



ANNUAL REPORT

**Report for the period
1 October 2005 to 31 December 2006**

CHAIRMAN'S REPORT

In 2006, over 20,000 Victorians were diagnosed with a potentially life-threatening cancer and over a quarter will ultimately die from the disease. This clearly represents a significant burden on our society at a number of levels, affecting both our social and economic fabric. While biomedical and clinical research has already paid dividends in terms of improved patient care and clinical outcomes, it is increasingly clear that cancer researchers require access to ethically obtained patient tumour tissue (as well as normal samples) to substantially boost cancer research. Such tissue banking requires an appropriate ethical framework and quality assurance protocols. Historically, only a small amount of cancer tissue has been collected for research, often in a project-specific manner and with minimal resources or integration of effort. Importantly, we are entering a new era of targeted cancer therapy, which will require detailed genetic evaluation of tumour tissue to enable individualised patient therapy.

The Victorian Cancer Biobank (VCB) was established in 2006 as a not-for-profit consortium to provide researchers with high quality clinically annotated tissue samples to facilitate research efforts that will lead to improved patient outcomes. Through Science Technology and Innovation funding from the Victorian Government Department of Innovation, Industry and Regional Development, as well as Department of Human Services support, the VCB will provide a coordinated system of tissue collection across the recently established Integrated Cancer Service network, as well as a single port of call to distribute tissue to researchers in academia and the biotechnology sector.

The VCB concept evolved from a Tissue Bank working group established by The Cancer Council Victoria (CCV) in 2001. This group originally represented Tissue Banking activities of the founding members at Austin Health, Melbourne Health, the Peter MacCallum Cancer Centre and Southern Health. With CCV support, common protocols, consent forms and a database were produced. The vision to further extend and coordinate tissue collection and annotation for cancer research received solid support from a number of quarters including the Ludwig Institute for Cancer Research, The Walter and Eliza Hall Institute and the Victorian Breast Cancer Research Consortium and Bio21, with endorsement from a large number of affiliate organisations in both the public and private sector.

I am pleased to report on behalf of the VCB Consortium Committee that there has been rapid progress in implementing key VCB activities following the execution of the Consortium Agreement in June 2006. Two rounds of program grant agreements have resulted in the provision of tissue collectors, pathology fellows and additional infrastructure to Consortium member sites, with the expectation that activities will be expanded to additional sites in 2007.

Importantly, the appointment of Dr Anne Thompson as Executive Officer in late November 2006 will provide the means to effectively implement VCB's operations. Anne has an excellent pedigree for this task – with basic and clinical research experience, as well as valuable experience in multicentre research management through her former role as Chief Operations Officer of the ARC Centre for Kangaroo Genomics.

I would like to thank the huge number of individuals, in addition to Consortium Committee members, who provided much needed expertise and substantial amounts of their time to ensure the successful establishment of VCB. In particular, I would like to single out Woody Macpherson, who ensured that progress seemed effortless through her diligent and tireless work, David Fogarty and Julian Clark for their invaluable input into the preparation of a Business Plan, and Audrey Partanen, Lisa Devereux, Carmel Murone and Pam Mammers, whose first hand experience as Tissue Bank coordinators has ensured that an appropriate level of rigor and coordination is being applied to implementing the VCB vision.

Geoff Lindeman
Chairman, VCB Consortium Committee

EXECUTIVE OFFICER'S REPORT

In its first year of operation, the Victorian Cancer Research Tissue Bank, renamed the Victorian Cancer Biobank, has focused on establishing a solid foundation to ensure the future of the VCB. Building this foundation during 2006 has involved putting in place sound governance, management and financial structures.

