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 report: June 8, 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 8, 2021, JanOne Inc. (the "Company") issued a press release announcingthe successful completion of the initial batch production of JAN101, a patented sustained-release form of sodium nitrite aimed at improving vascular function and reducing neuropathic pain and other conditions resulting from poor blood flow.

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 8, 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: President and Chief Executive Officer

Dated: June 8, 2021

Exhibit 99.1

JanOne Advances Toward Initiation of Phase 2b Peripheral Artery Disease (PAD) Trial for Lead Product Candidate JAN101

Successfully Completes Initial Batch Production of JAN101, Demonstrating CGMP-scale Production Capabilities

LAS VEGAS, June 8, 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 the successful completion of Current Good Manufacturing Practices (CGMP) production of the first batch of JAN101 for its upcoming Phase 2b trial for treating Peripheral Artery Disease (PAD).

The initial batch, produced by manufacturing partner CoreRX, contains approximately 200,000 sustained release tablets and matching placebos of JAN101, a patented sustained-release form of sodium nitrite aimed at improving vascular function and reducing neuropathic pain and other conditions resulting from poor blood flow. JAN101 is highly selective, acting only in damaged tissue.

“Completion of the CGMP batch is an exciting achievement as we advance toward our planned Phase 2b PAD trial for JAN101,” said Tony Isaac, President and Chief Executive Officer of JanOne. “With CGMP compliance, we’ve proven our ability to economically scale-up production of JAN101 while preserving the product’s identity, strength, quality, and purity. We are now focused on bottling and labeling JAN101 for distribution to clinical test sites and engaging a contract research organization (CRO) to manage our Phase 2b trial, including the recruitment of subjects.”

Commenting on potential indications for JAN101, Isaac added, “Therapeutic options available for patients with PAD are extremely limited, and we believe our solution has the potential to transform the standard of care to an easy twice-a-day pill that substantially improves moderate to severe PAD and minimizes pain associated with the disease. We are also exploring the potential of JAN101 as a treatment for other conditions involving vascular complications, including chronic kidney disease, and, with our initial batch, we now have additional product available for collaborations with independent investigators on this and additional indications.”

The U.S. Food and Drug Administration (FDA) regulates the quality of pharmaceuticals through its main standard CGMP. Completion of CGMP production signifies that JanOne is fully compliant with the FDA’s formal regulations regarding the design, monitoring, control, and maintenance of manufacturing processes and facilities for JAN101.

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 Phase 2b trials are expected to begin in the near future. JanOne is dedicated to funding resources toward innovation, technology, and 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 and whether JAN101 can treat other conditions involving vascular complications, including chronic kidney disease. 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.

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