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LIFE SCIENCES

Investor Presentation

Vitrafy Life Sciences Limited

ACN 622 720 254

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Introduction

Current cryogenic technologies significantly enhance patient treatments and accessibility to Life Science products that would otherwise be unavailable. Whilst cryopreservation is vital, low cellular survival rates make the process expensive, requires higher yields from patients and cannot successfully preserve certain products at all.

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Introduction

As a result, Vitrafy has developed new technology and cold chain solutions for the advancement of biomedical cryopreservation.

These include:

- Cryopreservation algorithms
- Freezing apparatus’
- Thawing apparatus’
- Smart packaging
- Tailored racking and packing solutions
- Vitrafy’s integrated supply chain management solution

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Life Sciences Cryopreservation Solution

- Vitrafy has created its own unique methodology and processing protocol to give a more precise and consistent result when cryopreserving biological material as different cell types require specific cooling rates.
- Our unique algorithm calculates the required operating conditions which then informs the Vitrafy technologies automation software for processing parameters.
- What makes our process unique is that cryopreservation and thawing can be achieved at variable rates ranging from 1°C to 1000°C per minute to the core of the product. This is important as different cell types require a specific optimal cooling and warming rates.

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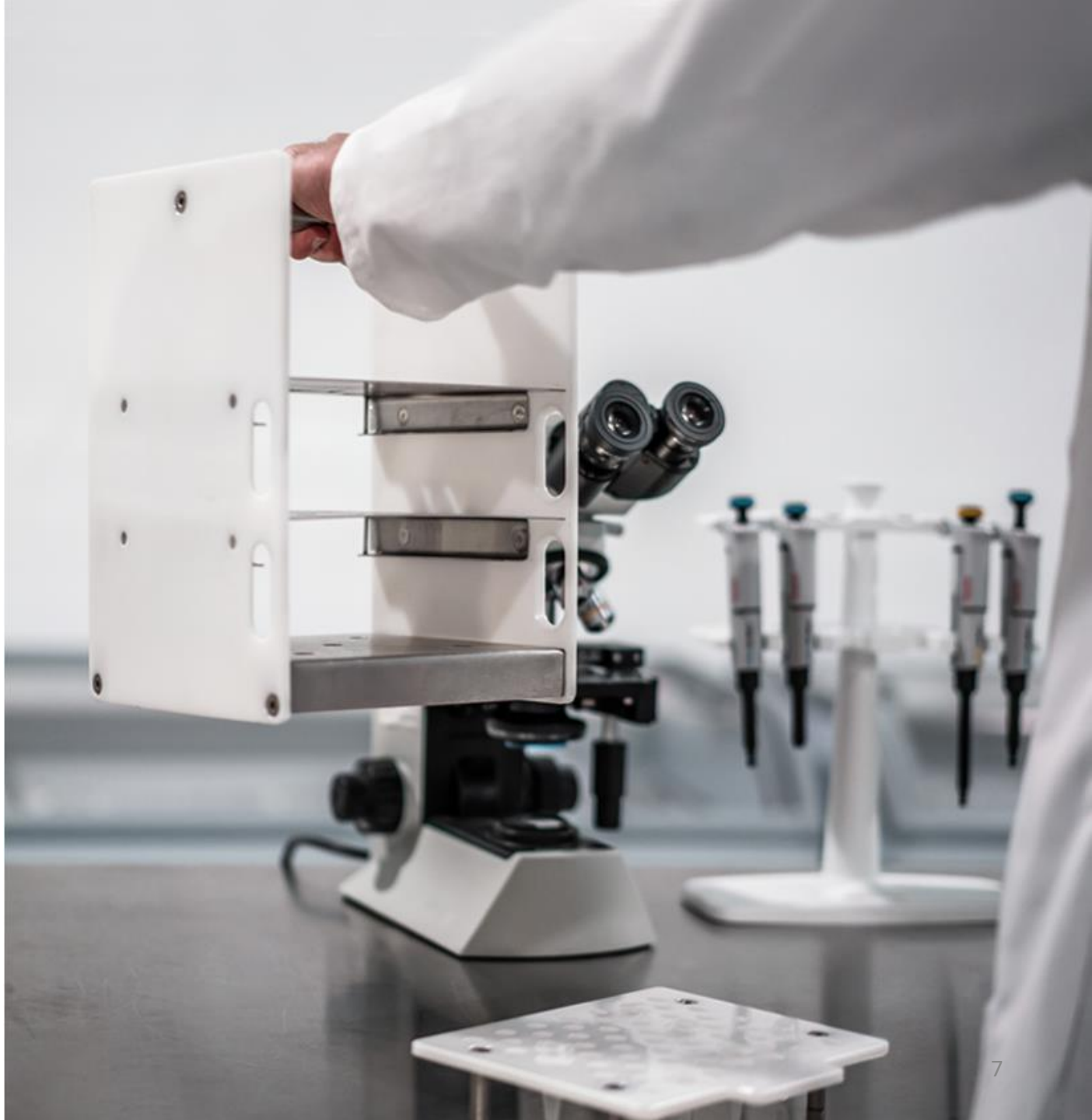

Vitrafy Results

Validation testing of the Vitrafy technology has seen significantly higher post thaw survival rates compared to current cryopreservation processing protocols.

We have now developed and completed 3 protocols each with their own operating conditions and times with the following results:

Protocol	Test Results vs Fresh Control
10% DMSO	100 replicates @100%
4% DMSO	100 replicates @98%
Zero Cryoprotectant	100 replicates @98%

Data represent numerous replicates. Cell numbers were measured by direct counting of erythrocytes (using a Scepter™ cell counter), with high cell counts suggesting an intact plasma membrane that retains normal semipermeable properties.

All cryoprotectant combinations above exceed the current American Association of Blood Banks standard, which mandates a post thaw recovery >/= 80% of the original red cells present prior to glycerolizing.

