

The background features a blue and green color gradient. A network of interconnected nodes and lines, resembling a molecular or crystal structure, is overlaid on the left side. A large, semi-transparent circular graphic with a double-line border is positioned on the right side, containing the company name.

RMJ Holdings, LLC

DEVELOPING RMJH-111B:
MAGNESIUM REINVENTED

REGARDING FORWARD-LOOKING STATEMENTS

Forward-looking statements in this information are based on current plans and expectations that are subject to uncertainties and risks. The following factors, among others, could cause our actual results to differ materially; our ability to obtain the capital required for research and operations; the inherent risks in drug development including the progress of our clinical trials and demonstrating efficacy; development time/cost and the regulatory approval process. Forward-looking statements here speak only as of December 31, 2019, and we assume no obligation to update forward-looking statements or the reasons why actual results could differ. This information is not a solicitation or offer to sell securities.

CORPORATE HIGHLIGHTS

- Significant unmet cardiovascular need... 25 million+ initial US market
- Delivery technology provides threefold uptake- "Magnesium reinvented"
- Successful Phase 1 / 2 clinical trial with FDA agreement on roadmap
- Pivotal Phase 3 trial designed for rapid completion and 505(B)(2) approval
- Strong IP with protection for platform & pipeline
- Opens a new category in hypertension - attractive for value-based payments
- Licensing strategy: Fastest path to monetization
- Seasoned, experienced senior team to execute novel trial design

ESSENTIAL HYPERTENSION: BIG UNMET NEED FOR INNOVATION

- ≈46% (≈100 million) adults in US are hypertensive (by 2017 guidelines)
- Risks from CVD, stroke & heart attack
- ≈25% hypertensive patients treated with diuretics initially and ≈50% later
 - Lower BP goals 2017... **treat above 120/80**
 - **CDC:** Hypertension innovation a top health priority
- Essential Hypertension in US accounts for:
 - ≈14% of all cause mortality [>300,000/year]
 - ≈ 6% of all disability (2007)

Magnesium rarely used due to poor tolerance of *currently* available forms that lack RMJH-111B's enhanced uptake & engaged retention

RMJH-111B COMMERCIAL OVERVIEW

- **First drug candidate applying patented inverted micellar nanodroplet technology globally licensed exclusively by RMJ Holdings, LLC with fast to market roadmap.**
- *Initial* target market **25 million people on thiazide-like diuretics.**
 - **Initially** as an adjunct to chronic use *approved* medication, 505(B)(2) pathway
 - RMJH-111B **reduces kidney harm** due to magnesium wasting that is exacerbated by *all* classes of approved anti-hypertensive medication. The ‘holy grail’ of blood pressure regulation includes modulating tiniest blood vessels that RMJH-111B restores. Existing anti-hypertensives, by contrast, do not reach the critical tiny arterioles often with adverse effects.
 - Value from **indications, multi-medication** combinations and then as polypills. This doubles the number of **peak sales years**.
 - **Pipeline and platform of additional drug indications included, slide 6**

