

ASX/Media Release (Code: PRR) 17 January 2012

#### QUARTERLY ACTIVITY REPORT For Quarter ending 31 December 2011

Australian health care company Prima BioMed (Prima) (ASX: PRR) is pleased to provide the following Quarterly Report on its activities for the three month period ending 31 December 2011.

#### **Highlights**

- CVac<sup>™</sup> granted Manufacturing Authorisation in Germany for CANVAS study
- Launch of partnership with The City Hospital in Dubai Healthcare City to commercialise CVac<sup>™</sup> in the Middle East
- Update on Research Program on Oral Delivery System for cervical cancer vaccines
- Update on Cripto-1 immunotherapy cancer treatment program

### CVac<sup>™</sup> granted Manufacturing Authorisation in Germany

In October the Company announced that its manufacturing partner for CVac<sup>™</sup> in Europe, the Fraunhofer Institute for Cell Therapy and Immunology IZI, had received manufacturing authorisation (according §13 German Drug Act (AMG)) to produce the CVac<sup>™</sup> immunotherapy ovarian cancer vaccine.

The authorisation was a key component of Prima's regulatory application to commence the planned CANVAS (*CAN*cer *VA*ccine *S*tudy) trial in Europe.

The authorisation was provided after a successful Good Manufacturing Practices (GMP) inspection by Landesdirektion Leipzig, in consultation with the Paul-Ehrlich-Institut. The authorisation covers the complete CVac™ manufacturing for testing in clinical trials.

GMP inspection and subsequent manufacturing authorisation is a prerequisite for the production of any medicinal product intended for human administration in Europe. The process is governed by European Directives and the German Drug Act (AMG). The process includes checking that all stages of manufacture and quality controls are carried out in accordance with the basic principles of GMP. Such inspections assure that the facilities, equipment, personnel involved in production as well the process validation are suitable.

Manufacturing authorisation is only provided once the regulator is assured that manufacture and testing is carried out according to the latest standards prevailing in science and technology.

# Launch of partnership with The City Hospital in Dubai Healthcare City to commercialise $CVac^{TM}$ in the Middle East

Also in October, Prima announced the formal launch of its partnership with The City Hospital in Dubai Healthcare City (DHCC) to make CVac<sup>TM</sup> commercially available in the Middle East region.

The program was officially launched at a ceremony to mark the third anniversary of The City Hospital, and came after Prima announced in May 2011 that it had been granted approval for the marketing and distribution of CVac<sup>TM</sup> in DHCC.



Prima now expects to be in a position to commence the first sales of CVac<sup>TM</sup> in DHCC in the near future.

The partnership represents a significant milestone for Prima. It is the first commercialisation of CVac<sup>TM</sup> anywhere in the world, and allows the Company to provide treatment for cancer patients in the Middle Eastern region and generate revenues in a growing health care market. The Company also plans to seek opportunities to expand the application of CVac<sup>TM</sup> in the UAE to treat other mucin-1 positive tumours, in addition to ovarian cancer.

At the same time, Prima also announced the launch of another partnership with The City Hospital, for a Therapeutic Apheresis service. The Therapeutic Apheresis program will provide a treatment that removes harmful proteins, chemicals or cells in the blood that cause disease. It will be used in blood disorders, kidney problems, metabolic diseases, neurological disorders and auto-immune conditions. It represents the first time that a service of its type has been offered in Dubai.

#### Update on Research Program on Oral Delivery System for cervical cancer vaccines

In December the Company provided updates on two of its other clinical programs.

The first was an update on its research program to develop an oral delivery system for cervical cancer vaccines. Prima announced in November 2009 that it had engaged University of New South Wales (UNSW) and University of Queensland (UQ) to undertake a research program to develop an oral delivery system for vaccines for cervical cancer.

The Company's research program has progressed to the testing of various formulations of a nanoparticle oral vaccine delivery system in a mouse model. Work carried out to date has shown that a coated nanoparticle protein delivery system is feasible and can be administered safely in a mouse model.

In 2012, the UNSW and UQ laboratory teams will work to determine which oral formulation best delivers an immunogenic dose of protein to the lower gastrointestinal tract.

This collaborative work will be supported, in part, by a competitive Australian Research Council (ARC) grant. Such grants are determined on the merit of the research and are highly sought after and regarded by the academic community.

