

# Investor Presentation

22 November 2022

**Capital  
Accelerating  
Global Growth**



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This Presentation is dated 22 November 2022 and has been prepared and authorised by PolyNovo Limited ABN 96 083 866 862 (PolyNovo or Company) in connection with the Company's proposed non-underwritten equity raising of up to A\$33.0 million of new fully paid ordinary shares in the Company (New Shares) comprising: (a) an institutional placement to sophisticated, professional and other institutional investors to raise up to A\$30.0 million (Placement) comprising the issue of up to 15.8 million New Shares utilising the Company's existing Placement capacity pursuant to Listing Rule 7.1; and (b) a placement to certain directors of the Company (or entities associated with them) to raise approximately A\$3.0 million subject to shareholder approval at an EGM expected to be held in January 2023 (Conditional Placement) (the Placement and the Conditional Placement together, Equity Raising or Offer).

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This Presentation includes certain historical financial information extracted from PolyNovo's audited consolidated financial statements for the year ended 30 June 2022 (collectively, Historical Financial Information). The Historical Financial Information is presented in abbreviated form insofar as it does not include all the presentation and disclosures, statements or comparative information as required by the Australian Accounting Standards (AAS) and other mandatory professional reporting requirements applicable to general purpose financial reports prepared in accordance with the Corporations Act. The Historical Financial Information.

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PolyNovo reserves the right to withdraw or vary the timetable for any part of the Offer without notice. Cooling off rights do not apply to the acquisition of New Shares.

# Important notice and disclaimers



Macquarie Capital (Australia) Limited ABN 79 123 199 548 and Bell Potter Securities Limited ABN 25 006 390 772 (Joint Lead Managers) are acting as joint lead managers to the Placement.

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The Limited Parties make no recommendations as to whether you or your related parties should participate in the Offer nor do they make any representations or warranties to you concerning the Offer, and you represent, warrant and agree that you have not relied on any statements made by a Limited Party in relation to the Offer and you further expressly disclaim that you are in a fiduciary relationship with any of them. The Limited Parties do not accept any fiduciary obligations to or relationship with you, any investor or potential investor in connection with the Offer or otherwise.

The Joint Lead Managers and their affiliates and related bodies corporate are full service financial institutions engaged in various activities, which may include (but are not limited to) underwriting, securities trading, financing, corporate advisory, financial advisory, investment management, investment research, principal investment, hedging, market making, market lending, brokerage and other financial and non financial activities and services including for which they have received or may receive customary fees and expenses. In the ordinary course of their various business activities, the Joint Lead Managers and their affiliates or related bodies corporate may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of PolyNovo, and/or persons and entities with relationships with PolyNovo. The Joint Lead Managers and their affiliates and related bodies corporate may also communicate independent investment recommendations, market colour or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments. One or more entities within the Joint Lead Managers' respective groups may provide other financial services to PolyNovo or its affiliates and related bodies corporate. The Joint Lead Managers are acting as lead managers and bookrunners to the Placement for which they have received or expect to receive fees and expenses.

Determination of eligibility of investors for the purposes of all or any part of the Placement is determined by reference to a number of matters, including legal requirements and the discretion of PolyNovo and the Joint Lead Managers. To the maximum extent permitted by law, PolyNovo, the Joint Lead Managers and their respective Limited Parties expressly disclaim any duty or liability (including for negligence) in respect of the exercise of that discretion or otherwise. Any participant in the Placement acknowledges that allocations under the Placement are at the sole discretion of the Joint Lead Managers and PolyNovo. To the maximum extent permitted by law, the Joint Lead Managers and PolyNovo disclaim any duty or liability (including for negligence) in respect of the exercise of that discretion. Furthermore, PolyNovo reserves the right to vary the timetable for the Placement (with the consent of the Joint Lead Managers) including by closing the Placement bookbuild early or extending the Placement bookbuild closing time (generally or for particular investors), without recourse to them or notice to any participant in the Placement. Moreover, communications that the Placement or Placement bookbuild is "covered" (i.e. aggregate demand indications exceed the amount of the New Shares) are not an assurance that the Placement will be fully distributed.

# Equity raise to accelerate global growth



- The business is currently performing well
- PolyNovo is profitable in the key US market and is now looking to invest in and **accelerate multiple new growth opportunities** and a **5X increase in production capacity**
- Growth is expected to be delivered through **four growth vectors**: geographic expansion, new indications, new products and capacity expansion
- Building on recent business momentum, PolyNovo is undertaking an equity raising to **continue to accelerate growth** in the US, **translate its success** in the US to the rest of the world (including the newest markets in Canada, India and Hong Kong), and **deliver new manufacturing capacity**
- Taking into account the costs associated with delivering this growth, management expect PolyNovo will be **profitable in FY24F**

# Accelerating our growth

# Strong track record of execution, now to accelerate business momentum



## Achieving record sales

- First ever A\$5m+ sales month in September, with \$5.4m sales recorded, followed by over A\$5m in October
- Record Q1 sales of A\$12.5m, up 73% on STLY

## Investing to support growth

- Building strong commercial presence in key geographies, including the US, UK, ANZ, India, Canada and Hong Kong
- Talks to accelerate entry in Japan and China

## New indications & products

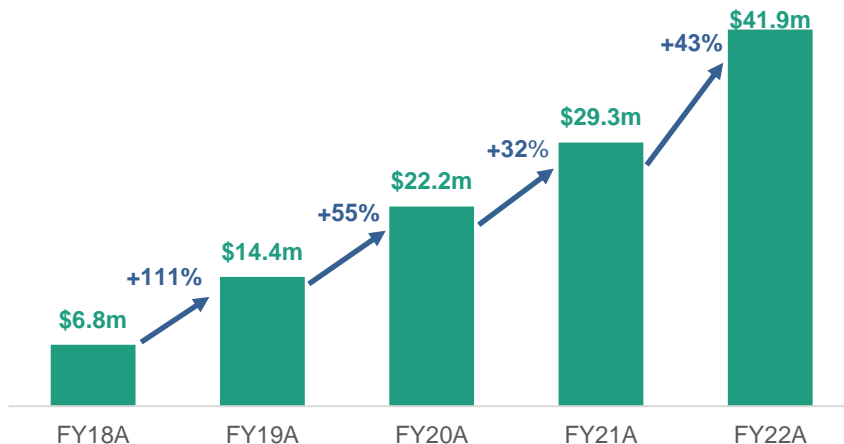
- Surgeon-led insights providing avenues for expansion in indications
- FDA 510(k) clearance received for NovoSorb MTX
- Channel expansion opportunities, i.e., Diabetic Foot Ulcer in US
- New products and new category opportunities via alliances: breast reconstruction, soft tissue reinforcement, orthobiologics (bone, tendon, ligament repair), delivery of therapeutics (anti-microbials, drug elution, cell-based therapies)

