Hypertension is driven by guidelines and protocols. These are developed locally and internationally by the various professional associations (American cardiology association etc). These are important as any new medication would need to be placed in the guidelines for it to be used. What data would be required by these associations to include the product in the guidelines?

> Indeed, increasingly so. Our PI (George Bakris) and Co-PI (Michael Weber) are editors of the consensus guidelines (14 vardiovascular organizations). Separately, at the request of the section chief, they also advise the CardioRenal section of the US FDA.

The proposal is to use the product (magnesium) in combination with current hypertension drugs (CCB, diuretics etc). This is good as you are not looking to displace other drugs which is difficult. That said what data would be required by the Drs to add the product to their standard treatment protocol?
–

> Suboptimal blood pressure control is the rule rather than the exception. All existing categories of anti-hypertensive medications are known to reduce or waste magnesium. Replenishment of magnesium links strongly both to improved efficacy as well as better renal and heart safety / tolerability. Real world evidence is also available for discussion about magnesium's impact on lowering blood pressure.

What is the pricing assumption? CCB, diuretics are extremely cheap now as there are many generics on the market. Price is critical for any real value to be delivered.

> Since API is inexpensive and the softgel unique to RMJ Holdings, the plan is to go for larger market share (initial goal is 15%) with a modest royalty (10%) and an attractive introductory price point.
>
> Adverse effects from mineral depletion are a major cause for non-compliance with drugs prescribed.

4. How will you commercialize this? Hypertension is driven by GPs which requires large expensive sales forces.

> The plan is for a licensing aggrement with companies the seek novelty in cardiovascular medicine.

5. Have you reached out to any of the big Cardio companies to see the level of interest? I would not be surprised if they were concerned with the ability to set a good price and that the product will be a 505 b 2 and not a NCE.

> The FDA agrees the RMJH-111b has a 'bridge' to parenteral magnesium that qualifies for 505(b)(2) approval. This shortens time to approval and reduces costs.

6. It would be helpful to understand the communication with the FDA regularly team. Understand what questions they have raised and what data they are looking for.

> With confidentiality in polace, RMJ Holdings has the Clinical Study Report summary and the minutes of the end of Phase 2 meeting with the FDA.
> An amendment with additional details of agency requirements for full drug approval will soon be filed.

7. Is there any Key opinion leader engagement? I would like to understand what the top cardiologist think of the product and its profile. Are they excited? Did they see a big unmet medical need in hypertension.

Yes and yes… the following engaged opinion leaders and stakeholders:

RMJ Holdings

ADVISORY BOARD / CLINICAL STUDY LEADERS

- Ronald Elin: https://louisville.edu/medicine/departments/pathology/faculty/elin
- Peter Feig: https://biography.omicsonline.org/united-states-of-america/sarfez-pharmaceuticals/peter-feig-160736
- Harry Gavras: https://www.bumc.bu.edu/busm/profile/haralambos-gavras/
- Alan Reich: https://www.seyfarth.com/AllanReich
- Franz-Joseph Seidensticker: https://www.bain.com/our-team/franz-josef-seidensticker/
- Robert Horn: https://www.huschblackwell.com/professionals/robert-horn
- George Bakris: https://www.uchicagomedicine.org/find-a-physician/physician/george-bakris
- Michael Weber: https://www.cardiometabolichealth.org/michael-weber.html