HEALTH+MEDICAL RESEARCH

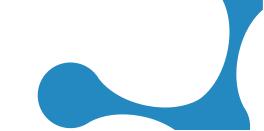


Medical Devices Fund

Online Information Session

15 February 2022





Medical Devices Fund - Outcomes





Agenda

Item

1. Welcome and Introduction

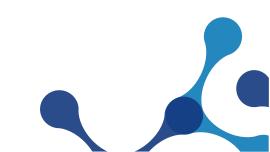
2. About the Medical Devices Fund and the Expert Panel

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"



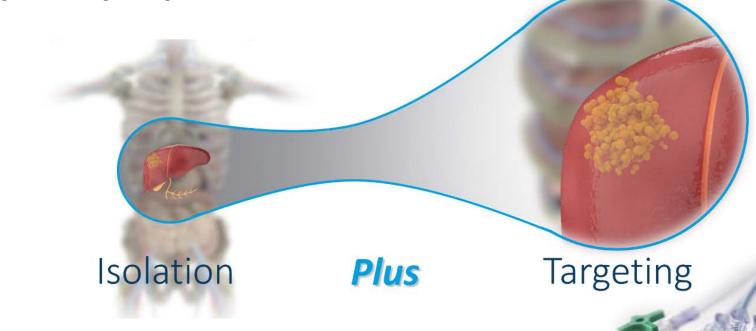
David Radford, CEO, +61 407 218 922 davidradford@allvascular.com

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





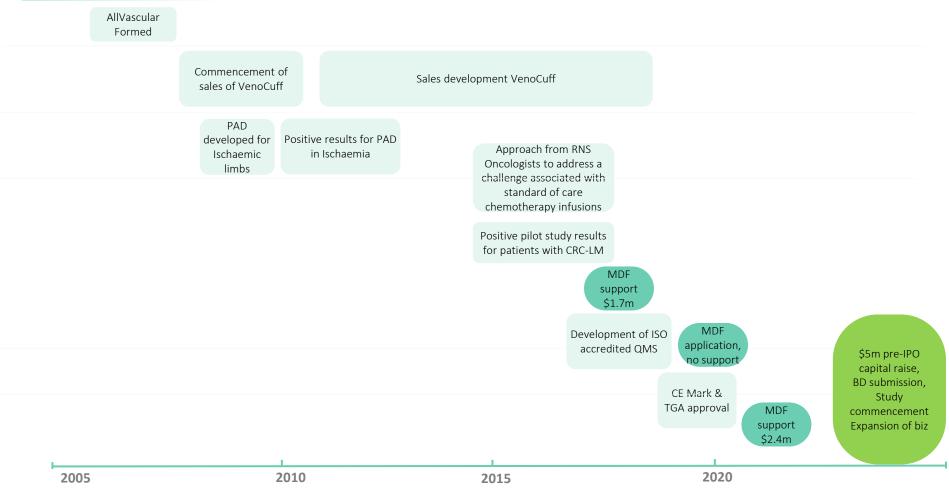
The AVAS[®] enables a new approach for the delivery of existing and future chemotherapies by isolating, targeting and infusing the organ.



- 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

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