RMJH-111B ADDITIONAL DRUG INDICATIONS RELATED TO MAGNESIUM NEED IN DIFFERENT CELLS AND ORGANS

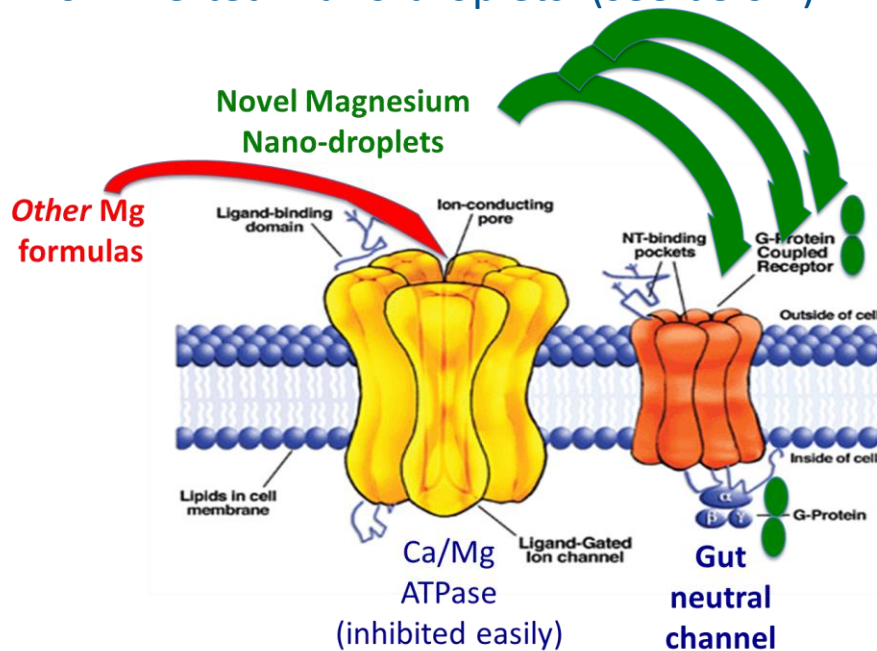
<u>Indications Magnesium Needed</u>	Clinical applications of restoring cell Magnesium
Hypertension	Essential, medication induced
Atrial Fibrillation (A-Fib)	Lack of heart magnesium provokes electrical instability
Myocardial Infarction (Heart Attack)	80+% of MI people have low cell magnesium
Mitral Valve prolapse	Lack of collagen repair of ring that holds the valve
Congestive heart failure (CHF)	Adequate magnesium improves ejection fraction
Atherosclerosis / Stroke	Blood vessels that are repaired function better
Restless legs	Low cell magnesium correlated with twitchy muscles
Fatigue	Low cell magnesium means ATP energy unavailable
Fragile blood vessels	Collagen and elastin impaired repair
Hyperlipidemia	Magnesium protects essential fats in transport
Eclampsia of Pregnancy	Parenteral use, safety of large amounts needed
Platinum chemotherapy	Wastes magnesium; often given IV at each chemo
Diabetes	Metabolic syndrome; Hgb A1c >5%
Migraine headaches	Magnesium relaxes tiny blood vessels in spasm
Osteoporosis	Magnesium lack often a main cause of bone loss
Chronic kidney disease	All forms benefit from restoring cell magnesium
Sickle cell anemia	Cells sickle when acidic; less when magnesium buffers metabolic acids

FROM ADJUNCT TO ALL CARDIOVASCULAR+

- **Initial target market 25 million people on thiazide-like diuretics.**
 - **Starting** as an adjunct to a chronic use approved medication. **Initial indication** allows for more rapid, less risk, less expensive drug approval.
 - **RMJH-111B** cooperates with all categories of anti-hypertensive medications.
 - Business Week, 9/19/2019, p 37-43 confirms carcinogenic residue in generic antihypertensive medications.
 - **Peak sales years doubled due to multiple indications** (slide 6), drug combinations & as polypills.
- **Successful Phase 1 / 2** study resulted in FDA agreement on...
 - **505(B)2 path** with a single Phase 3 pivotal trial of 1000 finished cases
 - **Pivotal trial** can be completed within one year from first subject enrolled.
- Supplemental **NDAs** are planned for additional indications, special populations and other applications of the core technologies in Phase 4, post market surveillance (slide 17).

RMJH-111B NOVEL DRUG CANDIDATE

Company has exclusive rights to 'nano-droplet' technology through composition of matter patent (US Patent #8,017,160). Claims include enhanced uptake and chaperoned delivery of oral magnesium to cells hungry for this essential mineral. This fundamental technology 'reinvents' magnesium through application of novel uptake and cell delivery of inverted 'nano-droplets' (see below).



Softgel novel trade secrets

- Charge-neutral nano-droplets (micelles, **tiny drops**) are formed that are taken up by neutral cell channel pores
- **Enhances** magnesium uptake *even* when the usual calcium/magnesium ATPase uptake ion channel is saturated
- **Stable softgel** with long shelf-life
- **Safety, tolerability & efficacy** data from Phase 1 / 2 clinical outcome trial support company's drug approval roadmap

INTELLECTUAL PROPERTY, ISSUED GLOBALLY

United States Patent **Granted 9/13/2011** **#8017160 Expires 8/15/2023**
Additional patents **to be filed beginning Q2 2020**

Claim: Magnesium complex consisting of a magnesium salt; a phosphatide a di-carboxylic acid/or tri-carboxylic acid; and a water and glycerol solution

	Granted	Patent No.	Expires		Granted	Patent No.	Expires
Canada	11/27/12	#2535932	08/12/24	Ireland	12/26/18	#1660103IE	08/12/24
Europe	12/26/18	#1660103	08/12/24	Netherlands	12/26/18	#1660103NL	08/12/24
Switzerland	12/26/18	#1660103CH	08/12/24	Poland	12/26/18	#1660103PL	08/12/24
Czech Republic	12/26/18	#1660103CZ	08/12/24	Sweden	12/26/18	#1660103SE	08/12/24
Germany	12/26/18	#602004053583.ODE	08/12/24	Hong Kong	01/10/20	#1089975	08/12/24
Denmark	12/26/18	#1660103DK	08/12/24	Mexico	11/15/11	#292147	08/12/24
France	12/26/18	#1660103FR	08/12/24	Australia	03/14/13	#2011201073	08/12/24
United Kingdom	12/26/18	#1660103GB	08/12/24	Israel	05/31/15	#173754	08/12/24

