
**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 3, 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 3, 2020, JanOne Inc. (the “Company”) issued a press release announcing the confirmation of stability data of JAN101 engineering batch and selection of Eurofins CDMO (Alphora Research, Inc.) as the Company’s partner for bottling and labeling of JAN101.

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 3, 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: Chief Executive Officer

Dated: September 3, 2020

JanOne confirms stability data of JAN101 development batch and prepares for commercial GMP production to support the upcoming PAD and potential Covid-19 clinical trials

Bottling and labeling partner Eurofins CDMO (Alphora Research, Inc.) to ensure JanOne clinical research maintains compliance with GMP and FDA regulations

LAS VEGAS, NV Sept. 3, 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, has confirmed stability of its developmental batch run of JAN101. Working closely with selected bottling and labeling partner, Eurofins CDMO, the company is currently on track to initiate GMP production of JAN101 to support planned Phase 2b trials to treat peripheral artery disease (PAD). Required clinical batches of properly bottled and labeled product will also be available to support immediate start of clinical research to use JAN101 as a potential treatment for Covid-19 vascular complications should JanOne gain FDA IND approval. The company is currently finalizing its Covid-19 vascular treatment investigational new drug application (IND) for submission to the FDA.

Eurofins CDMO is a world leader in pharmaceutical development services. Its Canadian facility, Alphora Research Inc., will work with the JanOne clinical teams and manufacturing partner to ensure the integrity of all active and placebo bottles of JAN101. Precise randomized packaging and labeling is required so patients and caregivers are unaware of whether they are receiving the placebo or active formulation but also for accurate participant tracking and clinical data collection.

Business development executive for Eurofins CDMO (Alphora Research Inc.), Stefan Soderman, Ph.D. said, “We are very pleased to support JanOne’s project to treat vascular conditions. We are looking forward to a long-term relationship with the company.”

It is expected that the IND for JAN101 as a Covid-19 vascular complication treatment will be submitted to the FDA in the coming weeks. Bottling and labeling of clinical trial batches are expected to begin in early October led by Eurofins CDMO. The company remains on track for its PAD Phase 2b clinical trials expected to begin in early 2021.

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

About Eurofins CDMO

Eurofins CDMO is a leading global Contract Development and Manufacturing Organization that provides clients with Active Pharmaceutical Ingredients (API's) / Drug Substance and Drug Product development for small molecules

and biologicals. Its service offering encompasses Drug Substance/API Development, Solid State Research and Development, Pre-formulation, Formulation and Development, Analytical Development, GMP Manufacturing and Clinical Packaging and Logistics. Operating with facilities in Europe, North America and India, Eurofins CDMO is accredited through the FDA, EMA, ANSM, ANSES, FAMHP, PMDA, and Health Canada. For more information: <https://www.eurofins.com/cdm>

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, (iii) when the Phase 2b trials for PAD commence, and (iv) when and whether the company will submit an IND for the treatment of Covid-19 vascular complications, and (v) when manufacturing of JAN101 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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