



## **RedCrow Analysis Report**

# **SEN-JAM PHARMACEUTICAL OVERVIEW AND ANALYSIS A REDCROW PLATFORM INVESTMENT OPPORTUNITY**



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# **I. SEN-JAM COMPANY PROFILE**

Sen-Jam Pharmaceutical's mission is to improve the lives of others by creating proprietary products that are efficacious, safe, and accessible by all. We make therapeutics that reduce pain and pain-related symptoms. Our goal is to create value by finding novel pharmaceutical solutions for large, unmet needs while forging global sales, distribution, and licensing agreements. We are currently collaborating with several strategic partners. We have 24 patents awarded and pending.

Sen-Jam is pursuing products designed to mitigate the painful side effects associated with several important areas of health concern. Our 3 lead drugs are at varying stages of development for treatments including Viral Respiratory Infections (e.g. COVID-19), Opioid Withdrawal, and Alcohol Hangover Prevention.

Our Viral Respiratory Infection product (SJP-002)

Typically, the common cold and other viral respiratory infections creates havoc on our normal daily activities approximately one or two times a year, and always occurring at the worst possible time. Our OTC product can be safely taken at the earliest onset, dramatically reducing symptoms, including head congestion, coughing, sore throat and sneezing, allowing minimal disruption to your day. We will be progressing this product forward toward the end of 2020.

COVID-19, requires an immediate call to action for all. Sen-Jam's, ingenuity and resourcefulness can meet the challenge. By retooling our SJP-002 product, we will perform in-vitro studies testing a candidate against SARS-CoV-2, the virus causing COVID-19. We believe our candidate will have the anti-viral and the immunomodulating capabilities required to reduce the lung damage and the mortality associated with COVID-19. We plan to fast track our program, collaborating with researchers around the world, to initiate clinical trials as soon as possible.

[Recent Activity: In-Vitro Study underway testing SJP-002 against the COVID-19 virus]

Our Opioid Withdrawal product (SJP-005)

The number one reason an opioid dependent person cannot reduce their daily opioid consumption, is because the withdrawal symptoms are too painful. This has led to 3-5M people diagnosed with Opioid Use Disorder in the US, with 10-15 million opioid dependent. SJP-005 offers health care providers and their patients a non-opioid pain reliever that can also reduce opioid withdrawal symptoms, enabling an individual the ability to reduce their daily opioid consumption. We have completed pre-clinical studies that show a 50% reduction in withdrawal symptoms, and will be working to complete our pre-IND work in 2020, and open an IND in 2021, while submitting to the NIH for non-dilutive funding to expedite our program.

[Recent Activity: Granted US patent allowance for SJP-006, our sister product for reducing opioid dependence]

Our Alcohol Hangover Prevention product (SJP-001)

Relief will soon arrive! There are 2+ Billion hangovers a year in the US, while most people suffer alcohol's effects even when drinking moderately, studies have shown the economic impact of alcohol hangovers cost society \$180B annually in lost productivity. Our first lead product, when taken just prior to drinking, reduces the inflammation and subsequent pain commonly referred to as hangover. Individuals wake up, feeling refreshed and productive. SJP-001 will be the first FDA approved OTC product for the prevention of alcohol hangover. We received our US patent September 2019, (expires 2036) and have an open IND with the FDA to begin our phase 1 study. Our pre-clinical study in humans have shown efficacy with statistical significance.

[Recent Activity: Paper published on The Effects of SJP-001 on Alcohol Hangover Severity: A Pilot Study and Notice of Intent to Grant EPO patent]



# RedCrow Crowd Analytics Report

Discover Profile Live: 10/18/19

sen-jam  
PHARMACEUTICAL



## RedCrow Crowd Analytics

The Network Analytics Report provides companies with web-based data quantifying their engagement with RedCrow. Above average statistics suggest positive interest from the RedCrow Crowd.

2,093

Page Views

6:20

Avg Time on Page

86.67%

Bounce Rate

1,652

RedCrow Views

5

Rating Out of 5

RedCrow Averages

Page Views:

117

Avg Time: 2:72

Bounce Rate: 64.91%

Views: 94

Rating: 4.64

Note: "Page Views" & "RedCrow Page Views" differ as RedCrow monitors unique views rather than by session as Google does

## Comments and Feedback

-This is a much needed product excited to learn more

-This an important endeavor that provides a tangible and scalable tool which can be employed to help fight back against a critical problem that is ripping apart huge swaths of an entire generation. Kudos to the team for their unwavering efforts to help make our world a better place.

-A ground breaking and desperately needed solution to the Opioid Crisis offering the possibility of a non-opioid medication that also appears to be effective and inexpensive while waiting in the wings the emerging opioid related fentanyl epidemic rears its head.

-This is awesome

## Degree Of Importance Of Problem

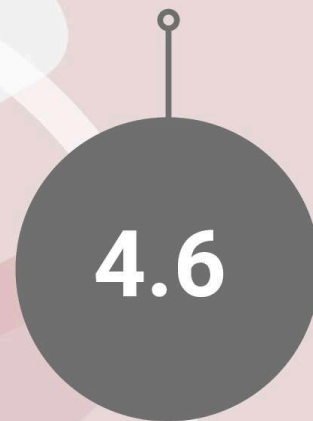
Measures the RedCrow Network's understanding of the impact the company can create.

## Validation Of Solution

Quantifies the RedCrow Network's thoughts on the ability of the company to gain significant market share

## Network Enthusiasm

Indicates the degree of interest of the RedCrow Network to learn more about the company



## Social Impact

Quantifies the RedCrow Network's assessment of the company's potential to make a positive social impact.

## Likely To Recommend to Provider or Friend

Describes the RedCrow Network's overall impression of the company.

Overall RedCrow Averages:

4.60

3.96

3.82

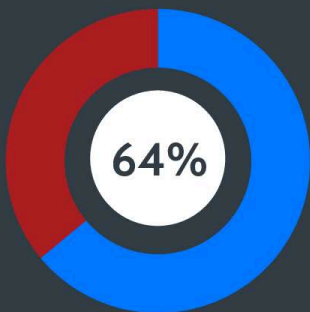
3.91

3.84

4.02

Feedback:

# Objective Metrics Overall Performance



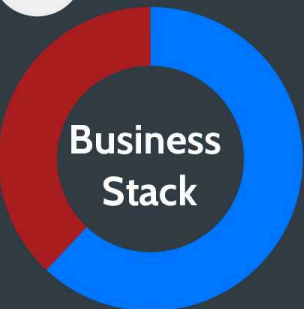
sen-jam  
PHARMACEUTICAL



## Objective Metrics Survey

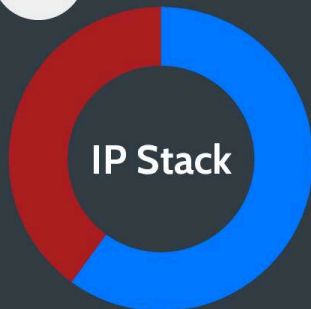
The Objective Metrics Survey measures objectively quantifiable data and aids in the understanding of how far along a company is in its journey towards success. A category % score represents fractional progress in that category. A score of 100% Indicates completion of the criteria in that category.

62%



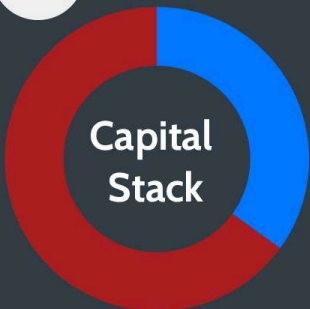
Business Stack

58%



IP Stack

36%

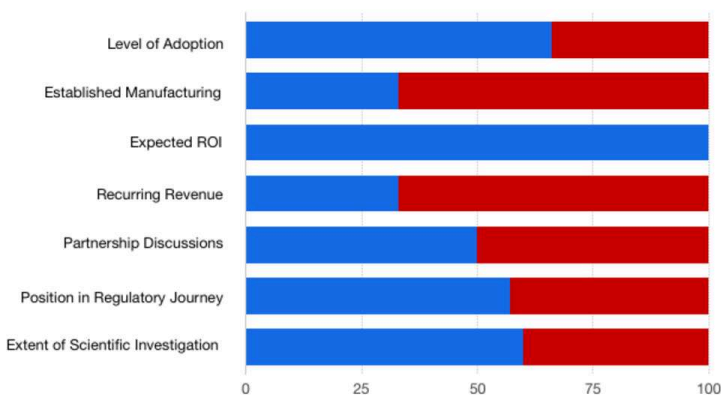
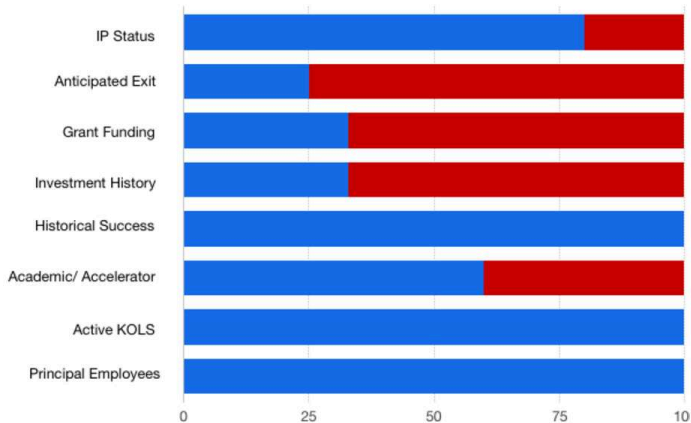


Capital Stack

89%



Personnel Stack



## **V. OBJECTIVE MEASURE QUESTIONS AND RESPONSES**

**Which principal employees are on your team?**

CEO, CMO/Sales Executive, and CTO/CMO

**How many actively engaged advisors and KOLs do you have?**

5

**How many university/incubator/accelerator active affiliations does your company have?**

3: StartUp Health - Health Transformer, Stony Brook University - Alliance Partner/Mentor, Northwell Health - Actively working with affiliate Wellbridge Addiction Care on Proof of concept with Physician's champion.

**Has your management team had historical entrepreneurial success?**

Yes, with more than one successful exit

**Does your company have professional investors (not friends and family)?**

No

**Have you received non-dilutive grant funding?**

No

**When is your anticipated exit?**

In 24-48 months

**Describe the status of your Intellectual Property.**

Patent Issued

**What is the extent of your scientific investigation?**



Clinical

**Where is your company in the regulatory cycle?**

Phase 1 trials

**What is the status of any partnership discussions you are having?**

LOI

**Does your company have recurring revenue?**

Pre-Revenue

**What is your expected ROI at exit?**

Greater than 25X

**Are you using established manufacturing facilities?**

N/A

**What level of adoption do you have with your first product?**

Pilot Site(s)

# FINANCIAL METRICS

4%

PROJECTED  
CAPTURE OF MARKET  
IN 5 YEARS

\$25 B

TOTAL  
ADDRESSABLE  
MARKET

82%

PRE-MONEY TOTAL %  
OWNERSHIP OF FOUNDERS

3x

AVG. REVENUE MULTIPLE  
AT ACQUISITION IN THIS  
VERTICAL

0

DEBT TO EQUITY  
RATIO

\$175k

MONTHLY  
BURN RATE

\$50x

0

RUNWAY  
(MONTHS)

12

75%

R AND D  
/BURN

80%

25%

SGA/BURN

20%

25%

SALES AND  
MARKETING/  
BURN

20%

PROPOSED

CURRENT



## VII. FINANCIAL SNAPSHOT

**1. What is your current monthly burn rate?**

It varies from as little as \$10k/month if we are only funding I/P and travel and lodging for conferences to \$50k/month if we are Pre-Clinical Trials and Strategic Partnering/Licensing work.

