-Executive Directors:  Graham Macdonald	18
Ron Shnier	11
Peter Bush	12
Susan Pond	11
TOTAL	52
	<u> </u>
7 Payments to related entities of the entity and their	Current
associates	quarter \$A'000
7.1 Aggregate amount of payments to these parties included in item 1.2	100
7.2 Aggregate amount of loans to these parties included in item 2.3	-
7.3 Explanation necessary for an understanding of these transaction	actions
Payment for accounting advisory services to Aeris	
Environmental Ltd of which Mr M Stang is a Director and Peter Bush is Chief Executive Officer.	25
Corporate overheads, administration and laboratory	
supplies expenses paid to Regional Healthcare Pty Limited of which Mr M Stang is a Director.	75

Previous quarter \$A'000

> 1,250 500

1,750

#### 8 Financing facilities available

Add notes as necessary for an understanding of the position.

	Total	Amount
	facility	drawn
	\$A'000	\$A'000
8.1 Loan facilities	-	-
8.2 Credit standby arrangements	-	-
8.3 Other (please specify)	-	-

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

Not applicable

9 Estimated cash outflows for next quarter	\$A'000
9.1 patent and research expenses	464
9.2 staff costs and directors' fees	201
9.3 occupancy cost	89
9.4 corporate overheads	17
9.5 legal and professional fees	15
9.6 other operating costs, including working capital	32
9.7 Total estimated cash outflows	818

# 10 Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)

- 10.1 Name of entity
- 10.2 Place of incorporation or registration
- 10.3 Consideration for acquisition or disposal
- 10.4 Total net assets
- 10.5 Nature of business

Acquisitions	Disposals
n/a	n/a

#### **Compliance statement**

- This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Sign here: Robert Waring

(Director/Company Secretary)

Print name: Robert J Waring Date: 31 July 2017