PHASE 1 / 2 TRIAL RESULTS

- Initial study (N=15 on active; 6 on placebo) confirmed strong trend with correlation between improvement in serum magnesium and blood pressure reduction.
- No adverse events; well tolerated
- Benefits observed across the active group
- On analysis, statistical significance (necessary for New Drug Approval) would have been achieved if 80-100 people had been studied
- FDA agrees results suffice to proceed to a single Phase 3 trial addressing all essentials for new drug approval (NDA)

RMJH-111B PHASE 1 / 2 STUDY CONCLUSIONS

Substantial blood pressure improvements over a short treatment period along with the demonstrated safety and tolerability plus other documentation satisfied FDA that Phase 2 is complete. The *initial* indication is as an adjunct to an approved chronic use medication where better outcomes and lower risks are anticipated and documented in the final, pivotal Phase 3 trial. Forward plans include supplemental new drug applications for essential high blood pressure (eHBP) and other cardiovascular indications during Phase 4 (post market surveillance). A pipeline of other drug indications / disease states will be pursued as resources and capacity permit (Slide 6).

PHASE 3 PIVOTAL STUDY DESIGN

- Parallel, double-blind study, N=1,000 finished cases (1050 enrolled)
 - 3:1 randomization, 750 on RMJH-111b + 250 on placebo
 - 10 weeks double blind treatment
 - 10 weeks open-label extension
 - 8 weeks randomized withdrawal of responders
 - 42 weeks to exit trial
- **Clinic sSBP** as primary end point; other objectives to address clinical, payor, and consumer needs
- **Serum magnesium** confirms need, efficacy and safety
- Enhanced **arteriolar Magnesium** helps *both* **BP & kidneys**

PHASE 3 PIVOTAL STUDY DESIGN (DERISKED)

- **Clinical risk minimized with substantial increase in number of participants warranted by literature and real-world experience with magnesium**
 - **Careful planning and design addresses all aspects needed for NDA.**
 - **Strategic design supported by end of Phase 1 / 2 FDA meeting minutes.**
 - **WCT (Worldwide Clinical Trials under Dr Neal Cutler) can serve as CRO with trial designed to commence early in the 2nd quarter 2020.**
 - **RMJ's team includes members who have successful drug approvals with other hypertension drugs such as beta-blockers and ACE inhibitors.**
 - **Other members of RMJ's team edit the hypertension clinical management guidelines used by payors and policy experts.**
- **The most recent guidelines (2017) call for earlier treatment of high blood starting now at 120/80 rather than 130/90.**

DERISKED PHASE 3 STUDY AND NDA ROADMAP

- Retrospective analysis of the data from the Phase 1 / 2 study showed strong favorable trends and correlations such that <0.05 p value (significance appropriate for approval) would have been achieved if only 80 additional subjects had been included.
- Statistical design for the Phase 3 trial includes 300 additional patients which will result in the study being overpowered to achieve significance in a 'once and done' approach to drug approval. The initial 300 participants to complete the protocol will then be re-randomized to assess adaptation (technically tachyphylaxis) over an additional eight weeks. Participants will return two weeks after completing the study for safety and final assessments. This step is critical for approval and including it in this trial will ensure a once and done and save substantial dollars and a year's time.
- FDA agrees that RMJ has built a 505(b)(2) bridge to the approved parenteral magnesium suitable for the oral indication.
- Strategically, more than 80 percent of the trial costs are up front. By overpowering the study with an additional few hundred subjects lowers the total cost per finished case dramatically while shortening the time to drug approval by at least a year.

RMJH-111B NDA APPROVAL MILESTONES

- Fundamental, proprietary advance in magnesium uptake and retention
- 1st in and out of clinic for new drug category; Phase 2 complete
- Single dose, single study enough for 505(B)2 NDA
- Phase 3 design: 'Once and done'
 - Quality cases rapidly enrolled, analyzed and reported
- Chemistry, clinical, non-clinical, statistics & toxicology clarified with Cardio-Renal division of FDA

FDA NDA APPROVAL REQUIREMENTS

Company's Phase 3 protocol and roadmap includes agency's guidance regarding what is required to de-risk the five key areas for drug approval.