**2. How many months of runway do you currently have?**

12

**3. What is your proposed burn rate?**

\$175k/month

**4. How many months of burn will this raise give you?**

0

**5. How many months to your next significant milestone after the raise?**

18

**6. What is your current monthly %SGA burn?**

20%

**7. What is your current monthly % R and D burn?**

80%

**8. What is your current % marketing and sales burn?**

20%

**9. What is your proposed monthly %SGA burn?**

25%

**10. What is your proposed monthly % R and D burn?**

75%

**11. What is your proposed % monthly sales and marketing burn?**

25%

**12. What is your debt/ equity ratio?**

0

**13. What is your pre-money, combined % ownership of founders?**

82%, 86% if add back option pool

**14. What is your TAM (total addressable market)?**

25,000,000,000

**15. What percentage of the TAM can you realistically capture in 5 years?**

\$1Billion

**16. What is the average revenue multiple at acquisition for your vertical?**

3X

**17. How much of the TAM do you need to capture to provide investors in this round a 20x ROI, assuming no future dilution?**

.6%

## VII. IP SNAPSHOT

### **Does your company have any licensing agreements?**

**Yes:** SJP-001- Prevention of Symptoms Associated with Alcohol Hangover - We have a non-binding strategic partnership/license agreement with Rally Labs/Blowfish for the United States. Rally Labs currently has a treatment product (day after) that is sold Direct to Consumer and in over 10,000 retail stores. Rally Labs is also interested in our cold product (SJP-002). We have recently agreed to a license agreement for SJP-001 with Boryung, a Korean Biopharma manufacturer, for Korea. In 2019 we engaged with Destum Partners to find a license partner for SJP-005, Inhibition of symptoms associated with opioid withdrawal, where approximately 15 companies are interested in what we are doing later stage and we are currently engaged in discussion with Molteni Farmaceutucial and JanOne.

### **Are you aware of any potentially “blocking patents?”**

**No**

### **Does your company own any US issued patents?**

**Yes:** 10,420,756 - Methods and Composition to Inhibit the Symptoms Associated with Veisalgia (Alcohol Hangover)

### **Does your company have any pending provisional patent applications?**

**No**

### **Does your company have any pending US utility patent applications**

**No**

### **Does your company have any non-US issued or pending patents?**

**Yes:** The following patent applications have passed the 12 month period and are either in the non-provisional status or national phase.  
SJ1-001/Australia - 2016235484, SJP-001/Brazil - BR 11 2017 020307 3,

SJP-001/Canada - 2,980,162, SJP-001/China - 201680030862.6, SJP-001/EPO - 16769429.8, SJP-001/Israel - 254641, SJP-001/Japan - 2018-501141, SJP-001/Mexico - MX/A/2017/012132, SJP-001/New Zealand - 735777, SJP-001/South Africa - 2017/06794, SJP-001/South Korea - 10-2017-7031097, SJP-002/Methods and Compositions to inhibit Symptoms Associated with Upper Respiratory Tract Infections (Common Cold) - US16/009,751, SJP-003/Methods and Compositions to Inhibit Adverse Effects Associated with Vaccinations - US16/115,830, SJP-004/Methods and Compositions to treat Enteropathic Arthritis - US16/355,147, SJP-005/Methods and Compositions to Inhibit Symptoms Associated with Opioid Withdrawal - US16/133,398, SJP-006/Methods and Compositions to Inhibit Dependence on Opioids - US16/133,458, SJP-007/Methods and Compositions to Inhibit Tolerance to Opioids - US16/133,522

**Does your company have a registered trademark for your company name?**

**Yes**

**Does your company have a registered trademark for your company logo?**

**No**

# **VIII. REDCROW BUSINESS AND SCIENTIFIC ADVISORY BOARDS' EVALUATION REPORT**

The following data is presented as an aggregation of structured, data-driven feedback provided to RedCrow from members of the RedCrow Business and Scientific Advisory Boards. These groups consist of dedicated clinical and business experts who have devoted time to understanding and assessing the scientific, clinical, and business claims of Sen-Jam Pharmaceuticals.

Scores are based on a scale from one to five, with five being the highest score achievable in any category. Each category score contains subcategories, but is presented solely as a score per category. Further, the scores presented are averaged from the reviewers' feedback. More detailed data, dividing the categories into subcategories, are included for investors who wish to take a closer and more detailed look.

The purpose of having a data-driven evaluation system is to create an easily understood method of identifying strengths and weaknesses in each company's presentation. Multiple inputs are taken in order to avoid any one assessment from having outsized influence. Additionally, the quantified data provide the opportunity to surface and challenge unconscious biases that may occur with a more subjective approach. Data sets from one company can be compared to other companies' data sets as well as the overall averages of all companies who have participated in the RedCrow Due Diligence process. The net result of our analysis is to provide companies and potential investors with a document that provides comparative insights into each company's clinical and scientific strategies.

Results in this report are based on a snapshot of Sen-Jam Pharmaceuticals, taken at the time of the evaluation. This network-based report is not intended to replace the individual investor's due diligence when evaluating Sen-Jam Pharmaceuticals for a possible investment.



Performance Compared to Other RedCrow Companies



AVG SCORE OF  
A COMPANY  
ON REDCROW



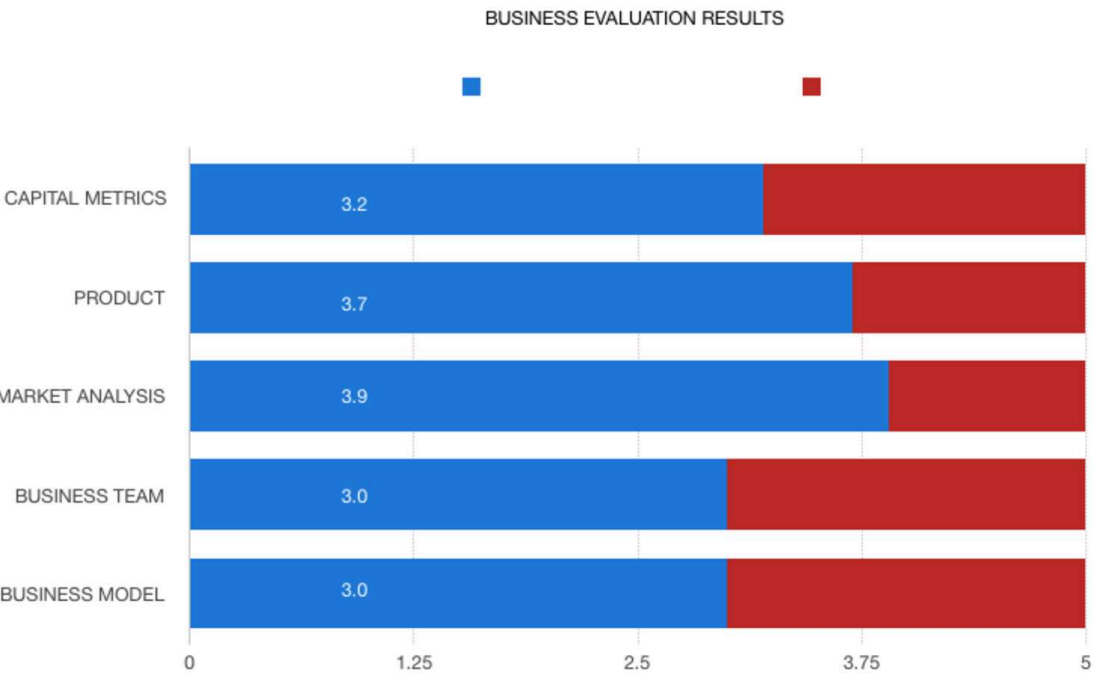
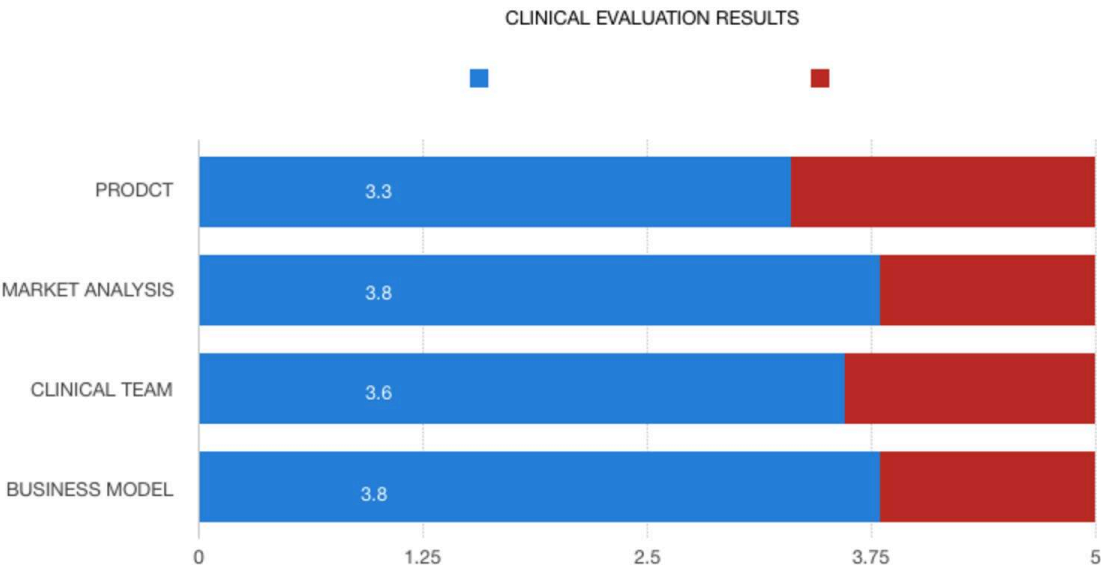
3.4	BUSINESS MODEL	3.5
3.6	CLINICAL TEAM	3.5
3.0	BUSINESS TEAM	3.2
3.9	MARKET ANALYSIS	3.9
4.0	SOLUTION	3.8
3.2	CAPITAL METRICS	3.4

SEN-JAM  
PHARMECEUTICALS

AVERAGE SCORE OF  
COMPANIES ON REDCROW



**EXHIBIT A: SCIENTIFIC, BUSINESS, AND COMBINED EVALUATION CATEGORY SCORES**



**EXHIBIT B: SUB-CATEGORY AVERAGED SCORES - SCIENTIFIC EVALUATION**  
**(Scores out of 5)**

<b>Solution</b>	<b>3.7</b>	<b>Regulatory Strategy</b>	<b>4.7</b>
<b>IP Protection</b>	<b>3.0</b>	<b>12 Month Research Goals</b>	<b>3.3</b>
<b>Value Creation</b>	<b>3.7</b>	<b>12 month Milestones</b>	<b>3.3</b>
<b>Degree of Innovation</b>	<b>2.7</b>	<b>Scientific Team Expertise</b>	<b>5.0</b>
<b>Peer Review</b>	<b>3.0</b>	<b>Prior Relevant Scientific Experience</b>	<b>3.3</b>
<b>Problem Statement</b>	<b>4.0</b>	<b>Scientific Advisor Prominence</b>	<b>4.0</b>
<b>Competitive Advantage</b>	<b>4.3</b>	<b>Advisor Engagement</b>	<b>3.3</b>
<b>Market Validation</b>	<b>3.3</b>	<b>Clinical Barriers</b>	<b>3.0</b>
<b>Competitor Comparison</b>	<b>4.3</b>		

