1.0 EXECUTIVE SUMMARY

Established in 1998, New Zealand Blood Service (NZBS) is the only provider of blood and blood products and services to clinicians for the people of New Zealand. In addition to this primary activity NZBS also provides services for matching patients and donors prior to organ/tissue transplantation, tissue banking (skin and bone) and stem cell services and support to the New Zealand Bone Marrow Donor Registry (recruiting donors and matching patients who require bone marrow/stem cells with donors).

These services are provided free of charge to all people in New Zealand in accordance with the organisation's single enduring purpose to ensure;

Health needs of the people in New Zealand are supported by the availability of safe and appropriate blood and tissue products and related services.

Blood is collected from approximately 110,000 voluntary non-remunerated donors throughout the country either at one of our nine leased static sites (donor centres) or at temporary mobile blood drive venues up and down the country.

Eligibility criteria is available on the website http://www.nzblood.co.nz/give-blood/donating/am-i-eligible/. Approximately 4% of the population are blood donors who have donated in the last 2 years.

NZBS employs close to 600 staff. The majority are either nursing or laboratory trained. Safety is a key focus for the organisation. The organisation's national office is located in Auckland.

Funded on a fee-for-service basis, NZBS has a current annual budget of \$120.3M. NZBS works closely with its customers, the District Health Boards (DHBs) to ensure appropriate blood and blood product utilisation and availability of product at all times.

NZBS has key relationships with regulators Medsafe, IANZ (International Accreditation New Zealand) and global plasma fractionator CSL Behring in Melbourne, Australia. CSL Behring fractionate, under a toll manufacturing agreement, plasma collected in New Zealand into a range of blood products which are then returned to New Zealand for distribution and use throughout the country.

2.0 OVERVIEW

2.1 Background

New Zealand Blood Service (NZBS) was established in 1998 under the New Zealand Public Health and Disability Act 2000 and is an appointed entity pursuant to section 63 of the Human Tissue Act 2008 being primarily responsible for the performance of functions in relation to blood and controlled human substances in New Zealand.

NZBS is a Crown entity under the Crown Entities Act 2004. Pursuant to section 7 of the Crown Entities Act 2004, NZBS is required to give effect to Government policy when directed by the responsible Minister, the Minister of Health.

NZBS is also classified a public benefit entity as its primary objective is to support the New Zealand healthcare community through managing the collection, processing and supply of blood, controlled human substances and related services.

In that regard *safety is the cornerstone* of everything NZBS does and this is reflected in the quality of blood and blood products available to patients in New Zealand.

2.2 Core Functions

The core functions of NZBS are specified in section 55 of the New Zealand Public Health and Disability Act 2000 (NZPHD Act) and subsequent Gazette Notices to that legislation.

The key function of NZBS identified in the NZPHD Act is:

To manage the donation, collection, processing, and supply of blood, controlled human substances, and related or incidental matters, in accordance with its statement of intent (including the statement of forecast service performance) and (subject to section 65 of the NZPHD Act) any [Ministerial] directions given under the Crown Entities Act 2004.

NZBS adheres to the fundamental principles contained in the New Zealand Health Strategy. In particular:

- NZBS provides blood, blood products and services to healthcare providers, thus contributing to the good health and well-being of all New Zealanders throughout their lives;
- NZBS delivers timely and equitable access to blood and tissue products and related services to all New Zealanders regardless of ability to pay;
- NZBS maintains a high level of public confidence;
- NZBS involves consumers through liaison with hospitals and recipient groups;
- The special relationship between Māori and the Crown under the Treaty of Waitangi is recognised through the NZBS Māori Responsiveness Strategy; and
- As a national entity NZBS seeks community involvement on key issues through consultative processes.

2.3 Key Relationships

NZBS has relationships with a number of different stakeholder groups (other than the Minister of Health). Key relationships exist between NZBS and:

- donors;
- > DHBs and their patients;
- private hospitals;
- > other users of blood products and services;
- > the National Haemophilia Management Group;
- the Ministry of Health;
- CSL Behring, global plasma fractionator;
- patient advocacy groups (namely Leukaemia and Blood Cancer NZ, Haemophilia Foundation of NZ and Immunodeficiency Foundation of NZ)
- > Individual NZBS employees.

