

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 22, 2021

JANONE INC.

(Exact name of Registrant as Specified in Its 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, Nevada
(Address of Principal Executive Offices)

89119
(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:

- 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

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 22, 2021, JanOne Inc. issued a press release announcing that it has selected CPC Clinical Research (CPC), a full-service clinical research organization (CRO), as manager for its upcoming Phase 2b clinical trial of lead product candidate JAN101 for treating Peripheral Artery Disease (PAD).

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 22, 2021
104	The cover page of this Current Report on Form 8-K, formatted in Inline XBRL

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: July 22, 2021



JanOne Selects CPC Clinical Research as Trial Manager for Phase 2b Study of JAN101 for Peripheral Artery Disease Patients

CPC to Manage Planning, Organization, and Day-to-Day Execution of the Trial

LAS VEGAS, July 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 that it has selected CPC Clinical Research (CPC), a full-service academic research organization (ARO), as manager for its upcoming Phase 2b clinical trial of lead product candidate JAN101 for treating Peripheral Artery Disease (PAD). CPC will be responsible for the planning, organization, day-to-day execution, and management of the Company's study, and will collaborate with JanOne's appointed regulatory partner Avania, announced last month.

CPC is an ARO recognized for its expertise in comprehensive clinical trial design and management for both national and international clinical research. CPC has over 30 years of experience in managing Phase 1 to 4 clinical trials and has provided services for over 150 clinical studies. CPC is led by Marc Bonaca, MD, MPH, a renowned cardiologist and vascular medicine specialist, who has worked on numerous PAD clinical trials.

"CPC has an outstanding reputation for clinical trial management and we are thrilled to have their team on board for our upcoming Phase 2b trial," said Tony Isaac, President and Chief Executive Officer of JanOne. "CPC executes with the highest standards of excellence, and their oversight puts our study in the best possible position for scientific success and integrity."

Dr. Bonaca, Executive Director of CPC Clinical Research, commented, "A dominant morbidity in PAD is functional decline related to altered energetics and pain. Finding effective therapies to improve symptoms and lessen this morbidity has been challenging with few effective therapies available to patients. We believe that the mechanism of action of JAN101 holds promise for improving symptoms and function in symptomatic PAD and may offer a new avenue of treatment to patients and the medical community."

JanOne's pivotal Phase 2b study of JAN101 for PAD will evaluate the efficacy of two doses (40 and 80 mg) of JAN101 to treat diabetic patients with PAD in a placebo-controlled 6-month study. Plans are to study 300 diabetic adults with PAD in 3 cohorts of 100 patients each. The

primary endpoint will be the ability of patients to walk without pain or muscle fatigue as a result of vascular function restored by JAN101. The secondary endpoints will be reduction in pain over the course of treatment, improved blood flow into the affected muscle, and improved quality of life.

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 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 those relating to the upcoming Phase 2b clinical trial of lead product JAN101 for treating peripheral artery 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.

Investor Relations & Media Contact

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