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 25, 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 25, 2020, representatives from JanOne Inc. (the "Company") held a conference call to discuss drug candidate JAN101 for the treatment of peripheral artery disease and potential applications for Covid-19 vascular complications. A transcript of the conference call is furnished as Exhibit 99.1 to this Current Report on Form 8-K

During the question and answer session of the conference call, Tony Isaac, the Company's Chief Executive Officer, was asked about the Company's cash situation and cash burn. Mr. Isaac responded that the Company's legacy assets (including ARCA Recycling, Inc., which operates the Company's recycling business ("ARCA Recycling")) generate profit and revenue. A follow-up question to Mr. Isaac was whether "are you profitable presently," to which Mr. Isaac responded, "Yes, we are." The Company hereby clarifies that Mr. Isaac, in reliance upon the advice of the Company's Chief Financial Officer, based his response on his immediately prior reference to the Company's legacy assets and was specifically referring to the fact that, during the "present" period commencing on June 28, 2020, the first day of the Company's current quarter, through August 25, 2020, ARCA Recycling has been profitable on a stand-alone basis, excluding corporate overhead and other corporate allocations.

This information shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date of this report, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Description
99.1	Transcript

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/ Virland A. Johnson
Name: Virland A. Johnson
Title: Chief Financial Officer

Dated: August 26, 2020

Exhibit 99.1

JanOne Inc. (JAN) CEO Tony Isaac on Drug Candidate JAN101 - Telebriefing and Corporate Update Call Transcript

Aug. 25, 2020 9:38 PM ET
|
About: JanOne Inc. (JAN)
Subscribers Only
Earning Call Audio
JanOne Inc. (NASDAQ:JAN) Telebriefing and Corporate Update Call August 25, 2020 4:15 PM ET

Corporate Participants

Tony Isaac - Chief Executive Officer

Tony Giordano - Chief Scientific Officer

Amol Soin - Chief Medical Officer

Conference Call Participants

Jeremy Roe - Integra

Robert Carlson - Janney Montgomery Scott

Operator

Good afternoon everyone and thank you for joining us for the JanOne Telebriefing and Corporate Update Call. Tony Isaac CEO, Tony Giordano, PhD, Chief Scientific Officer and Amol Soin, MD, Chief Medical Officer will provide prepared remarks followed by a question-and-answer session.

I will now take a brief moment to read the Safe Harbor statement. During the course of this conference call, we will make certain forward-looking statements and assumptions. All statements that address expectations, opinions or predictions about the future are forward-looking statements. Although that reflect our current expectations and are based on our best view of the industry and of our businesses, as we see them today, they are not guarantees of future performance. These statements involve a number of risks and uncertainties and since those elements can change, and in certain cases are not within our control, we urge you consider and interpret them in that light.

We also urge you to review the company's SEC filings for a discussion of the principal risks and uncertainties that affect the company's business and performance and of the factors that could cause actual results to differ materially. JanOne does not intend and undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless otherwise required by law.

I will now turn the call over to Tony Isaac, JanOne's CEO. Thank you may begin.

Tony Isaac

Thank you, operator and welcome to everyone. Thank you for joining us to hear more about JanOne. As you may be aware JanOne transitioned last year from the recycling business into the biopharma business. And last November almost a year ago, JanOne acquired an exclusive license to over 30 patents to do with peripheral artery disease, PAD and the pain associated with it using sodium nitrite, the product was then known as TV1001SR and now known as JAN101.

We bought the license from LSU, the UAB Research Foundation and TheraVasc. We believe that JanOne is a great candidate for the company being [large stage buy that] [ph] asset for to do clinical studies and address the market that is closer to potential commercialization.

The initial research patents and development were performed by Dr. Chris Kevil at the LSU Health and Dr. Rakesh Patel at the UAB Research Foundation. Both are respected individuals and scientists in their field.

Dr. Tony Giordano, our Chief Scientific Officer holds position as a Director of Innovation in The Cleveland Clinic and the Abbott Laboratories. He brings a lot of knowledge and expertise on the sodium nitrite and continues to help the company develop JAN101. We also have Dr. Amol Soin, who is our Chief Medical Officer and he is a recipient of the Patients Choice Award an honor given to only the top 1% of doctors in the country that deal with pain.