The expectations of these stakeholders are assessed by a variety of means including regular contact (through routine service delivery and associated activities), focus group meetings and programmes, and documented requests and requirements.

2.4 Governance

NZBS is governed by a Board appointed by the Minister of Health (see Appendix 1 for Board member profiles). Current Board members have a range of appropriate and complementary skills and experience to govern what is a very complex technical manufacturing entity.

NZBS forecasts and reports on performance to the Minister of Health through the Governance and Crown Entities function within the Ministry of Health.

The NZBS Board performs the roles and responsibilities of a Crown Entity board as defined in the Crown Entities Act 2004 and any subsequent amendments.

3.0 OPERATIONAL STRUCTURE

3.1 New Zealand Blood Service locations



NZBS was established to integrate the former hospital based blood services into a single national organisation. NZBS maintains four major hubs (Auckland, Hamilton, Wellington and Christchurch) supported by two collection co-ordinating centres (Palmerston North and Dunedin) and regional static collection sites in Manukau, Takapuna and Tauranga.

Donor Services are responsible for recruiting donors and carrying out all blood collection activities. Regular mobile blood drives are held in towns and regions across New Zealand. Approximately 880 blood drives are held each year, with 50% of donations being made at blood drives.

Technical Services are responsible for the testing and manufacture of blood and blood products including donation accreditation testing which is carried out at two sites (Auckland and Christchurch). These sites are set up to support each other in the event of equipment failure or other interruption of service including civil defence or other emergencies.

Blood donation processing occurs in Auckland, Hamilton, Wellington and Christchurch. NZBS directly manages the hospital blood banks for six major (tertiary) DHBs and provides support to all other hospital blood banks (36 in total) who utilise the recently installed NZBS electronic Blood Management System, eTraceline.

A comprehensive range of diagnostic testing and support services is also provided to DHBs and other health sector customers across New Zealand. NZBS operates New Zealand's only tissue typing service from its centralised national laboratory in Auckland. This laboratory provides key testing and assessment services to DHBs undertaking organ and haematopoietic stem cell transplants.

New Zealand's only Skin Bank is sited at the Auckland national laboratory and Bone Banks are located in Auckland, Waikato, Palmerston North, Wellington, Christchurch and Dunedin.

All facilities are leased with landlords either commercial or DHBs. The Blood Centre in Christchurch, opened in November 2014, was designed and built in partnership with Ngãi Tahu Property Limited.

NZBS maintains a refurbishment programme for its collection and processing network to ensure the network remains fit for purpose into the foreseeable future. As technologies change and the requirement for additional donors (albeit dependent on demand patterns), the programme ensures this can be accommodated in a Good Manufacturing Practice (GMP) compliant environment.

3.2 Key organisational metrics

NZBS is a demand driven organisation that is expected to operate in a financially responsible manner as defined by S51 of the Crown Entities Act 2004. NZBS receives no direct Crown funding. Rather it is required to cover all of the organisation's costs as well as capital requirements through the pricing of products and services it supplies to its customers – primarily the District Health Boards.

The 2017/18 annual revenue budget was set at \$118.45m however based on current demand patterns the current year revenue outlook is now forecast at \$117.03m.

In 2016/17 NZBS sent 66,785kgs of frozen source plasma collected throughout New Zealand to CSL Behring in Broadmeadows, Melbourne, Australia under its toll fractionation contract. This source plasma is then fractionated into a range of plasma-based products which are returned to NZBS for distribution and use in the New Zealand healthcare sector.

Medsafe regulates NZBS manufacturing and collection sites (governed by the standards of Good Manufacturing Practice (GMP). NZBS laboratories conducting medical testing are accredited and operated in accordance with IANZ (International Accreditation New Zealand) standards.

3.3 Self Sufficiency and the Hybrid Model

New Zealand historically has enjoyed a leadership position amongst blood services internationally by being self-sufficient in all major blood products and components. Self-sufficiency sees both fresh blood components and fractionated blood products utilised in New Zealand being manufactured from whole blood, plasma and platelets collected in

New Zealand. For a small, geographically remote country like New Zealand, self-sufficiency assists greatly in ensuring surety of supply.

