



ALTS SIGMA CORPORATION

3 Units

(Consisting of (i) 1 Non-Convertible Debenture in the Principal Amount of up to \$1,784,000 and 1 Warrant for the Purchase of up to 400,000 Shares of Common Stock at an Exercise Price of \$1.71 per share and (ii) 2 Non-Convertible Debentures, each in the Principal Amount of \$404,454.39 and each with 1 Warrant for the Purchase of up to 90,909 shares of Common Stock at an Exercise Price of \$1.71 per share)

We are offering 3 units (the “Units”), with 1 Unit consisting of one non-convertible debenture in the principal amount of up to \$1,784,000.00, prior to the OID, as that term is defined below (the “Big Debenture”), and one warrant for the purchase of up to 400,000 shares of our common stock, par value \$0.001 per share (“Common Stock”), at an exercise price of \$1.71 per share of Common Stock (the “Big Warrant”), and with 2 Units, each consisting of one non-convertible debenture in the principal amount of \$404,454.39, prior to the OID (“Small Debentures” and, together with the Big Debenture, the “Debentures”), and one warrant for the purchase of up to 90,909 shares of Common Stock, at an exercise price of \$1.71 per share of Common Stock (“Small Warrants” and, together with the Big Warrant, the “Warrants”) to four certain institutional investors through this prospectus supplement and the accompanying base prospectus.

The Debentures are unsecured and subordinated to any existing or future debt. The Debentures bear interest thereon at a rate of (i) 1% per month from and after August 20, 2024 (“Original Issue Date”) through and including October 31, 2024, (ii) 3% per month from and after November 1, 2024 through and including January 29, 2025, and (iii) 4% per month from and after January 30, 2025 through and including the date of repayment.

The Big Debenture will be issued with an original issue discount (an “OID”) initially of \$171,000, which OID can be expanded with up to two potential additions, the first in the amount of \$171,000 and, thereafter, in the amount of \$342,000, which OIDs will increase the principal amount owing on the Big Debenture. With the original OID, the initial principal amount owing under the Big Debenture is \$1,271,000.00; if, expanded, the principal amount would increase to \$1,442,000.00 and, thereafter, potentially to \$1,784,000.00. The first potential increase in the Big Debenture OID would occur if the initial principal amount and interest accrued thereon is not paid in full on or before October 31, 2024. The second potential increase in the OID would occur if the initial principal amount (including the first potential increase in the OID) and interest accrued thereon is not paid in full on or before January 29, 2025. The final maturity date for the Big Debenture is April 28, 2025.

Each Smaller Debenture will be issued with an OID initially of \$38,863.17, which OID can be expanded with up to two potential additions, the first in the amount of \$38,863.17 and, thereafter, in the amount of \$77,728.05, which OIDs will increase the principal amount owing on each of the Small Debentures. With the original OID, the initial principal amount owing under each of the Small Debentures is \$288,864.17; if, expanded, the principal amount would increase to \$327,726.34 and, thereafter, potentially to \$405,454.39. The first potential increase in each of the Small Debentures OID would occur if the initial principal amount and interest accrued thereon is not paid in full on or before October 31, 2024. The second potential increase in the OID would occur if the initial principal amount (including the first potential increase in the OID) and interest accrued thereon is not paid in full on or before January 29, 2025. The final maturity date for each of the Small Debentures is April 28, 2025.

The Big Warrant will be exercisable, at an exercise price of \$1.71 per share, as follows: (i) 100,000 shares of Common Stock as of Original Issue Date, (ii) contingently for an additional 100,000 shares of Common Stock as of October 31, 2024, if, as of such date, the Company has not repaid in full its obligations under the Big Debenture, and (iii) contingently for an additional 200,000 shares of Common Stock as of January 29, 2025, if, as of such date, the Company has not repaid in full its obligations under the Big Debenture. The Small Warrants will each be exercisable, at an exercise price of \$1.71 per share, as follows: (i) 22,727 shares of Common Stock as of Original Issue Date, (ii) contingently for an additional 22,727 shares of Common Stock as of October 31, 2024, if, as of such date, the Company has not repaid in full its obligations under the Small Debenture, and (iii) 45,455 shares of Common Stock as of January 29, 2025, if, as of such date, the Company has not repaid in full its obligations under the Small Debenture, and (iii).

The registered securities hereunder consist of the shares issuable upon the exercises of the initial tranche and the contingent second tranche of each of the Warrants, but not the third tranche of any of the Warrants. Each Investor is required to exercise the initial tranche of each Warrant within 15 days of the Original Issue Date. Upon the vesting of each contingent tranche of a Warrant vest, each Investor shall exercise such vested, contingent tranche within 15 days of the vesting of such contingent tranche. If the Company consummates any equity or debt financing before satisfying in full its obligations under the Debentures, then 50% of every net dollar received by the Company from any such financing transaction shall be paid by the Company to the holders of the Debentures, on a pro rata basis, as a mandatory pre-payment thereof. In the event the Company has repaid all sums owing under a Debenture to the Investor, except for an amount equal to any non-conditional OID, the Company has the right, not the obligation, to exercise the vested portion of the Warrant held by the Debenture holder through a set-off of any or all such unpaid OID, on a dollar-for-dollar basis. The Debentures also feature a “cashless” exercise provision. See the section entitled “Description of Units that We Are Offering” appearing on page S-6 of this Prospectus Supplement for a discussion of the “cashless” exercise provision.