## Team additions

- CEO Swami Raote appointed in July 2022
- Appointment of Dr. David McQuillan as Chief Technical and Scientific Officer
- R&D team expansion underway

## Track record delivering YoY revenue growth

Replicating successful expansion in new geographies globally



## US business profitable standalone

Proven ability to deliver positive cashflow and sustainable profitability  
Run rate continuing in FY23



# Multiple growth vectors for global growth



## 01 Geographic expansion

- Core markets (Australia, US) to provide expertise, evidence and business model support for international expansion
- Continue to strengthen US growth trajectory, adding 40 staff over FY23F (a 54% increase)
  - Simultaneously entering Canada, Hong Kong and India, with revenue expected from late CY22
- Exploring entry into China and Japan – the global # 2 and # 3 medical device markets

## 02 New indications for NovoSorb

- NovoSorb BTM is already a leader in third degree burns in Australia and on a steep growth curve in US burns<sup>1</sup>
- Opportunity to increase TAM through access to new markets with existing products, e.g.
  - Complex Trauma reconstruction, including Paediatric indications
  - Diabetic Foot Ulcers in US
- Surgeon led insights and innovation are driving us to work with clinicians and regulators for new indications and applications

## 03 New products

- Investing in R&D capabilities to support new product ranges
- Alliances with global category leaders and academia for Clinical & Health-economics evidence
- Up-stream application and marketing, insight generation, biologic sciences, expand pre-clinical, process and product engineering, and package engineering
- Opportunity to enter breast reconstruction, soft tissue reinforcement, orthobiologics, delivery of therapeutics

## 04 Capacity expansion to satisfy growth

- New co-located facility with production, R&D and office facilities
- Designed for scale with focus on flexibility, modularity and automation
- Will service an additional A\$500m in revenue (~5x current production volumes)
- Additional investment in enabling functions e.g. HR, IT and Legal
- Total expected build cost of A\$25m, with spend predominantly incurred in FY24F



Funded by capital raising



Funded by future cash flows and/or incremental proceeds under the SPP

1. NovoSorb® BTM has FDA 510(k) clearance and is indicated for use in the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, vascular ulcers, surgical wounds, trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears) and draining wounds.

# 1) Geographic expansion

PolyNovo is actively building a commercial presence across newly launched markets including India, HK and Canada while preparing to launch into new potential markets Japan and China

## Europe

- Total UKI headcount 9, up from last year 5
- Added 31 new accounts in UKI in FY22A
- First sales to Denmark, Greece, Cyprus, Poland and Turkey in FY22A

## Canada

- 7 staff on the ground
- First sales expected late CY22

## USA

- 40 hires planned in FY23F bringing total headcount to 114

## South Africa

- Selling NovoSorb BTM since 2017
- Distribution agreement covers 5 countries

## India

- Commercial headcount of 20 FTEs by 2H23
- First sales expected in FY23F

## China

- Global #2 medical device market

## Japan

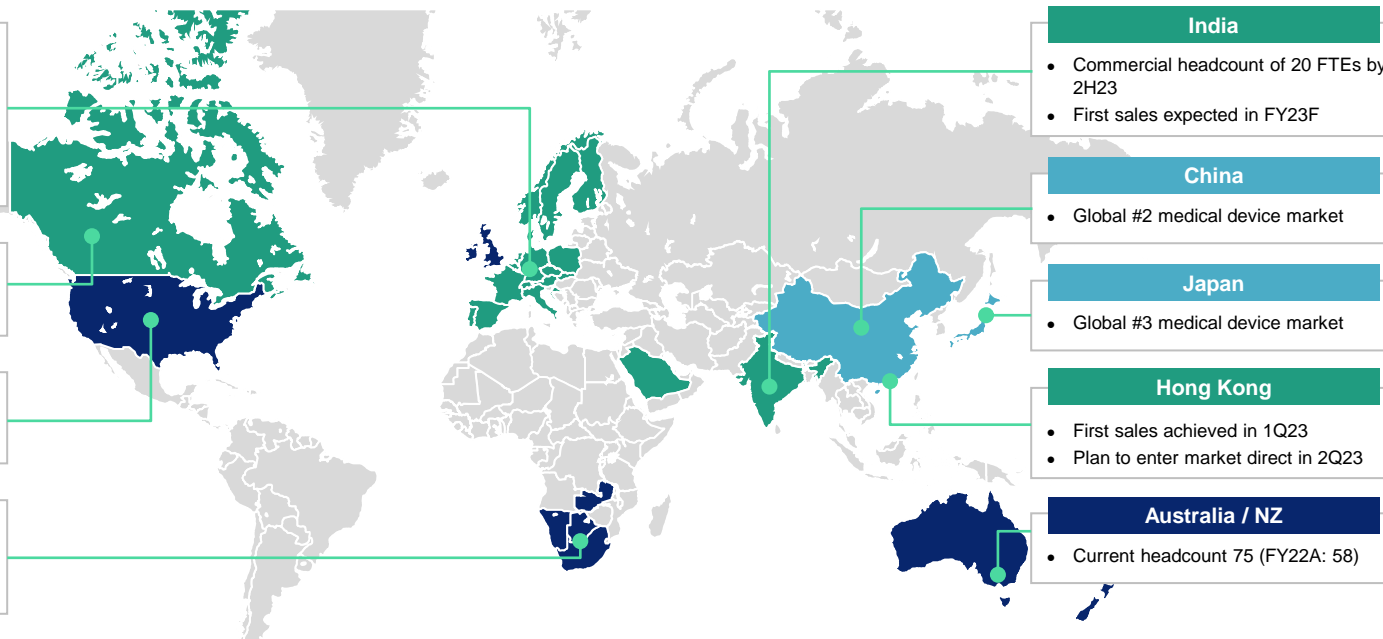
- Global #3 medical device market

## Hong Kong

- First sales achieved in 1Q23
- Plan to enter market direct in 2Q23

## Australia / NZ

- Current headcount 75 (FY22A: 58)

