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 11, 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 7.01. Regulation FD Disclosure

On August 12, 2020, executives of JanOne Inc. (the "Company") announced their intention to hold meetings with various third parties and potential investors in the coming months and plan to present the information contained in the fact sheet attached to this Current Report on Form 8-K as Exhibit 99.1.

The furnishing of the attached fact sheet is not an admission as to the materiality of any information therein. The information contained in the fact sheet is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the the U.S. Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, or through other public disclosures. For important information about forward looking statements, see the fact sheet attached hereto.

This information is "furnished" and not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Securities Exchange Act of 1934 or the Securities Act of 1933 only if and to the extent such subsequent filing specifically references the information incorporated by reference herein.

Item 8.01 Other Events.

On August 11, 2020, the Company issued a corrected press release announcing the completion of the stable formulation of JAN101 in preparation for its first GMP manufacturing batch to support upcoming clinical trials.

A copy of the corrected press release is attached as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Description
99.1	JanOne Inc. Fact Sheet dated August 2020
99.2	Press Release of JanOne Inc., dated August 11, 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 12, 2020

Investor Relations Contact: Nasdaq: JAN
(800) 400-2247 www. janone.com
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JanOne (Nasdaq: JAN) is a biopharma company uniquely focused on developing medications to treat diseases that cause severe pain, with its initial focus on vascular conditions such as Peripheral Artery Disease (PAD). By alleviating disease associated pain at the source, this may also reduce the need for opioid prescriptions often used to treat severe pain, thus can potentially lead to an impact on prescription opioid abuse. To that end, the company is also exploring solutions for non-addictive acute pain medications. Its lead drug candidate, JAN101, has demonstrated positive data in Phase 2a clinical trials, with Phase 2b trials expected to begin in early 2021 for the treatment and prevention of peripheral artery disease (PAD), a condition that affects over 8.5 million Americans. Other potential indications for JAN101 include diabetic neuropathy, wound healing and vascular inflammation. 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.

Key Growth Drivers

Product Candidate: JanOne acquired an exclusive license to the worldwide right to TV1001SR, now known as JAN101, a twice-daily, orally dosed slow-release formulation. Over $13.5 million[1] has been spent on the development in research and clinical work, excluding patent and Intellectual property expenses. Sodium nitrite is an approved drug for acute use and is on the list of The World Health Organizations list of 100 essential medications. Results from Phase 2a clinical trials support the use of sodium nitrite for the treatment and prevention of PAD and as a non-addictive treatment for Diabetic Neuropathy. While not a predetermined endpoint for the trial, subjects who participated in the trial also reported a reduction in pain as a result of the increased blood flow to the extremities and prompted a clinical study into diabetic pain where patients reported a significant reduction in pain.

Market Opportunity: In 2017, the global market for PAD was estimated at nearly $36.1 billion and is expected to grow at a compound annual growth rate (CAGR) of 7.6% to $52.0 billion by 2022, according to BCC Research.[2]

Patent Portfolio: The company has a portfolio of 30 worldwide patents and other intellectual property relating to sodium nitrite, the sustained release of sodium nitrite, and a provisional application to assist in the treatment of COVID-19 vascular complications. The patent portfolio presents diverse licensing opportunities and potentially royalty opportunities if JanOne intellectual property is used with other drug candidates.

Manufacturing underway: The company has a manufacturing agreement with CoreRx Inc. for the formulation and manufacturing of JAN101. CoreRx operates over 150,000 square feet of cGMP lab and manufacturing facilities, including six formulation suites, 18 manufacturing suites, and two analytical labs.

FDA 505 (b)(2) pathway: To streamline development and approval of the U.S. Food and Drug Administration (the "FDA"), the company expects to pursue FDA 505(b)(2) pathway for new drug approval as a result of an already approved acute use associated with JAN101.

Recent Highlights

- In July 2020, several esteemed colleagues joined JanOne's Scientific Advisory Board
- In July 2020, JanOne received confirmation from the FDA for the investigational new drug (IND) sponsorship transfer covering its sodium nitrite tablets previously held by Soin Neuroscience
- In August 2020, JanOne engages CATO-SMS a world leading clinical research organization to assist in the development of JAN101 to Treat COVID-19 Vascular Complications
- In August 2020, JanOne completes stable formulation of JAN101 in preparation for its first GMP manufacturing batch to support upcoming clinical trials

Market Snapshot—NASDAQ: JAN

Price: $4.83 (8/10/20) **Avg. Vol:** 170K **52-Wk. Range:** $2.00-$9.24 **Shares Outstanding:** 2.0M **Market Cap**: $9.7M