The Debentures and the Warrants are not and will not be listed for trading on any national securities exchange. None of the three institutional investors is a “U.S. Person,” as such term is defined in Regulation S under the Securities Act of 1933, as amended (“Securities Act”), and each is an “accredited investor” as such term is defined in Rule 501(a) under the Securities Act.

The closing of this offering is expected to occur on or about August 23, 2024, subject to the satisfaction of customary closing conditions.

As of the date of this Prospectus Supplement, the aggregate market value of our outstanding Common Stock held by non-affiliates was approximately \$36,495,291. This value was computed by reference to the highest closing price of our Common Stock on The Nasdaq Capital Market within the preceding 60 days (\$2.92 per share on August 19, 2024) multiplied by 13,271,015 shares held by non-affiliates. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities in a public primary offering with a value exceeding one-third of our public float in any 12-month period so long as our public float remains below \$75.0 million. During the 12 calendar months prior to and including the date of this prospectus supplement (excluding this offering), we have sold \$1,092,000 in securities pursuant to General Instruction I.B.6 of Form S-3.

Our Common Stock is listed on The Nasdaq Capital Market under the symbol “ALTS.” On August 21, 2024, the last reported sale price of our Common Stock as reported on The Nasdaq Capital Market was \$2.75 per share. There is no established trading market for the Debenture or Warrant, and we do not expect a market to develop.

Our business and investing in our shares of Common Stock involves a high degree of risk. See the section entitled “Risk Factors” appearing on page S-4 of this Prospectus Supplement, on Page 3 of the accompanying Base Prospectus, and the risk factors described in the documents incorporated by reference into this Prospectus Supplement and Base Prospectus for a discussion of information that should be considered in connection with an investment in our securities.

We have retained Mint Capital Advisors, Ltd. to act as our exclusive placement agent in respect of the solicitation of the three institutional investors in this offering. The placement agent has no obligation to buy the Units from us or to arrange for the purchase or sale of any specific number or dollar amount of the Units. We have agreed to pay the placement agent fees in an amount equivalent to 7.5% of the aggregate \$1,600,000.00 tendered to us in connection with the sale of the three debentures.

	Debtenture	Total
Aggregate Offering price	\$ 1,600,000	\$ 1,600,000
Proceeds, before expenses, to us (1)	\$ 1,480,000	\$ 1,480,000

(1) The amount of the offering proceeds to us presented in this table does not include proceeds from the exercise of the Warrants in cash, if any.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the Units or passed upon the adequacy or accuracy of this prospectus supplement. Any representation to the contrary is a criminal offense.

Delivery of the Units to the investors is expected to occur on or about August 23, 2024, subject to satisfaction of customary closing conditions.

The date of this prospectus supplement is August 23, 2024.

TABLE OF CONTENTS

Prospectus Supplement

ABOUT THIS PROSPECTUS SUPPLEMENT	S-1
CAUTIONARY STATEMENTS REGARDING FORWARD-LOOKING INFORMATION	S-1
PROSPECTUS SUPPLEMENT SUMMARY	S-2
THE UNITS	S-3
RISK FACTORS	S-4
USE OF PROCEEDS	S-6
DIVIDEND POLICY	S-6
DESCRIPTION OF THE UNITS	S-6
PLAN OF DISTRIBUTION	S-10
LEGAL MATTERS	S-12
EXPERTS	S-12
WHERE YOU CAN FIND MORE INFORMATION	S-12
INFORMATION INCORPORATED BY REFERENCE	S-12

Prospectus

	<u>Page</u>
ABOUT THIS PROSPECTUS	1
AVAILABLE INFORMATION	2
INCORPORATION OF CERTAIN INFORMATION BY REFERENCE	2
FORWARD-LOOKING STATEMENTS	3
RISK FACTORS	3
BUSINESS	4
SELECTED CONSOLIDATED FINANCIAL DATA	31
DESCRIPTION OF SECURITIES WE MAY OFFER	32
DESCRIPTION OF CAPITAL STOCK	33
DESCRIPTION OF PREFERRED STOCK	36
DESCRIPTION OF DEBT SECURITIES	37
DESCRIPTION OF WARRANTS	43
DESCRIPTION OF RIGHTS	45
DESCRIPTION OF UNITS	46
USE OF PROCEEDS	46
PLAN OF DISTRIBUTION	46
LEGAL MATTERS	48
EXPERTS	48