On 22 June 2006, the four founding members, Austin Health, Melbourne Health, Peter Mac and Southern Health and the Cancer Council Victoria as the Lead Agency, reached a major milestone in the establishment process with the signing of the Consortium Agreement. This paved the way for the formation of the Consortium Committee, which held its inaugural meeting on 10 July 2006. In addition to representing the founding member sites, members of the Consortium Committee provide a broad range of expertise and skills in the areas of cancer treatment, cancer research, pathology, law and ethics, finance, marketing, and cancer advocacy. These skills will ensure sound guidance as the Biobank moves forward.

Throughout the remainder of the year, the committee worked steadily, meeting monthly to refine the Business Plan that underpins the management and financial structures of the VCB. During the third quarter of 2006, Flinders Consultancy Pty Ltd conducted an independent review of the Business Plan. Their report contained a series of recommendations that were accepted with minor amendments by the Committee in September. These were included in the revised Business Plan, which was adopted by the Consortium Committee in October.

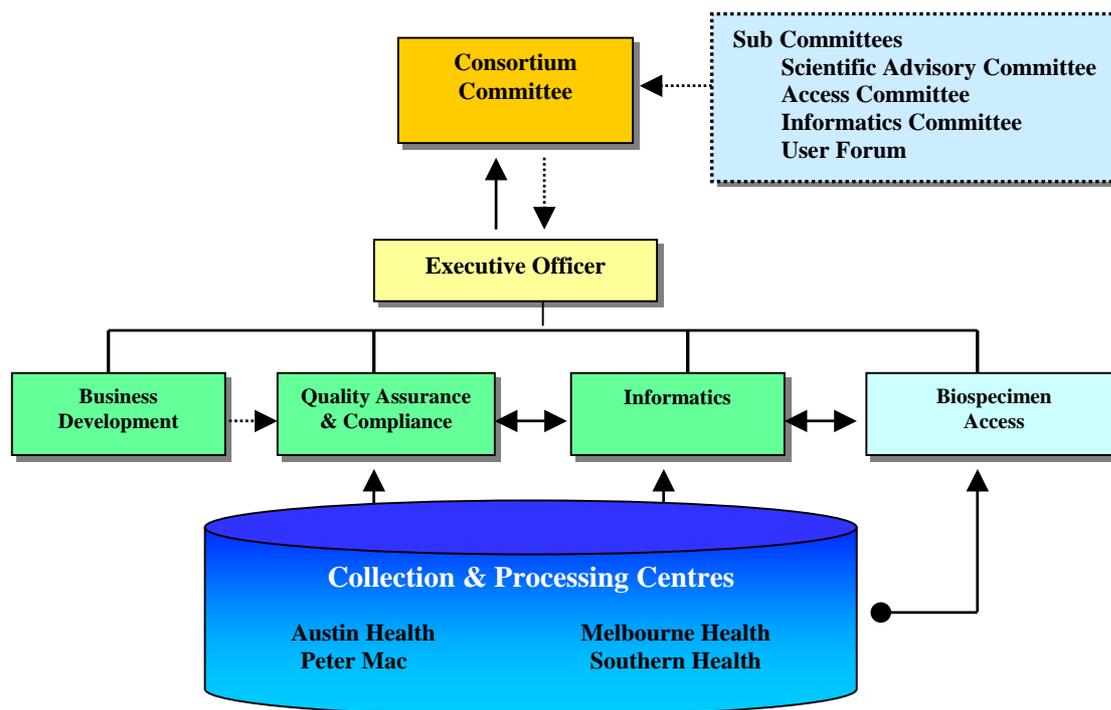
One of our key objectives is to improve capabilities in molecular pathology. The provision of accurately annotated tissue will enable molecular pathologists and cancer researchers to differentiate between cancer origins and types and facilitate the development of targeted therapies. To support this important step towards the individualisation of cancer therapies, funding has already been allocated for additional pathology registrars to be appointed to the Anatomical Pathology departments associated with the four Biobank sites. One registrar has already been appointed and the remainder of the appointments will occur in early 2007. Our commitment in this area will significantly enhance the prospects for translation of research into better clinical outcomes.

