South Rampart Pharma, LLC

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Team:

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CEO and Co-founder

Nicolas Bazan, MD PhD

Scientific Co-founder

Robert Dickey IV, MBA

CFO

Shayne Gad, PhD

Dir. Regulatory Affairs & Toxicology

John Wetzel, PhD

Dir. CMC & Formulation Development

Amount of Financing Sought:
$30M

Funding To Date:

$7.75M total
$5.85M by Ochsner Health
$1.9M NIH/NINDS

Use of Funds:

Ph 1 and Ph 2a clinical trials in neuropathic, acute and chronic pain

Business Description: There is a global need for safer pain medicines. Pain affects more adults than diabetes and cancer combined and costs the U.S. healthcare system an estimated $635 billion annually. Current pain medications are either highly ***addictive*** (opioids) or can cause ***harm*** to the ***liver*** (acetaminophen) and ***kidneys*** (NSAIDs). South Rampart Pharma has developed a ***new class of small molecule non-opioid compounds ('SRPs'), effective at reducing pain and fever without liver and kidney toxicity or abuse potential***. In addition, as a small molecule, SRP's advantage over biological therapies is that they will be inexpensive to scale. In 2021, the FDA opened South Rampart's first IND for pain, enabling Phase 1 clinical trial patient enrollment to begin in January 2022.

Management: Headquartered in New Orleans, SRP was founded by CEO, **Hernan A. Bazan, MD DFSVS FACS**, The Endowed John Ochsner Innovation Professor of Surgery, Section of Vascular/Endovascular Surgery at Ochsner Health. Scientific co-founder **Nicolas G. Bazan, MD PhD**, Director of the Neuroscience Center in the LSU Health Sciences Center, has had continuous NIH funding since the early 1980s and previously co-founded a company that went through a successful IPO. The team also includes a CFO with deep expertise in the life science industry, a Regulatory Affairs and Toxicologist specialist who has taken nearly 140 molecules to successful IND's and clinical trials, and a Formulation/CMC expert who has been involved in the preparation of numerous INDs and NDAs. The **NIH/NINDS** awarded the co-founders a 'Fast-Track' grant (2020-2023) to support the development of this novel technology.

Technology: SRPs are novel pain compounds that have the potential to treat **neuropathic**, **acute** (**postoperative**), and **chronic** pain without the narcotic risk or liver and kidney toxicity of other pain medicines (**Fig. 1**, *Innovation Pipeline*). **SRPs are covered by composition of matter IP nationalized in key world markets.**

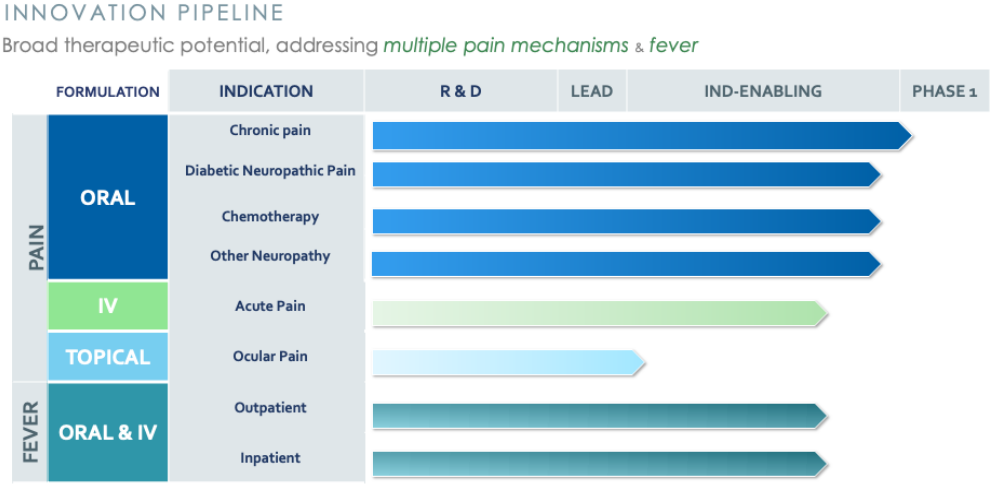

Fig. 1*: *Innovation pipeline. *The FDA granted an opened IND in 2021 for the SRP-3D (DA) oral formulation, with patient enrollment in the first Ph 1 trial in Jan 2022. Once completed, Ph 2a trials in neuropathic and chronic pain will be done. Currently, an IV formulation is being developed for acute pain indication.*

