
**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): September 24, 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 September 24, 2020, JanOne Inc. (the “Company”) issued a press release announcing the commencement of production of the JAN101 cGMP batch.

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	<u>Press Release of JanOne Inc., dated September 24, 2020</u>

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: President and Chief Executive Officer

Dated: September 24, 2020

JanOne Successfully Begins Production of JAN101 cGMP Batch for Phase 2b Peripheral Artery Disease (PAD) Trial and Potential Covid-19 Study

Company continues to make progress on its potential treatment for PAD, a disease affecting 200 million people worldwide

LAS VEGAS, NV Sept. 24, 2020 – 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 the Company has started production of JAN101 under Current Good Manufacturing Practices (cGMP) for the company’s anticipated Phase 2b trials to treat Peripheral Artery Disease (PAD) and as a potential treatment for Covid-19 vascular complications.

This development follows the successful completion of the JAN101 prototype and engineering batches and positive stability data. The initial production batch will be 250,000 sustained release tablets and matching placebos. The Phase 2b trial is expected to begin in early 2021. PAD presents a large market opportunity as there currently are no effective treatments for the disease.

“The initiation of this batch is a major milestone for the Company, as it demonstrates that we now have the ability to economically scale up production of JAN101,” said Tony Isaac, President and Chief Executive Officer of JanOne. “This cGMP batch will help set the stage for our anticipated Phase 2b PAD trial, as well as the exploration of JAN101 as a treatment for vascular complications caused by Covid-19, with additional product available for collaborations with independent investigators on other indications.”

JAN101 is a patented sustained release form of sodium nitrite aimed at improving vascular function, reducing neuropathic pain and other conditions resulting from poor blood flow. It is highly selective, acting only in damaged tissue. In animal studies, sodium nitrite has been shown to promote blood vessel growth and function, prevents tissue inflammation and necrosis, and prevents diabetic nephropathy, a leading cause of death in diabetics. Additionally, three human clinical studies have found that sodium nitrite significantly reduces pain.

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 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 Phase 2b trials are expected to begin in early 2021. JanOne is dedicated to funding resources toward innovation, technology, and education for PAD, associated vascular conditions and neuropathic pain. JanOne continues to operate its legacy businesses under their current brand names, which are undergoing review to determine appropriate strategic alternatives. For more information, visit 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 (i) whether JAN101 can treat vascular complications in Covid-19 patients, (ii) whether the company can obtain FDA approval for its Covid-19 study, and (iii) if and when the Phase 2b trials for PAD will commence. These forward-looking statements can be identified by terminology such as "will," "aims," "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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Investor Relations & Media Contact

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