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts, this prospectus supplement and the accompanying base prospectus, both of which are part of a registration statement on Form S-3 that we filed with the U.S. Securities and Exchange Commission (the “SEC”) using a “shelf” registration process. The first part is the prospectus supplement, including the documents incorporated by reference, which describes the specific terms of this offering. The second part, the accompanying base prospectus, including the documents incorporated by reference, provides more general information. Before you invest, you should carefully read this prospectus supplement, the accompanying base prospectus, all information incorporated by reference herein and therein, as well as the additional information described under “Where You Can Find More Information” on page S-12 of this prospectus supplement. These documents contain information you should consider when making your investment decision. This prospectus supplement may add, update, or change information contained in the accompanying base prospectus. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying base prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document filed after the date of this prospectus supplement and incorporated by reference in this prospectus supplement and the accompanying base prospectus — the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying base prospectus and in any free writing prospectuses we may provide to you in connection with this offering. We have not authorized any other person to provide you with any information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and seeking offers to buy, shares of our Common Stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the offering of the Common Stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the Common Stock and the distribution of this prospectus supplement outside the United States. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

We further note that the representations, warranties, and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in the accompanying base prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

When used herein, “Company,” “we,” “us,” or “our” refers to ALT5 Sigma Corporation, a Nevada corporation, and our subsidiaries.

CAUTIONARY STATEMENTS REGARDING FORWARD-LOOKING INFORMATION

The information included or incorporated by reference into the base prospectus and this prospectus supplement contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “targets,” “likely,” “aim,” “will,” “would,” “could,” “should,” “predict,” “potential,” “continue,” and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. Actual results may differ materially from those expressed or implied in such forward-looking statements as a result of various factors. We do not undertake, and we disclaim, any obligation to update any forward-looking statements or to announce any revisions to any of the forward-looking statements, except as required by law. Certain factors that could cause results to be materially different from those projected in the forward-looking statements include, but are not limited to, statements about:

- our history of losses and working capital deficit;
- our ability to continue as a going concern;
- the known and unknown impact of the Covid-19 pandemic on our Company;
- dependence on our key personnel;
- need for additional financing to complete our Phase IIb/IIIa studies for JAN101, which is a potential treatment for Periphery Artery Disease;
- need for financing for the continued development of our newly acquired JAN123, which is a potential treatment for Complex Regional Pain Syndrome;
- regulatory and legal uncertainties;
- the impact of quarterly results on our common stock price; and
- dilution to our stockholders upon the exercise of outstanding common stock options and restricted stock unit grants.

We urge you to consider these factors before investing in our Common Stock. The forward-looking statements included in this prospectus supplement, the accompanying base prospectus, and any other offering material, or in the documents incorporated by reference into this prospectus supplement, the accompanying base prospectus, and any other offering material, are made only as of the date of the prospectus supplement, the accompanying base prospectus, any other offering material, or the documents incorporated by reference. For more detail on these and other risks, please see “Risk Factors” in this prospectus supplement, our Annual Report on Form 10-K for our 2023 fiscal year ended December 31, 2023, filed with the SEC on April 8, 2024, and our other filings with the SEC.

S-1

PROSPECTUS SUPPLEMENT SUMMARY

The following information below is only a summary of more detailed information included elsewhere in, or incorporated by reference in, this prospectus supplement and the accompanying base prospectus, and should be read together with the information contained or incorporated by reference in other parts of this prospectus supplement and the accompanying base prospectus. This summary highlights selected information about us and this offering. This summary may not contain all of the information that may be important to you. Before making a decision to invest in our Common Stock, you should read carefully all of the information contained in or incorporated by reference into this prospectus supplement and the accompanying base prospectus, including the information set forth under the caption “Risk Factors” in this prospectus supplement and the accompanying base prospectus, as well as the documents incorporated herein by reference, which are described under “Where You Can Find More Information” and “Information Incorporated by Reference” in this prospectus supplement.

Our Company

General

ALT5 Sigma Corporation (formerly known as JanOne Inc.) and subsidiaries (collectively, “we,” the “Company,” or “ALT5”) is a unique Nasdaq-listed multidisciplinary organization with a focus on healthcare and fintech. The Company is one of the constituents of the Russell Microcap Index, as of June 28, 2024.

In connection with broadening of our focus on healthcare and fintech, on May 10, 2024, we executed and delivered a definitive Agreement and Plan of Merger (the “Merger Agreement”) with ALT5 Sigma, Inc., a Delaware corporation (“ALT5 Sigma”), pursuant to which we acquired all of the capital stock of ALT5 Sigma, which, as of the May 15, 2024, closing of that transaction, became a first-tier, wholly-owned subsidiary of ours and ALT5 Sigma’s subsidiaries became our second-tier wholly-owned subsidiaries.

In that transaction, we issued approximately 1,799,100 shares of our common stock and 34,207 shares of our newly designated Series B Preferred Stock (the “Series B Stock”) to the legacy equity holders of the capital stock of ALT5 Sigma. The shares of our common stock represented approximately 19.9% of our then-issued and outstanding shares of common stock. Each of the issued shares of our common stock was valued at \$4.14, which was the Nasdaq NOCP on Thursday, May 9, 2024, the day immediately prior to the date on which the parties executed and delivered the Merger Agreement. The Series B Stock is not redeemable, is not convertible, directly or indirectly, into any class or series of our capital stock, does not provide for the payment or accrual of any dividends, has no non-statutorily mandated voting rights, and provides for a liquidation preference of \$250 per share under certain limited circumstances.