**EXHIBIT C: SUB-CATEGORY AVERAGED SCORES - BUSINESS EVALUATION**  
**(Scores out of 5)**

<b>Problem Statement</b>	<b>4.7</b>	<b>Plans to Scale</b>	<b>4.0</b>
<b>Competitive Advantage</b>	<b>3.7</b>	<b>Likelihood of Exit in 36 Months</b>	<b>4.0</b>
<b>Market Validation</b>	<b>3.3</b>	<b>Ability to Reach 12 Month Milestone Projections</b>	<b>3.0</b>
<b>Solution</b>	<b>4.0</b>	<b>Funding Strategy</b>	<b>4.0</b>
<b>IP Protection</b>	<b>3.7</b>	<b>Likelihood Financing of Next Round will Last Through Next Milestone</b>	<b>2.3</b>
<b>Value Creation</b>	<b>3.3</b>	<b>Credible ROI Multiple for this Round</b>	<b>3.0</b>
<b>Marketing Plans</b>	<b>2.3</b>	<b>Capital Strategy</b>	<b>3.6</b>
<b>Payors &amp; Pricing</b>	<b>3.3</b>	<b>Business Team</b>	<b>4.0</b>
<b>Realistic Commercialization</b>	<b>2.3</b>	<b>Successful Team Exits</b>	<b>3.0</b>
		<b>Governance Structure</b>	<b>3.0</b>

# IX. SCIENTIFIC AND BUSINESS SUMMARY QUESTIONS, RESPONSES, AND REDCROW SCIENTIFIC AND BUSINESS ADVISORY BOARDS' SPECIFIC FEEDBACK

RedCrow advisors' comments in **red**, Sen-Jam Pharmaceutical team responses to RedCrow comments in **blue**.

## Introduction:

Sen-Jam Pharmaceutical is on a mission to change the way individuals treat their pain and inflammation. Instead of treating pain and inflammation after it exists, Sen-Jam believes it can be prevented in the first place, allowing an individual to use less pain medication overall and reduce their chance of experiencing unwanted side effects. Our proprietary technology utilizes small molecules that are repurposed into several new pharmaceutical products creating the strongest oral anti-inflammatory available with the lowest side effect profile. Our technology can be used to reduce the pain and inflammation created by the body's innate immune response before a cascade of pain and flu-like symptoms causes a debilitating day.

We currently have two lead products:

*SJP-001 for the prevention of alcohol hangover:* Why wake up with a hangover, and then try to treat it the next day by taking unproven high doses of pain relievers? Sen-Jam's first product (naproxen + fexofenadine) will be an FDA approved Over-The-Counter (OTC) product that when taken prior to drinking alcohol will reduce alcohol's unwanted side effects (pain and inflammation) the next day. This new and innovative product, will allow individuals to enjoy their next day, while also reducing an individuals need for excessive doses of untested supplements.

We had a US patent granted in 2019 with 11 other countries pending and an open FDA IND application.

*SJP-005 for the mitigation of opioid withdrawal symptoms:* Currently, individuals who are dependent on opioids suffer from withdrawal symptoms when they attempt to lower their opioid consumption. SJP-005, a combination of Ibuprofen + ketotifen (an antihistamine and potent TLR4 inhibitor), when administered around the clock, has the potential to lower the pain and flu-like symptoms associated with opioid withdrawal. Naltrexone, a weak TLR4 inhibitor, has been FDA approved to treat opioid withdrawal and reduce opioid craving. Animal studies

utilizing our product, SJP-005, have shown a significant reduction in functional observation signs during opioid withdrawal when compared to placebo.

We have US patents pending for 1) mitigation of opioid withdrawal 2) prevention of opioid dependence 3) prevention of opioid tolerance.

**Please present in detail your startup's problem statement. Include data on the clinical scale of this problem and current market solution.**

SJP-001 for the prevention of alcohol hangover:

Currently, there are an estimated 2.6 billion alcohol hangovers each year in the US alone. While individuals try untested and unproven supplements in hopes of gaining relief from alcohol's unwanted next day's effects (estimated market is 3 Billion dollars). A Danish study revealed that 70% of individuals enter a pharmacy in search of an alcohol hangover remedy. And, 70% of university students surveyed stated they would buy an alcohol hangover prevention product, if one existed.

Until now, individuals have found treating their alcohol hangovers to be extremely evasive. Hangovers not only ruin your day with debilitating symptoms, but have been shown to reduce a person's next day cognitive and physical abilities, leading to 180 billion dollars in the US annually in lost productivity (presenteeism and absenteeism).

The current hangover treatment market mainly consists of both FDA recognized OTC products containing high doses of aspirin and untested, unproven supplements. Both of these categories of treatment expose the consumer to health risks. First, neither category has been shown to be effective in clinical trials. Second, a person may be exposed to large quantities of unnecessary and dangerous substances, causing new and unwanted side effects.

The FDA recognizes that treatment options should be made available for alcohol hangover. FDA recognized treatments include a mixture of high dose aspirin (1000mg) with or without a GI protectant in a rapid absorbing formulation. These products are available OTC and are taken the next day, after an individual wakes up with a hangover. This FDA recognized "recipe" is part of the FDA Drug Monograph system created in the 1970's, utilizing a high dose of aspirin (1000mg), which requires time to achieve effective pain control. If the pain of a hangover persists (after 6 hrs), you are instructed to administer another high dose of aspirin (1000mg).

The supplement market represents the larger hangover treatment market. Although these products may be manufactured in FDA compliant facilities, they have not undergone clinical trials to attest to their safety and efficacy. Therefore, they cannot be marketed as a hangover treatment and their labeling 'side steps' FDA requirements. This lack of regulation can create a dangerous consumer health issue.

SJP-005 for the mitigation of opioid withdrawal symptoms:

The current treatment for reducing opioid withdrawal symptoms, in an opioid dependent individual, is by replacing a short acting opioid with a long acting opioid (methadone or buprenorphine/naloxone). These products are difficult for patients to access due to prescribing



regulations. In addition, patients are likely to have opioid withdrawal symptoms while being stabilized on these pharmacologic agents, known as the induction hurdle. Another option for treating opioid dependence is to use a naltrexone implant (Vivitrol). However, before this opioid antagonist implant can be inserted, a patient must undergo a 10 day opioid abstinence period, leading to opioid withdrawal symptoms. Once a patient is stabilized on methadone or buprenorphine/naloxone (medication assisted therapies (MAT)), there may come a time, when dose reduction is attempted. Again, a patient will experience opioid withdrawal symptoms. Because the intensity and duration of these symptoms are so severe, opioid drug use persists, in part to avoid withdrawal.

PLEASE REFER TO CHART 1

SJP-005 – Seeking to Improve the Pathway to Recovery

References:

- (1) CDC – Provisional Drug Overdose Death Counts
- (2) The Underestimated Cost of the Opioid Crisis
- (3) Overdose Death Rates
- (4) Comparative effectiveness of extended-release naltrexone vs. buprenorphine-naloxone
- (5) Trends in the Use of Methadone, Buprenorphine, and Extended-Release Naltrexone
- (6) Medication-Assisted Treatment With Buprenorphine: Assessing the Evidence

Currently, providers have few options to offer to their patients. Providers typically recommend a 'cocktail' of different agents that reduce individual symptoms of opioid withdrawal (ibuprofen, hydroxyzine, ondansetron, loperamide, zolpidem, clonidine, etc). However, these individual agents, alone or in combination, have not been rigorously examined for efficacy, and could expose an individual to drug-drug interactions and unwanted side effects. The only FDA approved drug for mitigation of opioid withdrawal symptoms was approved in 2018, called lofexidine (Lucemyra). Lofexidine has the same mechanism of action as clonidine, an antihypertensive and alpha-2 adrenergic agonist. Both of these agents reduce the symptoms generated by the sympathetic nervous system's over active response to opioid withdrawal. Although lofexidine's FDA approval established a safe dosing regimen and efficacy in reducing opioid withdrawal symptoms by 20-30% after 7 days, these antihypertensive agents are poorly tolerated, causing greater than 30% incidence of hemodynamic side effects, mainly hypotension. Also, lofexidine costs \$22/tablet, >\$1,000/week, making clonidine (\$0.10/tablet), the antihypertensive of choice for opioid withdrawal symptoms.

A non-opioid pharmacologic intervention that could reduce opioid withdrawal symptoms and reduce long term opioid craving with minimal side effects, would provide relief to those patients attempting to lower their opioid consumption, in conjunction with methadone or buprenorphine/naloxone induction or during dose reduction, or during the opioid abstinence phase with naltrexone implant. Such a product could help to reduce relapse rates and help patients to become opioid free.

Clinical Advisory Board Responses:



- The statements made for the most part are opinion. There is a touch of science and pharmacology but ultimately these are the companies opinion. Jim: All of our work is backed by research, science, and pharmacology.
- Mitigating opioid withdrawal symptoms may help addicts become opioid-free.

**Business Advisory Board Responses:**

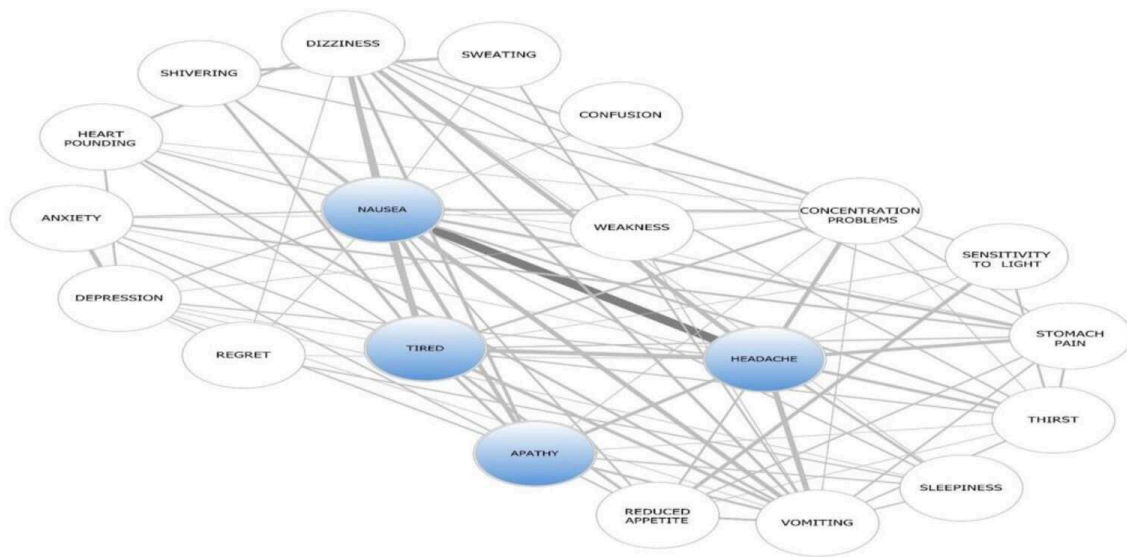
- Both hangover prevention and opioid dependence reduction are well defined and, I think, the scope of the problem is generally understood.
- The main points are well-defined, although additional data on target market penetration relative to market size would serve to further define the extent of the problem addressable by Sen-Jam and the upside for investors.

