JanOne®
NASDAQ: JAN

A Company Dedicated to Mitigating Pain with Non-Opioid Solutions

Inquiries: 1 (800) 400-2247 | ir@janone.com

Mission Statement

JanOne strives to become the leader in non-addictive pain mitigating therapies. Starting with indications with unmet medical needs, the Company will strategically plan development pathways that will lead to rapid approvals for its two lead candidates. Simultaneously, the Company will continue looking for additional technologies to add to its portfolio.

About JanOne

JanOne (Nasdaq: JAN), a biopharmaceutical company specializing in developing non-addicting pain killers and treatments for underlying causes of pain.

- Two 505b2 qualified drugs ready for registration trials.
- Orphan drug status for Jan123.
- Both drug candidates are low cost, non-addictive and safe.
- Lower risk and clear pathways to registration with low development costs.
- Highly skilled management team with many years of drug development experience.

JanOne has two drug candidates for treating chronic pain

- **Jan101** Sodium Nitrite based sustained release formulation with 505b2 designation. First indication is PAD (Peripheral Artery Disease)
- **Jan123** Low dose Naltrexone with BiPhasic release formulation. Jan123 has 505b2 and Orphan drug designation. First Indication for CRPS (Complex Regional Pain Syndrome).

Naltrexone has been approved and used in humans for years. Sodium Nitrite is a well - known and well-characterized food additive.

Why 505b2 and Orphan Drug Designation Are Important

505b2 Designation

- Acknowledges the drug has already been approved for either a different indication or for a different delivery method.
- FDA requirements are less stringent since the drug has a history of human experience and is well-characterized

Orphan Drug Designation

- Allows potential tax credits for clinical trials.
- Exemption from FDA mandated user fees.
- The potential for 7 years of market exclusivity after approval.

Chronic Pain is a Major Issue In The US

Chronic Pain Affects 21% of Americans, CDC Reports - Nearly 7% have pain severe enough to restrict daily activities*

During 2021

An estimated **51.6 million** adults **(20.9%)** had chronic pain lasting 3 months or longer

17.1 million (6.9%) had high-impact chronic pain -- pain severe enough to restrict daily activities.*

*Judy George, Deputy Managing Editor, MedPage Today April 13, 2023
*S. Michaela Rikard, PhD, of the CDC's National Center for Injury Prevention and Control, and co-authors.

JanOne Will Target Peripheral Artery Disease (PAD) And Complex Regional Pain Syndrome (CRPS)

- CRPS Affects 200,000 people in the US each year. Jan123 has received Orphan Drug designation for CRPS.
- PAD Affects 8 million people in the US each year. Jan101 will be developed for PAD under 505 b2 designation.
- There are currently no therapies to treat the cause of pain or tissue damage associated with PAD.

PAD Is An Attractive Target For Jan101

Peripheral artery disease (PAD) restricted flow of blood to the legs as a consequence of atherosclerosis

Large Potential Market with Unmet Medical Need. Over 230 million people worldwide suffered from PAD. The US has 8 million PAD patients, with medical costs of $21 billion/year.

There are currently no therapies to treat the cause of pain or tissue damage associated with PAD. Treatment for pain in severe cases can include bypass surgery, spinal cord stimulation, limb salvage, or amputation.

JanOne proposes to show the effectiveness of sustained-release Sodium Nitrite to increase blood flow, reduce pain, and improve mobility in PAD patients

Jan101: The Nitrite Solution: Sustained Release Sodium Nitrite

Oral, sustained release formulation of Sodium Nitrite

- ✓ Well established safety profile
- ✓ Excellent bioavailability
- ✓ Lack of induced tolerance
- ✓ Non-narcotic

Does not mask pain, but instead treats the cause of pain by improving tissue and vascular dysfunction.

Summary of Sustained Release Animal Data

- Sustained release of Nitrite resulted in faster and more robust angiogenesis in Hind Limb Ischemia model of PAD.
- Sustained release of Nitrite resulted in improved cardiac function in Transverse Aortic Constriction model of heart failure, whereas bolus release was inactive.
- Sustained release Nitrite did not change blood pressure in pigs, thus is unlikely to cause headaches and dizziness in human subjects.
- Sustained release Nitrite should improve efficacy in human subjects and reduce side effects since high CMax will be eliminated.

Phase IIa PAD Study of Sodium Nitrite (SONIC Trial)

Placebo controlled, dose raging study to evaluate the safety, pharmacokinetics, and tolerability of multiple doses of oral Sodium Nitrite in patients with PAD.