ALT5 Sigma is a fintech that provides next generation blockchain-powered technologies to enable a migration to a new global financial paradigm. ALT5, through its subsidiaries, offers two main platforms to its customers: “ALT5 Pay” and “ALT5 Prime.” ALT5 Sigma processed over US\$1.2 billion in cryptocurrency transactions in 2023.

ALT5 Pay is a crypto-currency payment gateway that enables registered and approved global merchants to accept and make crypto-currency payments or to integrate the ALT5 Pay payment platform into their application or operations using the plugin with WooCommerce and or ALT5 Pay’s checkout widgets and APIs. Merchants have the option to convert to fiat currency (US Dollars, Canadian Dollars, Euros, and British Pounds Sterling) automatically or to receive their payment in digital assets.

ALT5 Prime is an electronic over-the-counter trading platform that enables registered and approved customers to buy and sell digital assets. Customers can purchase digital assets with fiat and, equally, can sell digital assets and receive fiat. ALT5 Prime is available through a browser-based access, mobile phone application named “ALT5 Pro” that can be downloaded from the Apple App Store, from Google Play, through ALT5 Prime’s FIX API, as well as through Broadridge Financial Solutions’ NYFIX gateway for approved customers.

Through its biotech activities, the Company is developing innovative, actionable solutions intended to help end the opioid crisis. The Company is dedicated to funding resources toward innovation, technology, and education to find a key resolution to the national opioid epidemic, which is one of the deadliest and most widespread in the nation’s history. Its drugs in the clinical trial pipeline have shown promise for their innovative targeting of the causes of pain as a strategic option for physicians averse to exposing patients to addictive opioids. Our first drug candidate is a treatment for Peripheral Artery Disease (“PAD”), a condition that can cause severe pain and affects over 8.5 million people in the United States.

On December 28, 2022, we entered into a Purchase Agreement (the “Soin Purchase Agreement”) with Soin Therapeutics, LLC. Under the Soin Purchase Agreement, the Company acquired Soin Therapeutics and its LDN product, now known as JAN123. JAN123 is a novel formulation of 2.0 mg of LDN that results in a biphasic release of the product. The release properties of JAN123 provide for an immediate release of less than half the product with a slow, sustained release of the remaining product. Importantly, the rapid release of LDN has been reported to lead to vivid and lucid unpleasant dreams, which should be eliminated with the formulation of JAN123. Initially, a single tablet of JAN123 will be administered orally, once a day before sleep, with eventual titration up to two tablets (4 mg) before sleep.

Through March 8, 2023, the Company operated its legacy businesses through its Recycling Subsidiaries, consisting of: (a) ARCA Recycling, Inc., a California corporation (“ARCA Recycling”), (b) ARCA Canada Inc., a corporation organized under the laws of Ontario, Canada (“ARCA Canada”), and (c) Customer Connexx, LLC, a Nevada limited liability company (“Connexx”). ARCA Recycling and ARCA Canada recycle major household appliances in North America by providing turnkey appliance recycling and replacement services for utilities and other sponsors of energy efficiency programs. Connexx is a company that provides call center services for recycling businesses. On March 9, 2023, we entered into a Stock Purchase Agreement (the “Recycling Purchase Agreement”) with VM7 Corporation, a Delaware corporation (“VM7”), under which it agreed to acquire all of the outstanding equity interests of the Recycling Subsidiaries. The principal of VM7 is Virland A. Johnson, our Chief Financial Officer.

The information contained in or accessible from our website is not incorporated into this Prospectus Supplement and it should not be considered part of this Prospectus Supplement. We have included our website address in this Prospectus Supplement solely as an inactive textual reference

Corporate Information

The Company was incorporated in Minnesota in 1983, although, through its predecessors, we began operating our legacy recycling business in 1976. On March 12, 2018, we reincorporated in the State of Nevada. Effective as of September 10, 2019, we changed our name to JanOne Inc, and, effective as of July 15, 2024, we changed our name from JanOne Inc. to ALT5 Sigma Corporation. We run our operations through JanOne Inc., as well as through our wholly-owned subsidiaries, JanOne BioTech Holdings, Inc., and Soin Technologies, LLC.

Where You Can Find Us

Our principal executive office is located at 325 E. Warm Springs Road, Suite 102, Las Vegas, Nevada 89119, and our telephone number is (702) 997-5968. We report on a 52- or 53-week fiscal year. Our 2024 fiscal year will end on December 28, 2024. Our 2023 fiscal year ended on December 30, 2023. Our 2022 fiscal year ended on December 31, 2022. We maintain a corporate website at <https://alt5sigma.com>. Except as specifically set forth herein, the information which appears on our website is not part of the prospectus or this prospectus supplement. Please see our Annual Report on Form 10-K for the 2023 fiscal year ended December 30, 2023, as filed with the SEC on April 8, 2024, and our other subsequent filings with the SEC for additional information about our business, operations, and financial condition.

S-2

THE UNITS

The following summary contains basic information about the Units described herein. The summary is not intended to be complete. You should read the full text and more specific details contained elsewhere in this prospectus supplement.

