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 22, 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 22, 2021, JanOne Inc. issued a press release announcing the selection of Avania as its regulatory partner in the upcoming Phase 2b trial of lead product candidate JAN101 for treating Peripheral Artery Disease.

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 22, 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 22, 2021

Exhibit 99.1

JanOne Selects Regulatory Partner for Phase 2b Trial as Investigational Plan is Prepared for FDA Filing

Global Contract Research Organization (CRO) Avania to Manage All Regulatory Affairs in Connection with JanOne's Phase 2b Trial Preparedness and Execution

LAS VEGAS, June 22, 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 its selection of Avania as its regulatory partner in the upcoming planned Phase 2b trial of lead product candidate JAN101 for treating Peripheral Artery Disease (PAD). Avania will manage all regulatory operations associated with trial preparedness and execution including ensuring compliance with the FDA's requirements for investigational practices and managing correspondence with the FDA on JanOne's behalf throughout the duration of the trial. Avania has recently completed the filing of the annual report for IND 111703 on behalf of JanOne.

Tony Isaac, President and Chief Executive Officer of JanOne, commented, "We are pleased with our selection of Avania as our regulatory partner for our upcoming planned Phase 2b trial and will rely on their globally recognized expertise as we prepare to first file our pre-Phase 2 briefing package this summer and, following our planned meeting with the FDA, file our new protocol and related documents. Avania will assist us through each aspect of filing, including the clinical protocol, the Investigator's Brochure (IB), the General Investigational Plan, and Chemistry, Manufacturing, and Control (CMC) updates. We have made great progress year-to-date as we approach our protocol filing, and once approved by the FDA, we look forward to the expected initial recruitment of PAD subjects for this important trial."

Avania is an integrated global, full-service contract research organization (CRO) with specialized expertise in medical device, novel technology, and combination products. Avania advances products from feasibility all the way through post-approval trials in analytics, clinical trials, consulting, regulatory, and reimbursement.

JanOne recently announced its completion of Current Good Manufacturing Practices (CGMP) production of the first batch of JAN101, an initial step along the path to initiation of the Phase 2b PAD trial.

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 upcoming Phase 2b trials, and filing of the pre-Phase 2 briefing package and planned meeting with 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.

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