So JanOne is looking forward to development of those new treatments for pain as we continue our search for potential assets to add to our pipeline and find novel ways to reduce pain and save lives if we can. And this is to eliminate or to address at least the opioid abuse and the addiction to opioids. We're optimistic that we can get to a level where the PAD is relevant as a paid drug since it is the major cause of neuropathic pain in patients with the disease.

In addition also, we are addressing the possibility that we can use the same license, same drug to work or treat patients of COVID-19 because as you may have seen the lot of studies and articles in the medical papers that show that the COVID-19 is a vascular disease and that it can help the patients who are infected with that disease.

We are applying soon also for an IND, which is the investigative new drug application in order to be able to work on some cases for COVID-19 in the coming weeks.

I will now turn the call to Dr. Giordano and Soin, our Chief Scientific Officer and Chief Medical Officer as you may learn more about the technology and the potential treatment areas for our proprietary platform JAN101.

Amol Soin

Thank you, Tony. This is Dr. Amol Soin here; I'm Chief Medical Officer of JanOne. Thanks for attending this call and good afternoon, everyone. I want to start by talking about JAN101 as a basic overview and as you all know, JAN101 is our lead product to treat peripheral artery disease and pain. It's intended to address the 8.5 million Americans who may have peripheral artery disease, also known as PAD, a drug candidate JAN101, is the sustained release of sodium nitrate.

It has already been shown to be safe and a novel treatment for improving vascular function and reducing neuropathic pain, as well as other conditions resulting from poor blood flow. The drug is highly selective acting only in damaged tissue. Sodium nitrate and sustained release promotes blood vessel growth and function prevents inflammation of tissue necrosis. And it has been shown in some studies to help treat diabetic peripheral neuropathy, which is a leading cause of pain in diabetics.

There have already been three human clinical trials have been found to significantly reduce pain. And I actually ran one of these studies and it was a double blind randomized, placebo controlled trial studying diabetic neuropathic pain with JAN101. Not only did we see statistically significant reductions in pain at a higher dose, we also saw statistically significant improvement in nerve conduction velocity now that's really important because it shows that not only we are treating pain, we're actually helping improve nerve function. And I believe this could have significant implications in treating diabetic patients and particularly pain patients with neuropathic pain in the future.

But by alleviating the disease associated with pain at the source, we may be able to reduce the need for opioid prescriptions. Oftentimes, we use opioids to treat severe pain, particularly in diabetic peripheral neuropathy, and this can lead to abuse and diversion and overdose death. But this drug JAN101 can help treat pain without addiction and without sedation. And I can tell you as Chairman and Founder of the Ohio Pain Clinic, which is a network of pain management centers in Southwestern Ohio, I see this almost every day. And I've devoted a good portion of my professional life to helping people in pain and to try to help people live in pain without opioids is something that we've long been searching for.

I'm also the President Elect of the American Society of interventional Pain Management Physicians. This is the largest organized network of pain management physicians, and all of us physicians are searching for a drug that can treat pain without addiction and without sedation. And JAN101 checks both of those boxes.

I believe that if this drug reaches the market, personally, I think you'll see wide adoption amongst pain management practitioners and all of you guys know doctors, you probably see doctors and I think if you were to talk or meet with anyone that you know, that's a physician and tell them that there is an opportunity to treat neuropathic pain with the new medication that's non addicting and non sedating, I think you'd see some excitement there.

In addition to diabetic peripheral neuropathy, peripheral artery disease also is a very significant problem with 8.5 million Americans suffering from it. And this can also be painful, but we don't have a lot of good treatment options for that either. We expect to begin Phase 2b trials for PAD in early 2021.

With that, I'm going to turn it over to Dr. Tony Giordano, our Chief Scientific Officer to discuss the applications for JAN101 and patients suffering from COVID-19 related vascular complications,

Tony Giordano

Thank you, Amol.

I'd like to transition now into the COVID-19 story. When this pandemic first hit, and we start to learn about COVID-19, we became very excited about the potential of sodium nitrate in treating COVID-19 patients in large part this was because COVID-19, we knew affected the respiratory system, we knew that patients had difficulty getting oxygen. And what we knew about sodium nitrite is that it does improve pulmonary function, and it improves oxygen uptake in the blood. So we thought for these reasons, this could be something that we should try in COVID-19 patient.