Issuer	ALT5 Sigma Corporation
The units	(i) 1 Unit consisting of 1 Debenture in the initial principal amount of \$1,271,000, subject to contingent increases of an additional \$171,000 and \$342,000, and 1 Warrant for the purchase of up to 400,000 shares of Common Stock, at an exercise price of \$1.71 per share, and (ii) 2 Units, each consisting of 1 Debenture in the initial principal amount of \$288,864.17, subject to contingent increases of \$38,863.17 and \$77,728.05, and 1 Warrant for the purchase of up to 90,909 shares of Common Stock, at an exercise price of \$1.71 per share.
Common Stock outstanding prior to the offering	13,491,272
Common Stock to be outstanding after this offering	14,163,999 (if all of the vested Warrants and the balance conditionally vest and all are exercised in full for cash, as to each such occurrence, there can be no assurance)
Nasdaq Capital Market symbol	“ALTS”. There is no established public trading market for the Debentures or the Warrants, and we do not expect a market to develop. We do not intend to list the Debentures (which are not the subject of the Prospectus Supplement or the Warrants (the final conditional vesting tranches of which are not the subject of this Prospectus Supplement) on any securities exchange or nationally recognized trading system. Without an active trading market, the liquidity of the Debentures (which are not the subject of this Prospectus Supplement) or the Warrants (the final conditional vesting tranches of which are not the subject of this Prospectus Supplement) will be limited.
Use of proceeds	We intend to use the net proceeds from this offering for working capital and general corporate purposes. See “Use of Proceeds.”
Risk factors	This investment involves a high degree of risk. See “Risk Factors” and other information included or incorporated by reference in this prospectus supplement beginning on page S-4 and the accompanying base prospectus beginning on page 4 for a discussion of certain factors you should carefully consider before deciding to invest in shares of our Common Stock.

S-3

RISK FACTORS

Holding shares of Common Stock involves a high degree of risk. You should carefully consider and evaluate all of the information contained in this Prospectus Supplement, the Base Prospectus and in the documents that we incorporate by reference into this Prospectus Supplement and the Base Prospectus before you decide to purchase any shares of our Common Stock that may be sold into the public markets by the purchasers of the Units in connection with their prospective exercise of the Warrants included in the Units and their subsequent sale of those shares into the public markets. In particular, you should carefully consider and evaluate the risks and uncertainties described under the heading "Risk Factors" in this Prospectus Supplement and the Base Prospectus, or in the documents incorporated by reference herein and therein. Any of the risks and uncertainties set forth in this Prospectus Supplement and the Base Prospectus, as updated by annual, quarterly, and other reports and documents that we file with the SEC and incorporate by reference into this Prospectus Supplement or the Base Prospectus, could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the value of our Common Stock.

Risks Related to Ownership of Our Common Stock

The market price for our Common Stock is particularly volatile given our status as a company with a small and thinly traded public float, lack of profits, and the need for capital to fund our biopharmaceutical product development, which could and has led to wide fluctuations in our share price.

The market for our Common Stock is characterized by significant price volatility when compared to the shares of larger, more established companies that have large public floats, and we expect that our share price will continue to be more volatile than the shares of such larger, more established companies for the indefinite future, although such fluctuations may not reflect a material change to our financial condition or operations during any such period. For example, from August 22, 2023 through August 21, 2024, the reported sale price of our Common Stock has fluctuated between \$0.30 and \$5.10 per share. Such volatility can be attributable to a number of factors. First, as noted above, our Common Stock is, compared to the shares of such larger, more established companies, sporadically and thinly traded. The price for our Common Stock could, for example, decline precipitously in the event that a large number of our shares are sold on the market without commensurate demand. Secondly, we are a speculative or "risky" investment due to our lack of profits to date. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a larger, more established company that has a large public float. Many of these factors are beyond our control and may decrease the market price of our Common Stock regardless of our operating performance.

In addition to being highly volatile, our Common Stock could be subject to wide fluctuations in response to a number of factors that are beyond our control, including, but not limited to:

- variations in our revenues and operating expenses;
- actual or anticipated changes in the estimates of our operating results or changes in stock market analyst recommendations regarding our Common Stock, other comparable companies or our industry generally;
- market conditions affecting our business or the economy as a whole;
- developments in the financial markets and worldwide or regional economies;
- announcements of innovations or new products or services by us or our competitors;
- sales of our Common Stock or other securities by us or in the open market;
- changes in the market valuations of other comparable companies; and
- other events or factors, many of which are beyond our control, including those resulting from such events, or the prospect of such events, including war, terrorism and other international conflicts, public health issues including health epidemics or pandemics, such as the COVID-19 pandemic, and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability.

In addition, if the market for fintech or biopharmaceutical stocks or the stock market in general experiences loss of investor confidence, the trading price of our Common Stock could decline for reasons unrelated to our business, financial condition, or operating results. The trading price of our shares might also decline in reaction to events that affect other companies in our industry, even if these events do not directly affect us. Each of these factors, among others, could harm the value of our Common Stock. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, operating results, and financial condition.