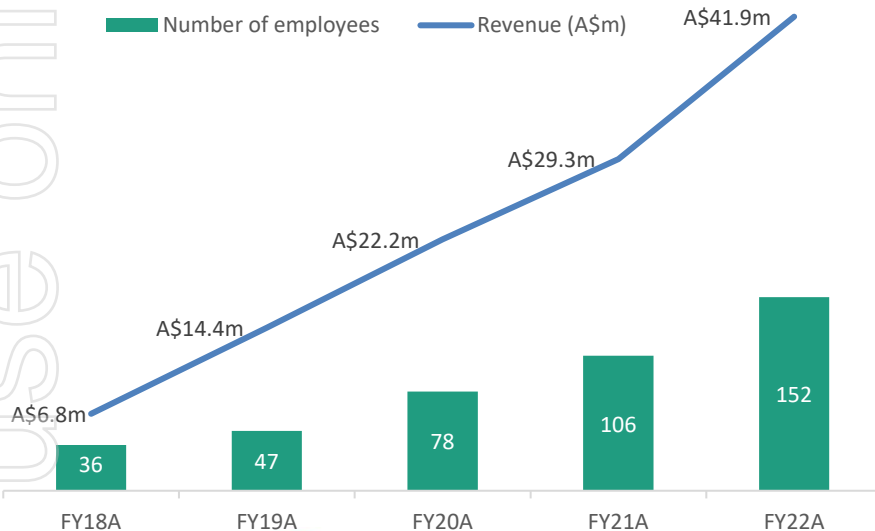
- 
- Current market
  - Entering in FY23F
  - Near term target markets

# Geographic expansion (cont.)



Increased investment in commercial capability to support revenue momentum across different geographies

	FY20A	FY21A	FY22A
<b>Global customer accounts</b>	196	293	428



In FY22A, PolyNovo added 46 staff across global markets

Increasing headcount increases sales. September and October momentum with revenue over A\$5m per month

Accelerated headcount expansion is a priority for FY23F:

- In existing markets (US / ANZ / UK)
- Establishing teams in new growth markets including India, Hong Kong, and Canada
- Expected to add 32 commercial staff in the US, and 20 in India in FY23F

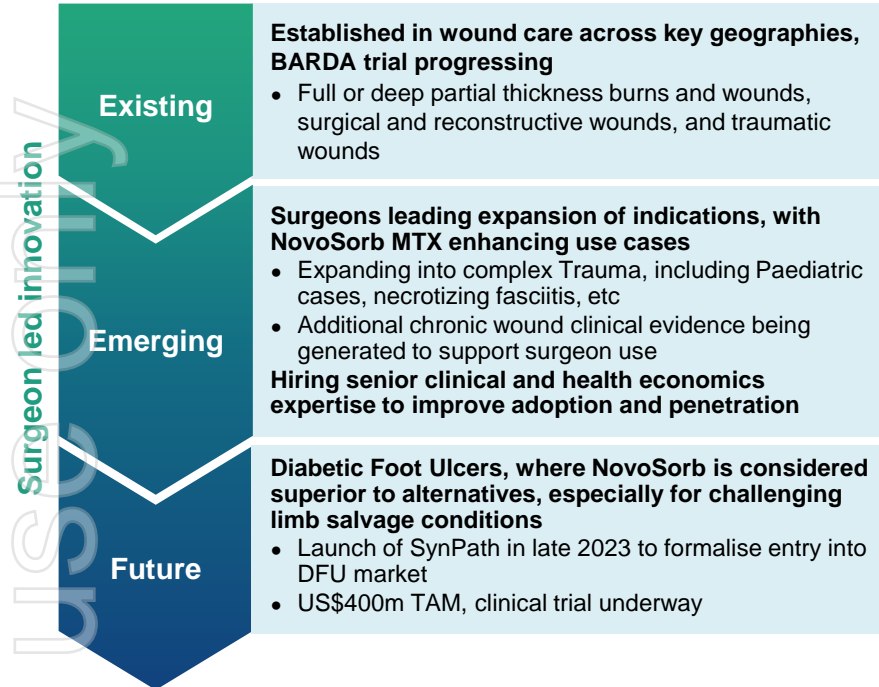
Confident correlation between headcount and revenue will be maintained

Pay back period for new geographies improving as product awareness builds and more experienced staff are attracted

# Expanding indications and new products to drive growth and broaden customer base and sales pools



## 2) New indications of NovoSorb



## 3) Leveraging technology to deliver new products

### Implantables

- Targeting the US\$2.5bn hernia and abdominal wall reconstruction market via the Syntrel family of products, and currently evaluating several design options with key opinion leaders
- Developing modified NovoSorb products for soft tissue reinforcement
- Breast reconstruction development in-house
- Exploring alliances for Orthobiologics (bone, tendon, ligament regeneration)



### Therapeutics

- Investigating NovoSorb-based products for Type I diabetes and supplying NovoSorb to Beta-Cell Technologies (3rd party) for clinical trials
- Co-Development of Composite Cultured Skin for single-stage skin replacement
- NovoSorb Drug Elution Depot (pellet), involving the integration of drug treatment into the NovoSorb polymer
- Incorporation of anti-microbials into NovoSorb polymer for controlled release for infection management



Committed to building R&D capabilities with appointment of Dr. David McQuillan, and expanding R&D team

## 4) Capacity expansion

To support accelerating business momentum and significant demand, PolyNovo intends to build a third co-located manufacturing facility to increase production efficiency and capacity

The new co-located facility is expected to dramatically increase scale and yield by incorporating modularity, flexibility and automation

- Expected to support an additional ~A\$500m of sales (~5x current capacity)
- Using the same equipment as the existing facility where it makes sense, with a focus on automation
- Separate module clean rooms for each part of the manufacturing cycle to allow multiple processes to run simultaneously

An in-house R&D lab is expected to accelerate development of new product pipeline by increasing availability of core equipment and R&D tools

Planning progress on the facility to date includes:

- Securing the required lease for the site including a rent free period
- Office fit-out expected to be delivered by May next year
- Construction costs to be incurred between FY23F to FY25F, with construction primarily over FY24F
- Total expected cost ~A\$25m