- ✓ 40 and 80 mg doses, BID
- ✓ 10 week treatment period, followed by 1 week dose escalation
- ✓ Primary Objective: Safety and Tolerability
- ✓ Primary Endpoint: Flow Mediated Dilation (FMD)

50
Subjects
at
11
Clinical sites

Phase 2a Study Conclusions

- No clinical safety concerns
- Clear evidence of biological activity
- PAD patients reported significant less pain following treatment.
- In a bridging study with diabetic neuropathy patients, treatment with sustained release formulation,Jan101 did not result in headaches or dizziness while improving nerve function and reducing pain in these patients.

Sustained release formulation should provide clinical benefits while reducing headaches and dizziness, which track the high C_{max} of the rapid release formulation

Overall Sodium Nitrite Summary

- Human studies have demonstrated bioactivity of oral Sodium Nitrite and also significant reduction in pain in two different patient populations.
- In a 3rd different patient population topical Nitrite was also shown to alleviate pain.
- The sustained release formulation maintains the same benefits as the immediate release while reducing headaches and dizziness;
- Numerous method of use and composition patents have been issued in the US, Europe, Australia, Japan, China and Israel.

Jan123 Low Dose Naltrexone Strategy

Treat the Orphan Disease of Complex Regional Pain Syndrome (CRPS) with Low Dose Naltrexone (LDN)

Jan123 Summary

1. Orphan Drug Designation Status obtained for Jan123 Low Dose Naltrexone (LDN) 2mg with a novel biphasic release

2. Proprietary biphasic formulation for Jan123 was developed to reduce side-effects common to LDN dosing.

3. Pre-IND meeting with FDA was successful in generating a development pathway

4. LDN has been extensively studied with literature reports of over 12,000 patients. An additional study of over 4,000 patients vs placebo demonstrated safety of oral naltrexone

5. Anticipate rapid market uptake with low cost to FDA approval due to anticipated 505(b)2 status

6. Anticipate next study to be a Pivotal/Registration Trial for FDA approval

JanOne Near Term Objectives

MAY – JUNE 2023

- Capital raise allowing the initiation of development activities.

JULY 2023

- Initiation of manufacturing of Clinical supplies for Jan123
- Type C meeting with FDA to discuss using food grade Sodium Nitrite for Clinical Trials