S-4

In addition, if the market for biopharmaceutical stocks or the stock market in general experiences loss of investor confidence, the trading price of our Common Stock could decline for reasons unrelated to our business, financial condition, or operating results. The trading price of our shares might also decline in reaction to events that affect other companies in our industry, even if these events do not directly affect us. Each of these factors, among others, could harm the value of our Common Stock. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, operating results, and financial condition.

We will have broad discretion as to the use of the proceeds from the sale of the Units and the prospective exercise of the Warrants included therein, and we may not use the proceeds effectively.

Subject to certain limited exceptions set forth in the offering documents, we intend to use the net proceeds from the sale of the Units and the prospective exercise of the Warrants included therein for working capital and general corporate purposes. We have considerable discretion in the application of the net proceeds thereof. You will not have the opportunity to assess whether such proceeds are being used in a manner agreeable to you. You must rely on our judgment regarding the application of the net proceeds derived from the sale of the Units and the prospective exercise of the Warrants included therein, which may be used for corporate purposes that do not improve our profitability or increase the price of our shares of Common Stock. Such proceeds may also be placed in investments that do not produce income or that lose value. The failure to use such funds by us effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

Substantial future sales of shares of our Common Stock could cause the market price of our Common Stock to decline.

We expect that significant additional capital will be needed in the near future to continue our planned operations. Sales of a substantial number of shares of our Common Stock in the public market, or the perception that these sales might occur, could depress the market price of our Common Stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our shares.

We have financed our operations, and we expect to continue to finance our operations, acquisitions, if any, and the development of strategic relationships by issuing equity, warrants and/or convertible securities, which could significantly reduce the percentage ownership of our existing stockholders. Further, any additional financing that we secure may require the granting of rights, preferences, or privileges senior to, or pari passu with, those of our Common Stock. Additionally, we may acquire other technologies or finance strategic alliances by issuing our equity or equity-linked securities, which may result in additional dilution. Any issuances by us of equity securities may be at or below the prevailing market price of our Common Stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our Common Stock to decline. We may also raise additional funds through the incurrence of debt or the issuance or sale of other securities or instruments senior to our shares of Common Stock. The holders of any securities or instruments we may issue may have rights superior to the rights of our holders of our Common Stock. If we experience dilution from issuance of additional securities and we grant superior rights to new securities over common stockholders, it may negatively impact the trading price of our shares of Common

Stock.

We do not anticipate paying dividends in the foreseeable future; you should not buy our stock if you expect dividends.

We have never paid a dividend on our Common Stock. The determination of whether to pay dividends on our Common Stock in the future will depend on several factors, including without limitation, our earnings, financial condition, and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our Common Stock may be less valuable because a return on your investment will only occur if our stock price appreciates. We currently intend to retain our future earnings to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our Common Stock in the foreseeable future.

We could issue preferred stock without stockholder approval with the effect of diluting then current stockholder interests and impairing their voting rights; and provisions in our charter documents could discourage a takeover that stockholders may consider favorable.

Our articles of incorporation, as amended, authorize the issuance of up to 2,000,000 shares of “blank check” preferred stock with designations, rights and preferences as may be determined from time to time by our board of directors. 259,729 shares of our Series A-1 Convertible Preferred Stock are authorized, of which 68,480 shares are issued and outstanding, leaving 191,249 shares of that series that are authorized, but unissued. 200,000 shares of our Series S Convertible Preferred Stock are authorized, of which 100,000 shares are issued and outstanding, leaving 100,000 shares of that series that are authorized, but unissued. 34,250 shares of our Series B Preferred Stock are authorized, of which 34,208 shares are issued and outstanding, leaving 42 shares of that series that are authorized, but unissued. 3,200 shares of our Series M Preferred Stock are authorized, of which 3,200 shares are issued and outstanding, leaving -0- shares of that series that are authorized, but unissued. 5,000 shares of our Series V Convertible Preferred Stock are authorized, of which 5,000 shares are issued and outstanding, leaving -0- shares of that series that are authorized, but unissued. We have 1,497,821 shares of “blank check” preferred stock remaining available for designation and issuance. Our board of directors is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting, or other rights that could dilute the interest of, or impair the voting power of, our common stockholders. The issuance of a series of preferred stock could be used as a method of discouraging, delaying, or preventing a change in control of us. For example, it would be possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our Company.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our Common Stock adversely, our Common Stock price and trading volume could decline.

The trading market for our shares of Common Stock will be influenced by many factors, including without limitation, the research reports that industry or securities analysts may publish about us, our business, our market, or our competitors. As of the date of this Prospectus Supplement, no analysts cover us, but, if any were to cover us and then adversely change their recommendation regarding our Common Stock, or provide more favorable relative recommendations about our competitors, our share price would likely decline. If any analyst who may cover us were to cease coverage of our Company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our Common Stock price or trading volume to decline.

S-5

Significant dilution will occur if outstanding options or warrants are exercised, or restricted stock unit grants vest.

As of August 21, 2024, we had 114,000 shares of our Common Stock underlying outstanding stock options and 1,922,188 shares of our Common Stock underlying outstanding warrants. If outstanding stock options or warrants are exercised or if shares of our Series A-1 Convertible Preferred Stock or shares of our Series S Convertible Preferred Stock are converted, dilution will occur to our stockholders, which may be significant.