Vitrafy technologies' truly innovative advancement has allowed us to develop a protocol **for preserving biological material without the need for cryoprotectant.**

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Lifeblood Phase 1 Platelet Results

Australian Red Cross Lifeblood

- **External validation studies on the devices and algorithm**
- **Completed by Australian Red Cross Lifeblood, the country's leading blood service provider**
- **Regulatory standard for cryopreserved Platelets is >50% survival**
- **Shelf life of platelets limited to 5-7 days**
- **Constant supply shortages**
- **LifeBlood completed and analyzed with 3 different assays**
  - **Recovery 97.5% - Significant result!**
  - **Zero presence of aggregates. Less is best (When platelets undergo changes that cause activation, they begin to aggregate and will form physical clumps that can be observed with the naked eye. A lack of aggregates indicates that the platelets are still largely in a relaxed state and have not undergone spontaneous activation)**
  - **100% Visual Swirl Test, confirmed shape and functionality and ensured no activation had occurred**

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Vitrafy Technology

https://vimeo.com/767082974/4896c7dff2

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Algorithm Development

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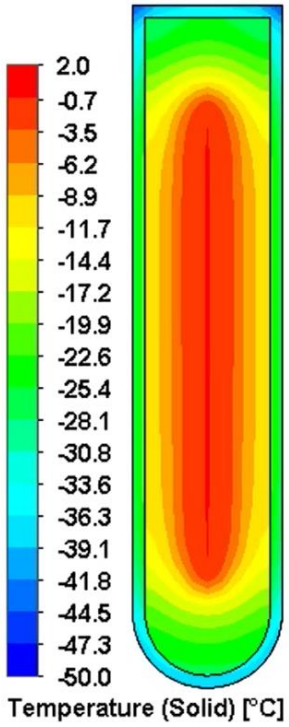
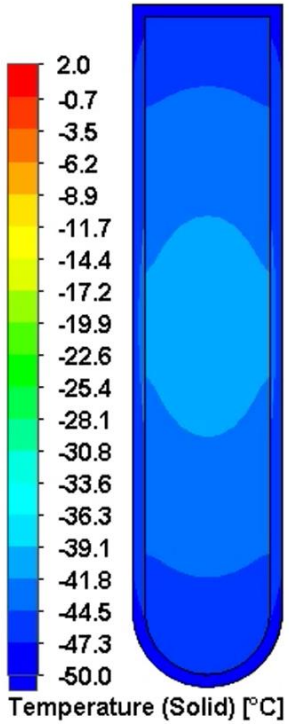
Cryopreserved Cryovial Comparison

Current Cryogenic Freezing



Controlled rate and rapid cryogenic freezing systems use a surface temperature reading to determine average temperature reduction per minute. Figure 1. demonstrates the igloo effect caused by current freezing systems. The rapid freezing creates a frozen crust on the external thermal layers of the product at -25c whilst the core is still in liquid phase +2c. The igloo effect slows down the heat removal process to the products core, thus causing cellular damage and death.

Vitrafy Freezing



The Vitrafy Cryogenic supply chain solution uses a 13 step recipe methodology which results in the optimum processing conditions for the select cell line or product. The machine operating conditions are then established and are automatically reconfigured to match the requirements to ensure a controlled and consistent preservation cycle to the core of the product. Figure 2 demonstrates the consistent temperature spread across the products thermal layers, preventing the igloo effect and resulting cellular damage and death.

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Cryovial Heat Removal Curve Comparison

Current Cryogenic Freezing

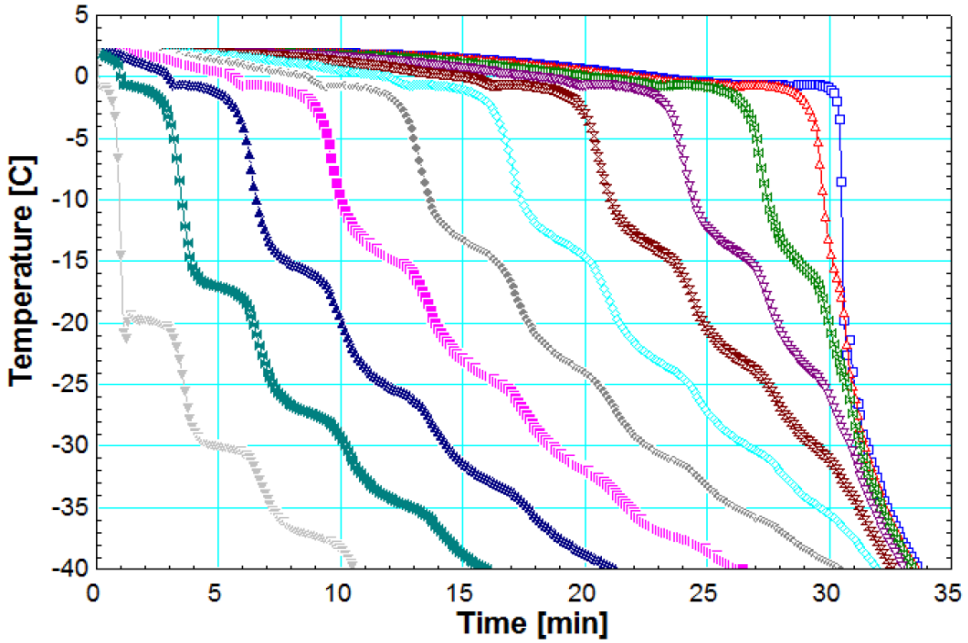

Figure 3. Represents the freezing process of the different thermal layers using a liquid nitrogen controlled rate freezing system.

