

CONFIDENTIAL

Regenerative Medicine Minnesota

Progress Report

Grant Title: Lyophilization Device

Grant Number: RMM-2016-BB-01

Requester: Henry Walker

Project Timeline: July 1, 2016– June 30, 2017

Brief description of project: Purchase of lyophilization device.

Where did this project take place? Mayo Clinic, MN Biobusiness Center, Rochester MN

People impacted by project and where they are from Within Mayo Clinic this device has lead to the initiation of multiple regenerative projects with broad impacts on the practice.

Specifically, in collaboration with the Department of Orthopedics, Department of Cardiovascular Medicine, Plastic Surgery, OBGYN, Neurosurgery (brain specific), Thoracic surgery and Colorectal Surgery are either opening or submitting IND and/or IRB applications for new, first in man trial efforts. The combination of the first and second RMM grants have resulted in securing the interest and financial funding from a new Minnesota-based regenerative company with product development and manufacturing interests aligning with the API. Due to API's capabilities, this new company Rion, chose to be located in Rochester, MN and has leased office space in close proximity to API's manufacturing space. Empowered by RMM support, API's enhanced manufacturing platform has thus been able to attract new industry focused regenerative medicine to Minnesota and is partnering with industry to advance new regenerative product platforms for patients in need.

What was the outcome of the project? Installation of the unit has infused benefactor dollars, start-up private company support dollars, new Mayo Regenerative Medicine funding and the opening of two new clinical trials with others to follow. The equipment opened manufacturing capacities previously not accessible in the upper mid west. The API is dedicated to strictly following quality procedures requiring planning and validations before engaging in manufacturing steps.

Please list any of the following that have resulted from your Regenerative Medicine Minnesota grant funding:

- Publications and/or manuscripts submitted for publication – As a manufacturing specific environment, intellectual property is prioritized over publications and by default may not be shared due to privacy contracts. Multiple technologies are in process as a direct result of the instrument. Following clinical trial application, these technologies will be published in the clinical context for safety and efficacy.
- Disclosures/patents – One disclosure under patent review in conjunction with Florida researchers has been submitted.
- Other grant applications and/or awards - Three DoD applications were submitted recently, results pending.

Responsible Spending:

Please let us know how you spent the money. Any unspent funds must be returned. – Funds were completely spent on the equipment itself. Mayo support was utilized to pay for installation and validation steps.