Chemistry / CMC: Validated methods (stress tested), GMP, GLP ✓

Clinical (Phase 3 trial; 505(b)2 path) ✓

Safety, tolerability, efficacy, adaptation, and anticipatory assessments

Non-clinical: Literature, global, in FDA preferred format ✓

Statistics: Designed to achieve 0.00125 significance; over powered ✓

Toxicology: Nothing additional needed ✓

RMJH-111B PLATFORM AND PIPELINE, EACH WITH DISTINCT LOOK, FEEL, DOSAGE AND FORM

Cardiovascular drug Platform:

- Essential hypertension starting with thiazides [Rx sooner & easier]
- Better blood lipids
- Atrial Fibrillation
- Congestive Heart Failure (CHF)

Follow-on Pipeline of Indications

- Preeclampsia and eclampsia of pregnancy
- Muscle cramps, restless legs, facial ticks & twitches
- Diabetes, metabolic syndrome & insulin resistance
- Kidney disease
- Osteopenia / Osteoporosis
- Migraine headache
- Sickle Cell Anemia (Orphan Drug candidate)
- Platinum Chemotherapy (cis-platinum *et al...*)

Inadequate hypertension control in people on diuretics is 1st indication for faster drug approval.

HYPERTENSION... HOW LOW TO GO?



American Heart Association, American College of Cardiology and 9+ other health professional organizations released comprehensive new high blood pressure guidelines (11/17).

“Normal BP” now <120/80 mm Hg.

Under new guidelines **nearly half of the U.S. adult population (46%) has high blood pressure**, rather than 1 in 3 U.S. adults (32%) with the prior definition.

**High blood pressure redefined for first time in 14 years:
Above 120 is the new treatment consensus guideline.**

ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, Hypertension. 2018;71:e13-e115, originally published November 13, 2017



RMJ Holdings, LLC

**BIG UNMET CLINICAL NEED FOR SAFER
HYPERTENSION MANAGEMENT**

HYPERTENSION RIPE FOR INNOVATION

HYPERTENSION TRENDS

Near term to best of RMJH Rx knowledge

- No new medications
- No new interventions
- No new procedures

Favorable Market Dynamics (US & Global):

- Payor trends toward **value**-based payment
- Updated **definition** of hypertension
- Cost/benefit analysis

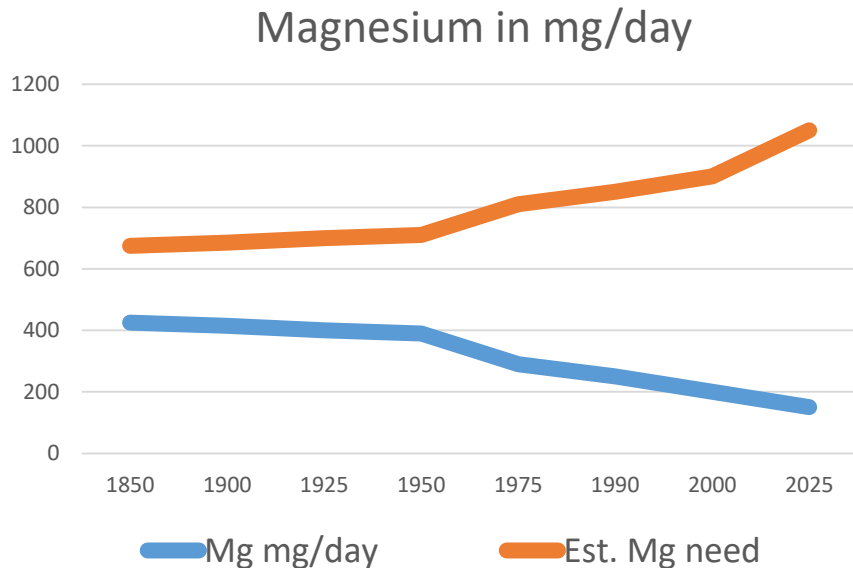
MAGNESIUM MARKETPLACE 2010-2020

150 MM US adults deficient in Mg that relates to *most chronic illness such as heart, blood vessels, brain and organ dysfunction*

- Ron Elin's Chronic Latent Magnesium Deficiency (CLMD); confirmed; consistent with 2017 hypertension guidelines
- 505(B)(2) bridge from IV to oral agreed by FDA
- Eclampsia & platinum chemo (100,000 US adults annually)
- \$4 Billion US *parenteral* market, (2011), Fresenius Kabi® & Pfizer®; IV magnesium costs ~\$2,000 per dose.

GROWING MG NEED: DIET INSUFFICIENT & CELL LEVEL DECLINING; SAFETY, & EFFICACY FROM RMJH-111B

Daily Ingestion Vs Need



Magnesium multi-tasks in life...