## Details of the offer and timetable

# Equity Raising summary



Offer structure and size <sup>1</sup>	<ul style="list-style-type: none"><li>Non-underwritten equity raising of up to A\$33.0m of new fully paid ordinary shares in the Company (“<b>New Shares</b>”) comprising:<ul style="list-style-type: none"><li>Institutional Placement to sophisticated, professional and other institutional investors to raise up to A\$30.0m (“<b>Placement</b>”) comprising of the issue of up to ~15.8 million new shares utilising existing Placement capacity pursuant to Listing Rule 7.1</li><li>A Placement to certain Directors of PolyNovo (or entities associated with them) to raise ~A\$3.0m subject to shareholder approval pursuant to Listing Rule 10.11 at an EGM expected to be held in January 2023 (“<b>Director Placement</b>”)</li></ul></li><li>Together, the Placement and Director Placement are the “<b>Equity Raising</b>” or the “<b>Offer</b>”</li><li>Up to ~17.4m New Shares to be issued under the Offer representing approximately 2.6% of issued capital</li><li>In addition, a Share Purchase Plan (“<b>SPP</b>”) to eligible retail investors will raise incremental proceeds of up to A\$17.0m</li></ul>
Offer Price	<ul style="list-style-type: none"><li>Raising price of A\$1.90 per New Share (“<b>Offer Price</b>”), which represents a:<ul style="list-style-type: none"><li>9.1% discount to last closing price of A\$2.09 per share as at Monday, 21 November 2022</li><li>10.5% discount to the 5-day VWAP</li></ul></li></ul>
Director participation	<ul style="list-style-type: none"><li>Certain PolyNovo Directors including Chairman, David Williams, intend to participate in the Offer through the Director Placement, committing \$3.0m</li><li>Director participation is subject to shareholder approval at the EGM expected to be held in January 2023</li></ul>
Ranking	<ul style="list-style-type: none"><li>New Shares issued under the Equity Raising will rank equally with existing shares on issue</li></ul>
Joint Lead Managers	<ul style="list-style-type: none"><li>Macquarie Capital (Australia) Limited and Bell Potter Securities are acting as Joint Lead Managers and Bookrunners to the Placement</li></ul>
Share Purchase Plan <sup>2</sup>	<ul style="list-style-type: none"><li>PolyNovo will offer Eligible Shareholders the opportunity to participate in a non-underwritten SPP to raise up to \$17.0m</li><li>Eligible Shareholders on the register at 7:00pm (AEDT) on Monday, 21 November 2022 in Australia and New Zealand will be invited to subscribe for up to \$30,000 of new shares free of any brokerage and transactions costs at the same price as the Institutional and Director Placement. Clients of eligible custodian shareholders may participate subject to conditions</li><li>PolyNovo will endeavour to maintain Eligible Shareholder’s pro-rata shareholdings in the company, while retaining the ability to scale back applications should it receive demand above \$17.0 million or to issue a higher aggregate amount, at its absolute discretion</li></ul>

Notes: 1. PolyNovo, with the agreement of the Joint Lead Managers, retains the absolute discretion to raise a smaller or larger amount for any of the component of the Offer. 2. Eligible shareholders are registered PolyNovo shareholders, as at 7.00pm (AEDT) on Monday, 21 November 2022, who have a registered address in Australia or New Zealand, do not hold PolyNovo shares on behalf of a person who resides outside Australia or New Zealand and are not in the United States or acting for the account or benefit of any person in the United States.

## Commentary

### Geographic expansion

- Additional commercial staff in US and expansion into Canada, Hong Kong and India
- Investigating additional new markets, including Japan and China

### New indications of existing products, and new products

- Fund ongoing R&D and clinical trials for commercialisation of new products and new indications of existing products
- Funded by operational cash flows and incremental proceeds anticipated from the SPP

### Manufacturing and R&D facility

- Development of a new manufacturing, R&D and office facility in Port Melbourne adjacent to current site
- Facility would accommodate next leg of growth by supporting significant increase in manufacturing capacity to ~A\$500m of sales
- Initial preparatory works ongoing with \$25m total spend expected to be incurred over FY23F to FY25F

Funded by capital raising

Funded by future cash flows and/or incremental proceeds under the SPP

## Sources and uses

Sources	Up to A\$m
Placement proceeds <sup>1</sup>	30.0
Director Placement proceeds <sup>2</sup>	3.0
<b>Total Sources</b>	<b>33.0</b>
Uses <sup>4</sup>	A\$m
Geographic expansion	6.0
Manufacturing and R&D facility	25.0
Costs of offer and working capital	2.0
<b>Total Uses</b>	<b>33.0</b>

Excludes any funds raised under the non-underwritten SPP to eligible retail investors which aims to raise up to \$17m<sup>3</sup>

## Pro forma shares and cash

Sources	Ordinary shares (m)	Net Debt / (cash) (A\$m)
Existing	661.7	4.8 <sup>5</sup>
Institutional Placement proceeds <sup>1</sup>	15.8	(30.0)
Director Placement proceeds <sup>2</sup>	1.6	(3.0)
<b>Pro-forma</b>	<b>679.1</b>	<b>(28.2)<sup>4,5</sup></b>

Excludes any funds raised under the non-underwritten SPP to eligible retail investors which aims to raise up to \$17m<sup>3</sup>

1. Maximum target Institutional Placement size. PolyNovo retains absolute flexibility with regard to the final Institutional Placement size and may upsize or downsize final allocations to successful eligible participants.
2. Based on current Director indications and intentions, subject to a shareholder approval at an Extraordinary General Meeting expected to be held in January 2023.
3. Reflects current intended cap on SPP size. PolyNovo may in its absolute discretion apply a smaller or larger cap.
4. Before transaction costs.
5. Comprises \$2.1m net cash and \$6.9m of lease liabilities.



# Indicative Equity Raising timetable



Key Event	Date <sup>1</sup>
Record Date for Eligibility to participate in SPP	Monday, 21 November 2022
<b>Trading Halt and announcement of Equity Raising</b>	Tuesday, 22 November 2022
Announcement of completion of Institutional Placement and trading halt lifted	Wednesday, 23 November 2022
Despatch of Notice of Meeting	Wednesday, 23 November 2022
Settlement of Institutional Placement Shares	Monday, 28 November 2022
Despatch SPP offer documents	Tuesday, 29 November 2022
Allotment of Institutional Placement Shares	Tuesday, 29 November 2022
SPP Opening Date	Wednesday, 30 November 2022
SPP Closing Date	Tuesday, 13 December 2022
Announcement of SPP Participation Results	Friday, 16 December 2022
Issue of New Shares under SPP	Tuesday, 20 December 2022
Trading of New Shares issued under SPP	Wednesday, 21 December 2022
Shareholder Meeting to approve Director Placement	Late January 2023
Settlement of Director Placement	Late January 2023
Allotment of Director Placement	Late January 2023

Notes:

1. Timetable is subject to change. PolyNovo reserves the right to alter the above dates at its discretion and without notice, subject to the Listing Rules and Corporations Act.

# Appendix A: Overview of PolyNovo

## NovoSorb<sup>®</sup>

- Base polymer developed by the CSIRO (Australian Government research) and spun out as PolyNovo
- Unique polymer technology, Carbamate, that is programmable for reabsorption rate and product attributes.
- Excellent biocompatibility, safety and toxicity profile.
- Biodegrades through hydrolysis and excreted through urine, respiration and macrophage activity.
- PolyNovo developed the polymer further with foaming process and new formulations

**Patented platform technology** of biodegradable polymers that can be utilised as:

- A foam dermal scaffold
- Thermoplastic extrusions
- Filaments for weaving or knitting
- A solution for spray or dip coatings of other devices
- Patents on drug and antimicrobial elution
- 47 patents granted in the family all owned 100% by PolyNovo



*Tim Moore, Principal Scientist*

## 01 Autograft

A graft of tissue from one location to another of the same individual's body.

Typically not processed

## 02 Allograft

Tissue graft from a donor of the same species.

May or may not be processed.