Another important objective in the establishment phase has been to consolidate relationships and expand the resources across the Biobank. Agreements for the allocation of funds for staff, equipment and reagents to support the collection and processing of tissues are now in place and the distribution of funds has commenced. An Advisory Group of Tissue Bank Managers has been formed and is scheduled to meet regularly in 2007 to inform the Executive Officer of issues at each site and ensure a coordinated and integrated program for tissue collection and distribution is developed. We are now well placed to move forward with the expansion phase in 2007.

I am extremely grateful to Woody Macpherson from the Research Management Unit of The Cancer Council Victoria who so tirelessly gave her time and considerable expertise to the establishment of the Biobank throughout the year. Her continuing patience and generous sharing of knowledge following my commencement in November has ensured a smooth transition to my new role.

Anne Thompson
Executive Officer, Victorian Cancer Biobank

GOVERNANCE & MANAGEMENT



Consortium Committee Members

Associate Professor Geoff Lindeman
BSc(Med),MBBS, FRACP, PhD

Chair
Melbourne Health

Professor David Bowtell
BVs (Hons), BAn Sci, PhD

Peter MacCallum Cancer Centre

Professor Tony Burgess, AC
BSc (Hons), PhD, FAA

Independent Member (Research)

Mr David Fogarty
FCPA

The Cancer Council Victoria

Professor Tony Landgren
MB BS FRCPA LLB

Independent Member (Pathology)

Mrs Avis Macphee
AAIMS

Independent Member (Consumer)

Professor Peter Rogers
BSc (Hons), PhD

Southern Health

Professor Andrew Scott
MBBS, MD, FRACP, DDU

Austin Health

Ms Malar Thiagarajan
BSc, LLB, LLM, Dip. Project Management

Independent Member (Ethics)

STAFF

Victorian Cancer Biobank Staff 2006

Dr Anne Thompson Executive Officer (from 27 November, 2006)

Austin Health

Ms Carmel Murone Tissue Bank Manager
Ms Tina Leeuwrick Tissue Bank Coordinator (0.4FTE)
Ms Angela Mountain Tissue Bank Coordinator (0.6 FTE)

Melbourne Health

Ms Audrey Partanen Tissue Bank Manager, Royal Melbourne Hospital
Ms Michelle McMahon Medical Scientist, Royal Melbourne Hospital
Mr Matthew Chapman Medical Scientist, Western and Sunshine Hospitals

Peter MacCallum Cancer Centre

Ms Lisa Devereux Tissue Bank Manager
Ms Samantha Cauberg Research Assistant (0.3 FTE)
Ms Laura Galletta Research Assistant
Ms Justine Biggs Research Assistant (0.4 FTE)

Southern Health

Ms Pam Mamers Tissue Bank Manager, Monash Medical Centre and Moorabbin
Dr Sophie Bittinger Pathology Registrar (from December 2006)

HIGHLIGHTS

1 October 2005 – 31 December 2005

- Business Plan refined, with substantial input from key Consortium Members
- \$7million Grant Agreement between Minister for Innovation and Cancer Council Victoria executed
- Financial and interim governance structures and arrangements agreed and implemented in consultation with DIIRD and DHS

1 January 2006 – 31 March 2006

- Consortium agreement drafted and legal review commenced with all parties.

1 April – 30 June 2006

- Consortium Agreement executed 22 June 2006
- Inaugural Consortium Committee Meeting 10 July 2006
- Confirmation of Business Plan by Consortium Committee

1 July – 30 September 2006

- Executive Officer VCRTB appointed
- Adoption of the recommendations of the Flinders Consultancy (with only minor amendments) by the Consortium Committee on 27 Sept 2006
- Key Outcomes for Grant Agreements decided (Collection rates etc) at Consortium Committee meeting held on 9 October 2006. Agreements prepared for execution
- Agreement that all four Consortium Member Hospital sites should employ an additional Pathology Registrar funded by the VCRTB. Agreements prepared for execution
- Contribution Agreements prepared for execution