- Nature's calcium channel blocker;
- Required to activate many enzymes;
- Protective of essential fats in transit;
- Needed to activate ATP for cell energy;
- Needed for mitochondrial proton gradient.

Less today in soil/diet (US & Global)

60-70+% US & Brazil confirmed inadequate daily intake of Mg results in chronic latent **magnesium deficiency**, being *in lower half* of serum Mg lab test range (CLMD).

DRI (adults): 310-400 mg/d may be too low

Piovesan D *et al*, BMC Bioinformatics, 2012; 13(S14): S10

Sales *et al*. Nutricion Hospitalaria, 2014; 30(1): 200-204

Nielsen FH. Nutrition Rev, 2010; 68: 333-340

[Elin RJ](#), Re-evaluation of the concept of chronic, latent, magnesium deficiency (CLMD). [Magnes Res.](#) 2011 Dec;24(4):225-227. doi: 10.1684/mrh.2011.0298

HYPERTENSION MARKET OPPORTUNITY

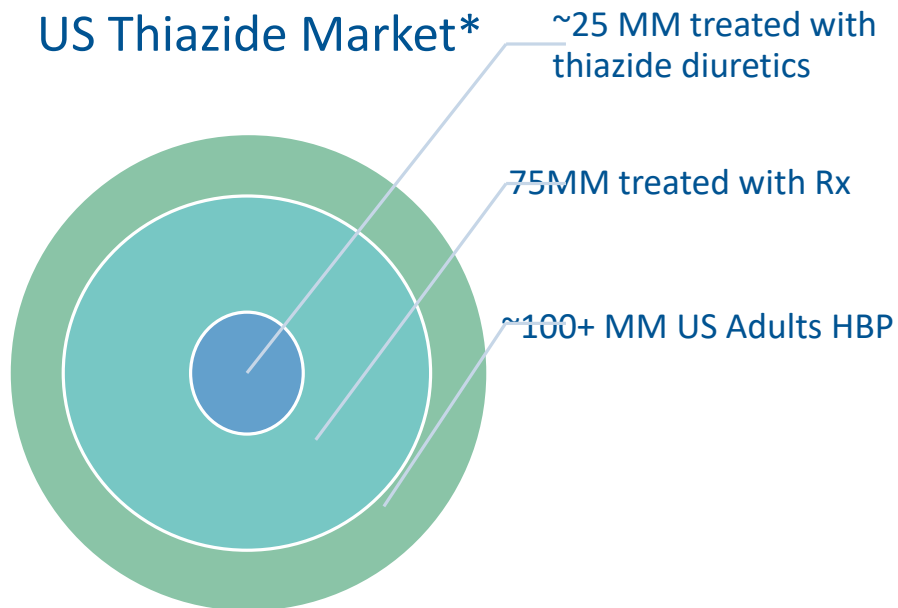
Global push to treat essential high blood pressure (eHBP) earlier, with safer, effective drugs to reduce adverse effects from existing therapies. RMJH-111B to the rescue.

HBP MARKET GROWING 1.5%/YEAR	RMJH-111B INITIAL INDICATION	HBP RX SALES, ANNUAL
<p>≈ \$40+ Billion US, 100+ MM eHBP people</p> <p>≈ \$60+ Billion ex-US, 200 MM eHBP people</p>	<p>≈ 20% diuretics <i>first treatment</i></p> <p>≈ 28% of all people with eHBP</p> <p>≈ 50% combo diuretics + others</p> <p>≈ 50% take Rx as prescribed</p> <p>Mg replenishment improves outcomes; reduces side-effects</p>	<p>≈ \$ 5 Billion US diuretics only</p> <p>\$7.5 Billion Ex-US</p> <p>≈ \$10 Billion US for combo diuretic therapy</p> <p>≈ \$15 Billion Ex-US for combo diuretic therapy</p>

<https://www.prnewswire.com/news-releases/global-hypertension-drugs-market-2016-2020---growing-older-population--patent-expiries-of-major-drugs--increase-in-awareness---research-and-markets-577465241.html>
http://www.who.int/gho/ncd/risk_factors/blood_pressure_prevalence_text/en/

MARKET VALUE AND PROJECTIONS

Internal projections, based on an anticipated 15% share of thiazide market plus minimal (~1%) off-label monotherapy use, put peak year sales for *this initial* indication at \$1.9 Bn.