## 03 Xenograft

Tissue graft from a different animal species.

Typically highly processed or engineered.

## 04 Synthetic

Created from chemical or naturally occurring biocompatible substances.

Engineered.

## Full thickness wounds

**Full thickness skin grafts are often employed for full thickness burns**

Integra (IDRT)



Primatrix



Matriderm



### BTM



**BTM is the leading synthetic resorbable dermal matrix on the market**

## Superficial / chronic wounds

**Nil**

Epifix (MiMedx)\*



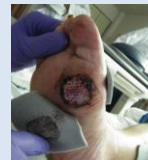
AmnioExcel



Omnigraft



Dermagraft






Pelnac



**BTM: Chronic Wounds**

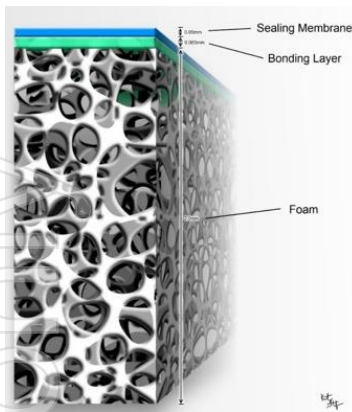


Current products		<ul style="list-style-type: none"> <li>• Bilayer biodegradable synthetic matrix used when the dermis has been lost or removed</li> <li>• Temporarily closes a wound and provides a scaffold for generation of a neodermis</li> <li>• Indications are for full or deep partial thickness burns and wounds, surgical and reconstructive wounds, and traumatic wounds</li> <li>• Increasing indications where surgeons have elected to use for skin cancer excision, scalp reconstruction, hidradenitis, and over free flap soft tissue reconstruction</li> </ul>
Current products		<ul style="list-style-type: none"> <li>• MTX is a synthetic dermal substitute comprised of NovoSorb foam providing a scaffold for wound healing across deep, complex structures such as bone and tendon</li> <li>• MTX is indicated for wounds that do not require temporising or protection from contraction, and there is a clear clinical need for NovoSorb MTX</li> <li>• It is indicated in cases where wound contraction and reduced time to healing are preferred, such as diabetic and venous ulcers, and smaller traumatic or post-surgical wounds</li> <li>• Total addressable US market of AU\$500m (in and outpatient)</li> <li>• Received FDA 510(k) clearance for MTX in September 2022</li> </ul>
Near term product launch		<ul style="list-style-type: none"> <li>• Designed to promote organised healing by providing a porous network of biodegradable synthetic polymers which act as a template to support the proliferation of vital cells involved in tissue repair</li> <li>• SynPath is indicated for chronic wounds such as diabetic foot ulcers and venous leg ulcers which can advance quickly, and if not treated promptly may necessitate amputation</li> <li>• Total addressable US market of US\$400m (in and outpatient)</li> <li>• Launch in US market once reimbursement is established circa late 2023</li> </ul>

PolyNovo are targeting a number of indications outside of burns, supported by NovoSorb MTX and SynPath:

- ✓ **Trauma**
- ✓ **Complex reconstructions (including paediatrics)**
- ✓ **Diabetic and venous foot ulcers / limb salvage**
- ✓ **Breast augmentation / re-constructions**
- ✓ **Hernias**

# When BTM is placed in a wound



## Sealing Membrane

Temporary, transparent polyurethane membrane designed to physiologically close the wound and limit vapor loss.

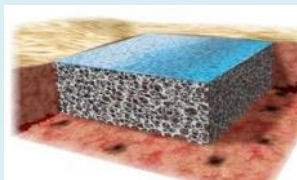
## Bonding Layer

Adhesive layer which bonds the foam and sealing membrane together.

## Foam

Semi-reticulated open foam that is biocompatible and biodegradable.

1



## NovoSorb BTM applied to debrided wound bed

The wound is 'physiologically closed', limiting contraction and risk of infection.

2



## NovoSorb BTM fully integrated

Full thickness tissue deposited within the foam. Once integrated, the seal is ready for removal.

3



## Sealing membrane removed

Neo-dermis is ready for final closure.

4



## Method of closure is the Surgeon's clinical choice

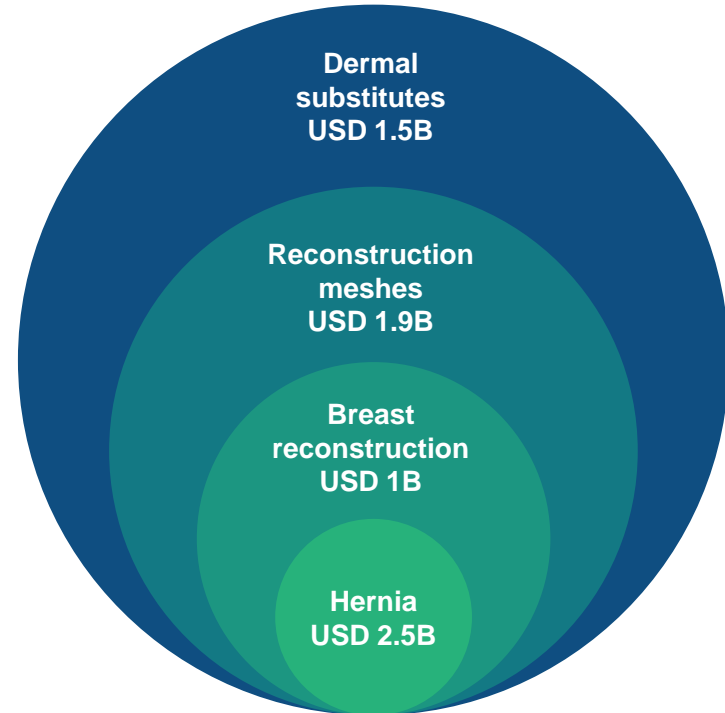
Large areas best closed with a split skin graft  
Small areas closed under moist dressing.

## **NovoSorb BTM is currently on sale**

- Unique biodegradable purely synthetic
- Market expansion for the use of dermal scaffolds

## **Pipeline development – a platform technology**

- Hernia devices preparing for manufacturing scale up with equipment purchases and factory fit out
- Breast product portfolio in evaluation phase prior to pre-clinical evaluation
- Drug Elution 5 drugs at initial exploration stages for mix/extrusion/consistency. Output is good requires further R&D resources to develop robust elution test data
- Beta Cell Technologies - Diabetes treatment with islet cell implants into a BTM dermal depot. BTM works well in pig studies with Islet cells secreting insulin. Further development of the Islet cell processes is underway to look for scaling the opportunities



## Appendix B: Key risks



## RISK FACTORS

As with any share investment, there are risks associated with an investment in the Company. The numerous risk factors are both of a specific and general nature. Some can be mitigated by the use of safeguards and appropriate systems and controls, but some are outside the control of the Company and cannot be mitigated.