Globally the demand for plasma products (in particular the driver for blood collection in New Zealand - Intragam-P, an immunoglobulin product used to treat immune system disorders and neurological conditions) continues to grow, albeit at a slower rate than we have seen in previous years.

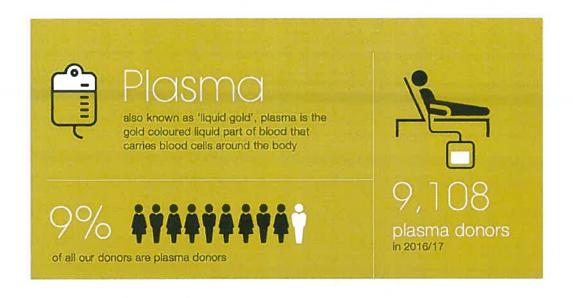
A product recall in November 2013 of certain immunoglobulin product effectively removed the underlying surety of supply for NZBS manufactured immunoglobulin product. To maintain assuredness of supply, NZBS in 2014 was required to adopt a modified hybrid model that saw the introduction of a second line commercial immunoglobulin product. (Essentially this is a product entirely clinically similar to that produced from domestic plasma but manufactured from overseas, paid plasma donations)

Supply of the second line product commenced in 2015. This second line product currently accounts for 12% to 13% of immunoglobulin product issues. Importantly its introduction has, over the intervening period, allowed NZBS to work towards reestablishing source plasma stock levels required for fractionation to pre 2013 incident levels.

By the end of the current financial year NZBS will be in a position to re-evaluate the option of returning to self-sufficiency acknowledging, however that maintaining self-sufficiency does create challenges with a generally increasing demand year-on-year for immunoglobulin products.

Indeed most other blood services around the world need to purchase plasma derived products from the international market in order to either supplement local collection/production or to totally meet demand.

NZBS is planning to review the sustainability of maintaining self-sufficiency from both the financial and long-term plasmapheresis donor availability perspectives as part of the evaluation process as to whether to maintain the hybrid model or move back to self-sufficiency.



4.0 KEY ISSUES AND ACTIVITIES

4.1 Financial sustainability

As a demand driven service within the public health and disability sector, NZBS has a constant focus on improving its performance, increasing efficiencies and containing costs. However NZBS is operating in a current environment that is seeing a reduction in overall fresh product volumes, primarily red cells, which is proving challenging.

In this financial year NZBS is operating at a budgeted deficit of \$1.86m and over the 4 year forecast period to 30 June 2021 is forecasting a cumulative deficit of \$2.53m. The decision to operate deficits has been carefully considered by the Board, noting the underlying financial viability of NZBS is maintained, primarily because an element of the forecast deficits arise from higher levels of depreciation combined with financial reporting standards compliance associated with non-cash leasing charges and foreign exchange contract reporting requirements.

A more detailed explanation of the forward outlook and compliance elements is contained in the NZBS Statement of Performance Expectations 1 July 2017 – 30 June 2018 and the 2016/17 Annual Report.

The 2016/17 Annual Report contains the latest set of publicly available financial statements and is available on the NZBS web-site www.nzblood.co.nz.

4.2 Susceptibility to changes in product mix and volume

The NZBS business model is extremely sensitive to changes in product mix, volume, fractionation yield and the Australian dollar to New Zealand dollar exchange rates.

The last 10 years has seen major shifts in the demand for fresh blood components both internationally and in New Zealand. Clinical use of red cell components has reduced significantly, with transfusion rates falling by over 25% in the last decade as clinicians respond to increasing evidence that a restrictive approach to transfusion in the perioperative setting leads to at least as good patient outcomes.

NZBS has worked closely with the DHBs to promote wise use of blood, with such programmes as "Why use 2 when 1 will do?"

The key driver for NZBS blood collection volumes is the fractionated plasma-based immunoglobulin product Intragam P. Utilisation of this product in New Zealand has increased at an average 6.2% per annum over the last 8 years. However recently growth has slowed dramatically and is currently less than 2% annual growth.