We may not be able to maintain compliance with the continued listing requirements of The Nasdaq Capital Market.

Our Common Stock is listed on The Nasdaq Capital Market. In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, a requirement that our closing bid price be at least \$1.00 per share and net stockholders' equity of not less than \$2.5 million. If we fail to continue to meet all applicable continued listing requirements for The Nasdaq Global Market in the future and Nasdaq determines to delist our Common Stock, the delisting could adversely affect the market liquidity of our Common Stock, our ability to obtain financing to repay debt, and fund our operations.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the Units referenced in this prospectus supplement, after deducting estimated offering expenses payable by us, and excluding any proceeds we may receive upon exercise of the Warrants, will be approximately \$1,480,000.

We intend to use the net proceeds from the sale of the Units for working capital and other general corporate purposes, which may include acquisitions. If, when, and as exercised, we intend to use the proceeds from the exercise of vested Warrants also for the same purposes. The amounts and timing of our use of proceeds will vary depending on a number of factors, including the amount of cash generated or used by our operations. As a result, we will retain broad discretion in the allocation of the net proceeds of this offering.

Pending our use of the net proceeds from the sale of the Units, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments, and U.S. government securities.

DIVIDEND POLICY

We have not declared or paid cash dividends on our Common Stock since our inception. Under Nevada law, we are prohibited from paying dividends if the distribution would result in our Company not being able to pay its debts as they become due in the normal course of business if our total assets would be less than the sum of our total liabilities plus the amount that would be needed to pay the dividends, or if we were to be dissolved at the time of distribution to satisfy the preferential rights upon dissolution of stockholders whose preferential rights are superior to those receiving the distribution. Our board of directors has complete discretion on whether to pay dividends subject to compliance with applicable Nevada law. Even if our board of directors were to decide to pay dividends, the form, the frequency, and the amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions, and other factors that the board of directors may deem relevant. While our board of directors will make any future decisions regarding dividends, if, when, and as circumstances surrounding us change, it currently does not anticipate that we will pay any cash dividends in the foreseeable future.

DESCRIPTION OF THE UNITS

We are offering 3 Units, with (i) 1 Unit consisting of one Debenture in the principal amount of up to \$1,784,000.00 and one Warrant for the purchase of up to 400,000 shares of our Common Stock, at an exercise price of \$1.71 per share of Common Stock, and (ii) 2 Units, each consisting of one Debenture in the principal amount of up to \$404,454.39 and one Warrant for the purchase of up to 90,909 shares of our Common Stock, at an exercise price of \$1.71 per share of Common Stock.

Debentures

The following summary of certain terms and provisions of the Debentures that are included in the Units, but are not the subject of this Prospectus Supplement, is not complete and is subject to, and qualified in its entirety by, the provisions of the Debenture, the form of which will be filed as an exhibit to our Current Report on Form 8-K to be filed on

not later than August 23, 2024. Prospective investors should carefully review the terms and provisions of the forms of the Debentures for a complete description of the terms and conditions of the Debentures.

Selling Price and OIDs

The Big Debenture will be issued with an original issue discount (an “OID”) initially of \$171,000, which OID can be expanded with up to two potential additions of \$171,000 and, thereafter, \$342,000, which OIDs will increase the principal amount owing on the Big Debenture. With the original OID, the initial principal amount owing under the Big Debenture is \$1,271,000.00; if, expanded, the principal amount would increase to \$1,442,000.00 and, thereafter, potentially to \$1,784,000.00. The first potential increase in the Big Debenture OID would occur if the initial principal amount and interest accrued thereon is not paid in full on or before October 31, 2024. The second potential increase in the OID would occur if the initial principal amount (including the first potential increase in the OID) and interest accrued thereon is not paid in full on or before January 29, 2025. The final maturity date for the Big Debenture is April 28, 2025.

S-6

Each Smaller Debenture will be issued with an OID initially of \$38,863.17, which OID can be expanded with up to two potential additions of \$38,863.17 and, thereafter, \$77,728.05, which OIDs will increase the principal amount owing on each of the Small Debentures. With the original OID, the initial principal amount owing under each of the Small Debentures is \$288,864.17; if expanded, the principal amount would increase to \$327,726.34 and, thereafter, potentially to \$405,454.39. The first potential increase in each of the Small Debentures OID would occur if the initial principal amount and interest accrued thereon is not paid in full on or before October 31, 2024. The second potential increase in the OID would occur if the initial principal amount (including the first potential increase in the OID) and interest accrued thereon is not paid in full on or before January 29, 2025. The final maturity date for each of the Small Debentures is April 28, 2025.

Interest

The Debentures bear interest thereon at a rate of (i) 1% per month from and after August 20, 2024 (“Original Issue Date”) through and including October 31, 2024, (ii) 3% per month from and after November 1, 2024 through and including January 29, 2025, and (iii) 4% per month from and after January 30, 2025 through and including the date of repayment.

