## HEALTH+MEDICAL RESEARCH

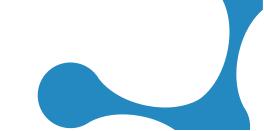


# **Medical Devices Fund**

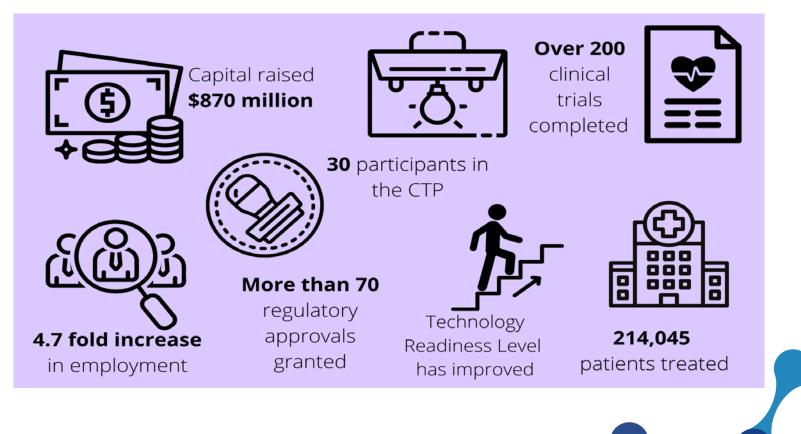
**Online Information Session** 

15 February 2022





## **Medical Devices Fund - Outcomes**





# Agenda

#### Item

1. Welcome and Introduction

2. About the Medical Devices Fund and the Expert Panel

3. Expectations when reviewing an application

4. Question and Answer

5. Wrap up









# Medical Devices Fund and the Expert Panel

Prof Hugh Durrant-Whyte Chair of the Expert Panel NSW Chief Scientist and Engineer







# **Expert Panel Expectations**

## Mark Phelps Expert Panel member VP, Customer Software and Business Development, Cochlear



# What should you keep in mind?

- 1. You are making the case for an investment not just a healthcare technology
- 2. You need a clear business model, value proposition and path to market
- 3. Seek to provide us with compelling evidence not grandiose claims
- 4. Be realistic with your financial projections consider risk as well as potential
- 5. Ensure you have the right Advisers, Capital/Corp Structure and Governance
- 6. Get your Intellectual property strategy, ownership and filings in order



Please be succinct and fact-based in your submission **GOOD LUCK!** 





# Past recipient journey

## David Lane Medical Devices Fund recipient AllVascular



# allvascular

"Improving the quality of life and clinical outcomes for cancer patients through novel, precision delivery solutions"



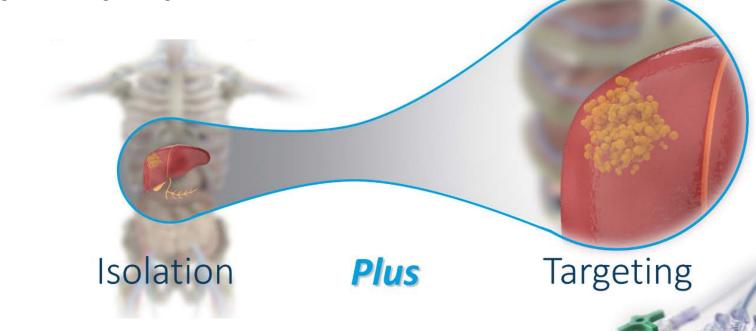
David Radford, CEO, +61 407 218 922 davidradford@allvascular.com