Internationally the annual rate of increase is in the order of 12 to 14%, evidencing the responsible prescribing of New Zealand clinicians.

NZBS works with the DHBs to support these changes in usage patterns as they are the right thing for patients; however they do result in significant logistical challenges for the organisation. It is crucial to NZBS to work collegially with the DHBs to ensure we understand their likely demand patterns and any changes which could impact on our collection and manufacturing planning. The aligning of the collection network with the

demand profile is ever present as NZBS works constantly to maintain efficiencies without impacting the underlying product safety and surety of product supply.

4.3 Executive Restructure

Succession planning at the Executive level was identified in 2016 as a major risk to the organisation. To address this a full review was initiated in October 2016 to determine how best to adjust the structure of the business in a way that better enabled NZBS to achieve its objectives now and into the future.

A new leadership structure was implemented during 2017 and three new Directors were appointed. This included a Director of Donor Services, Director of Technical Services and Director of Planning and Supply Chain.

Existing Executive members have been supportive of the changes and all have worked constructively together to ensure the necessary balancing of a more suitable structure and succession planning with the retention of key knowledge and skills.

The flow on from these leadership changes will continue to be a major internal focus for NZBS over the next year.

4.4 Recruitment and Retention of Blood Donors

To meet forecast demand NZBS needs to collect approximately 167,000 donations per annum. Currently less than 4% of the population are active blood donors (110,000 donors) yet 29,000 plus New Zealanders will require treatment with blood and/or blood products every year.

NZBS has an ongoing focus to promote blood donation within the community and has a Maori and a youth donor recruitment programme. Current forecasts require us to recruit over 20,000 new blood donors over the next 12 months and this will be supported by our donor acquisition programme. Responding to demand requires a focus on donors making appointments and blood-group specific donor recruitment and inventory management in order to minimise expiry.

World Blood Donor Day is celebrated on 14 June each year and is used as an opportunity to thank voluntary, non-remunerated blood donors in New Zealand and throughout the world.

4.5 Major Projects

NZBS ensures continuous improvement by undertaking projects that will enhance infrastructure and support to the New Zealand health care sector.

These major projects include;

a) eTraceline Implementation in 2017

eTraceline was the implementation of dedicated purpose built blood bank software into NZBS managed blood banks as well all other DHB managed blood banks located in hospitals throughout New Zealand.

This major capital project was approved by the Board in May 2015 and had a capital budget of \$8.1m. eTraceline is a 'best of breed' solution, specifically

designed to enhance the quality and safety of blood bank operations. eTraceline is fully integrated with the NZBS blood management system, eProgesa' and as NZBS provides 'vein to vein' service there are significant benefits in the move to specialist software which provides a functionally and geographically integrated solution.

eTraceline is used widely by other blood services such as Scotland's National Blood Transfusion Service and the Irish Blood Transfusion Service.

The project went live successfully in September 2017.

b) Relocation of the North Shore Donor Centre

With the current lease extended, relocation for this Donor Centre is planned for 2019/20 when this lease ends. A fit for purpose donor centre will be planned for Auckland's North Shore to meet future demand and collection requirements. A capital allowance of \$1.55m is allowed for this project.

c) Establishment of HPC Processing Facility in Wellington

The establishment of a Haematopoietic stem cell processing facility within the Wellington donor centre. This project has a \$400k capital allowance and is planned to be operational in mid-2018.

d) Expansion and Refurbishment of Auckland City Hospital Blood Bank

This is a joint project with Auckland District Health Board (ADHB) who as building owner has responsibility for structural matters, with NZBS responsible for the fit-out. NZBS will be engaged throughout the build process to ensure the internal space architects are able to plan and fit out concurrently. This extension and upgrade is planned for 2017/18 with a capital allowance of \$700k.

e) Auckland Donor Centre - sole site occupant

The Auckland Donor Centre based at 71 Great South Road Auckland will begin refurbishments from October 2018 when the whole site becomes sole occupancy once the current upstairs tenants move out.