And then very recently, in the prestigious medical journal, the New England Journal of Medicine, there was a report that shows SARS-CoV-2, which is the virus that causes COVID-19 actually damages endothelial cells that line the blood vessels. Now as Amol has already told, we've completed two clinical trials with JAN101 and in both of those trials, we were able to show that we improved endothelial cell function. And so not only do we think that this drug can have a positive effect on the pulmonary functions and pulmonary deficits associated with COVID-19, but it may have an important effect on the endothelial function that COVID-19 seems to be effective in these patients. And that's very important because it's actually been shown now that in patients that don't go into the hospital, there's still a potential for long-term tissue damage to these patients. And that's due to the lack -- in all likelihood, due to the lack of oxygen getting to these tissues.

So you get organ damage with the heart, you get organ damage with the kidneys, liver, lungs. And one of the things that we know from various preclinical studies is that JAN101 can protect tissues and organs from problems due to poor blood flow. So we think that that this could have a huge impact on all of these patients now, in particular the younger patient population that isn't ending up in the hospital, but that has these long-term effects of COVID-19 infections.

We recently received confirmation from the FDA, the Food and Drug Administration, that the original investigative new drug application or IND sponsorship was transferred for the JAN101 product from the original IND holder to JanOne. So we're now able to utilize that IND and move forward with these clinical trials.

The clinical candidate, JAN101, is now being formulated to treat and we're producing enough of this product, we're having enough of the product manufactured in a GMP facility to complete Phase 2 trials both in COVID-19 patients where we will file the IND. And shortly and once accepted by the FDA we will begin those Phase 2 trials. We've hired CATO SMS, a leading Contract Research Organization to a system development of JAN101 to treat COVID-19 applications and to submit the IND.

And we've also been working on with another very prominent CRO in the PAD field to move this product forward in treating peripheral arterial disease patients. And I did want to mention one other thing about PAD; I know Amol has already spoken about that. But in my personal experience in running the original PAD trials for TheraVasc, one of the things that we found is that again, not only did the drug significantly improve vascular function in these patients, there was also a report of significantly less pain. And these were patients with intermittent claudication and had significant pain walking down to the mailbox.

In fact, one of the patients called me up after the trial and said, "I've been on this project, I was in your clinical trial, I wasn't able to walk down to my mailbox without pain. I've been -- after 10 weeks on your drug, the pain subsided, I've been able to get around again, can I stay on the product?" I said, "Unfortunately, not the trials done." And he called me back again, about three, four months later and said, "Is there any way I can get more of your product, the pain is starting to come back again. And I'd really like to be pain free." And again, I told him, "Unfortunately, we can't give you the product at this point, but I'll certainly let you know when the next clinical trial begins." And again, hopefully the next clinical trial for PAD will begin sometime next year.

So we have a real opportunity here to help potentially treat patients with COVID-19 protecting them from the long-term tissue damage that we see associated with this pandemic and also potentially improving and reducing the amount of time before they are getting back to functionality and reducing hospitalization and then longer term going

after peripheral arterial disease and treating that disease so that patient's quality of life can improve back to what it was before they had the disease.

Thank you for your time and your attention.

Amol Soin

Thank you, Tony. I'm now going to move on to our pipeline update.

The company has made a strategic decision to initially pursue PAD, peripheral arterial disease in our planned Phase 2b PAD study is scheduled for early 2021. In this study, we'll evaluate the efficacy of two doses 40 and 80 milligrams of JAN101 to treat diabetic patients with PAD in a placebo controlled 12-week study.

We have plans to study 300 diabetic adults with PAD and three cohorts 100 patients each, our primary endpoint will be that the patient's ability to walk without pain or muscle fatigue as a result of vascular function restored by our drug candidate. Our secondary endpoints will be a reduction in pain over the course of treatment improves sensory nerve function and improved quality of life.

In conclusion, we continue to advance our high value late stage biotechnology asset and we believe that the targeted indication of peripheral artery disease, pain management in COVID-19 as a vascular disease represent a strong treatment area for our proprietary drug platform.

And the COVID-19 one is unique and interesting because we're looking at COVID-19 as a vascular disease. And this is something that may provide some significant advancements forward, in my opinion in treating this disease. So I work at a hospital in Dayton, Ohio, we have a network of eight hospitals in our system and our COVID units are full of patients. We've actually enrolled 200 patients in various COVID studies, everything from stem cells, to steroids, to convalescent plasma. And we continue to struggle with COVID-19 complications and issues.