**Please discuss, with specifics, your startup's solution to the problem listed above, including the efficacy of your solution, your competitive advantages, the status of your Intellectual Property, and your current regulatory status and strategy.**

*SJP-001 for the prevention of alcohol hangover:*

The best way to avoid a painful hangover is to abstain from alcohol consumption, altogether. However, each culture and each individual consumes alcohol for different reasons and at different amounts. Most individuals in their middle ages, (30-65 yo) suffer from painful hangovers while staying within their country's guidelines for moderate alcohol consumption (ex: US: 7 drinks/week for women and 14 drinks/week for men; Canada: 2 drinks/occasion and 10 drinks/week for woman and 3 drinks/occasion and 15 drinks/week for men). In addition, it has been found that individuals who naturally do not get hangovers from alcohol consumption (hangover immune), do not drink more alcohol than those individuals who do get hangovers.

Alcohol hangovers, represent a constellation of 20 symptoms, and are believed to be caused by alcohol and its metabolites. Although hangovers are generally thought to be due to dehydration, there is no clinical data to support this hypothesis. Rather, the constellation of symptoms, more likely could be associated with pain and inflammation from alcohol's effect on the innate immune system, as international researchers in this field have surmised. Therefore, an agent that reduced pain and inflammation would bring relief to this worldwide discomfort.



Our formulation, SJP-001, is a newly patented combination of two available and safe small molecules, naproxen with fexofenadine, administered prior to consuming alcohol. These two pharmaceutical agents will be formulated into one product to provide maximum efficacy utilizing the smallest and safest doses. When administered prior to consuming alcohol, both naproxen and fexofenadine provide maximum anti-inflammatory response counteracting alcohol's eventual and unwanted effects within the human body. Our product does not interfere with alcohol's absorption, metabolism or excretion, enabling each individual to experience alcohol as usual. The only difference will be how you feel the next day, unencumbered by pain and inflammation. By taking a small and safe preventative agent, an individual could drastically reduce administering high doses of pain relievers the next day or taking unproven supplements. Sen-Jam Pharmaceutical seeks to be the only FDA approved and patented OTC product for the prevention of alcohol hangover.

Our unique formulation utilizes fexofenadine, a unique, non-sedating antihistamine. Besides counteracting alcohol's histamine reaction, fexofenadine has been shown in animal models to protect against non-steroidal anti-inflammatory induced damage to the GI tract. In addition, our US patent, allows for a proton pump inhibitor to be added to our formulation, which could be a line extension in the future. Both naproxen and fexofenadine have a duration of action of 12 hours, allowing a single dose to be administered.

To test SJP-001's safety and efficacy we performed, in 2016, a small clinical trial with a Clinical Research Organization (Clinilabs, NY) under an Independent Review Board. Twelve individuals served as their own control in a 4 way crossover study. A peer reviewed alcohol hangover questionnaire was used to obtain alcohol hangover scores the next day after drinking. The study was not large enough (N=12) to show statistical significance. A good number of individuals did not report having any alcohol hangover symptoms when administered a placebo N=7, although their BrAC was calculated to be > 0.06%. However, N=5 individuals did

experience hangover symptoms when administered placebo. This group of individuals experienced a 60% reduction in overall hangover symptoms when administered SJP-001. No safety issues or adverse drug events were reported.

Based on our clinical trial and known safety data related to naproxen and fexofenadine, we opened an FDA Investigational New Drug Application (2017) to begin Phase 1 trials in the US (scheduled for Q2-2020). Our Phase 1 trial will provide pharmacokinetic data for two drugs that have never been combined before, in the presence of alcohol, and will also provide safety and efficacy data to be used in our subsequent dose ranging studies to be performed in Phase 2. We have modified our inclusion/exclusion criteria to omit those individuals who do not experience an alcohol hangover the next day. This first phase 1 study will provide Sen-Jam Pharmaceutical with a substantial inflection point, as it will also serve to reduce overall clinical development risk.

FDA regulatory studies for SJP-001 are relatively quick and inexpensive. Phase 1 consists of 48 individuals, entering an in-patient clinic for 24 hours, and returning each week for 4 weeks. Phase 2 involves dose optimization. Two Phase 3 studies will be performed, one in-patient, one out-patient involving > 300 individuals. Other studies that need to be performed before New Drug Application submittal include one animal study and CMC/Tox. We estimate our regulatory budget to be \$9,000,000.

Our US patent for SJP-001 for the prevention of Alcohol Hangover includes methods and composition. Our current composition can include naproxen or ibuprofen + fexofenadine or cetirizine, with or without a proton pump inhibitor. We have the right to extend our coverage to more pharmaceutical agents within each category (NSAID and non-sedating antihistamine). We have patents pending in 11 other countries, providing Sen-Jam with >90% world coverage. This patent protection will allow the opportunity for individual country licensing rights to be negotiated. We are currently in discussions with a South Korean pharmaceutical manufacturing company to in-license our SJP-001 technology in exchange for US FDA regulatory clinical trial expense from phase 1 to New Drug Application. We are also in early stage discussions to out-license our technology to US, Canada, and South Africa.

Meanwhile, we have garnered the interest of friends and family, who have, by themselves, served as willing volunteers. No volunteer (N=50, representing >300 episodes) has reported an unwanted side effect, while each has found our prototype product of SJP-001 to be so effective, reporting 80% efficiency.

#### *SJP-005 for the mitigation of opioid withdrawal:*

Our second lead product, SJP-005, was also created to prevent pain and inflammation. This product uses the same proprietary technology, but is offered in a prescription strength. SJP-005, like SJP-001, offers the most potent orally available anti-inflammatory and non-opioid pain reliever with the least side effects. Because it is prescription strength, it can reduce the overall amount of opioids needed to provide pain relief, reducing unwanted side effects from chronic opioid therapy. In addition to providing pain relief, SJP-005's combination of ibuprofen with ketotifen (an anti-histamine) can cross the blood brain barrier, stabilizing the body's neuroimmune system, preventing opioid's pro-inflammatory effect on microglia (the central

nervous system's innate immune system) reducing opioid-induced hyperalgesia, tolerance, dependence and withdrawal symptoms.

The technology used to create SJP-005, offers to the consumer and the provider a product that represents the most recent and up to date knowledge for reducing chronic opioid use. First, non-steroidal anti-inflammatory agents have been shown to lower overall opioid consumption, and help to provide non-opioid pain relief to an individual suffering through opioid withdrawal. Ketotifen, a potent TLR4 inhibitor, modulates microglia, inhibiting opioid's effect of producing a pro-inflammatory response of the neuroimmune system. The opioid's pro-inflammatory response results in high concentrations of NF- $\kappa$ B, IL-1 $\beta$ , IL-6 and TNF- $\alpha$  and leads to high concentrations of dopamine, believed to be responsible for opioid's euphoric effect. This opioid induced pro-inflammatory response is believed to be associated with hyperalgesia and tolerance. After chronic opioid administration, the microglia becomes sensitized to the opioid's effect. After dependence is established and the opioid is withdrawn, the microglia becomes over stimulated again, releasing pro-inflammatory agents, believed to be responsible for the constellation of symptoms known as opioid withdrawal.

A product, such as SJP-005, could be prescribed for a number of different indications. First, preoperatively, reducing the inflammatory response prior to surgical events to lower overall opioid consumption and reducing post surgical opioid dependence. Second, postoperatively, to reduce opioid consumption, opioid dependence and to reduce opioid withdrawal. And third, to treat opioid withdrawal symptoms in opioid dependent individuals.

To bring this product to the market as soon as possible, Sen-Jam Pharmaceutical is first pursuing SJP-005 for the mitigation of symptoms associated with opioid withdrawal, as this indication has established FDA endpoints for approval, and safety and efficacy can be more easily measured and quantified.

Patients who are dependent on opioids must maintain their daily opioid consumption in order to prevent opioid withdrawal symptoms. Opioid withdrawal symptoms represent a constellation of subjective and clinical symptoms, including physiologic effects that are often described as flu-like. Subjective symptoms include feeling sick, stomach cramps, muscle spasms/twitching, feeling of coldness, heart pounding, muscular tension, aches and pains, yawning, runny eyes, insomnia/trouble sleeping. Objective symptoms as measured by a clinician include sweating, restlessness, bone and joint aches, GI upset, tremor, yawning, anxiety or irritability, gooseflesh skin, and runny nose or tearing, while physiologic effects include increased heart rate, increased blood pressure and pupil dilation. A peer-reviewed tool for quantifying these opioid withdrawal symptoms is used to assess efficacy of a given treatment.

Ibuprofen has the potential to reduce the subjective symptoms of muscular tension, aches and pains and the objective symptoms of bone and joint aches, while also adding pain relief which is experienced by >70% of individuals undergoing opioid withdrawal. While ketotifen, being a sedating H-1 antihistamine has the potential to reduce the subjective symptoms of stomach cramps, heart pounding, runny eyes, insomnia/trouble sleeping and the objective symptoms of sweating, GI upset, anxiety, runny nose and tearing.

SJP-005's combination of 2 pharmacologic agents was specifically created to do more than treat opioid withdrawal symptomatically. Evidence supports that drugs of abuse alter

non-neuronal glial cell activity producing several behavior changes that contribute to substance use disorder. Glial cells consist primarily of microglia and astrocytes and are concentrated within the central nervous system (CNS). Recent studies show that morphine's activation of CNS neurons and microglia cause the activation of the Toll-like Receptor 4 (TLR4) pathway and cause the release of pro-inflammatory cytokines. Recent studies show TLR4 pathway activation is involved in the undesirable side effects of morphine and related opioids, such as withdrawal, tolerance and dependence.<sup>1</sup> The role of the TLR4 pathway has been shown through the study of inhibitors such as the investigational drug ibudilast. Ibudilast, a phosphodiesterase inhibitor with TLR4 inhibitor activity, decreases neurobiological markers indicative of the opioid-induced pro-inflammatory response, and attenuates both antagonist-precipitated and deprivation-induced morphine withdrawal in rodents.<sup>2</sup> In the first exploratory clinical trials in humans, ibudilast decreased some subjective ratings (anxious, perspiring, restless and stomach cramps) of opioid withdrawal symptoms.<sup>3,4</sup> However, ibudilast can also cause the dose-dependent side effect of GI upset which can range from 10-27%.<sup>5</sup> The glial cell TLR4 pathway has also been found to be the primary contributor to drug reinforcement by increasing dopamine concentrations in the nucleus accumbens.<sup>6</sup> This suggests that inhibiting TLR4 may also have a desirable effect on reducing opioid craving. Ketotifen, is classified as a sedating antihistamine, and is a potent TLR4 inhibitor.

