# 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): June 23, 2021**

# JANONE INC.
**(Exact Name of Registrant as Specified in Charter)**

| Nevada | 000-19621 | 41-1454591 |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (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 June 23, 2021, JanOne Inc. issued a press release announcing that its clinical packaging partner Xerimis has received the bottled and labeled clinical batch of JAN101 for the upcoming Phase 2b trial for treating Peripheral Artery Disease and is readying the supply for distribution to clinical sites throughout the U.S.

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 June 23, 2021 |

**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: June 23, 2021

Exhibit 99.1

# JanOne Readies Clinical Supply of Lead Product Candidate JAN101 for Distribution to Phase 2b Trial Sites

***Company Fully Prepared to Commence Phase 2b Trials of JAN101 for Peripheral Artery Disease (PAD) as Soon as New Protocol is Approved by the FDA***

LAS VEGAS, June 23, 2021 /PRNewswire/ -- JanOne Inc. (Nasdaq: JAN), a company focused on developing treatments for conditions that cause severe pain and drugs with non-addictive, pain-relieving properties, today announced that its clinical packaging partner Xerimis has received the bottled clinical batch of JAN101 for the upcoming Phase 2b trial for treating Peripheral Artery Disease (PAD) and is readying the supply for labeling and distribution to clinical sites throughout the U.S.

"We are pleased to report that our clinical supply of JAN101 is now ready for near-term release to our expected clinical trial sites in the upcoming Phase 2 clinical trial," said Tony Isaac, President and Chief Executive Officer of JanOne. "We are fully prepared and look forward to FDA approval of our new protocol."

JAN101 is intended to address the 8.5 million Americans who may have PAD. One of the more encouraging outcomes from patients who participated in early Phase 1 and Phase 2a trials of JAN101 was a reported reduction in associated PAD pain. According to a Stanford University research study, up to 24% of patients with PAD are at risk of high opioid use.[1] If JAN101 is successful, the potential increase in value to the medical community as a PAD treatment that also relieves associated pain without addictive properties could be significant. The U.S. market opportunity for JAN101 may result in a potential multibillion-dollar revenue stream for JanOne if the product candidate is approved as a new drug by the FDA.

**About JanOne**

JanOne (Nasdaq: JAN) is focused on developing treatments for diseases that cause severe pain. By alleviating pain at the source, JanOne aims to reduce the need for opioid prescriptions to treat disease associated pain that can lead to opioid abuse. The company is also exploring solutions for non-addictive pain medications. Its lead candidate, JAN101, is for potentially treating peripheral artery disease ("PAD"), a condition that affects over 8.5 million Americans. JAN101 demonstrated positive results in a Phase 2a clinical trial, and the Company is currently in preparations for Phase 2b trials. JanOne is dedicated to funding resources toward innovation, technology, and

1 https://pubmed.ncbi.nlm.nih.gov/30922747/

education for PAD, associated vascular conditions, and neuropathic pain. For more information, visit www.janone.com.

**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 to the commencement of the upcoming Phase 2b trials, the number of Americans who may have PAD, whether JAN101 will benefit the medical community, and the potential revenue stream if JAN101 is approved by the FDA. These forward-looking statements can be identified by terminology such as “will,” “aims,” “upcoming,” “may,” “expects,” “expected,” “potential,” “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 January 2, 2021 and other SEC filings (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.

**Investor Relations & Media Contact**
IR@Janone.com
1 (800) 400-2247