David Lane, CCO, +61 415 091 558 david@allvascular.com





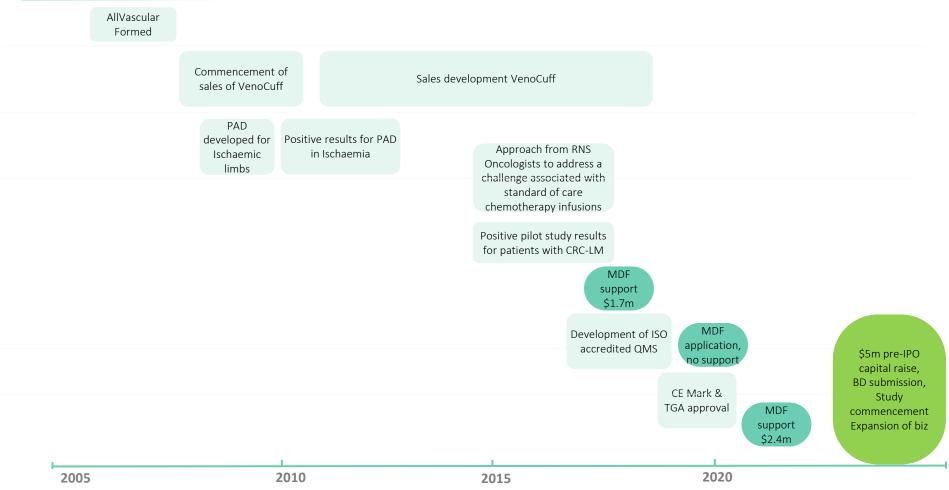
The AVAS<sup>®</sup> enables a new approach for the delivery of existing and future chemotherapies by isolating, targeting and infusing the organ.



- First clinical application: Treatment of Colorectal Liver Metastases (CRCLM)
- Second clinical application: Treatment of Pancreatic Cancer

### **Company History**





## Experience Growing the Company

#### Develop a Medical Advisory Board/ If possible a BOD

- Use the MAB and their extended network to validate the technology and market
- Use the BOD to challenge the strategic plan/direction

#### Build a Quality System Tailored to Your Business

- Quality System is the foundation of your business
- Don't let it run your business. It should assist in de-risking the product and business

#### Manufacturing

- Prototype as much as possible
- Build redundancy in manufactures
- Get in the clean room and understand every process even if it's outsourced

#### Regulatory Plan/ Reimbursement plan

- What are the Instructions for Use?
  - How does that drive regulatory strategy what data do you need?
  - Reimbursement strategy what data do you need?
  - Consider variations in different geographies US very different to AUS

#### Sound Study Design

- Commercial value not just scientific
- Make your Primary Endpoint achievable
- Design your study to make it easy to enroll patients

#### Develop a Strong IP Portfolio

- Choose an experienced IP attorney
- Develop a protective strategy around your core IP

#### Grants and support

- There are many grants and financial support available. Apply for all applicable
- MDF is the best available...go hard !
- Use the federal R&D Return

#### Strategic Plans drive Company direction

- Ensure that your strategic plan is grounded in reality
- Recalibrate often



## **MDF Process-Tips**

#### First Stage

- First impressions count
- Invest the time and focus to present the best possible submission
- Use it to validate and confirm your strategic plan
- Assume that you are the expert and selling your project to investors
- Talk to prior recipients and understand what works/doesn't
- Prepare a professional video if funds allow. Ensure the key messages are clear and communicated strongly

#### Second Stage

- The detail behind the project....budgets and forecasted cash requirements
- What are the outcomes that can be delivered in the timeframes
- Does the submission dovetail and develop on from the initial submission
- Focus and detail are critical at this stage-spend the time to review all work critically.
- Use external eyes to critique if required

#### **Final Stage**

- Use the best presenter to ensure you capture the audience
- Keep the presentation short and focused-no waffle
- Answer the questions with examples and supporting evidence
- Remain grounded and "real". There are always alternatives-be prepared to discuss weaknesses/challenges in the product/therapy



## **MDF Value to a Company**

#### Reputational

- Credibility that financing from NSW Health brings from the MDF process
- Highly credentialled Review Panel with clinical and commercial experience have assessed and passed your product for funding
- Networks within NSW health and clinically-makes life a little easier

#### Funding

- Enables completion of targeted projects
- Non dilutive capital
- Provides a potential tick of approval for further external investors
- Repeatable process as the Company develops

#### Process

- Brings focus to the Company's aspirations/goals
- Great foundation for future investment pitches
- May identify further opportunities for development



#### A Great Program

- All early stage medical device companies should consider the MDF grant
- There are no negatives nor investment other than time
- Positive outcomes generate value far in excess of the financial investment

#### Process

- Focus
- Confirms the direction of the Company
- Easily managed in the day to day running of the business
- Iterative and challenges thought processes

#### Downsides

• NONE

AllVascular has been awarded the grant twice and aided another Company in its submission. There are resources available to help/coach you through the process and we are happy to help with the development of med tech in NSW





# **Questions?**





HEALTH+MEDICAL RESEARCH

# **Further information**

www.medicalresearch.nsw.gov.au/medical-devices-fund

t +612 9391 9228

e MOH-OHMRGrants @health.nsw.gov.au



@MedResearchNSW