PEAK YEAR SALES PROJECTION

Based on low price/high market share strategy; 10% royalty

Annual cost of RMJH-111B =
\$540 x ~3.75 million treated

= ~\$1.9 Billion annual gross
(Projected royalty revenue =
\$190 Million, US annual)

*Trends in Antihypertensive Medication Use and Blood Pressure Control Among United States Adults With Hypertension, Qiuping Gu, Vicki L. Burt, Charles F. Dillon, Sarah Yoon, *Circulation*. 2012;126:2105-2114, originally published October 22, 2012



RMJ Holdings, LLC

RMJ HOLDINGS AND RMJH-111B

ABOUT US

RMJ HOLDINGS, LLC, MANAGEMENT

Russell M. Jaffe MD, Ph.D., CCN, Founder and Chief Executive Officer

Dr. Jaffe, an internal medicine physician, clinical pathologist, immunologist, and biochemist, founded RMJH after identifying a need for enhanced uptake and chaperoned delivery of essential minerals, the first of which is Magnesium. He is a Diplomate of the National Board of Medical Examiners and the American Board of Pathology for Clinical and Chemical Pathology. He founded **ELISA/ACT®** Biotechnologies (EAB) the exclusive provider of the lymphocyte response assay (**LRA by ELISA/ACT**) tests – the gold standard in delayed hypersensitivity testing. He also founded **PERQUE®** which develops and sells a new generation of nutritional supplements, available only through doctors and healthcare professionals which have the advanced, mostly proprietary formulas to provide superior, safer results in restoring, maintaining, and enhancing health. His companies are operated and managed by a long serving team. His primary business focus is RMJ Holdings.

David H. Fater, Executive Vice President

David Fater has extensive experience as a Chief Executive Officer with drug discovery companies focused on stroke and traumatic brain injury as well as a medical device company focused on cardiology. He has also been the Chief Financial Officer for three healthcare companies in which he led the Initial Public Offering. Prior to his corporate experience, he was an international partner with Ernst & Young.

Mischelle Hall, Chief Operating Officer

Mischelle Hall has 20 years of pharmaceutical and nutraceutical marketing and operations experience. She has led Marketing for several organizations focused on multiple categories including hypertension, antidepressants, and women's health. Mischelle earned an MBA from Georgia State University.

Diana Wardak, Chief Financial Officer

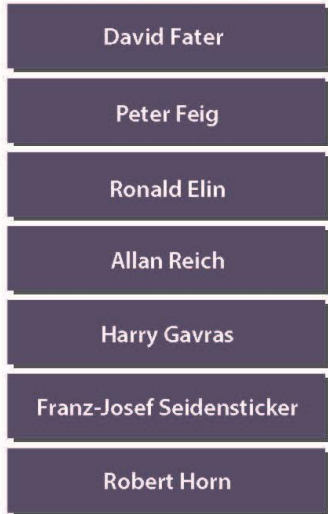
Diana Wardak is a CPA with over 15 years of experience helping organizations in different industries achieve success in revenue growth, compliance and audits. She has both a BA (Law and Political Science) and a BS (Accounting) from Strayer University.