1 October – 31 December 2006

- Major update to Business Plan completed and approved by Consortium Committee at 9 October meeting
- Executive Officer VCRTB commenced employment 27 November
- Program Grant Agreements; Round 1, Tissue Collection and associated Contribution Agreements for funding executed by all Consortium Members. First quarter payments distributed to all sites
- Program Grant Agreements and associated Contribution Agreements for additional Pathology Registrar at all sites for 3 years executed by all Consortium Members. Payments to be distributed on evidence of appointment. Two Registrars appointed
- Round 2 Agreements, Tissue Collection Program Grant Agreements and associated Contribution Agreements for Tissue Collection funding signed by two Consortium Members. First quarter payment to be distributed in January.
- An Advisory Group of Tissue Bank Managers from each site formed to inform the Executive Officer of local issues during a proposed rapid expansion phase in 2007. Four meetings scheduled in 2007.

FUTURE DIRECTIONS

Staff

Two additional staff positions will be filled early in 2007 in the central office, which is located at the Cancer Council of Victoria. A Quality Assurance and Compliance Manager (QA&CM) will be appointed to ensure that the Biobank provides the highest quality biospecimens and associated data to researchers by setting and maintaining standards consistent with world's best practice. The role will involve working with the Tissue Bank Managers at all sites to ensure compliance with agreed procedures and to address issues affecting the quality and range of biospecimens available. An Administrative Officer will also be appointed to provide much needed support as the VCB moves forward.

Rapid expansion of staff numbers is also expected at each of the Tissue Bank sites during 2007. All four tissue bank sites have signed two rounds of Program Grant Agreements and associated Contribution Agreements for Tissue Collection and a third round will be circulated in January 2007. Each Agreement includes salary for the employment of a full time staff member to collect tissue samples for a period of 12 months. It is therefore anticipated that 12 new positions will be created in 2007.

Tissue Collection

The three rounds of funding that have been allocated will increase resources and expand the tissue collected at the current sites. However, it is important that the VCB continues to build relationships with the Associate Member sites to provide biospecimen products to researchers from as many tumour streams as possible. Future Tissue Collection Agreements in 2007 will support expansion to Associate Member sites.

Discussions have commenced with several associate members of the Victorian Cancer Biobank including the staff from the Royal Women's Hospital. Expansion during 2007 will provide for a staff member to be located at the Royal Women's Hospital site providing access to increased amounts of breast tissue and a new source of ovarian tissue to the VCB. This tissue will be processed into biospecimen products in the Anatomical Pathology Department at the Royal Women's Hospital then transferred to the Royal Melbourne Hospital site for long-term storage and access.

DNA from normal donors is a very important resource for cancer researchers undertaking large scale genetic investigations. Currently access to DNA from anonymous donors is unavailable. Ethics approval is being sought to enable the VCB to work with the Victorian Transplantation and Immunogenetics Service to establish DNA bank. It is anticipated that up to 1000 DNA samples will be available to researchers by the end of 2007.

Governance & Management

Access Committee

With the donation of tissue comes an expectation from both the donor and the public that the tissue will be used by researchers to advance scientific knowledge in a way that leads to improved diagnosis or treatment of cancer.

Prior to the establishment of the Victorian Cancer Biobank, each of the member tissue banks had a Tissue Bank Committee that would review each application from researchers for access to tissue to ensure that the proposed research met these expectations both scientifically and ethically. To improve accessibility and provide fast and efficient access to biospecimens, this

process will be centralised. The Consortium Committee has approved the establishment of an Interim Access Committee to develop an appropriate set of Policies and Procedures that will specify the process for application, conditions of use of biospecimens and reporting requirements. The Interim Access Committee will include two members from the Tissue Bank Management Committees of the current Consortium members.

