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): August 6, 2020

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 August 6, 2020, JanOne Inc. (the "Company") issued a press release announcing the engagement of Cato SMS to assist the Company in the development of JAN101 to treat COVID-19 vascular complications.

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 August 6, 2020

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: August 6, 2020

FOR IMMEDIATE RELEASE

JanOne Engages CATO SMS, a World-Leading CRO, to Assist in the Development of JAN101 to Treat COVID-19 Vascular Complications

Study to Explore JAN101's Potential to Treat Ischemia[1] and Endothelial dysfunction[2] in COVID-19 patients.

LAS VEGAS, Aug. 6, 2020 – JanOne Inc. (Nasdaq: JAN), a company focused on bringing treatments to market for conditions that cause severe pain and drugs with non-addictive, pain-relieving properties, has entered into an agreement with CATO SMS, a world-leading, international regulatory and clinical contract research organization (CRO). CATO SMS will assist JanOne in expanding its current FDA authorized Investigational New Drug (IND) for JAN101, an oral, sustained release formulation of sodium nitrite, to treat vascular complications to potentially restore endothelial cell function in COVID-19 patients. In addition, JAN101 is expected to enter Phase 2b trials in early 2021 to treat Peripheral Artery Disease (PAD).

A recent study published in the New England Journal of Medicine[3] indicates the possibility that the respiratory complications from COVID-19 may originate from restrictions and damage to the vascular system and endothelial cell dysfunction. The implication is that the endothelial cells that line the blood vessels are severely compromised and limit the body's ability to carry oxygen to major organs in the body, including the lungs. Previous JAN101 clinical studies have shown promise in repairing and restoring vascular function with minimal adverse events, which may potentially prove to be beneficial to COVID-19 patients.

"If COVID-19 is, in fact, a vascular disease that attacks endothelial cells restricting the ability of cells to deliver oxygen to vital organs, our sodium nitrite tablets could potentially offer a safe and effective treatment for that aspect of the disease," said Tony Giordano, PhD, JanOne's chief scientific officer. "By mitigating severe organ and tissue damage, JAN101 can potentially have a significant impact on the long-term health of these patients."

CATO SMS will work directly with the JanOne leadership team and scientific advisory board to execute submission of an investigator-initiated IND for use of JAN101 as a potential treatment for certain aspects of bodily damage created by COVID-19. "We have all seen the devastating impacts of COVID-19 and the severe damage it appears to cause to vital organs that may be a result from an attack on the vascular system," commented MerriBeth Adams, Senior Vice President, Regulatory Affairs at CATO SMS. "We are grateful for the opportunity to work with JanOne and to do our part to potentially bring such an important treatment to COVID-19 patients."

1 https://pubmed.ncbi.nlm.nih.gov/18508974/

2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7229726/

3 Pulmonary Vascular Endothelialitis, Thrombosis, and Angiogenesis in Covid-19, New England Journal of Medicine, July 9, 2020

In partnership with CATO SMS, JanOne is currently preparing an investigator-initiated IND package for the FDA, which it expects to submit in the coming month. If cleared to proceed by the FDA, clinical management of any ensuing research trials could start quickly and be conducted by Dr. Amol Soin, JanOne's chief medical officer. "JAN101 has a unique approach to treating end organ damage that may result from COVID-19, which hopefully will help patients. I look forward to commencing human trials in Dayton, Ohio in the near future," said Dr. Soin.

JanOne's CEO Tony Isaac said, "Treatments for COVID-19 complications such as those JAN101 is looking to address are essential, and we believe our decision to engage CATO SMS' expertise to guide us through the FDA's regulatory process is the right choice." In the future, JanOne looks forward to working with CATO SMS and the FDA to seek an emergency use authorization for JAN101 in COVID-19 patients.

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) JAN101's expectation of when it will enter Phase 2b trials to treat PAD, (ii) whether JAN101 is beneficial to COVID-19 patients, (iii) whether JAN101 can offer a safe and effective treatment to COVID-19, (iv) whether JAN101 can treat vascular complications to potentially restore endothelial cell function in COVID-19 patients, and (v) the timing of the submission by the company of the IND package for the FDA. 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.

About JanOne

JanOne (NASDAQ: JAN) is focused on bringing medications to market to treat 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, ARCA Recycling and GeoTraq, both of which are undergoing review to determine appropriate strategic alternatives. For more information, visit janone.com

About CATO SMS

CATO SMS is a provider of specialized clinical research solutions. The company was formed when CATO Research LLC and Specialized Medical Services-oncology B.V. (SMS-oncology) merged in 2019. With more than 30 years of experience focusing on the needs of small and emerging biopharmaceutical companies, CATO SMS effectively designs and executes studies— from strategy to approval — in complex indications and modalities across a variety of therapeutic areas, with a proven center of excellence in oncology. CATO SMS' regulatory, therapeutic, and operational expertise supports clients with achieving their goals and exceeding their expectations. Visit CATO-SMS.com for more information.

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