Vitrafy Freezing

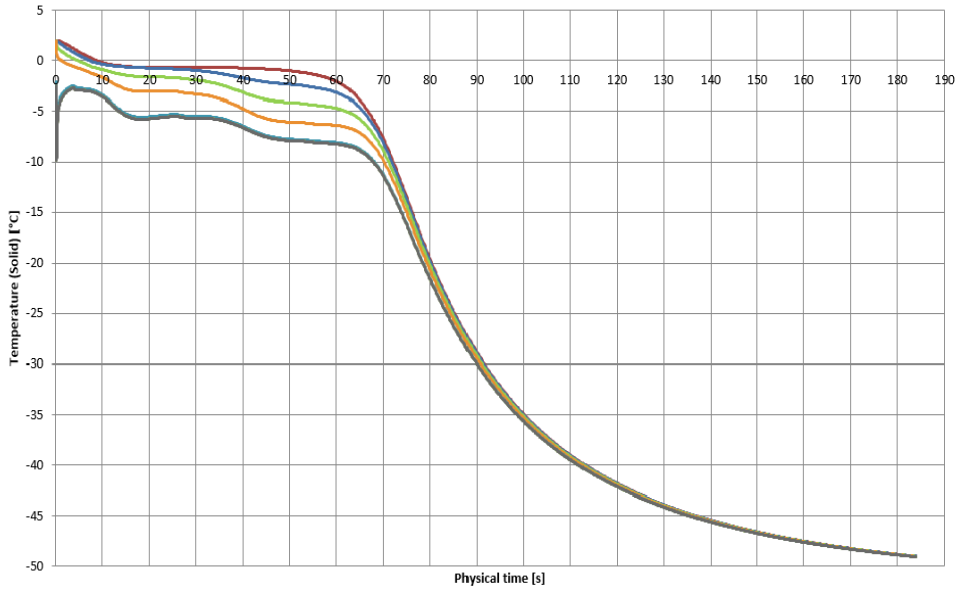

Figure 4. Represents the consistent temperature reduction across the products thermal layers using the Vitrafy 2-stage controlled rate freezing system.

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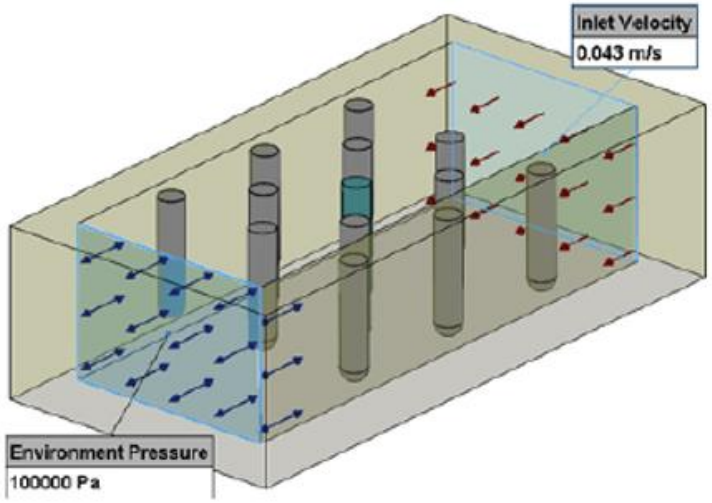
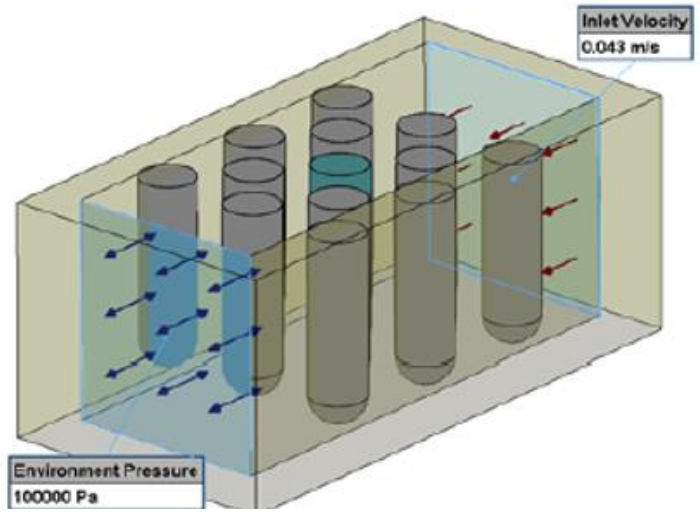
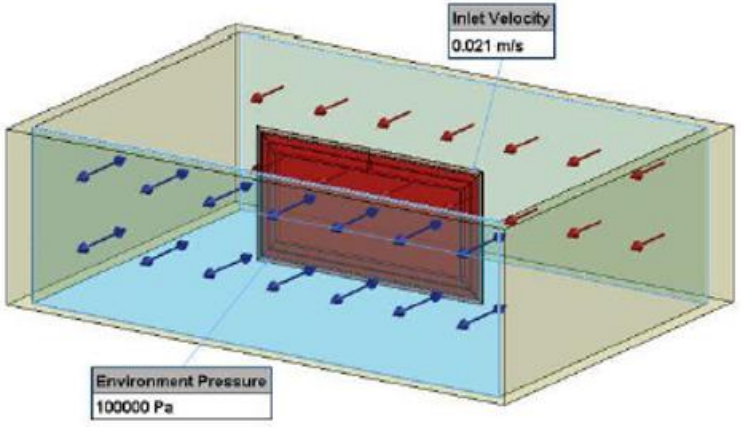
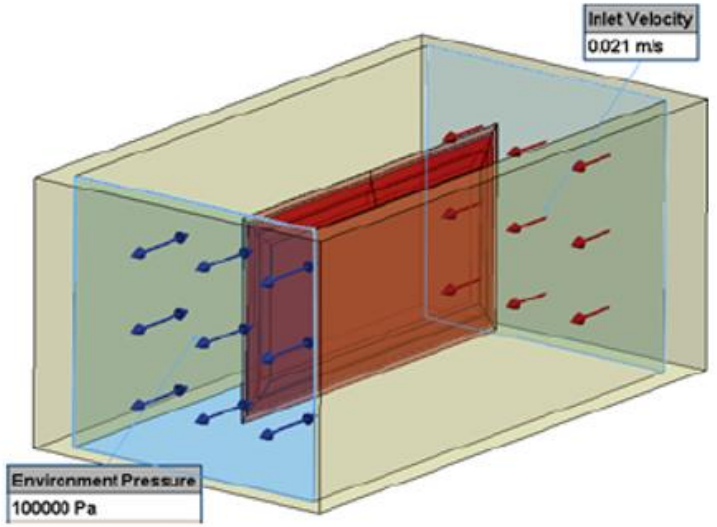
Scalability