The layout will incorporate LEAN methodologies and ensures the site will be configured to meet the foreseeable future needs of the blood service. National Office, the Donor Centre, Laboratories including specialist areas will all be incorporated under the one roof. This redevelopment is planned as a minimum three year programme being very dependent on NZBS ability to meet this projects funding requirements.

f) Business systems and IT infrastructure

\$3.87m is planned with key expenditure areas including a focus on the donor experience (self-administered health questionnaire). Software upgrades in blood management systems, investment into business systems and network infrastructure are also included.

g) Equipment

\$4.47m reflects the ongoing need to maintain all NZBS equipment over the supply chain. With GMP compliance requirements to be met, maintenance is critical to ensure the safety and surety of the blood supply.

5.0 Challenges

NZBS is operating in an environment of falling and volatile demand for fresh and manufactured blood products. Whilst we are focusing considerable efforts on continuous business improvement activity to ensure we maximize efficiency and productivity, this creates a challenging financial outlook.

NZBS has kept price increases to the DHBs at modest levels in recent years as directed by the Minister's Letter of Expectation but this creates an increasing financial management challenge as the pricing mechanism is the primary lever available to NZBS to maintain its financial management responsibilities that incorporate capital funding requirements.

In order for NZBS to continue to provide an excellent blood service for the people of New Zealand, we need to invest in infrastructure and technology developments as well as ensuing our quality systems, our information technology and most importantly our staff, are operating at the highest levels.

As the DHBs continue to appropriately reduce demand, this challenge will become more pressing. It may be timely in the near future to revisit the current fee for service/unit cost funding model that has been in place for the past 20 years.

We would also welcome a discussion about access to necessary capital for site and laboratory redevelopment. We do not own property or the means of production of the country's blood supply. As signaled in the next few years we will need to extensively redevelop our hub site in Auckland, which will require a major investment in a long term tenanted facility. This investment will be extremely challenging for NZBS and is a major strategic decision for the NZBS Board to consider in the near future.

NZBS is, and must continue to be, responsive to customer (DHB) demand whilst also managing manufacture and inventory holdings of biological products and reacting appropriately to international safety developments. Activities being undertaken in the current year and plans for the future aim to ensure NZBS continues to meet its legislated obligations in the most effective and efficient way possible.

NZBS is a high performing and strong organisation with enviable blood and transfusion medicine expertise. The organisation responds well to the demands of the health sector and we look forward to discussing our achievements and challenges with you in the near future.

APPENDIX 1: GOVERNANCE PROFILES

David Chamberlain - Board Chairman

David is a Principal at Melville Jessup Weaver (MJW), a leading firm of consulting actuaries in New Zealand. Prior to MJW, David was Head of Insurance at Kiwibank where he led the transformation and expansion of Kiwi Insurance Limited. He has over 25 years commercial experience in the financial services sector and has experience both as an Executive and as a Director.

Prior to joining Kiwibank in 2010, David worked as an independent consulting actuary for over 10 years. He has been an NZBS Board Member for 7 years, taking over the Board Chairman role in August 2011. As a consultant, David has advised a wide variety of clients on a wide variety of topics from strategy and investment through to financial compliance.

David has a Bachelor of Economics from Macquarie University in Sydney, is a Fellow of the New Zealand Society of Actuaries, Fellow of the Institute of Actuaries of Australia and a Chartered Member of the Institute of Directors. He is currently also Chairman of the Board of Trustees of the Medical Research Institute of New Zealand.

lan Ward - Deputy Chairman

Ian has considerable experience in the health sector. He is a recent past Board member of the Auckland District Health Board (ADHB) where he chaired the Audit and Finance Committee and was a committee member of the Board's Human Resources Committee and a member of the Hospital Advisory Committee. He was on the Board of ADHB from 2007 to 2016 as an elected person and also as a government appointee.

lan is a former Chief Executive of the Auckland Energy Consumer Trust, the 75.4% major shareholder of Vector Group Limited. Prior to that role, Ian has held Chief Executive and General Manager roles within diverse industries. He was the first General Manager of Finance and Corporate for the Auckland Regional Transport Authority (now Auckland Transport) and was the General Manager of Finance and Corporate of ADHB between 1998 and 2003.