Ibuprofen, in doses greater than 2400mg/day, has been characterized as a peroxisome proliferator-activated gamma receptor (PPAR-gamma) agonist. PPAR-gamma agonists have also been shown to reduce microglia pro-inflammatory cytokines. PPAR-gamma receptors are expressed in neurons, including microglia within the central nervous system. Recent studies show that stimulation of PPAR-gamma, utilizing pioglitazone, a hypoglycemic agent, reduces heroin self-administration and reinstatement of heroin seeking.<sup>7,8</sup> Although results in humans showed varying results.<sup>9</sup> However, all studies suggest a pro-inflammatory cytokine response modulated by both the TLR4 pathway inhibition and by PPAR-gamma activation, and these may serve as therapeutic targets to mitigate detrimental opioid withdrawal symptoms and behavior changes.<sup>10</sup>

High doses of NSAIDs administered chronically may cause GI injury, especially in patients >65 yo. Administering a TLR4 inhibitor in conjunction with chronic NSAID therapy has been shown to reduce NSAID induced GI injury by 50%<sup>11,12,13</sup>. Reducing the known side effect of ibuprofen with ketotifen, supports the rationale for creating a combination therapy. Ketotifen's side effect of high incidence is somnolence (10%), which may be an advantageous side effect for this indication.

Currently there are 3 million individuals in the US who have a diagnosis of Opioid Use Disorder. Twenty percent of those individuals (600,000) are seeking treatment and have access to current therapy options (MAT Therapy). These options include methadone, buprenorphine/naloxone and naltrexone implant. Each therapy differs by its pharmacologic mechanism of action, its induction hurdle, patient access, and efficacy. Overall, these pharmacologic interventions, currently result in 50% relapse rates in 6 months and 70% relapse rates within 1 year. Relapse occurs for many reasons, and at different times in the treatment phase. While each pharmacologic agent tries to reduce opioid withdrawal symptoms and long term opioid craving, no agent provides a high level of efficacy and consumer preference. A non-opioid pain reliever that could also reduce opioid withdrawal symptoms and reduce long term opioid craving, would



be a helpful product to use in conjunction with current therapies. We believe that our product would become the standard of care as an adjuvant agent with MAT.

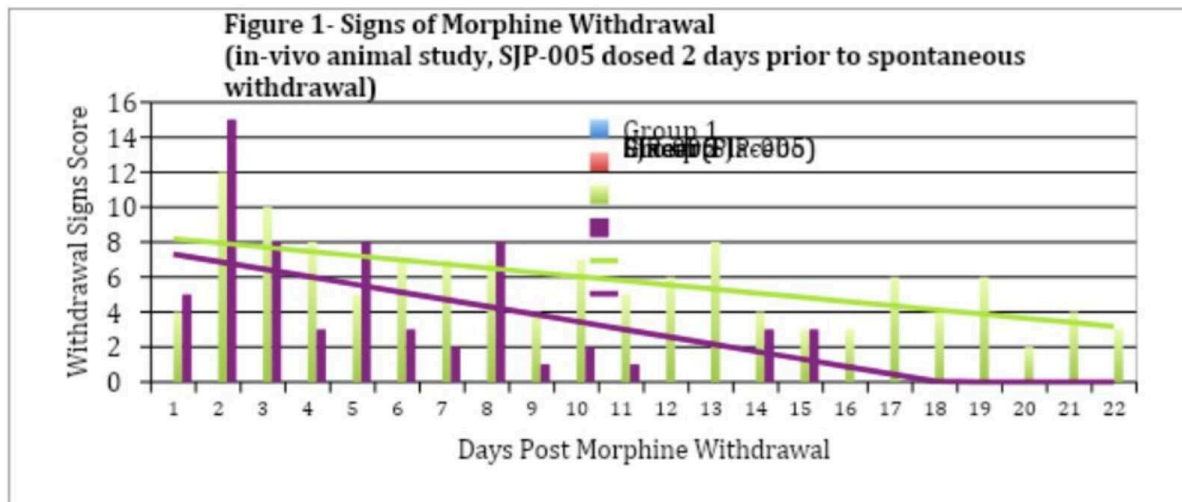
We have performed several pre-clinical in-vivo animal studies with SJP-005. First, we aimed to determine whether a combination of ibuprofen and ketotifen administered in doses equivalent to the usual dosage range in humans showed an effect in reducing opioid withdrawal behaviors in opioid dependent rats. SJP-005 (15mg/kg ibuprofen and 1 mg/kg ketotifen) administered twice daily was tested for its effects on spontaneous morphine withdrawal response in rats. Morphine was dosed in escalation, twice daily for 18 days and commenced with one last dose on Day 19. Day 19 represents T=0, the beginning of the withdrawal period. We examined specific signs of withdrawal in rodents and calculated the total scores as presented in Table 1.

**Table 1: Opioid Withdrawal Signs in Rats following Spontaneous Morphine Withdrawal Varying the Timing of SJP-005 Initiation**

Study	Jumping	Diarrhea	Hyper-sensitivity to Touch	Rearing	Wet Dog Shake	Erection	Vocalization	Genital Grooming	Ejaculation	Total
<b>T=0 days</b>										
Vehicle	0	0	107	12	0	15	73	0	3	210
SJP-005	0	0	88	10	0	1	56	0	1	156
Reduction %	0%	0%	18%	17%	0%	93%	23%	0%	67%	26% (p=0.059)
<b>T=-2 days</b>										
Vehicle	0	1	119	0	4	0	0	1	0	125
SJP-005	0	1	54	0	2	2	0	3	0	62
Reduction %	0%	0%	55%	0%	50%	n/a	0%	-200%	0%	50% (p=0.005)
<b>T=-4 days</b>										
Vehicle	2	9	92	0	0	26	126	0	5	260
SJP-005	1	6	86	2	0	17	105	0	9	225
Reduction %	45%	33%	7%	n/a	0%	35%	17%	0%	-82%	13% (p=0.433)
<b>*Statistics: one-way ANOVA.</b>										

All studies showed a reduction in opioid withdrawal behaviors when compared to placebo (vehicle 1%CMC), leading us to conclude that SJP-005 has the potential to reduce opioid withdrawal symptoms in humans. Results also show a difference in clinical response based on the timing of therapy initiation (0,2,4 days prior to the discontinuation of morphine), with T-2 showing the best and significant response (Figure 1). A 50% reduction in withdrawal symptoms was observed 12 days after vehicle versus 6 days after SJP-005. After 9.5 days, all withdrawal symptoms were absent after SJP-005, while symptoms were still observed in the vehicle group on day 12.





Our preliminary results provide proof-of-concept for our hypothesis that SJP-005, a combination of ibuprofen and ketotifen, will be able to mitigate opioid withdrawal symptoms in humans. Our in-vivo animal studies showed a reduction in multiple signs when compared to other investigational agents (i.e. ibudilast and pioglitazone).

Translating in-vivo animal data to humans is not an exact science. Ibudilast, an investigational drug for opioid withdrawal symptoms with TLR4 antagonist activity, only significantly reduced one sign of opioid withdrawal in a similar animal model. However, ibudilast has currently shown efficacy in humans (Phase 2 study) in reducing the subjective symptoms of anxious, perspiring, restless and stomach cramps. Based on SJP-005 showing a number of reductions in opioid withdrawal behaviors in our animal model, we believe that our product will surpass ibudilast in efficacy and have less side effects.

The competitive advantage of SJP-005 is described with the following charts. The current treatment paradigm for opioid use disorder stabilizes individuals with replacement opioids. This first step provides stabilization, but an individual still remains opioid dependent. Naloxone, provides life saving rescue, but creates immediate withdrawal. Naltrexone implant (Vivitrol), utilizes an opioid antagonist with weak TLR4 activity to reduce opioid craving, but an individual must sustain a 10 day abstinence period where withdrawal symptoms will occur. Clonidine and lofexidine can be used for opioid withdrawal symptoms, but exhibit a 30% incidence of hemodynamic side effects. Ibudilast, a phosphodiesterase inhibitor with TLR4 antagonist activity, is showing efficacy in reducing opioid withdrawal symptoms, but causes up to 30% GI upset. SJP-005, offers a combination product with GI protection to reduce opioid consumption, provide pain relief and can reduce opioid withdrawal symptoms and opioid craving

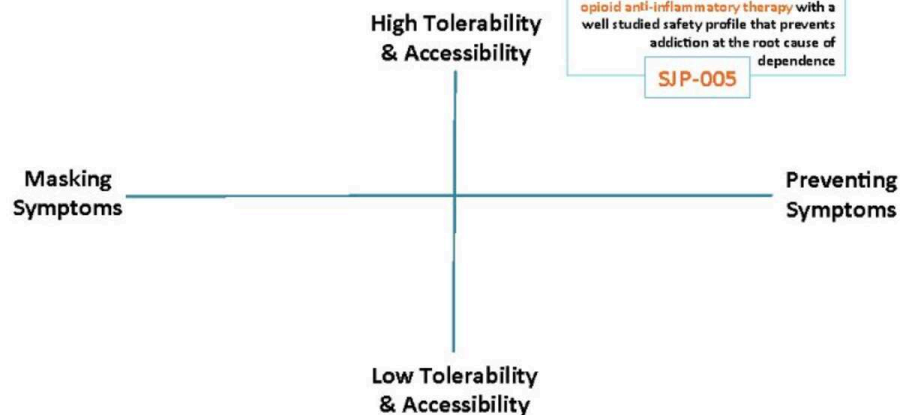
## TX PARADIGM & MECHANISM OF ACTION

	Opioids	Naloxone	Vivitrol	Clonidine & Lucemyra	Ibuprofen	SJP-005
TX of PAIN	Acute	-	-	-	-	Acute & Chronic
TARGET MOA	Opioid Agonist	Opioid Antagonist	Opioid Antagonist TLR4 Inhibitor	Anti-Hypertensive	PDE Inhibitor	COX Inhibitor TLR4 Inhibitor
TX of Withdrawal	Opioid Replacement	-	□ Craving	Masks Symptoms	□ Withdrawal	□ Withdrawal + Craving
Disadvantages	Dependence	Immediate Withdrawal	Induction Hurdle	30% Incidence of CV Side Effects	N/V	-
Advantages	Stabilizes	Rescue	Non-opioid	Non-opioid	Non-opioid	Non-opioid, GI Sparing

SJP-005's unique mechanism of action and non-opioid status, allows wide accessibility to all individuals interested in lowering their opioid consumption. SJP-005 could be prescribed by a primary care physician, or a surgeon looking for a product to reduce opioid dependence and withdrawal.

### THE SJP-005 VALUE

Unique MOA with high tolerability and accessibility



## References:

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2. Hutchinson, M. R. et al. Reduction of opioid withdrawal and potentiation of acute opioid analgesia by systemic AV411 (ibudilast). *Brain. Behav. Immun.* 23, 240–50 (2009).
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6. Hutchinson, M. R. et al. Opioid activation of toll-like receptor 4 contributes to drug reinforcement. *J. Neurosci.* 32, 11187–200 (2012).
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8. de Guglielmo, G. et al. Pioglitazone attenuates the opioid withdrawal and vulnerability to relapse to heroin seeking in rodents. *Psychopharmacology (Berl.)* 234, 223–234 (2017).
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12. [Zahavi I](#), et al. [Isr J Med Sci](#). 1996 May;32(5):312-5
13. [Eliakim R](#), et al. [Scand J Gastroenterol](#). 1993 Mar;28(3):202-4

## Clinical Advisory Board Responses:

- The information is presented well. The hypothesis and animal trials are promising. As with all new medications, human trials are needed to test the hypothesis.