AUGUST 2023

- Start of PK studies with -Jan101

JanOne Near Term Objectives

SEPTEMBER 2023

- Filing of IND for Jan123

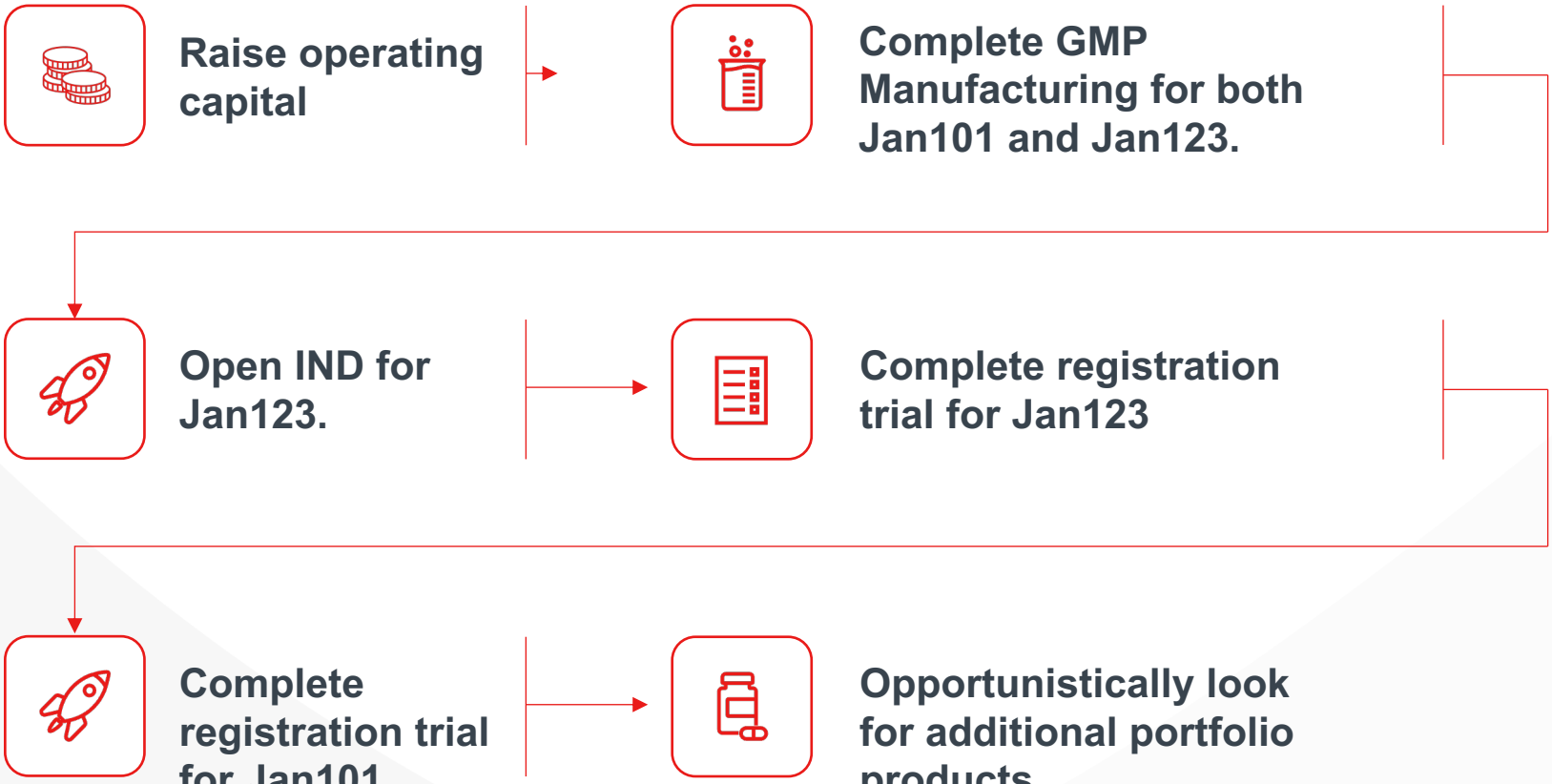
NOVEMBER 2023

- Completion of PK studies with Jan101
- Completion of manufacturing for Jan123

DECEMBER 2023

- Start of PK (pharmacokinetics) studies with Jan123

JanOne Strategy



Management Team

Tony Isaac – CEO

- Chief Executive Officer of the Company since May 2016.
- Mr. Isaac has served as Financial Planning and Strategist/Economist of Live Ventures Incorporated (Nasdaq: LIVE), a holding company for diversified businesses, since July 2012.
- Chairman and Co-Founder of Isaac Organization, a privately held investment company. Mr. Isaac's specialty is negotiation and problem-solving of complex real estate and business transactions.

Tony Giordano, Ph.D. – Chief Scientific Officer

- Senior management positions at eight different biotechnology companies, including four that moved translated drug discovery efforts into early-stage clinical trials.
- As CEO of TheraVasc, he was responsible for the development of TV1001 and while at Sulfagenix, he oversaw the launch of its medical food product.
- Most recently, he served as Senior Director of Special Projects in the Innovations group at the Cleveland Clinic where he worked with staff on advancing their programs to the clinic and to commercialization.
- He has previously consulted for numerous venture funds, biotechnology companies and was appointed by the Governor of Louisiana to his Innovation Council in 2008.

Management Team

Amol Soin, M.D. – Chief Medical Officer

- Chairman and founder of The Ohio Pain Clinic- a network of free-standing chronic pain management facilities in southwestern Ohio focused on non-opioid based treatments for chronic pain.
- He is a physician representative to Medicare via the Clinical Advisory Committee for Ohio and Kentucky.
- President of the Ohio Society of Interventional Pain Physicians,
- President – Elect of TriState Pain Society and was appointed by Governor Kasich to the Ohio Medical Board in 2012 to a 5 year term.
- He was selected as one of America's Top Doctors in Pain Management from 2006 – present, and has won multiple awards for research and patient care.

Investment Opportunity

1. Two Phase 3 ready drug candidates addressing **multi-billion dollar** markets. The potential for a licensing deal or acquisition is high.
2. 505 b2 designations for both candidates greatly increases approvability and provides a clear path to registration.
3. Lower development costs for 505 b2 products equate to lower capital needs.
4. Low valuation for a company with two drug candidates means high potential for stock growth upon meeting milestones.
5. High likelihood of having a drug approval in 2-3 years.
6. Experienced management team capable of getting the products approved.