This Section 1 identifies and highlights some of the risks that potential investors should consider prior to acquiring shares in the Company. However, the following is not, and does not purport to be, a comprehensive statement of all relevant risks and is not listed in order of importance. Potential investors should seek their own financial or other professional advice in relation to the risks and must make their own assessment regarding an investment in the Company.

### 1 Specific risks

#### (a) COVID-19 Risk

Due to the COVID-19 global pandemic, there are a number of additional risks faced by PNV and its businesses. These include the risk of:

- PNV or its manufacturing partners being unable to operate their factories due to lockdown or mandatory quarantine, impacting supply of products;
- PNV and its supply chains being interrupted due to lockdown or mandatory quarantine, impacting supply of products;
- PNV not being able to effectively manage its workforce during any periods of lockdown or mandatory quarantine, impacting on its ability to execute on its business strategy;
- PNV's access to customers being restricted, customers of PNV ceasing to operate and PNV not being able to collect outstanding receivables or customer materially adjusting trading terms, impacting PNV's net revenue; and
- a general downturn in the global economy due to the COVID-19 pandemic causing customers to reduce purchases, impacting on the overall sales of PNV.

#### (b) Business Strategy Execution

PNV's success will depend on its ability to successfully execute its business strategy. PNV's future growth, profitability and cash flows depend on the ability of PNV's management to successfully execute its business strategy, which is dependent on a number of factors, including its ability to:

- develop its portfolio through new product development and market execution;
- innovate and develop new products that are appealing to consumers;
- build and maintain sufficient production capacity (on time and within budget) and maintain this capacity to service demand;
- continue to expand its distribution channels within existing geographies to increase market presence, brand recognition and sales;
- successfully expand into priority international markets;
- expand margins through sales growth, the development of higher margin products and supply chain integration and efficiency initiatives;
- successfully execute on joint business plans with key customers to grow sales with select business partners; and
- effectively manage capital investments and working capital to improve the generation of cash flow.

There can be no assurance that PNV can successfully achieve any or all of the above initiatives or anticipated time frames. The failure by PNV to successfully execute its business strategy could have a material adverse effect on the Company's business, financial condition and results of operations.

## (c) Competition Risk

The innovative medical devices market is highly competitive, and if PNV's customers and partners are unable to compete effectively, by for example introducing comparable products, the Company's results may suffer. PNV faces competition from companies throughout the world. Some of these competitors have greater resources than PNV and may be able to respond more effectively to changing business and economic conditions. Competition in the innovative medical devices market is based on functionality compared with existing treatments, pricing of products, quality of products and packaging, perceived value and quality of brands, innovation, promotional activities, advertising, editorials, and other activities. PNV cannot predict the timing and scale of its competitors' actions in these areas or whether new competitors will emerge in the medical devices market, including competitors who offer comparable products at more attractive prices. In addition, further technological breakthroughs, new product offerings by competitors, and the strength and success of competitors' marketing programs may impede PNV's growth and the implementation of its business strategy. PNV's ability to compete also depends on the following factors:

- the continued strength of its products and brands;
- ongoing growth and innovation in the medical devices segments that PNV operates in;
- the success of PNV's branding, execution and integration strategies;
- the successful management of new products;
- successfully entering new markets and increasing penetration in existing geographies;
- the success of business acquisitions; and
- its ability to protect the Company's intellectual property, and utilise it to create value and support its business strategy.

## (d) Product Safety and Liability

Product safety or quality failures, actual or perceived, or allegations of product contamination, even when false or unfounded, could tarnish the image of PNV's brands and could cause consumers to choose other products. Allegations of contamination or other adverse commentary on product safety or suitability for use by a particular consumer, even if untrue, may require PNV to recall a product from all of the markets in which the affected product was distributed. Such issues or recalls could negatively affect the Company's profitability and reputation.

If PNV's products are perceived to be defective or unsafe, or if they otherwise fail to meet customer or regulators' expectations, the Company's relationships with customers could suffer, the appeal of one or more of its brands could be diminished, and the Company could lose sales or become subject to liability claims. In addition, safety or other defects in PNV's competitors' products could reduce consumer demand for the Company's products if consumers view them to be similar. Any of these outcomes could result in a material adverse effect on PNV's business, financial condition and results of operations.

## (e) Counterparty Risk

As a manufacturing and distribution company, PNV is heavily reliant on its main customers, suppliers and strategic partners.

Inputs for PNV's products consist of raw materials and packaging components and are purchased from various third party suppliers. The loss of multiple suppliers or a significant disruption or interruption in the supply chain could have a material adverse effect on the manufacturing and packaging of PNV's products. Increases in the costs of raw materials or other commodities may adversely affect the Company's profit margins if higher costs cannot be passed on in the form of price increases or unless the Company can achieve further cost efficiencies in its manufacturing and distribution processes.

In addition, failure by PNV's third party suppliers to comply with ethical, social, product, labour and environmental laws, regulations or standards, or their engagement in politically or socially controversial conduct, such as animal testing, could negatively impact their reputations. Any of these failures or behaviours could lead to various adverse consequences, including damage to PNV's reputation, decreased sales and consumer boycotts.

## **(f) Reliance on Key Customers**

A substantial portion of PNV's revenue is derived from certain customers or customer groups both in Australia and overseas. The loss or impairment of any of these relationships for any reason, a material reduction in prices or deterioration in trading terms would have an adverse effect on PNV's financial performance.

More generally, there is a risk that PNV may fail to retain customers for a number of reasons, including pricing, competition or a failure to meet consumer expectations of its products.

## **(g) Reputational Risk**

PNV's failure to protect its reputation, or the failure of the Company's partners to protect their reputations, could have a material adverse effect on the image of PNV's brands.

PNV's ability to maintain its reputation is critical to the image and consumer perception of its various products. PNV's reputation could be jeopardised if it fails to maintain high standards for product quality and integrity or if the Company, or the third parties with whom it does business, do not comply with regulations or accepted practices. Any consequential negative publicity may reduce demand for PNV's products.

Failure to comply with local laws and regulations, to maintain an effective system of internal controls or to provide accurate and timely financial information could damage PNV's reputation.

PNV depends on the reputations of its third party clients, which can be affected by matters outside of the Company's control. Damage to PNV's reputation or the reputations of its third party clients could have a material adverse effect on PNV's results of operations, financial condition and cash flows, as well as require additional resources to rebuild the Company's reputation.