ADVISORY BOARD / CLINICAL STUDY LEADERS

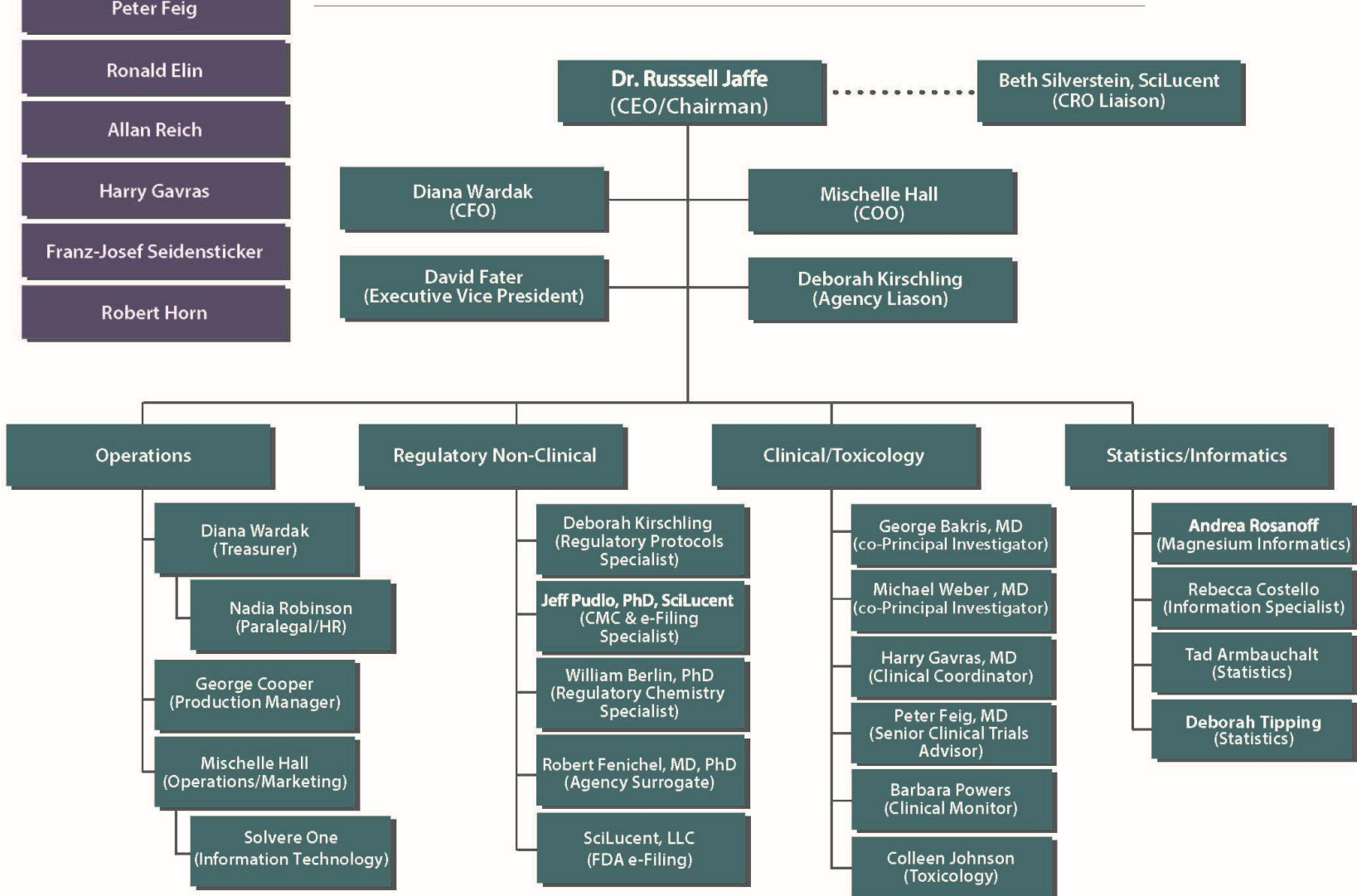
- Ronald Elin: <https://louisville.edu/medicine/departments/pathology/faculty/elin>
- Peter Feig: <https://biography.omicsonline.org/united-states-of-america/sarfez-pharmaceuticals/peter-feig-160736>
- Harry Gavras: <https://www.bumc.bu.edu/busm/profile/haralambos-gavras/>
- Alan Reich: <https://www.seyfarth.com/AllanReich>
- 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>