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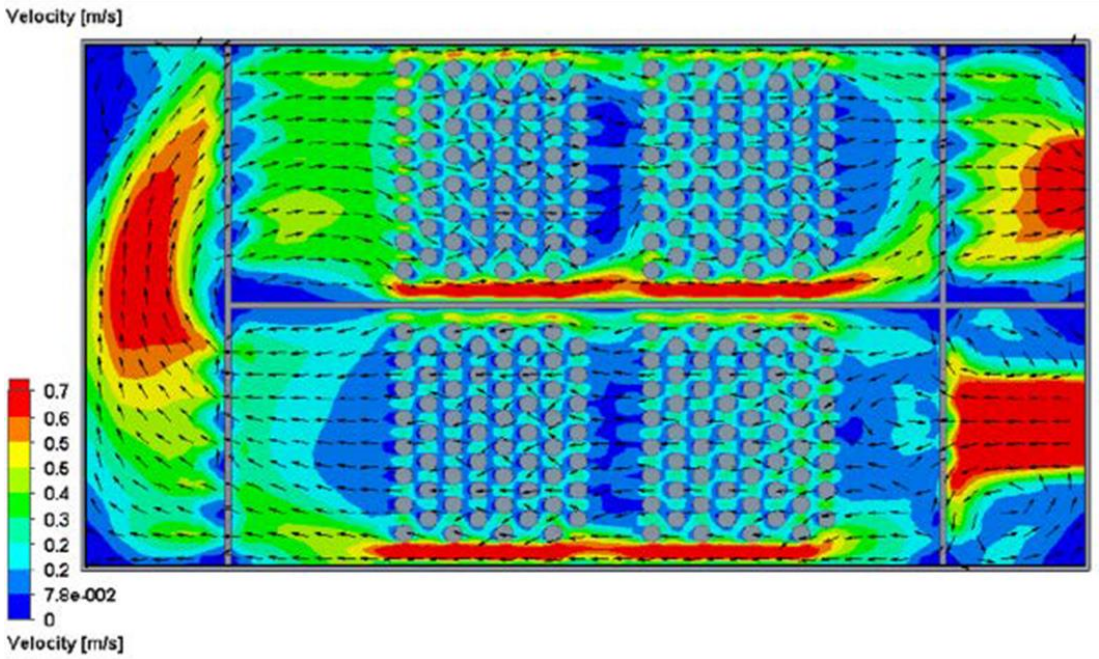
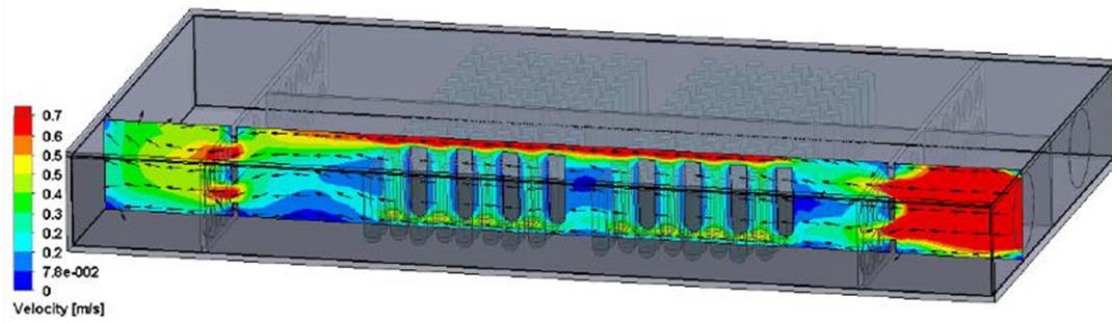
Replicable – Thermal Analysis





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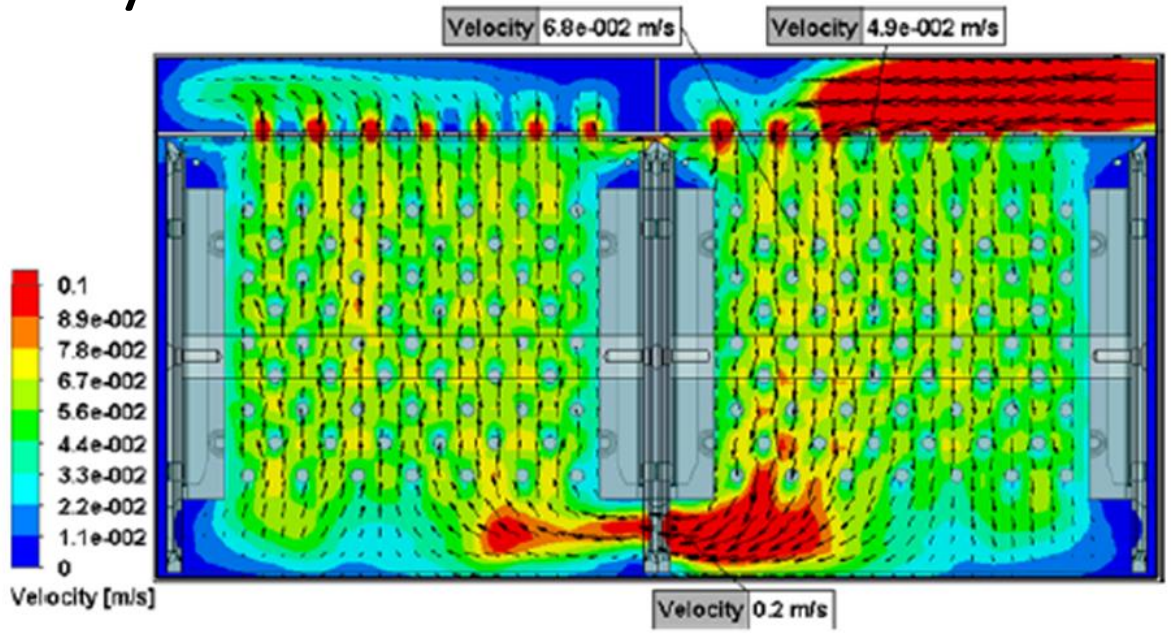