## **(h) Business Disruption**

PNV is engaged in developing, manufacturing and distributing innovative medical device devices for a number of medical applications, utilising the patented bioabsorbable polymer technology NovoSorb. As a result, PNV is subject to the risks inherent in such activities, including industrial accidents, environmental events, strikes and other labour disputes, disruptions in supply chain or information systems, loss or impairment of PNV's manufacturing facility(ies), product quality control, safety, licensing requirements and other regulatory issues, as well as natural disasters, pandemics, border disputes, acts of terrorism, and other external factors over which PNV has no control. The loss of, or damage to, the PNV manufacturing facility could have a material adverse effect on PNV's business, results of operations and financial condition.

## **(i) Growth Risk**

Should the Company's growth accelerate at a higher rate than anticipated, the Company may, through lack of availability of materials or packaging, inability to scale production in a timely manner, lack of manufacturing capacity, lack of suitable labour or other unforeseen circumstances, be unable to supply its products in a timely manner to meet the demand of its customers. Should this occur the Company may risk the loss of either third party manufacturing clients or suffer a reduction in the customer base for its own products. Such events could have an adverse effect on both the reputation of the Company as well as its financial results.

## **(j) Reliance on Key Management**

PNV, and each of its businesses, depend substantially on its key management, the loss of whose services might significantly delay or prevent the achievement of its business strategy.

The ability of PNV to retain and attract qualified individuals is also critical to its success. PNV may not be able to attract and retain suitable individuals currently or in the future on acceptable terms, or at all, and the failure to do so may adversely affect PNV's business.

## **(k) Access to Equity and Debt Funding**

Volatility in the financial markets could have a material adverse effect on PNV's ability to equity or debt fund its business.

PNV's ability to raise additional funds will be subject to, among other things, factors beyond the control of the Company and its Directors, including cyclical factors affecting the economy and share markets generally.

In addition, a deterioration in global financial markets could impact risk appetite among lending institutions which may impact PNV's ability to renew existing loan facilities or enter into new loan facilities.

The Directors can give no assurance that future funds can be raised by the Company on favourable terms, if at all.

## **(l) Impairment of Intangibles**

PNV has a substantial amount of intangible assets on its balance sheet relating to goodwill and identifiable intangible assets. Under the relevant accounting standards PNV is required to annually test for impairment all indefinite life intangible assets. If this annual testing revealed that some or all of PNV's intangible assets are impaired to a level below their carrying value, PNV would be required to write down the value of those intangible assets. Such write downs could have a material adverse effect on PNV's financial position.

## **(m) Regulatory and Legislative Risk**

PNV's business is subject to numerous laws and regulations in Australia and overseas. Changes in these laws and regulations, including their interpretation or enforcement, that affect, or will affect, the Company's business or products, including changes in accounting standards, tax laws and regulations, environmental or climate change laws, restrictions or requirements related to product content, labelling and packaging, regulations or accords, trade rules and customs regulations, could adversely affect PNV's financial results.

Regulation is specific to each geographic region. There are many important differences in regards to the suitability of key ingredients for specific markets and this can pose a risk to product registration across different jurisdictions.

Failure to remain up to date with these various regulatory requirements and any regulatory action or enforcement may adversely affect PNV's financial position.

## **(n) Intellectual Property Infringement**

PNV's commercial success depends at least in part on its ability to operate without infringing, misappropriating or otherwise violating the trade marks, patents, copyrights and other proprietary rights of others. PNV cannot be certain that the conduct of its business does not and will not infringe, misappropriate or otherwise violate such rights. As PNV gains greater visibility and market exposure as a public company, third parties may allege that PNV's products, services or activities infringe, misappropriate or otherwise violate their trade mark, patent, copyright or other proprietary rights in an attempt to gain a competitive advantage. Defending against allegations and litigation could be expensive, take significant time and divert management's attention. PNV may also be required to pay substantial damages or be subject to court orders prohibiting the Company and its customers from selling certain products or engaging in certain activities.

If PNV operates its business in a way which infringes, misappropriates or otherwise violates the trade marks, patents, copyrights and proprietary rights of others, this could have a material adverse impact on the Company's business, financial condition and results of operations.

## **(o) Insurance Coverage**

PNV currently has in place what it believes are adequate levels of insurance for property, general and product liability, directors and officer's liability, and worker's compensation to protect PNV from potential losses and liabilities. There is a possibility that events may arise which are not adequately covered by existing insurance policies. In this case the Company may suffer adverse effects to its financial results as well as to the value of its brands. The Company cannot guarantee that its existing insurance will be available or offered in the future. An inability of the Company to secure such cover in the future could restrict the ability of the Company to conduct its business, and this could have a negative impact on the financial results of the Company.

## **(p) Risk of Litigation, Claims and Disputes**

PNV is and may in the future be subject to litigation, claims and disputes in the course of its business, including competitor disputes, consumer disputes, supplier disputes, employment disputes, contractual disputes, disputes with governmental agencies or authorities or regulators, indemnity claims, and occupational and personal claims. Any such matters could involve prosecution, defence, and settlement costs, and consume management time in the dealing with any such litigation, claims and disputes.

## **(q) Climate Change**

There has been an increased frequency of natural disasters globally in recent years and it is expected that this trend will continue in the medium to long term.

PNV is exposed to a number of potential climate change related risks which include:

- increases in operating costs of assets due to carbon-pricing policies or other market mechanisms;
- disruption to PNV's access or increase in price of raw materials used in PNV's products as result of climate changes and extreme weather events;
- interruption to operations or supply chains from climate changes and extreme weather events; and
- general economic downturn caused by or impacted by climate change causing consumers to reduce discretionary spending, including consumption of PNV's products.

The occurrence of any of these risks could result in asset impairment, lost revenue, downturn in overall sales and have an adverse impact on the financial position of PNV.

## **(r) Unforeseen Expenditure Risk**

PNV's future growth is dependent on having adequate capital available to fund its business strategy. PNV expects that the proceeds from this Capital Raising will provide sufficient capital resources to enable PNV to achieve its stated business strategy.

Should PNV require additional funding, there can be no assurance that additional funds will be available on acceptable terms or at all.

## **(s) Increased input costs**

Any unexpected large increase in the cost of labour, raw materials, freight, energy and key consumables could have a material impact on PNV's operation and financial performance if these costs cannot be passed on to customers.

## **(t) Foreign Exchange Rate Fluctuations**

Fluctuations in currency exchange rates may negatively impact PNV's financial position and operating results.

Exchange rate fluctuations may affect the costs that PNV incurs in its operations. The main currencies to which PNV is exposed are US dollars and the Euro. The exchange rates between these currencies and the Australian dollar in recent years have fluctuated significantly and may continue to do so in the future.

A lower Australian dollar may increase the costs of PNV's ongoing and future capital expenditure programs, and may increase the costs of input materials to PNV. A higher Australian dollar may lead to a lower Australian dollar value for sales denominated in foreign currencies.