The development of an oral delivery system for cervical cancer vaccines is potentially a major breakthrough in drug delivery for cervical cancer treatment as it would provide a suitable large scale alternative method of drug delivery to injection, which is currently the prime method of delivery.

#### Update on Cripto-1 immunotherapy cancer treatment program

During the quarter, Prima also updated the market on its pre-clinical testwork on the Cripto-1 cancer monoclonal antibody (mAB) cancer treatment.

The Company has a licensing agreement for the development of a Cripto-1 mAB with leading Dutch antibody development company Bioceros (see ASX announcement, 17 August 2010).

The development program for a Cripto-1 mAB is progressing well, with several hybrid mAB's having been synthesized from hybridoma cell lines. The lead mAB's that have been synthesized bind to Cripto-1 positive MCF-7 breast cancer cell lines. The search continues for the most active humanized IgM or IgG mAB against the target, and will be the focus of work to be conducted in 2012.

Cripto-1 is a protein found in high levels on the surface of a number of different types of malignant tumor cells. It facilitates growth of the tumor cells, and contributes to their spreading throughout the



body. The antibody works by binding to the Cripto-1 molecule interfering with local development of the tumor, and preventing distant seeding of tumor cells. The antibody may be administered in combination with cytotoxic drugs (chemotherapy drugs) to create an even more lethal potent additive effect on tumor cell destruction.

There is a large global market for mAB treatments. According to leading pharmaceutical industry research group, GBI Pharmaceutical Research, the global mAB market was worth US\$46.8 billion in sales, in 2010.

#### For further information please contact:

Martin Rogers Chief Executive Officer Prima BioMed Ph: +61 2 9276 1242

E: martin.rogers@primabiomed.com.au Website: www.primabiomed.com.au

#### **About CVac<sup>™</sup> Ovarian Cancer Treatment**

CVac<sup>™</sup> is Prima BioMed's core product. It is a vaccine therapy treatment for ovarian cancer sufferers that is administered post-surgery and post-chemotherapy to delay the relapse and control the metastases of the cancer. There is a large un-met medical need for new treatments for ovarian cancer which has a very high morbidity rate, and there are currently no maintenance-based therapy products commercially available.

The Company has recently completed enrolment in its Phase IIb trial for CVac<sup>TM</sup> with the US FDA and plans to commence CANVAS(*CAN*cer *VA*ccine *S*tudy) a multinational, multi-centre, randomised, double-blinded, placebo-controlled trial of CVac<sup>TM</sup> in Europe and the US in the near future. The Phase IIb and CANVAS trials aim to further confirm the ability of CVac<sup>TM</sup> to reduce the instance of relapse in ovarian cancer patients, control the metastases of the cancer and increase the life expectancy of patients.

Prima's ultimate goal is to commercialise CVac<sup>™</sup> into the multi-billion dollar global pharmacy oncology market. The global market for ovarian cancer therapeutics was valued at US\$2.1b in 2007 and was estimated to have grown to US\$3.6b<sup>1</sup>.

Regulatory approval and commercialisation of CVac<sup>TM</sup> is the core focus for Prima.

#### **About Prima BioMed**

Prima BioMed is an ASX listed Australian health care company. The Company is focused on technologies in the fields of cancer immunotherapy and immunology.

Prima's lead product is  $CVac^{TM}$  ovarian cancer therapy treatment. It has completed two successful clinical trials and is progressing toward eventual commercialization in the United States, Australia, Europe, and globally.

The Company's broader, long term goal is to develop commercial cancer treatment technologies and programs for global markets.

1 Thomson Business Intelligence, Ovarian Cancer Therapeutics Industry Analysis 2007

# Appendix 4C – 2<sup>nd</sup> Quarter

# **Quarterly Report**

# For Entities Admitted on the Basis of Commitments

Introduced 31/3/2000. Amended 30/9/2001

#### Name of Entity:

ABN:

**Quarter Ended ("Current Quarter")** 

90 009 237 889

31 December 2011

#### **Consolidated Statement of Cash Flows**

		Current Quarter	Year-to-Date
	Cash flows related to operating activities	\$A'000	\$A'000
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) staff costs	(680)	(1,253)
	(b) advertising and marketing	(59)	(99)
	(c) research and development	(4,334)	(7,795)
	(d) leased assets	-	-
	(e) other working capital	(960)	(2,399)
1.3	Dividends received	-	-
1.4	Interest and other items of a similar nature received	853	1,101
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes benefit	764	764
1.7	Other - grants received	-	-
	Net operating cash flows	(4,416)	(9,681)

<sup>+</sup> See chapter 19 for defined terms.