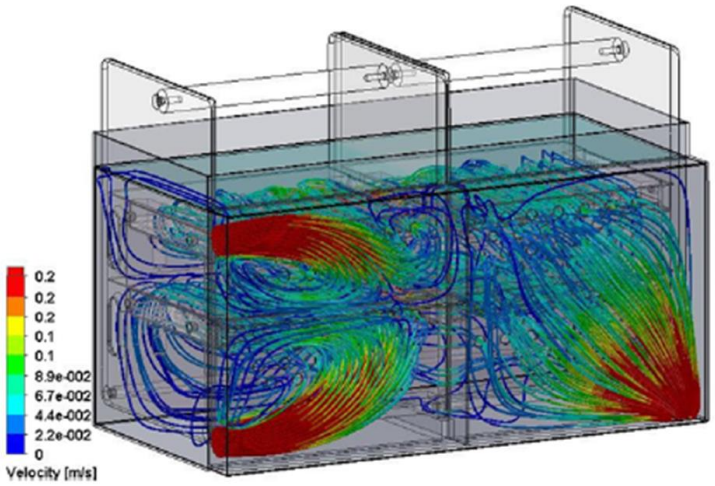

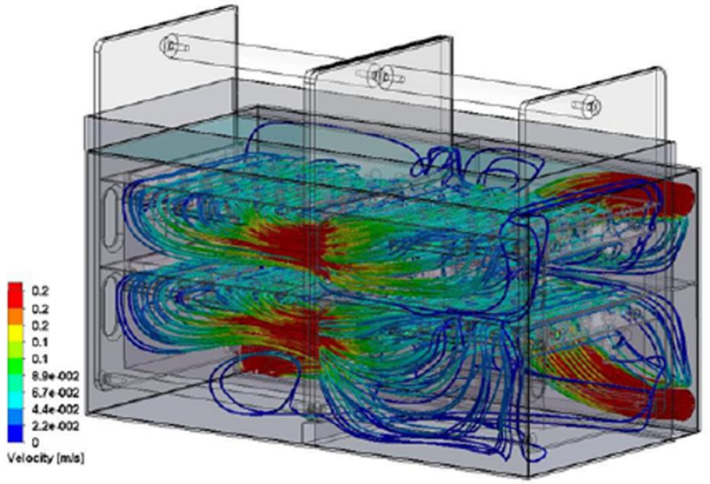

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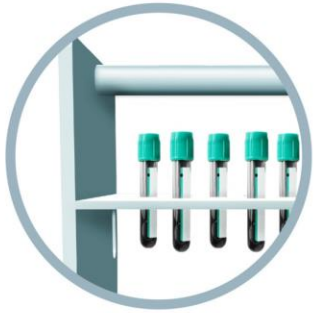
Vitrafy Life Sciences Products

BIOTHAW APPARATUS

VITRAFY LABORATORY PROCEDURES



TAILORED RACKING & PACKING

CRYOPRESERVATION APPARATUS

VITRAFY ALGORITHM

VITRAFY SMART PACKAGING

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Technology Applications of Vitrafy Technology

Our novel technology has widespread applications that can develop new products in multiple market segments with a wide range of applications. Delivering substantial licence fees and application per use royalties.

The development of Collaboration Agreements with commercial partners has been informed by detailed market analysis including assessments against our value proposition and competitive advantage and potential transaction fee royalties. Our preclinical initiative guided by our Scientific Advisory Board include:

Cellular Therapies	Mesenchymal Stem Cells and Chimeric Antigen Receptor T cells (CAR-T)
Blood Components	Whole Blood, White Blood Cells, Erythrocytes, Platelets and Plasma
Artificial Insemination	Sperm, Embryos, Blastocysts, Ovaries and Oocytes
Animal Reproductive Sciences	Artificial Insemination in Aquaculture

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Vitrafy Scientific Advisory Board

Scientific Advisory Board

Associate Professor John McBain has been appointed as the inaugural chair of the Scientific Advisory Board for Vitrafy and is also a non-executive director of the company.

Joining A/Prof Dr McBain as members of the Scientific Advisory Board is:

- **Associate Professor Dr Denese Marks**, National Research &Development Leader for the Australia Red Cross Lifeblood
- **Dr Debra Gook**, Senior Research Fellow, Head of Cryopreservation Services, Reproductive Services, MIVF & Royal Women's Hospital

The Scientific Advisory Board will serve several functions, including:

- provide strategic advice and make recommendations to the Board regarding current and planned research and development programs
- advise the Board regarding the scientific merit of technology or products
- advise the Board regarding technology applications and be involved in licensing opportunities
- provide strategic advice to the Board regarding emerging science and technology issues and trends.