## 2 General Risks

### (a) Market and an investment in Shares

The market price of PNV's shares will fluctuate due to various factors, many of which are non-specific to PNV, including the number of potential buyers or sellers of PNV shares on the ASX at any given time, recommendations by brokers and analysts, Australian and international general economic conditions (including as a result of the impacts of COVID-19), inflation rates, interest rates, changes in government, fiscal, monetary and regulatory policies, changes in law, fire, flooding, extreme weather events, natural disasters, global geo-political events and hostilities, acts of terrorism, state of emergency declarations, outbreaks of pandemics, outbreaks of war, and investor perceptions. These factors may cause PNV shares to trade at a lower price than the Issue Price under the Placement.

### (b) General Economic Conditions

The trading price of PNV shares may be adversely impacted by various factors, including new or changed governmental measures, business closures, lockdowns, quarantines, travel and other restrictions and resultant impacts on economies and financial markets. The historic share price performance of PNV provides no guidance as to its future share price performance.

Any deterioration in the domestic and global economy may have a material adverse effect on the performance of PNV's business and PNV's share price. It is possible that new risks might emerge as a result of Australian or global markets experiencing extreme stress, or existing risks, may manifest themselves in ways that are not currently foreseeable. The equity markets have in the past and may in the future be subject to significant volatility.

### (c) Dividends

Any decisions regarding the payment of dividends in respect of PNV's shares is determined at the discretion of PNV's board of directors, having regard to relevant factors, which include PNV's available profits, cashflow, financial condition, operating results, future capital requirements, covenants in relation to financing agreements, as well as economic conditions more broadly. There is no guarantee that a dividend will be paid by PNV in future periods or, if paid, paid at historical levels.

### (d) Liquidity risk

PNV is a listed entity. Therefore the ability to sell PNV shares will be a function of the turnover of the PNV shares at the time of sale. Turnover itself is a function of the size of PNV and also the cumulative investment intentions of all current and possible investors in PNV at any one point in time.

### (e) Risk of Dilution

Current shareholders in PNV who do not participate in the Offer as per their entitlement will have their percentage shareholding in PNV diluted. Investors may also have their investment diluted by future capital raisings or issues of new equity securities by PNV.

PNV may issue new equity securities in the future to finance acquisitions or pay down debt which may, under certain circumstances, dilute the value of a shareholder's interest in PNV.

# Appendix C: Selling restrictions

This document does not constitute an offer of new ordinary shares ("New Shares") of the Company in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the New Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

## **Canada (British Columbia, Ontario and Quebec provinces)**

This document constitutes an offering of New Shares only in the Provinces of British Columbia, Ontario and Quebec (the "Provinces"), only to persons to whom New Shares may be lawfully distributed in the Provinces, and only by persons permitted to sell such securities. This document is not a prospectus, an advertisement or a public offering of securities in the Provinces. This document may only be distributed in the Provinces to persons who are "accredited investors" within the meaning of National Instrument 45-106 – Prospectus Exemptions, of the Canadian Securities Administrators.

No securities commission or authority in the Provinces has reviewed or in any way passed upon this document, the merits of the New Shares or the offering of the New Shares and any representation to the contrary is an offence.

No prospectus has been, or will be, filed in the Provinces with respect to the offering of New Shares or the resale of such securities. Any person in the Provinces lawfully participating in the offer will not receive the information, legal rights or protections that would be afforded had a prospectus been filed and receipted by the securities regulator in the applicable Province. Furthermore, any resale of the New Shares in the Provinces must be made in accordance with applicable Canadian securities laws. While such resale restrictions generally do not apply to a first trade in a security of a foreign, non-Canadian reporting issuer that is made through an exchange or market outside Canada, Canadian purchasers should seek legal advice prior to any resale of the New Shares.

The Company as well as its directors and officers may be located outside Canada and, as a result, it may not be possible for purchasers to effect service of process within Canada upon the Company or its directors or officers. All or a substantial portion of the assets of the Company and such persons may be located outside Canada and, as a result, it may not be possible to satisfy a judgment against the Company or such persons in Canada or to enforce a judgment obtained in Canadian courts against the Company or such persons outside Canada.

Any financial information contained in this document has been prepared in accordance with Australian Accounting Standards and also comply with International Financial Reporting Standards and interpretations issued by the International Accounting Standards Board. Unless stated otherwise, all dollar amounts contained in this document are in Australian dollars.

Statutory rights of action for damages and rescission. Securities legislation in certain Provinces may provide a purchaser with remedies for rescission or damages if an offering memorandum contains a misrepresentation, provided the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's Province. A purchaser may refer to any applicable provision of the securities legislation of the purchaser's Province for particulars of these rights or consult with a legal adviser.

Certain Canadian income tax considerations. Prospective purchasers of the New Shares should consult their own tax adviser with respect to any taxes payable in connection with the acquisition, holding or disposition of the New Shares as there are Canadian tax implications for investors in the Provinces.

Language of documents in Canada. Upon receipt of this document, each investor in Canada hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the New Shares (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.



## European Union

This document has not been, and will not be, registered with or approved by any securities regulator in the European Union. Accordingly, this document may not be made available, nor may the New Shares be offered for sale, in the European Union except in circumstances that do not require a prospectus under Article 1(4) of Regulation (EU) 2017/1129 of the European Parliament and the Council of the European Union (the "Prospectus Regulation").

In accordance with Article 1(4)(a) of the Prospectus Regulation, an offer of New Shares in the European Union is limited to persons who are "qualified investors" (as defined in Article 2(e) of the Prospectus Regulation).

## Hong Kong

WARNING: This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the "SFO"). Accordingly, this document may not be distributed, and the New Shares may not be offered or sold, in Hong Kong other than to "professional investors" (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the New Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to New Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

## New Zealand

This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (the "FMC Act").

The New Shares are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

# International Offer Restrictions (cont.)



## Norway

This document has not been approved by, or registered with, any Norwegian securities regulator under the Norwegian Securities Trading Act of 29 June 2007 no. 75. Accordingly, this document shall not be deemed to constitute an offer to the public in Norway within the meaning of the Norwegian Securities Trading Act. The New Shares may not be offered or sold, directly or indirectly, in Norway except to "professional clients" (as defined in the Norwegian Securities Trading Act).

## Singapore

This document and any other materials relating to the New Shares have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of New Shares, may not be issued, circulated or distributed, nor may the New Shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part 13 of the Securities and Futures Act 2001 of Singapore (the "SFA") or another exemption under the SFA.

This document has been given to you on the basis that you are an "institutional investor" or an "accredited investor" (as such terms are defined in the SFA). If you are not such an investor, please return this document immediately. You may not forward or circulate this document to any other person in Singapore.

Any offer is not made to you with a view to the New Shares being subsequently offered for sale to any other party in Singapore. On-sale restrictions in Singapore may be applicable to investors who acquire New Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

## Switzerland

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