Mechanisms of Action. SRP-3D (DA) is a novel small molecule that exerts analgesia (pain reduction) in the nociception center of the brain through the metabolite AM404, a mechanism of action shared with acetaminophen (Tylenol®/Panadol®). As a non-opioid, SRP-3D (DA) will have a better safety profile than those treatments for pain. Unlike acetaminophen, the leading cause of acute liver failure in the U.S., SRP-3D (DA) does not generate the toxic metabolite NAPQI responsible for liver damage or disrupt hepatic tight junctions (**Fig. 2**, *MOA*). Also, it does not cause kidney

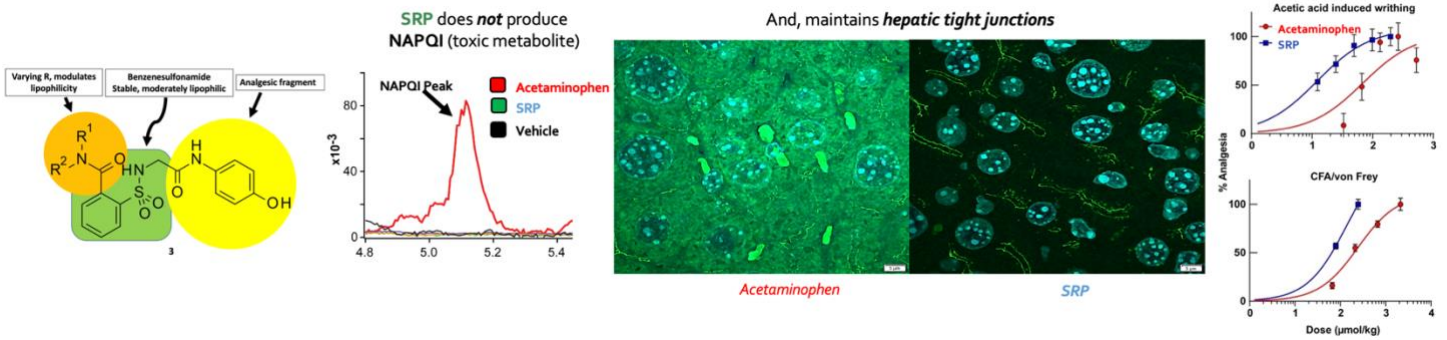

Fig. 2*: *Novel analgesic MOA for lack of hepatotoxicity. ***Fragments*** *encompassing SRP-3D (DA), the novel non-opioid and non-liver toxic analgesic asset. The* ***MOA*** *for the lack of liver toxicity compared to acetaminophen is because it does not produce* ***NAPQI*** *nor disrupts* ***hepatic tight junctions***. *Two representative in vivo models for the pain relief, acetic acid writhing and CFA/von Frey with electronic detection.*

toxicity like NSAIDs. As a result, SRP-3D (DA) can reduce both pain and fever without these risks, meeting a critical unmet need. SRP-3D (DA) reduces pain in four *in vivo* animal pain models, including the *von Frey inflammatory model*, *abdominal writhing*, *tail flick* and the *CFA/Hargreaves inflammatory model and thermal sensitivity studies*. And, it is antipyretic in two fever animal models.

FDA Strategy: With $30 million of funding (**Table**, *Clinical Milestones*) –

- The first Phase 1 trial using oral nanosuspension has begun the first cohort of the SAD arm in January 2022
- A second IND for neuropathic pain is planned for Q1 2022
- After that Phase 1 is completed in Q3 - Q4 2022, a Phase 2a trial in diabetic neuropathic pain will begin
- An intravenous (IV) formulation is being developed for postoperative acute pain and the IND submission is planned for Q3 2022

IV formulation Phase 1 trials will be accelerated by the results of the oral Phase 1 trial, allowing the IV Phase 1 trial to be completed by Q4 2022. **These efforts will result in the lead asset being Phase 2a ready by Q4 2022 in three pain pipelines: neuropathic, acute and chronic pain. South Rampart will also seek orphan disease designation for patients with liver disease and pain.**

$30M+	Q1 2022	Q3 - Q4 2022	Q1 - Q4 2023	Q3 2023
Milestone achieved	○ Jan 2022: 1st Ph 1 trial, oral formulation (SAD, MAD, PK) ○ 2nd IND, Neuropathic pain	○ IV formulation Ph 1 (Acute Pain) ○ Finish oral Ph 1 ○ 3rd IND, Acute Pain	○ Phase 2a, Diabetic neuropathic pain ○ Phase 2a Chronic Pain (+/- NIH EPPIC-Net)	○ Ph 2a, Acute pain ○ Orphan, Liver disease & pain

Table: Clinical Milestones achieved with Series A funding. Three pipelines, *diabetic neuropathic, chronic and acute pain* will be developed through Phase 2a-completion. The first FDA IND opened in 2021 paving the way for the Ph 1 trial in Q1 2022.