## Business Advisory Board Responses:

- Really an impressive level of detail. Explaining the mechanism of action, the existing clinical data, and the upcoming clinical program is appreciated.
- Thorough explanation of solution, well referenced. The discussion of the competitive landscape was great for SJP-005, additional discussion regarding competitive options for SJP-001 would enhance the presentation.

## Does this startup have any competitive advantages?

### Business Advisory Board Responses:

- Assuming this is a unique concept, they have a competitive advantage. The risk is that other options will come along.
- There are some existing patents, but it's difficult to ascertain how strong this portfolio really is. It's probably worth assuming that the large pharma companies have a warchest of patents to put up against this.
- IP in place for SJP-001 and pending for SJP-005 provide competitive advantages. Securing the right strategic partners for development and distribution will be key to capitalize upon these advantages.



#### Clinical Advisory Board Responses:

- I'd like to understand the nature of the patents. If the drug is effective, could someone prescribe ibuprofen and ketotifen in the doses in SJP-005 ? Jim: This would be an off-label use and they may not be able to get the proper dose ranges unless going to a compounding pharmacy. Compounding pharmacies make small run batches that are often very expensive. Off-label use could not be advertised for an indication.

#### How strong is Intellectual Property Protection?

##### Business Advisory Board Responses:

- They seem to have a patent for SJP-001. I'm unsure if this patent also covers 005. Jim: No, two different formulations and uses. 005 is patent pending. We just received patent allowance for 005, sister for opioid dependence.
- Patent in place for SJP-001, patent pending for SJP-005. Attainment of patent for SJP-005 will obviously strengthen the company's market position.

#### Clinical Advisory Board Responses:

- Again I need to understand the patent protection. Same issue for SJP-001. For example, Zyban was marketed for smoking cessation but once it was proven to work, everyone prescribed Wellbutrin because it was the same drug but was covered by insurance. Jim: Patent is for category of NSAIDs and H1 Antihistamines, entire dose ranges, and all forms of administration.

#### **Discuss how your startup creates value. Include cost saving advantages and novel therapeutic applications in this section.**

Sen-Jam Pharmaceutical's mission is to improve the lives of others by creating proprietary products that are efficacious, safe, and accessible by all. We make therapeutics that reduce pain and pain related symptoms. Our goal is to create value by finding novel pharmaceutical solutions for large, unmet needs while forging global sales, distribution, and licensing agreements. We are currently collaborating with several strategic partners.

Sen-Jam is pursuing products designed to mitigate the painful side effects associated with several important areas of health concern. Our lead products include, SJP-001 for the prevention of symptoms associated with alcohol hangover and SJP-005 for the mitigation of symptoms associated with opioid withdrawal.

Both SPJ-001 and SJP-005 are fixed dose combinations of 2 agents known to be safe and we will utilize the expedited 505(b)2 regulatory pathway for FDA approval.

Our suggested OTC Retail for SJP-001, the only patented FDA approved product for the prevention of alcohol hangover, will average \$2.89. This represents a 40% discount to the currently available treatment products that are not patented FDA approved and have questionable efficacy.

Our suggested Rx Retail price for SJP-005, will be priced at 50% of the most recent FDA approved product for opioid withdrawal, lofexadine (Lucemyra).

#### Business Advisory Board Responses:

- Their pricing makes this very attractive. The hangover withdrawal market is not a well perceived market, typically sold at convenience store counters. By having a lower price, they can win that customer.
- I suspect that they're pricing this too low. Remember that hangover is essentially an "elective disease". There's no reason really to price this as a value drug. Especially if Sen-Jam is backed by clinical data, they should be priced at a premium over the existing products. Pricing below the existing products is going to set the wrong impression in customers' minds.
- Sen-Jam's SJP-001 and SJP-005 products could significantly change treatment within their respective market niches. Assuming the clinical trial and approval processes go smoothly, there is the potential for compelling value creation.

#### Clinical Advisory Board Responses:

- I can see people flocking to buy what is likely to become known as 'the hangover pill' ; I would like to understand the patent protection and why prescribers would need to prescribe SJP-005 as opposed to its two components if it's less expensive or insurance covers these drugs separately but not in combination. [Jim: Patent protection for use and formulation. The products have never been combined before. It will be an Rx product and both components are available by prescription only.](#)
- Clinical trials and/or marketing/branding will take no less than 5 years before they get even close to making any money
- Competitive pricing

#### **Demonstrate any market validation your startup has received. Include, if appropriate, any customer engagement, partnerships, licensing agreements and discussions, and your total addressable market.**

We currently have a strategic partnership with Rally Labs/Blowfish to provide manufacturing, marketing, and distribution for SJP-001 in the US. In addition, we have recently agreed to an licensing agreement with a Korean Pharmaceutical manufacturer for Korea and we are in early discussion with companies in Canada & South Africa for regional licensing agreements. The total addressable market (TAM) for SJP-001 is \$3B US and \$10B Worldwide

We retained Destum Partners to source a licensing partner for SJP-005 and they identified 10 companies that are interested in what we are doing and want to engage after our phase 1/2 studies are completed. In addition, we are working with Northwell Health/Wellbridge Addiction Care and pain management and addiction physicians to conduct a "proof of concept" in patients who want to reduce the amount of opioids they are taking. The TAM for SJP-005 is \$3B US and \$5B Worldwide

#### Business Advisory Board Responses:

- Sales do not appear to have started, but getting a group
- I think we all understand how big the hangover and opioid reduction markets are!
- Based upon the stated market sizes, there will be interest in Sen-Jam's products for the hangover and opioid withdrawal industries. The company has achieved some traction via its preclinical studies, and interest shown by potential strategic partners reflects market interest in the products.



**Clinical Advisory Board Responses:**

- Early state pharmaceutical or nutraceutical.
- Validation through partnerships.

**Degree of Innovation:**

*SJP-001 for the prevention of alcohol hangover:*

SJP-001 represents an innovative product for the prevention of alcohol hangover. Some supplemental products change alcohol's metabolism, reducing alcohol's effect, while other supplements try to reduce inflammation with non-efficacious agents. FDA recognized products offered OTC, represent old pharmacologic agents (aspirin), when safer and more effective agents have been discovered over the last 30 years. The consumer, who is continually in search of an alcohol hangover treatment will quickly adopt to this new FDA approved (for safety and efficacy) treatment, being offered OTC. The consumer, who has not been searching for a treatment, will also find our product innovative and will also become early adopters. The product, which will garner a large social media hype, teaches that alcohol hangover is not due to dehydration, but rather inflammation. This latter type of consumer, would rather prevent alcohol's inflammatory response on their body and enjoy their social activity, then choose not to drink any alcohol.

Our open IND with the FDA was granted after our pre-IND meeting. Our regulatory pathway includes one animal study to evaluate GI toxicity when our product is administered with alcohol. Fexofenadine, a mast cell stabilizing, non-sedating antihistamine with TLR4 antagonist activity, has been shown in animals to protect against GI injury. Another reason, to use SJP-001 prior to alcohol consumption.

*SJP-005 for the mitigation of opioid withdrawal:*

SJP-005 represents, clinically, an incremental improvement over current options for the mitigation of opioid withdrawal symptoms. Both a NSAID and an antihistamine have been used, as needed, for the symptomatic relief of withdrawal. Utilizing an antihistamine with TLR4 antagonist activity, is clinically innovative, and represents the only recognized target known for opioid use disorder modification today. For physicians, adopting this NSAID/antihistamine combination would be a small clinical adoption. However, our product has the potential to make a big impact in the opioid use disorder market that is currently made of only repurposed pharmacologic agents from 50+ years ago.

## TX PARADIGM & MECHANISM OF ACTION

	Opioids	Naloxone	Vivitrol	Clonidine & Lucemyra	Ibuprofen	SJP-005
TX of PAIN	Acute	-	-	-	-	Acute & Chronic
TARGET MOA	Opioid Agonist	Opioid Antagonist	Opioid Antagonist TLR4 Inhibitor	Anti-Hypertensive	COX Inhibitor	COX Inhibitor TLR4 Inhibitor
TX of Withdrawal	Opioid Replacement	-	Craving	Misc Symptoms	Withdrawal	Withdrawal + Craving
Disadvantages	Dependence	Immediate Withdrawal	Injection Abuse	High incidence of CV Side Effects	NSAID	-
Advantages	Stabilizes	Rescue	Non-opioid	Non-opioid	Non-opioid	Non-opioid, GI Sparing

Opioid Use Disorder, similar to other CNS chronic illnesses, represents a science that drug development researchers have found challenging. Sometimes, animal models that can translate to humans are difficult to determine. Fortunately, multiple studies have provided evidence that unwanted side effects of opioids and other substances of abuse can be modulated by the glial cell of the neuroimmune system, opening up a new avenue of potential drug development discoveries.

### Clinical Advisory Board Responses:

- Numerous products on the market for both entities
- The approach is innovative, but the formulations consist of previous known medications.

### Peer-Reviewed Evidence:

*SJP-001 for the prevention of alcohol hangover:*

Clinical Need: [An effective hangover treatment – Friend or Foe](#)  
[America braces for a multibillion-dollar hangover](#)

Supporting Evidence: [The pathology of Alcohol Hangover](#)

Alcohol hangovers, represent a constellation of 20 symptoms, and are believed to be caused by alcohol and its metabolites. Although hangovers are generally thought to be due to dehydration, there is no clinical data to support this hypothesis. Rather, the constellation of symptoms, more likely could be associated with pain and inflammation from alcohol's effect on the innate immune system, as international researchers in this field have surmised. Therefore, an agent that reduced pain and inflammation would bring relief to this worldwide discomfort.

*SJP-005 for the mitigation of opioid withdrawal:*

Clinical Need: Seeking to Improve the Pathway to Recovery

References:

- (1) [CDC – Provisional Drug Overdose Death Counts](#)
- (2) [The Underestimated Cost of the Opioid Crisis](#)
- (3) [Overdose Death Rates](#)
- (4) [Comparative effectiveness of extended-release naltrexone vs. buprenorphine-naloxone](#)
- (5) [Trends in the Use of Methadone, Buprenorphine, and Extended-Release Naltrexone](#)
- (6) [Medication-Assisted Treatment With Buprenorphine: Assessing the Evidence](#)

Supporting Evidence: [Glial and Neuroinflammatory targets for treating substance use disorders](#)

Multiple studies have provided evidence that unwanted side effects of opioids and other substances of abuse can be modulated by the glial cell of the neuroimmune system, opening up a new avenue of potential drug development discoveries.

**Clinical Advisory Board Responses:**

- No FDA cleared competitors.

**Does this startup have a strategic marketing plan in place?**

Our marketing plans for investor outreach for both SJP-001 and SJP-005 will consist of utilizing Pitchbook, conferences, social media, trade organizations, RedCrow, regional pitch dinners, consultants, and investment bankers.

Our marketing plans for brand awareness for both SJP-001 and SJP-005 will consist of conferences, presentations, social media, articles and interviews.

Our marketing plans for SJP-001 strategic partnerships include evaluating the 11 non-US countries in which we have patents pending to understand the OTC or OTC equivalent space for our combination product. We will then put together a Regulatory Strategy based on how long to get to market and identify potential strategic partners and develop a strategic partner outreach program.

Our marketing plans for SJP-005 strategic partnerships will include working with Destum Partners and the 12 companies interested in us for out-licensing.