RMJ Holdings

Advisory Board

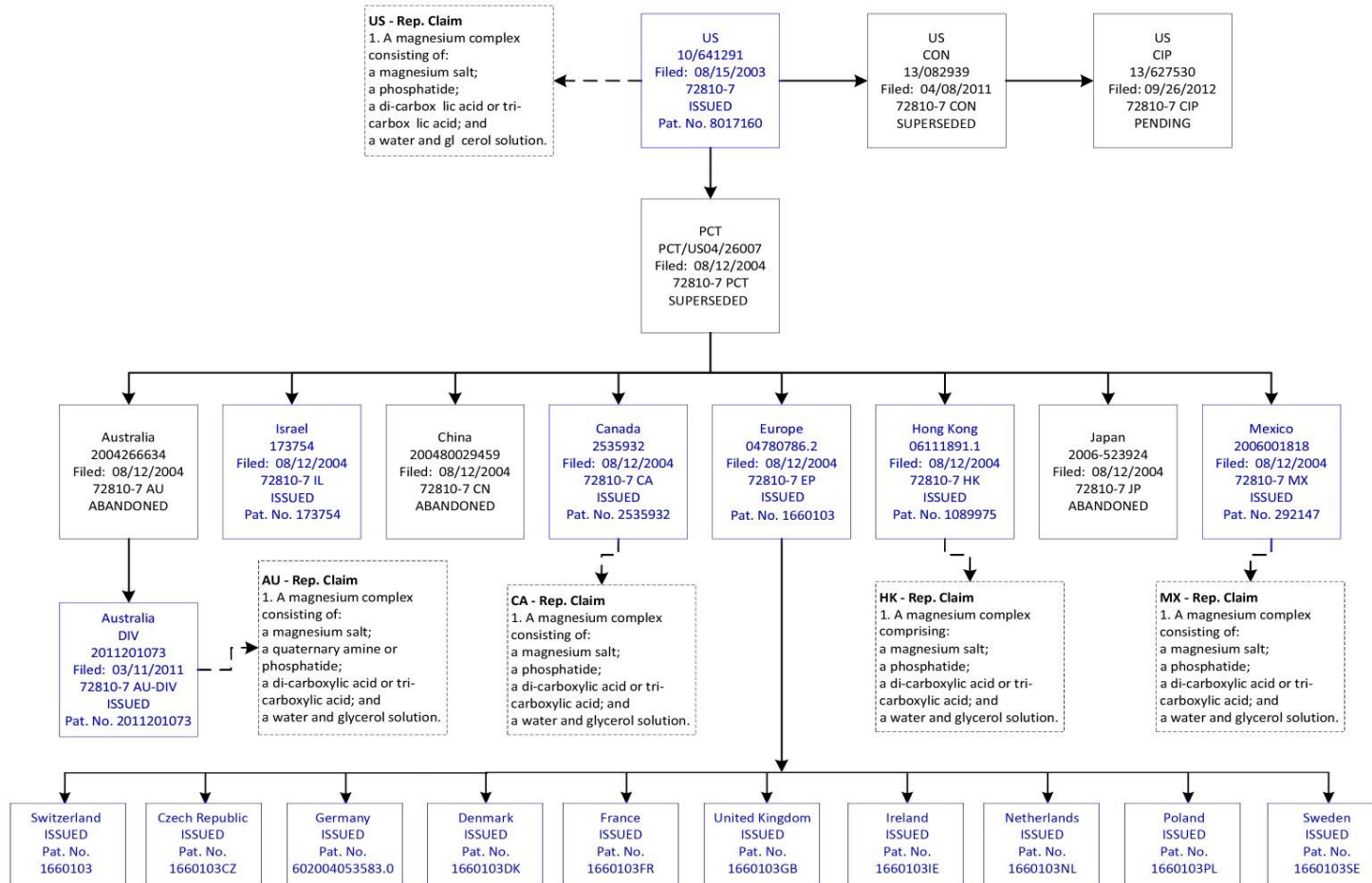


RMJ Holdings, LLC Organization Chart



PATENT TREE

ENHANCEMENT OF MAGNESIUM UPTAKE IN MAMMALS



RMJ HOLDINGS LLC USE OF PROCEEDS

	2019	2020					2021					GRAND
	Q4	Q1	Q2	Q3	Q4	TOTAL	Q1	Q2	Q3	Q4	TOTAL	TOTAL
AGREEMENT ON TERMS	X											
FUNDING		\$ 22,000,000										
PLACEMENT FEES AND EXPENSES		<u>(2,000,000)</u>										
NET PROCEEDS		<u>\$ 20,000,000</u>										
MILESTONES:												
FIRST PATIENT ENROLLED			X									
LAST PATIENT ENROLLED				X								
FIRST PATIENT COMPLETE					X							
MILESTONE NET FUNDING		<u>\$ 7,000,000</u>	<u>\$ 5,000,000</u>	<u>\$ 5,000,000</u>	<u>\$ 3,000,000</u>	<u>\$ 20,000,000</u>						
EXPENSES												
WCT Master CRO		\$ 3,000,000	\$ 3,000,000	\$ 2,000,000	\$ 2,000,000	\$ 10,000,000	\$ 1,000,000	\$ -			\$ 1,000,000	\$ 11,000,000
Data Manager		1,000,000	200,000	650,000	200,000	2,050,000	150,000	50,000			\$ 200,000	\$ 2,250,000
Drug Development		1,000,000	500,000	450,000	150,000	2,100,000					\$ -	\$ 2,100,000
RMJH Operations		300,000	300,000	300,000	300,000	1,200,000	300,000	300,000	300,000	300,000	\$ 1,200,000	\$ 2,400,000
Central Laboratory			600,000	750,000	150,000	1,500,000					\$ -	\$ 1,500,000
Advisory			200,000			200,000					\$ -	\$ 200,000
Regulatory Affairs		100,000	150,000	50,000	100,000	400,000	75,000	75,000			\$ 150,000	\$ 550,000
		<u>\$ 5,400,000</u>	<u>\$ 4,950,000</u>	<u>\$ 4,200,000</u>	<u>\$ 2,900,000</u>	<u>\$ 17,450,000</u>	<u>\$ 1,525,000</u>	<u>\$ 425,000</u>	<u>\$ 300,000</u>	<u>\$ 300,000</u>	<u>\$ 2,550,000</u>	<u>\$ 20,000,000</u>

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- Successful Phase 1 / 2 clinical trial with FDA agreement on roadmap
- Pivotal Phase 3 trial designed for rapid completion and 505(B)(2) approval
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NON-CONFIDENTIAL OVERVIEW DECEMBER 2019