Short-Term Milestones | Phase 1 trial

The initial Phase 1 trial began in January 2022 and it will yield safety and tolerability data and support the design of future Ph 2a trials in patients with particular pain conditions, first in neuropathic pain, followed by acute and chronic pain. The safety studies are de-risked by the two MOAs that explain SRP's lack of hepatotoxicity (**Fig. 2**). These subsequent studies will also address the effectiveness of SRP-3D (DA) through 'bucket studies' in subpopulations of patients at higher risk for toxicities associated with over-the-counter treatments, such as those with liver or kidney diseases. SRP will complete the neuropathic Phase 1 in the Q3 2022, with Phase 2a studies in neuropathic and chronic pain commencing in Q1 2023.

Long-Term Impact | 2nd Phase 1 trial and other pain Phase 2a trials

The long-term impact will be filling the current void in the availability of safer treatment of neuropathic and chronic pain and as a non-opioid option for the treatment of acute postoperative pain and in the emergency room. The co-founders' scientific team has deciphered the analgesia MOA of SRP-3D (DA) in the nociception area of the brain, further de-risking future Phase 2a proof of concept (POC) studies.

Taken together, the pathway to clinical development of SRP-3D (DA) has many advantages with the ultimate long-term impact to position SRP-3D (DA) as a small molecule for the safer treatment of neuropathic and chronic pain and as a non-opioid option for the treatment of acute postoperative pain and in the emergency room (**Fig. 3**, *Clinical Pathway to Development*). Lastly, as a result of these efforts, we will then be able to begin a process for the OTC pain relief market.

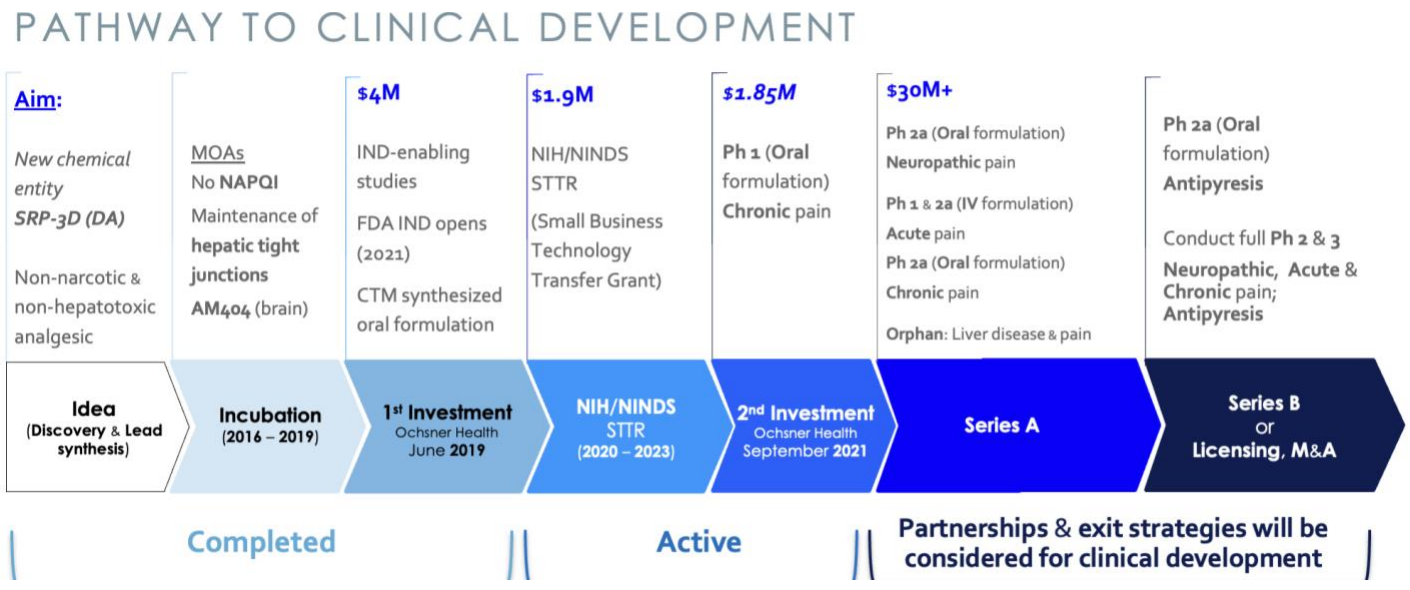

Fig. 3: Pathway to Clinical Development. *After incubating the pre-clinical development of the novel non-opioid and non-hepatotoxic lead asset SRP-3D (DA) in the co-founders' laboratories, two seed investments and an NIH STTR 'fast-track' totaling $7.75M have allowed the first Ph 1 trial in Q1 2022 and development of multiple pain pipelines (see above).*