**Business Advisory Board Responses:**

- It's still early for Sen-Jam. As they progress, it would be nice to see what channels they plan to access to get the product to market. OTC is a difficult, expensive way to go. It is probably the way to go, but they're going to need to understand the marketing effort required to make that a success. **Jim:** Our business model is to de-risk on clinical and regulatory development and license to a commercial partner who will take on the commercial risk.
- It's unclear if this product will be marketed under their own brand or another company's brand. **Jim:** This is for the commercial partner to decide. If it is under their own brand, and they have to supply the marketing, I believe they are underestimating the marketing costs associated with SJP 100. They not only have to prove it's efficacy, but they have to overcome the stigma related to hangover cures which many consumers view as a



"snake oil". This stigma is further compounded by the fact that consumers primarily see hangover cures at the front of convenience stores, not in a place where they look like a viable medical option. It would probably be best if their product was placed in the medicine aisle of a pharmacy.

- Sen-Jam seems to have a general marketing plan in place, with much dependent upon its future strategic partnerships. The presentation to this point has been extremely thorough and detailed - some additional thought and direction in this area would enhance the company's investor presentation

#### **Payors and Pricing:**

SJP-001 is an OTC product that will be priced competitively. We expect to enter 3 license agreements in 2020 and be ready for commercialization in 2022.

SJP-005 is an Rx product will have CPT code associated with opioid use disorder

#### **What is the status of the pricing analysis?**

##### **Business Advisory Board Responses:**

- The OTC product does have a pretty extensive pricing survey behind it. I just happen to think that it's being priced too low. *Jim: Many others have said the same thing. It's about ½ the price of current treatment products that have no efficacy, FDA approval, or patent. We have shown efficacy, will have FDA approval, and have achieved patent protection. Ultimately our commercial partner will set the price and our revenue will be a % of their revenue, so our revenue projections may be understated.*
- It seems based on earlier statements that they understand the pricing in the market. It's unclear if this pricing is for the consumer or as a license. *Jim: License*
- Management has indicated pricing ranges for both products, but has not indicated detailed analysis behind these numbers. *Jim: Market and valuation analysis was performed by Destum Partners.*

#### **When is realistic commercialization?**

##### **Business Advisory Board Responses:**

- Based on the timelines provided, it seems like the OTC hangover treatment product can come to market relatively quickly.
- 2022
- Management has indicated a timeline to launch for SJP-005 of five years. Unclear as to the projected launch date of SJP-001. *Jim: Could be available for commercial use in late 2022/early 2023.*

#### **What are the clinical barriers to adoption faced by the startup?**

##### **Clinical Advisory Board Response:**

- Need human studies to prove efficacy. Concern for abuse of 'hangover pill' - concern for underage usage or abuse.

**What is the current status of your research and what do you need to accomplish with respect to research in the next 12 months? What is your time frame to commercialization?**

*SJP-001 for the prevention of alcohol hangover:*

We have an open Investigational New Drug (IND) application and are ready to begin Phase 1 Clinical Trial in humans. Our research over the next 12 months will be to complete a Phase 1 & Phase 2 Clinical Trials and we believe we can be ready for commercialization within 3 years.

*For SJP-005 for the mitigation of opioid withdrawal:*

Current status of SJP-005 is to begin the pre-IND work to open an IND and begin a phase 1 Clinical Trial and we believe we can be ready for commercialization within 3 years.

**Business Advisory Board Responses:**

- The clinical milestones are aggressive, but I like that they're thinking big.
- They have an aggressive next 12 months, but I think the \$3mm raised should get them through the phase 1 trial for SJP-001
- The company and management has gained significant ground to date. Twelve month projections include numerous key milestones, the delay of even one could result in significant setbacks.

**Clinical Advisory Board Response:**

- It always takes longer than predicted
- They will not be ready for commercialization in 3 years through the FDA

**Composition of Clinical/Scientific Team:**

Jackie Iversen, RPh, MS – Founder/Head of Clinical Development (Full Time)

- ☐ Past Pain Research Fellow: Memorial Sloan-Kettering Cancer Center
- ☐ 15+ years Hospital Clinical Pharmacist
- ☐ 10 years Pharmacy Clinical Coordinator for Large Hospital System providing clinical education and Formulary selection.

Thomas Dahl, PhD – Partner/Head of Product Development & Regulatory Affairs (Part Time)

- ☐ Sr. Biotech/Pharmaceutical Executive with expertise in early stage ventures, including development program strategy, clinical trial design and interpretation.
- ☐ 25+ years experience in product development, both small molecules and biologics
- ☐ 35+ clinical trials under multiple INDs and CTAs across a variety of therapeutic indications.

Joris Verster, PhD – Partner/Scientific Advisor (Part Time)

- ☐ Leading International researcher on alcohol hangover
- ☐ Principle Investigator for multiple clinical trials for testing the cognitive effects of food and drugs



Andrew Scholey – Partner/Scientific Advisor (Part Time)

- Leading International researcher into the neurocognitive effects of natural products, supplements, and food components
- Founder of the Human Cognitive Neuroscience Unit at Northumbria University, UK

Frank Farraye, MD, MS – Partner/Scientific Advisor (Part Time)

- Gastroenterologist, Senior Associate Consultant in the Section of Gastroenterology and Hepatology at the Mayo Clinic in Jacksonville, Florida
- Past Clinical Director in the Section of Gastroenterology and the Inflammatory Bowel Disease Center at Boston Medical Center
- Master Degree in Epidemiology, Harvard School of Public Health

Charles France, PhD – Consultant

- Leading researcher on interactions between behavior and pharmacology and how those interactions impact the abuse liability of drugs
- Instrumental in our pre-clinical pharmacology studies to date

## Discuss your startup's economics below:

Sen-Jam Pharmaceutical LLC  
Pro-Forma Projections(000):



	Year									
	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
<b>Projected Financials(000)</b>										
Revenue <sup>1</sup>	\$0	\$9,250	\$18,250	\$21,525	\$52,387	\$47,871	\$68,464	\$90,138	\$107,086	\$124,919
<b>Expenses</b>										
- Research & Development <sup>2</sup>	\$3,075	\$12,524	\$19,575	\$17,129	\$2,685	\$2,744	\$2,807	\$2,872	\$2,941	\$3,013
- Sales, Gen, & Admin	\$1,938	\$2,034	\$2,136	\$2,243	\$2,355	\$2,473	\$2,596	\$2,726	\$2,863	\$3,006
EBITDA (Loss)	-\$5,013	-\$5,308	-\$3,461	\$2,153	\$47,347	\$42,654	\$63,061	\$84,540	\$101,203	\$118,901
Taxes <sup>3</sup>	\$0	\$0	\$0	\$861	\$18,939	\$17,061	\$25,224	\$33,816	\$40,513	\$47,560
Net Income	-\$5,013	-\$5,308	-\$3,461	\$1,292	\$28,408	\$25,592	\$37,837	\$50,724	\$60,770	\$71,341
- Capital Investment (\$3M+\$10M)	\$13,000									
Accumulated Cash	\$7,988	\$2,679	-\$782	\$510	\$28,919	\$54,511	\$92,347	\$143,071	\$203,841	\$275,182

### Notes:

1. Revenue includes License Fees and Royalty Payments for 001 & 005 only, i.e. No Revenue consideration for 5 other assets in portfolio
2. Product Development Cost and R&D Expenses
3. No Tax consideration for Net Operating Loss Carry-Forward

### Assumptions:

Exulta 001 - Prevention of Symptoms Associated with Alcohol Hangover

- a. World Licensing Revenue based on 1.8x US Revenue in 2023 --> 2.3x US Revenue in 2028 with a 20% Growth increase/Year after
- b. No consideration for planned sale of US Rights in 2021, targeting >\$25M
- c. R&D Expenses include cost of all US Regulatory work (~\$9M) and \$1M/Year starting in 2023 for Non-US Patent & Bridge Regulatory Cost
- d. No consideration for Korean Manufacturer (Licensee) funding FDA Regulatory work, value ~\$9M

Exulta 005 - Mitigation of Symptoms Associated with Opioid Withdrawal

- a. R&D Expenses include cost of all US Regulatory work (~\$48M - typically paid by Licensee) and \$.5M/Year starting in 2024 for miscellaneous costs
- b. No consideration (Revenue or Expense savings) for NIH/NIDA grants, we currently have a grant filed for \$2.7M with more to come

### How likely is this startup going to meet its financial forecasts?

#### Business Advisory Board Responses:

- It's unclear where 2021 revenue will come from given they don't expect to commercialize their product until 2022, this would put a \$9mm hole in their budget. *Jlm: We expect to engage in 1-3 licensing agreements to make up the 2021 revenue.*
- Financial forecasts are not unrealistic assuming milestones are reached as projected.

#### Plans to Scale:

Given the ebb and flow of the business to date we have used contractors on an as needed basis. We will continue to use this model to scale the company until we have greater predictability of sustained resource requirements. Key hires over the next 12 months will include clinical assistant, product development assistant, grant writer, controller/CFO, business development, operations manager, and office assistant.

#### Business Advisory Board Responses:

- Production costs seem reasonable. The only question is their freedom to operate and how potential licensing arrangements might affect the unit cost. Beyond that, though, this is easily scalable.
- Assuming they are primarily licensing the product to other companies, it should scale very easily.
- The use of strategic partnerships and licensing agreements will facilitate market penetration and manufacturing scale.

### Discuss your funding strategy. List any current and projected dilutive and non-dilutive capital.

Our current funding strategy is to raise \$3 million through a convertible debt note. This will be followed by a Series A round for \$10 million anticipated closing in Q3-2020. We are working with Hanover International to lay the ground work for the Series A to start in the coming months.

We have filed a NIH/NIDA HEAL (Help End Addiction Long-term) grant for \$2.7 million. We have plans to file additional grants.

### What is the likelihood that the startup will meet its fundraising goals?

#### Business Advisory Board Responses:

- \$10M in pharma investing should be a drop in the bucket.
- I worry that Investors will view the hangover cure negatively and that may potentially pollute the opinion of the company. The real strength in the company is the opiod withdrawal cure.
- Products are well-positioned in attractive industry niches. Assuming trials prove drug effectiveness, marketability should be good.