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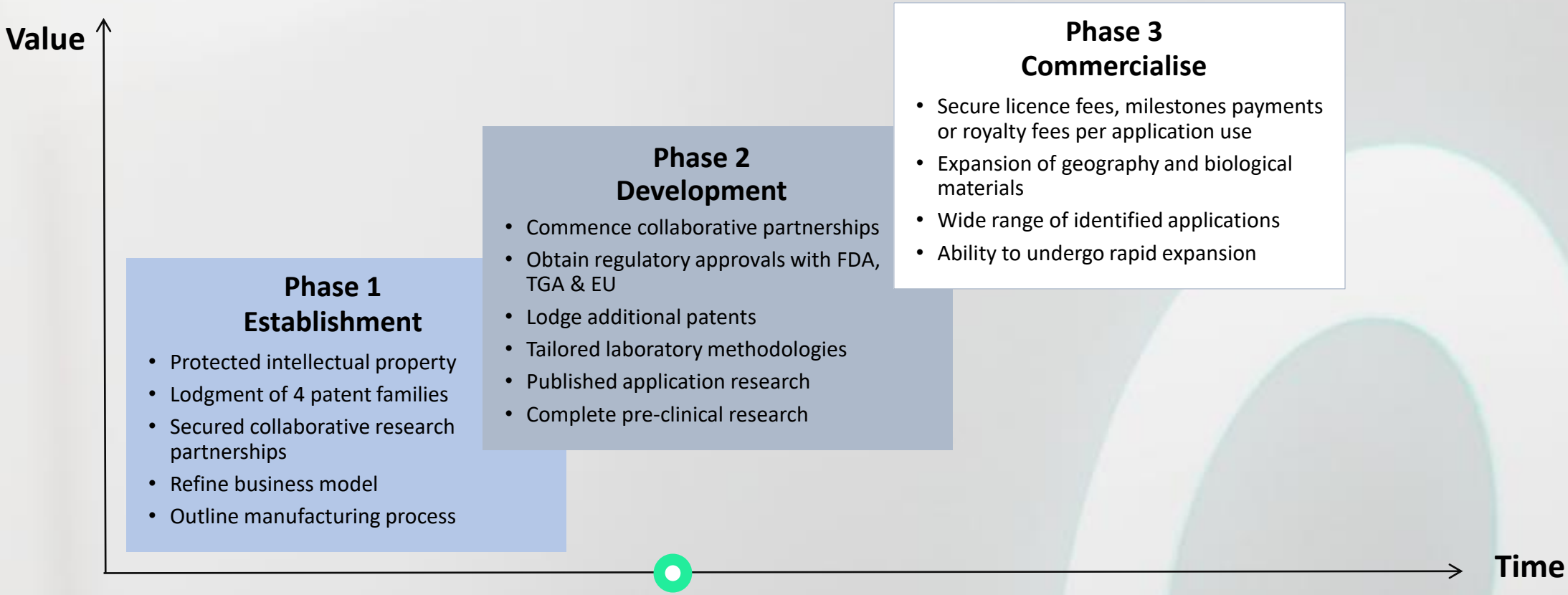
Commercialisation Plan



Commercialisation Plan allows for rapid uptake, high growth margins and delivers a global footprint

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Collaboration Partnerships Update

Australian Red Cross Lifeblood

New 5 year Collaboration Agreement executed.
Commenced clinical research on platelets.
New Material Supply Agreement executed.

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the women's
the royal women's hospital
victoria australia

Ethics approval for ovaries and sperm.
Pre-clinical sperm testing now underway in Ballarat.

HUON AQUACULTURE

Currently undertaking the cryopreservation of all Salmon Neo Male Broodstock for 2022 season.

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Bio Bridge Global USA Partnership

BioBridge GLOBAL

Texas Cord Blood Bank®

South Texas Blood & Tissue Center

GENCURE®

1. Equipment Certification to sell as standard freezing and thawing apparatus'

2. Equipment Certification for the freezing and thawing apparatus' to be used in minor product manipulations for the sale of Vitrafy specific products such as RBCs, Platelets and Stem Cells

- QA and QC program development
- Equipment validation programs for Vitrafy freezing and thawing apparatus'
- SOP and Documentation development
- cGMP compliant manufacturing assessment
- Regulatory assessment including filing where required:
  - TGA
  - FDA & EMA

3. Whole Blood
4. Umbilical Cord Blood
5. CAR T-Cells
6. Bone-Marrow Derived Stem Cell – HSC, MSC

- BMDSC optimisation on Vitrafy technology
- Publish data on optimisation outcomes
- Pre-clinical studies on BMDSC using Vitrafy technology
- Optimised Methodology and protocol development
- Phase 1 Clinical Trial with Vitrafy BMDSC
- Phase 2 Clinical Trial with Vitrafy BMDSC
- SOP and Documentation development