Price and volume quotes from Yahoo! Finance and other sources - [1]Including prior to JanOne's acquisition of the license - [2]https://www.bccresearch.com/market-research/healthcare/the-global-market-for-pain-management-drugs-and-devices.html

JanOne Inc. - 325 E. Warm Springs Road, Suite 102 - Las Vegas, NV 89119 - 800-400-2247 - **www.janone.com**

JAN101: A compound with potential broad application

- A safe novel treatment for improving vascular function, reducing neuropathic pain and other conditions resulting from poor blood flow
- Highly selective, acts only in damaged tissue
- Very safe, non-addictive and natural product (sodium nitrite)
- Promotes blood vessel growth and function

As indicated in multiple human trials, our current sodium nitrite compound has the potential to treat vascular and endothelial cell dysfunction complications experienced by COVID-19 patients.

Multiple phase 2a trials complete

Improved vascular function and pain reduction in multiple phase 2a trials				
Trial	Sickle Cell Anemia (17 subjects)	Peripheral Artery Disease (55 subjects)	Aging 55+ adults (30 subjects)	Diabetic Neuropathy (26 subjects)
Formulation	Topical sodium nitrite	Oral capsule	Oral capsule	Oral tablet Sustained release
Side effects	Minimal	Minimal	Minimal	Minimal
Quality of life impact	• Improved blood flow • Reduced pain • Reduced leg ulcers	• Improved vascular function • Reduced pain	• Improved vascular function • Improved cognitive performance • Improved grip strength • Improved balance	• Improved nerve function • Reduced pain

Experienced Management Team

Tony Isaac, CEO – A director of JanOne since May 2015 and CEO since May 2016. Tony Isaac spearheaded the successful turnaround of JanOne and has invested in various companies, both private and public, since 1980.

Tony Giordano, Ph.D., Chief Scientific Officer– Dr. Giordano has held senior management positions at eight biotechnology companies, including four that moved translated drug discovery efforts into early-stage clinical trials.

Amol Soin, MD, Chief Medical Officer– Dr. Soin has been recognized multiple times as one of America's Top Doctors and is the recipient of the Patient's Choice Award, an honor given only to the top 1% of physicians in the country.

Virland Johnson, CFO - was appointed Chief Financial Officer of the Company in 2017. In addition to his role as CFO for JanOne, he also serves as CFO for Live Ventures Incorporated (Nasdaq:LIVE).

Scientific Advisory Board

Chris Kevil, Ph.D., Chair of the Scientific Advisory Board, **Edgar Ross, MD**, **Rakesh Patel, Ph.D., Timothy Ness, MD, Ph.D., Alan Kaye,MD, PhD, DABA, DABPM, DABIPP, John Cooke, MD, Ph.D.**

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.

FOR IMMEDIATE RELEASE

JanOne Completes Stable Formulation of JAN101 in Preparation for Its First GMP Manufacturing Batch to Support Upcoming Clinical Trials

JAN101 formulation ready for Phase 2b peripheral artery disease trials and for potential treatment of COVID-19 vascular inflammation

LAS VEGAS, Aug. 11, 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, together with its manufacturing partner, has successfully completed the formulation of JAN101, its potential treatment for Peripheral Artery Disease (PAD) expected to soon be in Phase 2b trials. In addition, JAN101 is planned for use to treat COVID-19 vascular complications pending approval of the IND submission, expected to be completed in late August 2020.

JAN101 is one of the few promising treatments for vascular conditions using sodium nitrite that showed success in Phase 1 and Phase 2a trials for improving blood flow and vascular function. The company is preparing its IND packages for FDA submission for continued development as a treatment of PAD and to extend JAN101 to potentially mitigate severe organ and tissue damage caused by COVID-19. The successful formulation of JAN101 will allow the company to begin its engineering run and GMP manufacturing for multiple trials expected to begin in early 2021.

“Working with our manufacturing partner, we have been able to successfully produce JAN101, our sustained release formulation and expect our engineering batch to begin immediately,” said Dr. Tony Giordano, chief scientific officer at JanOne. “We believe we will have the initial GMP batch of 250,000 doses by mid-September 2020. This will provide us with enough tablets to carryout our proposed Phase 2b PAD trials and the COVID-19 treatment study IND, which we are confident will gain approval.”

The company will now focus on commercial production capability of JAN101 and is currently negotiating to purchase 1,000 kilos of sodium nitrite from a multinational biopharmaceutical company to support GMP manufacturing batches of more than 20 million doses of JAN101.

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

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) when JAN101 will enter Phase 2b trials to treat PAD, (ii) whether JAN101 can treat vascular complications in COVID-19 patients, and (v) whether the company is able to negotiate a sufficient amount of sodium nitrite on terms acceptable to it or at all. 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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