#### Use of Funds:

*SJP - 001 - Prevention of symptoms associated with alcohol hangover*

- . Phase 1 Clinical Trial
- . Phase 2 Clinical Trial
- . Further International I/P

- . Regional Licensing
- . Cytokine Profiling Study

*SJP - 005 - Mitigation of symptoms associated with opioid withdrawal*

- . Proof of Concept in humans with physician sponsor
- . Pre-IND work
- . Further I/P
- . Grant Research & Filing

*General:*

- . RedCrow – Complete listing on Platform (\$3M)
- . Legal
- . Additional I/P
- . Working Capital
- . Series A planning – Target close 3<sup>rd</sup> Qtr -2020

	Lead	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
RedCrow Platform Listing	Jim/Jackie	\$10	\$15	\$10								
Phase 1 Clinical Trial – SJP-001	Tom/Jackie			\$100	\$300	\$400						
Proof of Concept – SJP-005	Jackie/Tom	\$5	\$15	\$5								
Grant Research & Filing	Jackie/Tom	\$5	\$5	\$10	\$10	\$10	\$10	\$10	\$10	\$10	\$10	\$10
Regional Licensing – SJP-001	Jim		\$5	\$10	\$10	\$10	\$10	\$10	\$10	\$10	\$10	\$10
Series A - Planning & Close	Jim		\$5	\$5	\$15	\$15	\$15	\$15	\$15			
Phase 2 Clinical Trial – SJP-001	Tom/Jackie								\$240	\$240	\$240	\$240
Pre-IND work – SJP-005	Tom/Jackie					\$100	\$100	\$100				
Legal (General & I/P) & ACCT	Jim	\$35	\$15	\$25	\$25	\$25	\$25	\$25	\$25	\$25	\$25	\$25
Sales, General & Administration	Jim	\$5	\$10	\$20	\$50	\$50	\$50	\$50	\$50	\$50	\$50	\$50
<b>Total Projected Burn Rate</b>	<b>Jim</b>	<b>\$60</b>	<b>\$70</b>	<b>\$175</b>	<b>\$410</b>	<b>\$610</b>	<b>\$210</b>	<b>\$110</b>	<b>\$350</b>	<b>\$335</b>	<b>\$335</b>	<b>\$335</b>

**Will the current financing round support the startup through its next milestone?**

**Business Advisory Board Responses:**

- \$10M to finish 3 clinical trials worries me a little bit, particularly because pharma trials tend to require a lot of patients and following up patients could be difficult for both these indications. That said, I think it's definitely achievable.
- Round 1 needs to bring them through the phase 1 trial of SJP-100, if that happens they should be able to raise the additional \$10mm they need. I worry that they are overestimating revenue in 2021 which would mean that the next \$10mm is not enough.



- Management's forecasts appear to be well thought out, detailed and supported by past experience.

#### **Composition of Business Team:**

Jackie Iversen, RPh, MS – Founder/Head of Clinical Development (Full Time)

- Past Pain Research Fellow: Memorial Sloan-Kettering Cancer Center
- 15+ years Hospital Clinical Pharmacist
- 10 years Pharmacy Clinical Coordinator for Large Hospital System providing clinical education and Formulary selection.

Thomas Dahl, PhD – Head of Product Development & Regulatory Affairs (Part Time)

- Sr. Biotech/Pharmaceutical Executive with expertise in early stage ventures, including development program strategy, clinical trial design and interpretation.
- 25+ years experience in product development, both small molecules and biologics
- 35+ clinical trials under multiple INDs and CTAs across a variety of therapeutic indications.

Christine Leonard – Head of Marketing & Communications (Part Time)

- Award winning marketing strategist with a passion for brands that aim to improve lives.
- Lead marketing, business development/strategic insight for pharmaceutical and healthcare industries.

Jim Iversen – CEO (Full Time)

- 30+ years of providing Executive Leadership & Strategy across multiple industries.
- Chairperson of the Opioid Crisis Working Group, part of StartUp Health
- Directorships and M&A advisory services

#### **How qualified is the business team to bring this startup to a successful exit?**

Business Advisory Board Responses:

- Looks like a good team, though I'd like to see a CFO added to the team at some point in the near future. Jim: In the current budget for a CFO consultant -> hire. Have been in discussion with someone ready to join.
- The part time nature of the staff is concerning. Jim: P/T staff has been supporting the work that needs to get done and are available to come on full-time as needed.
- Management team has notable experience in the opioid market and product development but has no previous exits.

#### **Has the team, individually or collectively, had successful exits in the past?**

Jim Iversen has sold 3+ software companies, 2+ engineering companies, and 1 manufacturing company totaling \$80M.

Business Advisory Board Responses:

- The multiple exits is great. Though I'm a little worried that none of the exits have been in pharma.
- The management team has not established and taken a company to exit.

**Governance Structure:**

We are a member managed LLC with Jim Iversen being the member manager. The leadership team of Jackie Iversen, Tom Dahl, & Jim Iversen participate in setting the strategic direction of the company and running the day to day activities.

**Does the startup have adequate governance in place?****Business Advisory Board Responses:**

- I'd really like to see a CFO.
- Not clear from available info. Looks like Jim has full control.
- At this early stage, the company's management currently appears to be functioning as its board.

**Exit Strategy:**

Our exit strategy is to sell or license all of our assets by 2023

**What is the likelihood of an exit within 36 months?****Business Advisory Board Responses:**

- I think there's good potential here if they can enroll the trial quickly and show positive results. I could see an established player buying Sen-Jam for their pipeline.
- Based on their timeline, they are not far enough along on the trials SJP-005 to have enough proof of it's validity by this time.
- The trials, approvals, and licensing partnerships would have to occur with little or no delays to achieve a three year exit.

**Valuation Metrics:**

- ☐ 10-14 times forward looking 12 month EBITDA at exit
- ☐ Working on Discounted Cash Flow (DCF) Model with Bourne Partners

**What is a credible ROI multiple for this round?****Business Advisory Board Responses:**

- It all comes down to the clinical results and freedom to operate, but I think there could be a significant ROI here. It just comes with a fair amount of risk.
- Without knowing the valuation of the company at the time of the 3million investment it is hard to forecast what the ROI will be. They
- \$20M premoney valuation is steep for the company at this stage. Additional traction in the trial/approval process will help to support future valuations.

**What are the most important milestones for your startup within the next 12 months?**

Please present a timeline for achieving those milestones.



	Lead	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
RedCrow Platform Listing	Jim/ Jackie											
Phase 1 Clinical Trial – SJP-001	Tom/ Jackie											
Proof of Concept – SJP-005	Jackie/ Tom											
Grant Research & Filing	Jackie/ Tom											
Regional Licensing – SJP-001	Jim											
Series A - Planning & Close	Jim											
Phase 2 Clinical Trial – SJP-001	Tom/ Jackie											
Pre-IND work – SJP--005	Tom/ Jackie											

## 12 Month Milestones:

### Business Advisory Board Responses:

- The clinical milestones are aggressive, but I like that they're thinking big.
- They have an aggressive next 12 months, but I think the \$3mm raised should get them through the phase 1 trial for SJP-001
- The company and management has gained significant ground to date. Twelve month projections include numerous key milestones, the delay of even one could result in significant setbacks.

## Do you have any additional feedback?

### Business Advisory Board Responses:

- Impressive!
- Need to know entry valuation to determine ROI. Also need to know what sort of market penetration is implied by their revenue numbers to determine how realistic they are.  
Jim: \$20M Valuation Cap on Note. Overall market penetration of SJP-001 (Worldwide) & SJP-005 (US only) of 3-5% based on 3.5% annual inflation and a back-end loaded 10% of net revenue.
- Sen-Jam's lead products appear to be simple, exciting solutions to longtime medical issues. The company has already achieved some traction in its early stage, which should provide some proof of concept and increase investment attractiveness to investors. Although current focus is rightly on the development of its two lead products, a brief discussion regarding other potential products in the company's pipeline may be of interest to investors as support for future value enhancement.

Jackie: our third lead product has stepped up to the forefront, just recently, due to COVID19. SJP-002, a product we have been developing for viral respiratory infections, has been retooled (prescription strength) as a candidate to solve for the excessive inflammation and lung damage associated with COVID19. We are currently

collaborating with INSERM/AP-HP (French Public Health Service) to test our product in humans.

- Overall, it's a compelling story. But the costly/uncertain approval path, as well as the high-cost proposition of marketing/gaining payor coverage, make it a high-risk biotech play. It would be helpful to have more analysis of the financial projections. We are principally given TAM, but that lacks the granular segmentation that an opioid treatment would likely demand.

Jim: With a current US TAM of \$3B, and 3.5% annual inflation adjustment, Our licensing royalty projections, based on a back-end loaded 10% of net revenue, represents 3-5% TAM revenue (US only).

- FDA approval for prescription pharma is not easy and it is very expensive. The company plans to sell all its IP by 2023, post-validation. This may be possible, and is likely a better strategy than attempting to market directly. There is a lack of detail regarding marketing and payor coverage. Getting payors to sign up can take many months and is time consuming.

Jackie: Our platform of products includes both OTC and Rx strength, utilizing similar technology. Our OTC products would be competitively priced, while offering the consumer improved safety and efficacy with a preventative approach (rather than treatment) in several categories: pain, common cold and hangover prevention. Our OTC products empower the consumer to get the most out of every day.

One pharmaceutical agent in our opioid withdrawal product is not available in the US as an oral dosage form, therefore, a doctor and a patient in the US would find it difficult, time consuming and expensive to obtain outside of the US. While Medicare/payors will not have a generic alternative to recommend to their clients. An example of how this strategy overcomes the payor barrier, is the prescription strength combination product Entresto (sacubitril/valsartan) for heart failure, which is a very profitable drug product.

#### Clinical Advisory Board:

- I think the company faces all the usual hurdles and challenges that any company developing a new drug faces. I think they've identified a largely untapped market for the alcohol hangover drug. If the drug works, I could easily see this becoming 'the hangover pill' just like Plan B became 'the morning after pill'. As far as SJP-005, my biggest concern remains that the drug proves safe and effective in human trials and gets approved... that insurance won't cover the drug so doctors will instead prescribe the two primary ingredients separately in dosages similar to what is included in the combination drug. If there is a way to mitigate this risk, it would be important to understand that. I'd like to have seen a bit more about not just the existing solutions but also about who else is early stage/ working now to compete in this space. Overall I think this company did a great job of outlining the problem and solution and market size, and I find the presentation compelling and interesting. I think that both drugs have real potential.

Jackie: One pharmaceutical agent in our opioid withdrawal product is not available in the US as an oral dosage form, therefore, a doctor and a patient in the US would find it difficult, time consuming and expensive to obtain outside of the US. While Medicare/payors will not have a generic alternative to recommend to their clients. An



example of how this strategy overcomes the payor barrier, is the prescription strength combination product Entresto (sacubitril/valsartan) for heart failure, which is a very profitable drug product.

Ibudilast, an investigational drug, is being developed for mitigation of opioid withdrawal and has shown efficacy in phase 2 studies. Ibudilast is similar to one of our drugs in our combination product, except, exhibits 20-30% incidence of nausea and vomiting which is not ideal. Our combination product would be superior to ibudilast because of our preferred side effect profile, while also offering non-opioid pain relief.

The idea is sound. Trying to cater to the "hangover" market is good. Numerous people suffer on a weekly basis. Taking medication prior to an event is a tough sell. The assumption is people plan on getting intoxicated besides college age adults most people do not plan on getting intoxicated. This is going to be a tough sale. The opioid withdrawal process is over simplified in the discussion. Will need to have clinical studies to support their claims which will take a lot of time and money.

Improving the happiness and productivity of individuals the day after drinking alcohol is our goal. This simple plan for the next day can be achieved by reducing the inflammation caused by alcohol. Some people experience inflammation from alcohol only after a drink or two. Yet, social experiences and sometimes work related social events where alcohol consumption occurs demands a preventative solution to ensure you are at your peak ability the next day. After each of our volunteers have had this experience, they have chosen to take our product each time they drink. At Sen-Jam Pharmaceutical, we recognize that binge drinking is unhealthy to an individual and we suggest that individuals remain within the recommended daily/weekly alcohol consumption guidelines.

Although all drug development takes time and money, by repurposing small molecules that have proven safety profiles, a drug can reach FDA approval at a significantly reduced cost (\$50M vs \$1B) and time schedule (3yrs vs 15 yrs).

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