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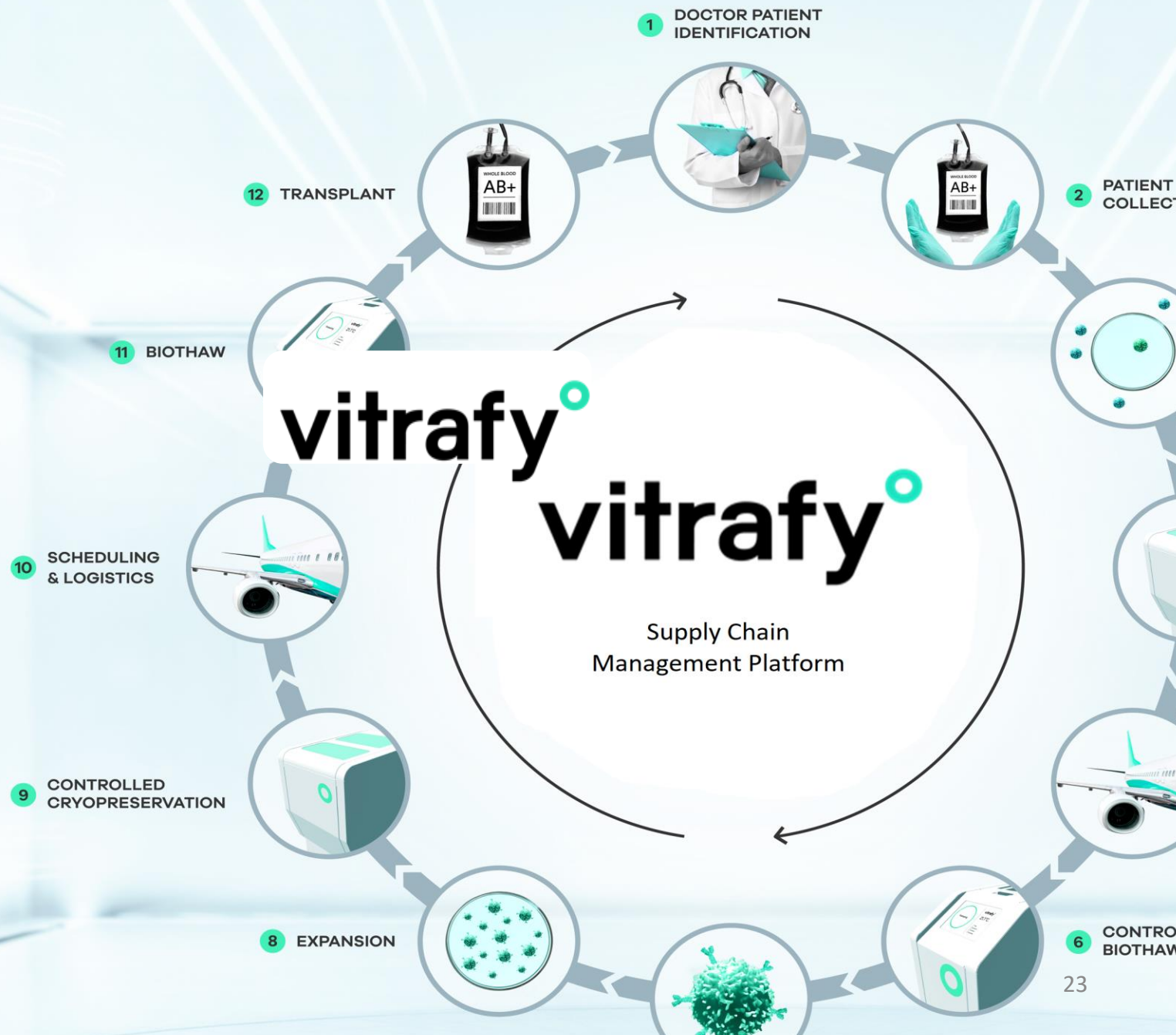
Vitrafy and Cellular Therapies

Our novel technology has widespread applications in current and emerging cellular therapies, such as CAR-T treatments.

Stem Cells and CAR-T products require successful cryopreservation of sensitive biological material that to date, has had notoriously low and inconsistent success rates of between 50-70%.



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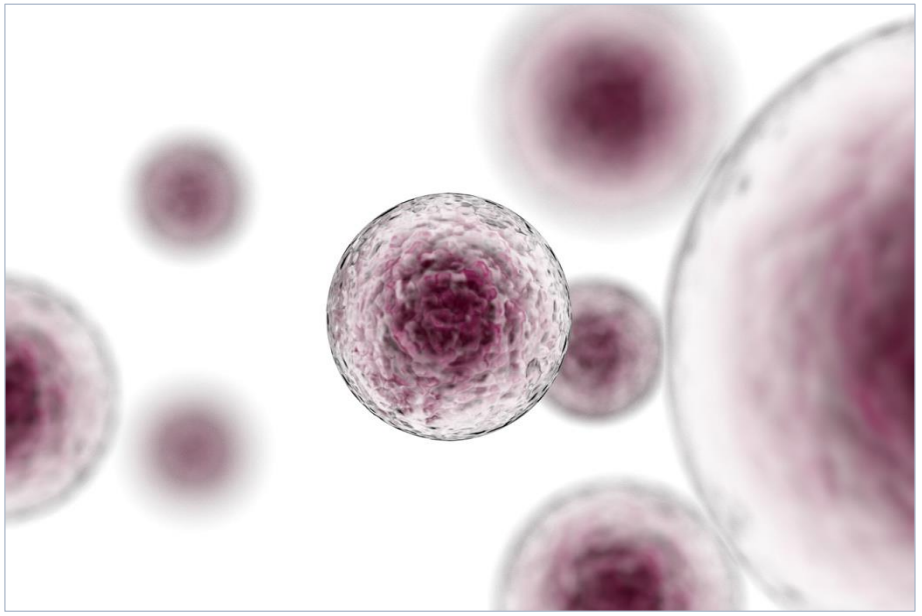
BioBridge Global: Cellular Therapies



6. CAR T-cell Supply Chain

BBG owns and operates a bio-manufacturing centre that manufacturers innovative CAR T-cells therapies.

This facility does not exist in or is currently available in commercial scale within Australia. This agreement allows Vitrafy to undertake:

- CAR t-cell supply chain optimisation on Vitrafy technology
- CAR t-cell pre-clinical studies using Vitrafy technology
- Optimised Methodology and protocol development
- cGMP compliant manufacturing assessment
- SOP and Documentation development
- QA and QC program development
- Equipment validation programs for Vitrafy CAR t-cell supply chain

Jurisdictions and Regulatory Requirements

Vitrafy will concentrate development opportunities from Australia into the USA and Europe. The company will require certification to undertake application development and to sell our medical devices. This will require Vitrafy to undertake regulatory assessment including filing with FDA, TGA and EMA. The certification process will take approximately 18-24 months.