And I think some of those complications and issues result from the fact that COVID-19 is indeed a vascular disease because when you think about it, we're seeing long-term damages to the heart and other organs and even the lungs. And there's so many mysteries about COVID-19, right? And some of it doesn't make sense because we call it an inflammatory disease. We say there's cytokine storm; get anti-inflammatories like ibuprofen aren't bad. And some steroids which treat inflammation are shown to not help the situation. But what does all this have in common? Drugs like ibuprofen, non-steroidals and steroidal anti-inflammatory, does that some of those drugs actually damage or impair vascular function?

So if we actually had a drug that could treat the vascular component of the disease, I think you would see a significant leap forward. And I truly look forward to studying this drug as an exciting new and novel treatment for the disease. Because I believe COVID-19 or a variant of this disease state may be around for a long time, even if we have a vaccine that comes out and having an option opportunity to treat and potentially prevent long-term complications could be truly transformative. And this is one thing that JAN101 has that the other candidates that I've studied in my hospital system. As I mentioned, we've enrolled over 200 patients in various studies. This was one thing that's unique to this drug candidate that the others don't have. And I look forward to being a part of that study.

The planned Phase 2b study for PAD and the planned IND submission for COVID-19, are compelling upcoming catalysts for the advancement of our company. We have a world-class team in place, and we believe that value proposition of JanOne in conjunction with our intellectual property, are sure to gain continued recognition from investors in the medical community alike. We continue to make progress with the FDA and intend to announce applications that address COVID-19.

Thank you for dialing in to hear more about our company and its applications. Now I'd like to turn the call back over to the operator for the Q&A portion of the call.

Question-and-Answer Session

Operator

Thank you. At this time, we'll be conducting a question-and-answer session. [Operator Instructions] Our first question comes from Jeremy Roe with Integra. Please proceed with your question.

Jeremy Roe

Hey, guys, thanks so much for taking my call. I really appreciate it. And after hearing the presentation, to be honest, I'm a lot more excited about it than what I understood, it was that you guys were doing. I also believe that this is a vascular disease. But real quick, can you talk a little bit about the safety profile and the prior clinical work that was done here. And why you feel that this can move to Phase 2 right away for the indications both COVID and PAD?

Tony Giordano

Yes. So, I was running TheraVasc when we were originally developing this product. And one of the things actually, when COVID hit, one of the things that excited me the most is I thought, okay, this drug could potentially benefit patients because of the oxygen and pulmonary functions. But the other thing I knew is that the drug is extremely safe, I mean, so the sodium nitrate is normally found in your circulation, it converts to nitric oxide in areas that are

damaged by different [Technical Difficulty] oxygen. And then, that nitric oxide promotes the endothelial function, but everywhere else sodium nitrite does nothing.

So we've been in -- between our trials and our collaborators trials, we've treated over 100 patients to-date with sodium nitrate. And the only side effects we saw were headaches and dizziness. And that was associated and no one dropped out of the trial. They were not severe. They all resolved without any kind of treatment. And that was because of the bolus release of nitrate causing the blood vessels to dilate and in getting blood flowing quickly away from the brain causing a headache.

So while that trial was going on, we actually developed a sustained release formulation that we tested in pigs. And looked at to see if it would change the blood pressure and it did not have any effect on blood pressure at all in the pigs. So we knew then that we were getting away from that vasodilation that we saw with the immediate release. We then and this is the trial that Amol ran, went ahead and tested that sustained release in diabetic neuropathy patients and no one, there was no difference between the three treatment groups in reported headaches and dizziness. So the only side effect we saw was headaches and dizziness.

Now there is one other side effect that's associated with high levels of sodium nitrite. And that's methemoglobinemia. But we've never come close to even see any methemoglobinemia somewhere around 10% to 15% is worrisome. And we've never gotten above 2%. And that was at a dose that we're not planning on using, the doses that we're planning on using, we never saw any methemoglobinemia increase in methemoglobin levels. So in short, I think this drug is extraordinarily safe, and will be very well tolerated.

Operator

Next question comes from [Ray Batar] [ph], a Private Investor. Please proceed with your question.

Unidentified Analyst

I just have a few questions for you regarding the patents. Do they cover regular sodium nitrite and sustained release sodium nitrite for the indications or is it only the latter? And have you filed for your COVID patent or some protection around COVID-19? Thank you.