		Current Quarter \$A'000	Year-to-Date \$A'000
1.8	Net operating cash flows (carried forward)	(4,416)	(9,681)
Cash	flows related to investing activities		
1.9	Payment for acquisition of:  (a) businesses (item 5)  (b) equity investments  (c) intellectual property  (d) physical non-current assets  (e) other non-current assets	- - (191)	- - - (320) -
1.10	Proceeds from disposal of:  (a) businesses (item 5)  (b) equity investments  (c) intellectual property  (d) physical non-current assets  (e) other non-current assets	- - -	- - - -
1.11 1.12 1.13	Loans to other entities Loans repaid by other entities Other (provide details if material)	- - -	- - -
Net in	nvesting cash flows	(191)	(320)
1.14	Total operating and investing cash flows	(4,607)	(10,001)
Cash	flows related to financing activities		
1.15 1.16 1.17 1.18 1.19 1.20	Proceeds from issues of shares, options, etc. Transfer of shares Proceeds from borrowings net finance costs Repayment of borrowings Dividends paid Other - capital raising costs	1,080 - - - - -	1,649 - - - - -
Net fi	nancing cash flows	1,080	1,649
Net in	ncrease (decrease) in cash held	(3,527)	(8,352)
1.21	Cash at beginning of quarter/year to date  Exchange rate adjustments to item 1.21	51,110 (108)	55,919 (92)
1.23	Cash at end of quarter	47,475	47,475

<sup>+</sup> See chapter 19 for defined terms.

# Payments to Directors of the Entity and Associates of the Directors

# Payments to Related Entities of the Entity and Associates of the Related Entities

_		Current Quarter \$A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	213
1.25	Aggregate amount of loans to the parties included in item 1.11	-

1.26	Explanation	necessary for a	n understanding	of the	transactions
------	-------------	-----------------	-----------------	--------	--------------

	Directors' fees and	l consulting fees at norma	l commercial rates
--	---------------------	----------------------------	--------------------

# **Non-Cash Financing and Investing Activities**

2.1	Details of financing and investing transactions which have had a material affect on consolidated Assets and liabilities but did not involve cash flows
2.2	Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

# **Financing Facilities Available**

Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).

		Amount Available \$A'000	Amount Used \$A'000
3.1	Loan facilities	1	-
3.2	Credit standby arrangements	12,000*	-

#### Note:

3.2 \$12 million equity drawdown facility in place with Foretrend Securities Pty Ltd.

<sup>+</sup> See chapter 19 for defined terms.

#### **Reconciliation of Cash**

(as s	nnciliation of cash at the end of the quarter hown in the consolidated statement of cash flows) are related items in the accounts is as follows.	Current Quarter \$A'000	Previous Quarter \$A'000
4.1	Cash on hand and at bank	601	864
4.2	Deposits at call	9,961	13,334
4.3	Bank overdraft	1	-
4.4	Other (Term Deposit)	36,913	36,913
	Total: Cash at end of quarter (item 1.23)	47,475	51,110

# **Acquisitions and Disposals of Business Entities**

		Acquisitions	Disposals
		(Item 1.9(a))	(Item 1.10(a))
5.1	Name of entity	-	-
5.2	Place of incorporation or registration	-	-
5.3	Consideration for acquisition or disposal	-	-
5.4	Total net assets	-	-
5.5	Nature of business	-	-

# **Compliance Statement**

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.

Sign Here: Date: Tuesday 17<sup>th</sup> January 2012

**Company Secretary** 

Print Name: Ian Bangs

#### **Notes**

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
- 2. The definitions in, and provisions of, *AASB 1026: Statement of Cash Flows* apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 itemised disclosure relating to acquisitions
  - · 9.4 itemised disclosure relating to disposals
  - · 12.1(a) policy for classification of cash items
  - 12.3 disclosure of restrictions on use of cash
  - · 13.1 comparative information
- 3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

<sup>+</sup> See chapter 19 for defined terms.