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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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 19, 2020

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**JANONE INC.**

(Exact Name of Registrant as Specified in Charter)

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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)

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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. ☐

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**Item 7.01. Regulation FD Disclosure**

On August 19, 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 presentation attached to this Current Report on Form 8-K as Exhibit 99.1.

The furnishing of the attached presentation is not an admission as to the materiality of any information therein. The information contained in the presentation 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.

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 9.01. Financial Statements and Exhibits**

(d) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#"><u>JanOne Inc. Investor Presentation</u></a>

**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 19, 2020

# Developing Unique Vascular and Pain Management Medications

Summer 2020

Nasdaq: JAN

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## Disclaimer

This presentation 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) reducing the need for opioids at the prescription pad, (ii) when Phase 2b trials will commence, and (iii) other indications that may benefit from JAN101, including vascular complications resulting from Covid infection. These forward-looking statements can be identified by terminology such as "will," "aims," "expects," "potential," "anticipates," "future," "may," "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 presentation, whether as a result of new information, future events, or otherwise.

## Who is JanOne?

Company has exclusively licensed know how and patents after successful pre-clinical, Phase 1 and Phase 2a studies for the biological impact and potential for sodium nitrite to improve pulmonary function

A biopharma company whose mission is to develop and introduce drugs into market that will treat conditions that cause severe pain and non-addictive answers to treat pain

Ultimately, treating diseases at the source can potentially reduce the need for opioids at the prescription pad

Phase 2b trials for the treatment of Peripheral Artery Disease are expected to begin Q1 2021

Listed on NASDAQ: JAN

**Peripheral Artery Disease**, a condition affecting over 60 million people globally, is the company's initial focus

## Peripheral Artery Disease (PAD) market opportunity

### US PAD Market:

- 8.5 Million People



### Top Five EU PAD Markets:

- 13.5 Million People



\*Assumes peak market share of 15% at \$4 per dose, \$8 per patient per day. Chronic dosing defined as 2 doses per patient per year (adjusted to 75% to account for non-compliance)

## A promising treatment for vascular conditions and pain

Sodium nitrite advanced for treating vascular diseases and neuropathic pain

JAN101, a sustained release sodium nitrite tablet, to treat PAD - Phase 2b trials expected by Q1 2021

- Multiple Phase 2a studies provided evidence of clinical benefit to improve pulmonary function, increase blood flow and reduce associated neuropathic associated pain
- Over \$13 million invested in the development of Jan101\* prior to the IND transfer

In addition to PAD, other indications that may benefit:

- Diabetic Neuropathy
- Wound healing
- Vascular complications resulting from Covid infection

\*Does not include IP and patent protection expenses

Nasdaq:JAN

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## JAN101: A compound with 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
- Prevents tissue inflammation and necrosis
- Prevents diabetic nephropathy, a leading cause of death in diabetics
- Significantly reduces pain as observed in three human clinical studies

### JAN101

#### Plans to Enter Phase 2b

clinical trials for the treatment of PAD

## Sustained release formulation (JAN101)

### In vitro sustained release formulation

- 30% released in first hour
- 70% over remaining 7-8 hours

### Pig study with 80 mg tablets

- No change in blood pressure (indicator of vasodilation) over 24-hour period after administration
- Induces markers within 30 days angiogenesis (new blood vessels)
- Positive trend in angiogenic index after 30 days (new vessel formation)

### In clinical trial with JAN101

Diabetic neuropathy patients did not report increases in headaches and dizziness

## 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	TV1001 oral capsule	TV1001 oral capsule	JAN101* oral tablet sustained release
Side effects	Minimal	Minimal	Minimal	Minimal
Quality of life impact	<ul style="list-style-type: none"> <li>Improved blood flow</li> <li>Reduced pain</li> <li>Reduced leg ulcers</li> </ul>	<ul style="list-style-type: none"> <li>Improved vascular function</li> <li>Reduced pain</li> </ul>	<ul style="list-style-type: none"> <li>Improved vascular function</li> <li>Improved cognitive performance</li> <li>Improved grip strength</li> <li>Improved balance</li> </ul>	<ul style="list-style-type: none"> <li>Improved nerve function</li> <li>Reduced pain</li> </ul>

\*Formerly TV1001SR

## Pivotal Phase 2b PAD study expected early 2021

Evaluate the efficacy of two doses (40 mg and 80 mg) of JAN101 to treat diabetic patients with PAD in a placebo-controlled, 12-week study

300 diabetic PAD adults (≥18 years) - 3 cohort of 100 patients

### Primary endpoint

- Ability to walk without pain or muscle fatigue as a result of restored vascular function

