

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

JanOne Inc.

Form: 8-K

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): July 21, 2020

JANONE INC.

(Exact Name of Registrant as Specified in Charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

000-19621
(Commission
File Number)

41-1454591
(IRS Employer
Identification No.)

325 E. Warm Springs Road, Suite 102
Las Vegas, NV 89119
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: 702-997-5968
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	JAN	The NASDAQ Stock Market LLC (The NASDAQ Capital Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On July 21, 2020, JanOne Inc. issued a press release announcing that it has received confirmation from the Food and Drug Administration for the Investigational New Drug sponsorship transfer of its sodium nitrite tablets previously held by Soin Neuroscience.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Description
99.1	Press Release of JanOne Inc., dated July 21, 2020 .

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, we have duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

JanOne Inc.

By: /s/ Tony Isaac
Name: Tony Isaac
Title: Chief Executive Officer

Dated: July 21, 2020

JanOne Receives FDA Authorization for Transfer of Investigational New Drug (IND) Application for its Sodium Nitrite Tablets

IND transfer clears path for Phase 2b trials of potential Peripheral Artery Disease (PAD) treatment and opens the door to explore other vascular applications

LAS VEGAS, NV, July 21, 2020 - JanOne Inc. (NASDAQ: JAN), a company focused on bringing treatments to market for conditions that cause severe pain and drugs with non-addictive pain-relieving properties, has received confirmation from the Federal Food and Drug Administration (FDA) for the investigational new drug (IND) sponsorship transfer covering its sodium nitrite tablets previously held by Soin Neuroscience. The sodium nitrite sustained release tablet is the clinical candidate TV1001SR, formulated to treat PAD and other vascular conditions. Manufacturing of TV1001SR is underway and phase 2b trials for PAD are expected to begin later this year. There is no current treatment for PAD and over 8.5 million Americans suffer from the disease.

Sodium nitrite has demonstrated positive results on vascular conditions, such as PAD, diabetic neuropathy and even vascular decline associated with normal aging. In previous preclinical and clinical studies, sodium nitrite has shown promise repairing and restoring vascular function with minimal adverse events. In addition, in an aged mice study, nitrite administration has been shown to reduce the production of vascular inflammation and thrombosis (blockages).

"The transfer of the IND is significant not only for advancing JanOne's clinical research for PAD treatment but other indications as well," remarked Dr. Tony Giordano, JanOne's chief scientific officer.

The TV1001SR IND was previously held by Soin Neuroscience, whose founder Dr. Amol Soin, now serves as JanOne's chief medical officer. Dr. Soin, in collaboration with Dr. Giordano and JanOne's scientific advisory board chair, Dr. Christopher Kevil, are the nation's leading experts on sodium nitrite. This includes its use for treatment of vascular conditions such as PAD, vascular inflammation caused by PAD and diabetic neuropathy. The transfer of the IND from Soin Neuroscience to JanOne was managed by JanOne's clinical partner, Cato Research, an international regulatory and clinical contract research organization (CRO) with a proven track record for cardiovascular pharmaceutical agents.

Tony Isaac, Chief Executive Officer of JanOne commented, "We would like to thank Cato Research for their assistance in the IND transfer process. They are true partners from strategy to approval. We look forward to moving forward with our clinical trials for PAD and to explore other possibilities for the application of TV1001SR."

About JanOne

JanOne is a unique NASDAQ-listed company that is focused on bringing medications to market to treat diseases that cause severe pain in an effort to reduce the need for prescriptions opioids often used to treat disease associated pain. The company is also exploring solutions for non-addictive pain medications. The lead candidate is for treating peripheral artery disease (PAD), a condition that affects over 8.5 million Americans, with plans currently underway for phase 2b trials. JanOne is currently

dedicated to funding resources toward innovation, technology, and education for PAD and neuropathic pain. The company continues to operate its legacy businesses, ARCA Recycling and GeoTraq, under their current brand names, but has recently announced both are undergoing a review to determine appropriate strategic alternatives in an effort to focus on its biopharma interests. Please visit www.janone.com for additional information.

Forward-Looking and Cautionary Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. In accordance with the safe harbor provisions of this Act, statements contained herein that look forward in time that include everything other than historical information, including statements relating when Phase 2 trials for PAD will begin, involve risks and uncertainties that may affect the company’s actual results. These forward-looking statements can be identified by terminology such as “will,” “expects,” “anticipates,” “future,” “intends,” “plans,” “believes,” “estimates” and similar statements. JanOne may also make written or oral forward-looking statements in its periodic reports to the U.S. Securities and Exchange Commission (the “SEC”) on Forms 10-K and 10-Q, Current Reports on Form 8-K, in its annual report to stockholders, in press releases, and other written materials and in oral statements made by its officers, directors or employees to third parties. There can be no assurance that such statements will prove to be accurate and there are a number of important factors that could cause actual results to differ materially from those expressed in any forward-looking statements made by the company, including, but not limited to, plans and objectives of management for future operations or products, the market acceptance or future success of our products, and our future financial performance. The company cautions that these forward-looking statements are further qualified by other factors including, but not limited to, those set forth in the company’s Annual Report on Form 10-K for the fiscal year ended December 28, 2019 (available at <http://www.sec.gov>). JanOne undertakes no obligation to publicly update or revise any statements in this release, whether as a result of new information, future events, or otherwise.

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