Tony Giordano

Hi. Thanks. Again, that's a great question. And, of course, a critical question in this field. And yes, so sodium nitrite since it's been out there forever, the [Technical Difficulty] that covered but JanOne has licensed a patent to say, a

pretty extensive patents state that covers various uses of sodium nitrate to treat PAD, inflammatory diseases, pain, neuropathic, non-neuropathic pain and infections.

In addition, we do have a patent that has issued the formulation of the sustained release sodium nitrate. So we have patents on the Jan101 product itself, which is a sustained release sodium nitrite and methods of use of those sodium nitrate products.

Now to your second question, we have actually filed as soon as, as I mentioned to the previous caller. As soon as the pandemic hit, we started to think about that this might have value in treating COVID patients even before we knew about the endothelial function, which has convinced us that this will have value. So as soon as we started thinking about this, we filed another patent for JanOne to protect this product in treating COVID-19 infection -- for use in treating COVID-19 infections.

Operator

Our next question comes from Robert Carlson with Janney Montgomery Scott. Please proceed with your question.

Robert Carlson

Hi guys. Could you talk a little about your cash situation and your cash burn?

Tony Giordano

Tony, Isaac, do you want to handle that one?

Tony Isaac

Sure. So JanOne owns some legacy assets that is, that make profit and revenues and we already disclosed that we have intentions of potentially disposing of those assets. But until we get the right price and dispose them, they will be generating the revenues and we have enough assets to keep things going and we are really profitable.

Robert Carlson

Are you profitable presently?

Tony Isaac

Yes, we are.

Operator

Our next question comes from [Kim Besler with Rochelle Global] [ph]. Please proceed with your question.

Unidentified Analyst

Hi, Jimmy Besler here. My question relates to use with COVID-19 patients that don't end up in the hospital or that are exposed to and get COVID-19 but are never identified as such the disease passes on its own volition. How do you identify those potential customers that didn't end up in the hospital?

Amol Soin

Yes. This is Amol Soin, Chief Medical Officer and I'll be running the initial COVID study that we do. First, I will be enrolling patients that are currently inpatient in the hospital. So those patients that you know may be asymptomatic carriers or potentially we may not see travel through the hospital. We would be enrolling them in this initial study.

Our current hospital has a COVID unit right now and it's actually folders, no beds available, we have plenty of patients to enroll for the initial study.

Tony Giordano

And can I expand on that a little bit to as far as in the future, as Amol said, the critical thing is getting patients in that we could identify and treat and see benefits so that we can get this approved and out on the market and start using it. And I think, to your question of how do you identify those patients that are not hospitalized and that maybe don't show the symptoms, but that can have complications later. I think that as this disease, this pandemic runs its course, we're finding more and more of those patients are being identified. We were just -- I was talking to my daughter the other day and telling her about what we're trying to do with this and how it's going to help protect vascular functions. And she relayed to us, she's out in Denver, she's a marathon runner. She likes to -- and she said she relayed to us that in her running club now, a couple of the younger people who did come down with COVID infections are not having real problems with endurance. And they're going to the cardiologist and going to different doctors to find out, why are they not being able to run and why is their heart racing so much.

So I think that as this disease starts to run its course they're going to be a lot of patients who begin to identify that they are having some problems after the fact. Now, it would be very tough to do a clinical trial on them right now, but if we show that the product works and the trial that Amol has designed, then I think given the safety profile of this product, it's very likely that these other patients would benefit as well.

Operator

Our next question comes from [Richard Cidroen] [ph], a private Investor. Please proceed with your question.

Unidentified Analyst

Yes. And maybe you've already discussed it on the Phase 2b trial plan for the PAD. You said it was going to start when, end of this year, early next year? And also how does it differ from the trials we've done before for this drug treatment?

Tony Giordano

Okay. So the Phase 2b trial will start sometime next year. We have selected a CRO, a Contract Research Organization to manage the trial that has extensive experience running PAD trials and in fact after our clinical advisory board reviewed proposals from six different CRO's and did bid defenses with a number of these, we ended up with this CRO.

The difference of the two trials is primarily in the number of patients. We learned from the last trial that diabetic patients with peripheral arterial disease responded much better than non-diabetic patients to our treatment. And so that's why Amol told you at the beginning, that this trial would be focused on diabetic patients with PAD. So, that's one aspect. And then the second aspect is that, we did see an improvement in walking distance, which is the gold standard for the FDA. And so we have designed this trial with enough patients to see what we hope will be a statistically significant improvement in walking distance.