Earlier in his career, Ian was Managing Director of Educorp Services Ltd, the company formed out of Tomorrows Schools to provide a full range of educational services to all schools in the Waikato/Bay of Plenty Region, Group Director of Change Management at Carter Holt Harvey Limited after being General Manager of the Finance Pulp and Paper Group at Carter Holt Harvey, and was the General Manager of Finance and Special Projects for the Property and Construction Sector of Fletcher Challenge Group. During his career, Ian has held a number of governance roles in the public and private sectors covering director and trustee responsibilities.

Dr Bartrum (Bart) Baker

Bart is a Consultant Haematologist and Clinical Director of the Regional Cancer Treatment Service at Palmerston North Hospital. He is an active and experienced committee member with groups including Leukaemia and Blood Foundation Medical, NZ Leukaemia Study Group and Scientific Committee and NZ Bone Marrow Transplant Study Group.

Bart is a member of the Haematology Society of Australia and New Zealand and the American Society of Hematology, and is registered with the New Zealand Medical Council as a specialist in Internal Medicine and in Pathology (Haematology).

Bart has a Bachelor of Medicine and Bachelor of Surgery with distinction from the University of Otago, is a Fellow of the Royal College of Pathologists of Australasia and of the Royal Australasian College of Physicians.

Cathryn Lancaster

Cathryn is the General Manager of McKesson Australia and New Zealand (ANZ). She is a director, senior manager and consultant, with experience in the commercial, public and healthcare sectors. Cathryn has significant experience in governance, including an elected three term Director of the New Zealand Health IT Cluster.

She is also a trustee of the Rangi Ruru Girls School Foundation Trust. Cathryn has a Bachelor of Commerce from the University of Otago, is a member of the New Zealand Institute of Directors and an associate of the Chartered Institute of Management Accountants (CIMA).

Fiona Pimm

Fiona is an independent consultant and director with over thirty years' experience in the health sector and extensive governance experience. Fiona was previously General Manager of Primary & Community Services and Maori Health at South Canterbury District Health Board.

Fiona has a PG Diploma in Public Health and MBA from Massey University. She is on the NZ Medical Council Advisory and Health & Disability Commission Consumer Advisory committees and is a member of the Institute of Directors.

Professor Peter Browett

Peter is a Consultant Haematologist at Auckland City Hospital and Professor of Molecular Medicine and Pathology within the Faculty of Medical and Health Sciences at the University of Auckland. Peter is currently a Committee Member of the Auckland City Hospital Transfusion Advisory Committee and a Board Member and Medical Advisor to Leukaemia and Blood Cancer New Zealand.

Peter is a member of the Auckland Medical Research Foundation Board and chairs their medical committee. He is also on the Board of the Cancer Society of New Zealand Auckland Division. He has also been involved in several clinical and laboratory studies related to research on blood disorders, in particular leukaemia.

Peter is a graduate of the University of Otago Medical School, and after postgraduate training in clinical and laboratory haematology in Auckland, he was a Wellcome - HRC research fellow in the Department of Haematology, Royal Free Hospital School of Medicine, London.

Victoria Kingi

Victoria is the Managing Director of her own consultancy company specialising in property asset development working with Māori land trusts and post Treaty settlement entities. She chaired the Māori Housing Advisory Committee responsible to the Associate Minister of Housing charged with developing the first National Māori Housing Strategy for the Ministry of Business, Innovation and Employment.

Victoria is a Director of Pacific Coast Retirement Village and is also the Deputy Chairperson of Nga Potiki a Tamapahore Trust - a Treaty Settlement Trust, and a trustee of Mangatawa Papamoa Blocks - a Māori Land Incorporation, both based in Tauranga.

Commercial in Confidence

NZBS Briefing for Incoming Minister November 2017

Victoria holds a Bachelor of Laws (with honours) and earlier in her legal career, Victoria worked for Russell McVeagh, Auckland, specialising in resource management and planning law and after an academic year at the University of British Columbia, Vancouver, returned to New Zealand and specialised in Trusts and estate planning with law firm Taylor Grant Tesiram. Victoria lives in Tauranga with her family and is of Nga Potiki, Te Arawa, Ngati Porou and Ngāi Tahu descent.