### Secondary endpoints

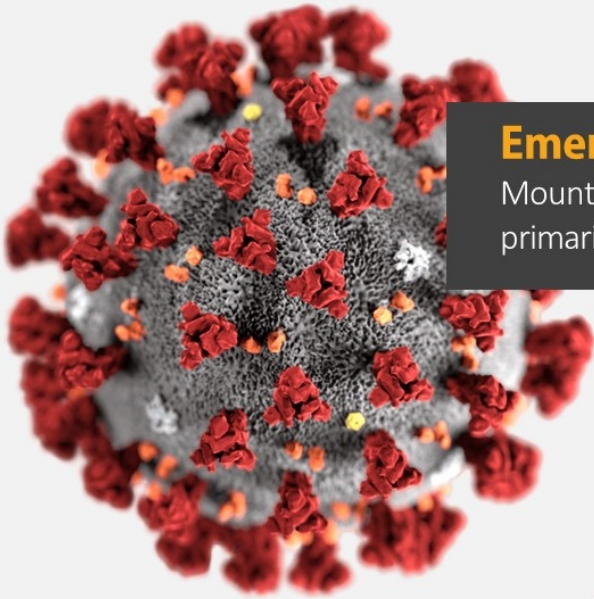
- Reduction in pain over course of treatment
- Improved sensory nerve function
- Improved quality of life

Research Candidate	Name	Phase 1	Phase 2a	Phase 2b	Phase 3
Peripheral Artery Disease (PAD)	JAN101				

## Sodium nitrite patents with broad pharmacologic value

JanOne patent portfolio provides significant potential for broad application of sodium nitrite for various vascular conditions and for a non-opioid, non-addictive pain treatment, including potential for treatment of vascular indications as a result of COVID-19

	United States	Europe	Australia	Israel	Japan	China
Method of use: Ischemia	Pending	Issued	Issued	Issued	Issued	Issued
Method of use: Inflammation, including PAD	Issued					
SR formulation	Issued	Issued	Issued			
Use of SR formulation	Pending				Pending	
Method of use in pain	Pending	Pending	Pending	Pending	Pending	Pending
COVID-19 Treatment	Provisional US patent filed					



## Emerging opportunity

Mounting evidence indicating that COVID-19 may primarily attack the vascular system

Endothelial cell dysfunction and inflammation causing severe tissue damage due to lack of oxygen being carried to vital organs, including the lungs, causing respiratory complications

## NATURE REVIEWS IMMUNOLOGY

Check for updates

## COVID-19: the vasculature unleashed

Laure-Anne Teuwen<sup>1,2,3</sup>, Vincent Geldhof<sup>1</sup>, Alessandra Pasut<sup>1</sup> and Peter Carmeliet<sup>1,4</sup> 

On the basis of emerging evidence from patients with COVID-19, we postulate that endothelial cells are essential contributors to the initiation and propagation of severe COVID-19. Here, we discuss current insights into the link between endothelial cells, viral infection and inflammatory changes and propose novel therapeutic strategies.

Journal of  
Clinical Medicine

MDPI

Review

## Hypertension, Thrombosis, Kidney Failure, and Diabetes: Is COVID-19 an Endothelial Disease? A Comprehensive Evaluation of Clinical and Basic Evidence

## Endothelial cell infection and endotheliitis in COVID-19

www.thelancet.com Vol 395 May 2, 2020

## In the news

tctMD/the heart beat

NEWS

## COVID-19 Autopsies Put Endothelial Damage, Angiogenesis in the Spotlight

Microbes and Infection 22 (2020) 146–159

Contents lists available at ScienceDirect

Microbes and Infection

journal homepage: [www.elsevier.com/locate/micinf](http://www.elsevier.com/locate/micinf)

Letter to the editor

Covid-19 accelerates endothelial dysfunction and nitric oxide deficiency

ESC  
European Society  
of CardiologyCardiovascular Research (2020)  
doi:10.1093/cvr/cvz140

ONLINE COMMENTARIES

CARDIOVASCULAR  
RESEARCH  
ONLINE

## COVID-19 as a cardiovascular disease: the potential role of chronic endothelial dysfunction

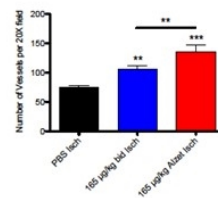
Nasdaq:JAN



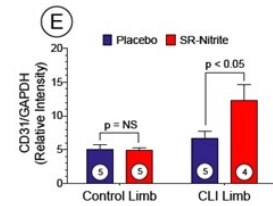
# JAN101 improves endothelial cell/vascular function

**COVID-19 is believed to attack endothelial cells causing significant tissue inflammation and damage**

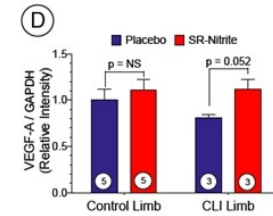
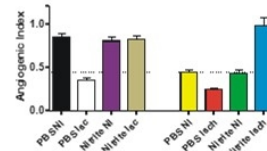
Sustained release nitrite increases vascular growth



Treatment increases markers for vessel growth (angiogenesis)