So I think that the limitation of the patients that perform -- that tend to perform best being diabetic patients with PAD and the increase in the size of the trial to see a statistically significant difference in walking distance are the two main differences in this trial.

And then again, one of the other things that Amol said and I almost neglected because we're so used to talking about pain now, is that in that first trial, we actually weren't looking at pain. We had no idea that that sodium nitrate or JAN101 will have any effect on pain whatsoever. But, what happened is that as we ran the trial, these are patients with severe intermittent claudication. They have pain in their legs and at the end of the trial, when they answered a quality of life questionnaire; the one aspect that really jumped out was that the patients who are treated reported statistically significant reduction in pain. So that was something that we didn't understand. And then as I mentioned, the patient who was in the trial called me and talked about his pain going away and then after not being on the drug

trial for some time his pain returning again. So this trial will be different from that previous trial and that we will actually be looking for indications of reduction in pain and improvement in their quality of life related to pain.

Operator

Our next question comes from [Kent McLaughlin] [ph], a Private Investor. Please proceed with your question.

Unidentified Analyst

Thanks for sharing your information, finding it very informative. But just curious, these are just real general questions. But is there anybody -- right now also competing in the same space using sodium nitrate that that you know of that's developing other products?

Amol Soin

That's a good question. There was a company a while ago when TheraVasc was first starting out, called Aires Pharmaceuticals that was developing sodium nitrate for COPD, and they were developing in its inhaled formulation. They had seemed to have some very interesting early results. But then had struggled raising additional financing and ended up being acquired by another company. And so the best of my knowledge that program has been shelved by the other company and for strategic reasons and they decided to move out of COPD.

There is a company called Hope Pharmaceuticals, that's also out there that has their product sodium nitrate as a -- sodium nitrite is an approved drug for cyanide poisoning. So Hope Pharmaceuticals markets this drug for cyanide poisoning, and they're looking at other indications as well but theirs is an injectable formulation. So to our knowledge, there is no other company that is developing an oral formulation of sodium nitrate at this time.

Unidentified Analyst

Okay. So right now it is orally, I know there's another couple of companies like [indiscernible] or Metrics is working on more of a compound that's entailed. But which will actually leads me to the next question? I've been reading different sizes of this market between 16 billion and 24 billion. Have you guys put any pen to paper on thinking what you could carve out in this space?

Amol Soin

Well, I mean, the PAD market, it's a very hard market to look at. There are millions -- 8 million PAD patients in the U.S. alone. But right now there's really not very effective treatment. Cilostazol is probably the only treatment that is

prescribed. When the cases get severe enough, of course, the vascular surgeons come in and try to improve blood flow [indiscernible] through surgery. So there's not a whole lot of drugs out there right now. Cost of the disease is tremendous, both in cost of treatment because of surgeries and potential amputations and in lost revenue because of poor quality of life.

I think that that, when we had looked at it before, we had felt that reimbursements would probably be pretty reasonable in this case, because, again, the lack of anything else that is currently out there other than cilostazol, and the fact that, the alternative is surgery. So, I think that the market size is likely to be in the million dollar range.

Unidentified Analyst

And the last question, so you talked about your clinical trials, and you mentioned, you're going to be doing those in Ohio. Is that right?

Amol Soin

Yes. The initial COVID pilot study we're going to do, we're going to do in Ohio. But the other studies and Tony will comment on this in a minute, those will be larger multicenter studies.

Unidentified Analyst

That kind of leads me, my question is, here in the specific Northwest, you plan on having anything to be up in the Seattle region?

Tony Giordano

Yes. The PAD trial and even -- the PAD trial, we're actually looking to probably bring on 50 sites across the United States. We realized from our last trial with PAD patients that there were some sites that recruited very well, and then other sites that did not recruit well. And so the strategy on this one will be to enroll sites across the U.S. so that we can get patients from different regions of the U.S. And that was one thing we did find in the PAD trial, the original PAD trial is because of the lack of treatments. We were getting patients who were coming in and commuting some three to four hours to get enrolled in the trial. So we know that the catchment area could be pretty large. So yes, we do intend to have sites across the U.S. for that trial.

Operator

Okay. This concludes today's conference. We thank you for your participation. You may disconnect your lines at this time and have a great day.