Australian Case Study:

In Australia the Vitrafy technology is likely to be assessed by the TGA as Class IIa due to its intended purpose.

- As developer of the technology, to gain certification as a class IIa medical device, Vitrafy will undertake a TGA Conformity Assessment Certificate Part 4 – Production Quality Assurance. (CAC)
  - QA and QC program development and cGMP compliant manufacturing assessment required to complete the CAC.
- The preparation process for a CAC can be quite lengthy and complex. The TGA timeframe will be 18-24 months from lodgement of the CAC.

Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 2 rule 2.2:

2.2 Non-invasive medical devices intended to channel or store blood, etc

(1) This clause applies to:

(a) a non-invasive medical device that is intended by the manufacturer to channel or store blood or body liquids that are to be infused, administered or introduced into a patient;

and

(b) a non-invasive medical device that is intended by the manufacturer to be used to store an organ, part of an organ, or body tissue that is to be later introduced into a patient; and

(c) a non-invasive medical device that:

(i) is intended by the manufacturer to be used to channel or store a liquid or gas that is to be infused, administered or introduced into a patient; and

(ii) may be connected to an active medical device classified as Class IIa or higher.

(2) The device is classified as Class IIa.

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Regulatory Milestones

- In conjunction with Bio Bridge Global, Vitrafy has appointed renowned regulatory experts, Health Policies Associates to support in Vitrafy's regulatory process
- Health Policy Associates is Boston based and extremely well regarded for undertaking FDA and regulatory approvals with practical and efficient solutions to companies involved in new medical device technologies, pharmaceuticals, and biologics for 25 years
- Vitrafy has now completed its Quality Management System (QMS) in line with ISO 13485 standards and regulations for FDA QSR compliance
- The QMS has also been created to be compliant with EU MDR requirements, for CE certification
- Qualio has been engaged for all electronic QMS processes to ensure efficient, scalable and transferable regulatory document controls
- Det Norske Veritas (DNV) has been appointed as our Notified Body to complete Vitrafy's QMS Audit for ISO 13485 certification. The first meetings have occurred.

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Vitrafy Intellectual Property

Vitrafy's intellectual property thicket strategy has been developed and executed in partnership with one of Australia's leading intellectual property firms, Davies Collison Cave (DCC).

Together with DCC, a cumulative intellectual property thicket strategy has been developed to ensure ongoing patent filing.

Vitrafy has executed on its proactive global intellectual property filing strategy with 5 patent families covering over 100 individual claims within the portfolio with no challenges.

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Vitrafy Intellectual Property – Patent families

Official No.	Owner	Priority Date	Countries	Status
Family 1 – Method and apparatus for freezing of biological products				
2019385712	Vitrafy Life Sciences Ltd	22/11/2018	National Phase Entry AUS, CN, EU, HK, JP, NZ, USA	Application filed
Family 2 – Method and apparatus for freezing of consumable products				
PCT/AU2021/050313	Vitrafy Life Sciences Ltd	08/04/2020	International	PCT International Patent Application Filed
Family 3 – Method and apparatus for preservation of biological material				
PCT/AU2021/051517	Vitrafy Life Sciences Ltd	18/12/2020	International	PCT International Patent Application Filed
Family 4 – Method and apparatus for preservation of biological material				
PCT/AU2021/050024	Vitrafy Life Sciences Ltd	14/01/2021	International	PCT International Patent Application Filed
Family 5 – Packaging for preservation of biological material				
2021904254	Vitrafy Life Sciences Ltd	23/12/2021	Australia	Provisional Patent Application Filed

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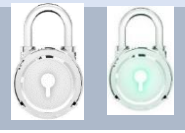
Vitrafy Intellectual Property – Trademark families

Official No.	Countries	Priority Date	Trademark	Classes
Family – Vitrafy & design				
2138226	AUS, CA, CN, EU, HK, Int'l, NZ, ROK, SG, ZA, CH, UK, USA, VT	24/11/2020		09, 10, 11, 37, 40, 42
Family – Vitrafy LIFE SCIENCES & design				
2220654	AUS, CA, CN, EU, HK, Int'l, NZ, ROK, SG, ZA, CH, UK, USA, VT	18/10/2021		16, 39, 44
Family – Vitrafy LIFE SCIENCES & design				
2221299	AUS	20/10/2021		16, 39, 44
Family – LifeChain				
2212522	AUS, CA, CN, EU, HK, Int'l, NZ, ROK, SG, ZA, CH, UK, USA, VT	21/09/2021	**LifeChain Word Mark**	09, 10, 11, 16, 39, 42, 44
Family – LifeChain & device (series)				
2237544	AUS, CA, CN, EU, HK, Int'l, NZ, ROK, SG, ZA, CH, UK, USA, VT	17/12/2021		09, 10, 11, 16, 39, 42, 44
Family – LifeChain Lock Logo (series)				
2237534	AUS, CA, CN, EU, HK, Int'l, NZ, ROK, SG, ZA, CH, UK, USA, VT	17/12/2021		09, 10, 11, 16, 39, 42, 44

Commercialisation / Licensing Opportunities

- Materially advanced the development of our commercialisation strategy (including addressable market assessments) focussing on our identified priority application areas:
    - advanced cellular therapies;
    - blood/blood components;
    - assisted reproductive technologies (ART)/IVF; and
    - animal ART.

- We have received a number of **inbound licensing enquiries**/expressions of interest from large US or global industry participants
    - preliminary discussions and analysis have commenced.

- Appionted **Mintz Levin** a Boston based law firm specialiising in Life Sciences licencing and began the implementation of a **US-based licensing process.** The Company will formally engage with interested parties via a structured process to seek to identify potential commercial terms (including milestone payments and royalty streams) before making any commitments to proceed. We have also incorporated a US subsidiary company in late August.

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LIFE SCIENCES

Vitrafy Life Sciences Limited

ACN 622 720 254

vitrafy.com