Nitrite therapy induces angiogenesis in diabetic tissue





## Potential benefits of treating COVID-19 patients with sodium nitrite

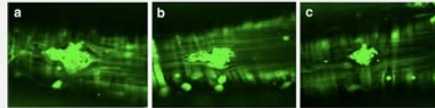
In various animal studies, JAN101 has demonstrated **positive benefits that align with COVID-19 complications**

- Reduces kidney damage
- Prevents tissue necrosis
- Reduces thrombosis
- Increases angiogenesis

### Increased angiogenesis in pigs

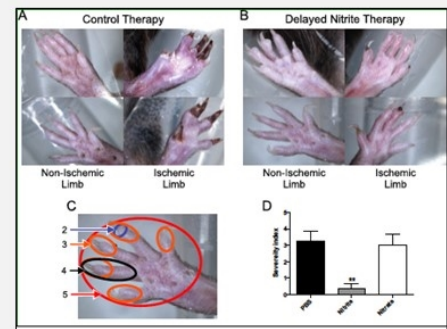


### Nitrite reduces thrombosis in mice



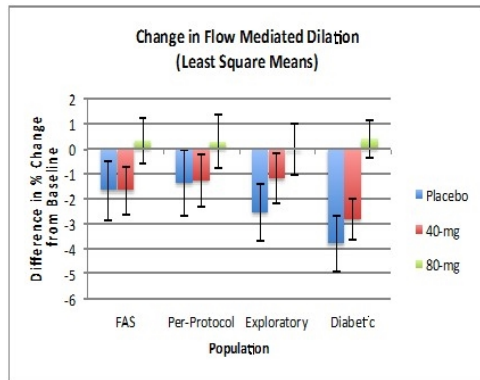
From Kramkowski et al (2017)  
Naunyn-Schmiedeberg's Arch Pharmacol 390:85-94

### Prevents tissue necrosis in diabetic mice

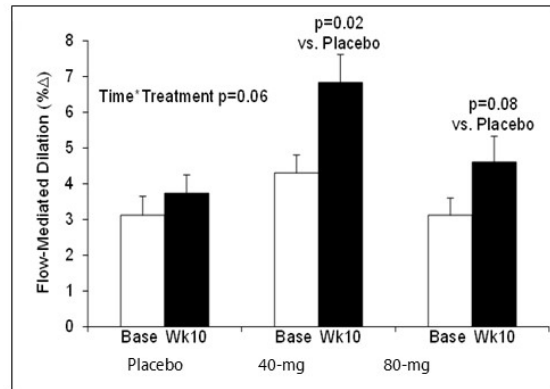


## Nitrite improves vascular function in humans

Using flow-mediated dilation imaging technology we can assess vascular function improvement in patients with complications including blood flow and thrombosis



**PAD Patients**



**Healthy Subjects**

## The JAN101 COVID-19 vascular treatment opportunity

As indicated in multiple human trials, our current sodium nitrate compound may be a successful treatment for the vascular complications experienced by COVID-19 patients

- Shown to improve vascular function
- Shown to reduce vascular complications such as thrombosis
- Protects major organs from tissue damage due to poor blood flow
- Inhibits inflammation, including mitigating the “cytokine storm”, a massive release of cytokine proteins that destroy endothelial cells (cells that protect the lining of vessel tissue)
- Nitrite has proven to be well tolerated and safe

### **Intend to seek emergency use authorization**

Expanding existing JAN101 IND for clinical study to treat COVID-19 vascular complications

## Management team

Tony Isaac  
Chief Executive Officer



Tony Giordano, PhD  
Chief Scientific Officer



Amol Soin, MD  
Chief Medical Officer



Virland A. Johnson  
Chief Financial Officer



Michael Stein  
In-house Counsel and  
Corporate Secretary

## Scientific advisory board



Christopher Kevil, PhD  
Chairman



Rakesh Patel, PhD



Timothy Ness, MD, PhD



Edgar Ross, MD



Alan Kaye, MD, PhD,  
DABA, DABPM, DABIPP



John Cooke, MD, PhD



Joshua Beckman, MD, MS

## Stock data

Price*	\$5.06
Market cap	10.24M
Shares outstanding	2.01M
Average volume	246,042

\*Yahoo Finance 8/18/20

Nasdaq:JAN

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## **Evolving solutions for vascular conditions and pain**

- Phase 2b trials for JAN101 for treating PAD expected to start Q1 2021
- PAD treatment presents significant domestic and international market opportunity
- JAN101 is well-tolerated with a strong safety profile
- JAN101 increases blood flow and reduces vessel inflammation, thus reducing pain
- Existing sodium nitrite IND can be expanded for other vascular conditions
- JAN101 therapeutic profile may prove effective for treating COVID-19 vascular complications
- Partnership and royalty opportunities with strong sodium nitrite patent position
- Management and scientific advisory board are leading experts in vascular disease and neuropathic pain



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[www.janone.com](http://www.janone.com)