Informatics Committee

The Informatics Committee will provide expertise and guidance to the VCB Consortium Committee regarding all aspects of informatics planning and implementation to ensure that the needs of the VCB are met. This will include advising on the planning, development and implementation of a centralised web-based informatics platform that will enable researchers to search for tissue located in any of the four tissue bank repositories and to submit requests to the Access Committee on-line. Currently, software exists at all sites to capture and store clinical data. However, further resources are required to provide for centralised access to biospecimen and clinical data and to ensure the information is accurate and up-to-date.

To avoid duplication and maximise the use of resources, the VCB will link with cancer information initiatives currently operating in Victoria. Discussions with the Bio21:MMIM project team have already commenced and will continue in 2007. The Informatics Committee will provide advice on establishing and managing links with Bio21:MMIM and other cancer information initiatives.

Membership of the Committee will include representatives from the clinical research community and the laboratory based research community with knowledge of various informatics platforms. The inclusion of an independent informatics expert on the Committee will also provide expertise for developing specifications for software products and evaluate products and services available from external providers.

Marketing and Communication

Establishing a strong stakeholder and public profile is essential to achieving the objectives of the Victorian Cancer Biobank laid out in the Business Plan and will also be important for future commercial success that will contribute to the VCB becoming financially sustainable.

The consultancy company, Science in Public is currently developing a Marketing Plan that will provide a well planned and coordinated approach to conveying our message to the community. The Plan will be submitted to the Consortium Committee for approval early in 2007.

Some communications tools and materials have already been developed including a logo and branded stationery and an Information Brochure for Prospective Donors. The website is under development and should be functional by April 2007.

FINANCIAL STATEMENTS

VICTORIAN CANCER BIOBANK

Statement of Income and Expenditure

for the period 18 December 2005 to 31 December 2006

	2006 \$
INCOME	
Income Brought Forward	-
CURRENT YEAR INCOME	
Grants	
- DIIRD	2,000,000
- DHS	200,000
Total Current Year Income	<u>2,200,000</u>
CURRENT YEAR EXPENDITURE	
Administration	4,010
Conferences	299
Consultants	18,726
Legal fees	6,356
Payroll costs	10,260
Special grants	1,516,000
Special projects	66,666
Travel	286
Total Current Year Expenditure	<u>1,622,603</u>
Net Surplus for the year	<u>577,397</u>
Balance of Net Surplus to carry forward	<u>577,397</u>

FINANCIAL STATEMENTS

VICTORIAN CANCER BIOBANK

Balance Sheet

as at 31 December 2006

	2006
	\$
CURRENT ASSETS	
Cash at Bank / Investments	1,924,397
Total Current Assets	<u>1,924,397</u>
TOTAL ASSETS	1,924,397
CURRENT LIABILITIES	
Research Grants Accrued	324,003
Total Current Liabilities	<u>324,003</u>
NON-CURRENT LIABILITIES	
Research Grants Accrued	1,022,997
Total Non-Current Liabilities	<u>1,022,997</u>
TOTAL LIABILITIES	1,347,000
NET ASSETS	<u><u>577,397</u></u>
EQUITY	
External Grants Reserve	577,397
TOTAL EQUITY	<u><u>577,397</u></u>

Cash Flow Statement

for the period 18 December 2005 to 31 December 2006

	2006
	\$
CASH FLOWS FROM OPERATING ACTIVITIES	
Receipts from government grants	2,420,000
Net (payment)/refund of Goods and Services Tax	(193,466)
Payments to research beneficiaries	(259,233)
Payments to suppliers & employees	(42,904)
NET CASH PROVIDED BY / (USED IN) OPERATING ACTIVITIES	<u>1,924,397</u>
NET INCREASE / (DECREASE) IN CASH HELD	1,924,397
Cash at the beginning of the financial year	-
CASH AT THE END OF THE FINANCIAL YEAR	<u><u>1,924,397</u></u>