Mandatory Prepayment

If the Company consummates any equity or debt financing before satisfying in full its obligations under the Debentures, then 50% of every net dollar received by the Company from any such financing transaction shall be paid by the Company to the holders of the Debentures, on a pro rata basis, as a mandatory pre-payment thereof.

Mandatory Payment and Set-Off

In the event the Company has repaid all sums owing under a Debenture to the holder thereof, except for an amount equal to any non-conditional OID, the Company has the right, not the obligation, to exercise the vested portion of the Warrant held by the holder thereof through a set-off of any or all such unpaid OID, on a dollar-for-dollar basis.

Conversion

The Debentures are not convertible into any shares of capital stock of the Company.

Registration

The Debentures are not being registered hereunder, or qualified under the securities laws of any state, and are only described herein as they are part of the Units. The Debentures and the contingent second tranche of each of the Warrants are being offered and sold pursuant to an exemption from the registration requirements of the Securities Act and such laws.

Warrants (and contingent vested tranches)

The following summary of certain terms and provisions of the Warrants included in the Units (the contingent second tranche of each of which is not the subject of this Prospectus Supplement) that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Warrants, the forms of which will be filed as an exhibit to our Current Report on Form 8-K to be filed on not later than August 23, 2024. Prospective investors should carefully review the terms and provisions of the forms of the Warrants for a complete description of the terms and conditions of the Warrants.

Exercise Price and Term

The exercise price of the Warrants is \$1.71 per share of Common Stock. Each Investor is required to exercise the initial tranche of each Warrant within 15 days of the Original Issue Date. Upon the vesting of each contingent tranche of a Warrant vest, each Investor is required to exercise such vested, contingent tranche within 15 days of the vesting thereof. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our shares of Common Stock and also upon any distributions of assets, including cash, stock, or other property to our stockholders.

The Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of Common Stock underlying the Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of common shares purchased upon such exercise.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to us upon exercise of a Warrant in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in the Warrant.

Exercise Limitation

A holder will not have the right to exercise any portion of the Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or 9.99% upon the request of the holder) of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. However, a holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

S-7

Transferability

Subject to applicable laws, the Warrants may be offered for sale, sold, transferred, or assigned without our consent.

Fractional Shares of Common Stock

No fractional shares of Common Stock will be issued upon the exercise of the Warrants. Rather, the number of shares of Common Stock to be issued will be rounded to the nearest whole number.

Trading Market

There is no established public trading market for the Warrants being sold as part of the Units, and we do not expect a market to develop. We do not intend to apply for listing of the Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Warrants will be limited.

Rights as a Stockholder

Except as otherwise provided in the Warrants or by virtue of such holder's ownership of our shares of Common Stock, the holder of a Warrant does not have the rights or privileges of a holder of our shares of our Common Stock, including any voting rights, until the holder exercises the Warrant and, then, only in respect of the shares of Common Stock so exercised.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Warrants and generally including any reclassification, reorganization, or recapitalization of our shares of Common Stock, the sale, lease, license, assignment, transfer, conveyance, or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the outstanding shares of Common Stock or more than 50% or more of the voting power of the common equity of the Company, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding shares of Common Stock, the holders of the Warrants will be entitled to receive upon exercise of the Warrants the kind and amount of securities, cash, or other property that the holders would have received had they exercised the Warrants immediately prior to such fundamental transaction.

Amendment and Waiver

The Warrants may be modified or amended or the provisions thereof waived with the written consent of the respective holder and us.

Registration

The contingent second tranches of each of the Warrants Debentures are not being registered hereunder, or qualified under the securities laws of any state, and are only described herein as they are part of the Units. Those tranches and the Debentures are being offered and sold pursuant to an exemption from the registration requirements of the Securities Act and such laws.

Common Stock

The material terms and provisions of our Common Stock are described under the caption "Description of Capital Stock" beginning on page 33 of the Base Prospectus. As of the date of this Prospectus Supplement, our authorized capital consists of 200,000,000 shares of Common Stock, par value \$0.001 per share, and up to 2,000,000 shares of blank check preferred stock, par value \$0.001 per share, with designations, rights, and preferences as may be determined from time to time by our board of directors. 259,729 shares of our Series A-1 Convertible Preferred Stock" are authorized, of which 68,480 shares are issued and outstanding, leaving 191,249 shares of that series that are authorized, but unissued. 200,000 shares of our Series S Convertible Preferred Stock are authorized, of which 100,000 shares are issued and outstanding, leaving 100,000 shares of that series that are authorized, but unissued. 34,250 shares of our "Series B Preferred Stock" are authorized, of which 34,208 shares are issued and outstanding, leaving 42 shares of that series that are authorized, but unissued. 3,200 shares of our "Series M Preferred Stock are authorized, of which 3,200 shares are issued and outstanding, leaving -0- shares of that series that are authorized, but unissued. 5,000 shares of our "Series V Convertible Preferred Stock" are authorized, of which 5,000 shares are issued and outstanding, leaving -0- shares of that series that are authorized, but unissued. We have 1,497,821 shares of "blank check" preferred stock remaining available for designation and issuance.

Transfer Agent and Registrar

The transfer agent and registrar for the Common Stock is EQ BY EQUINITI, whose address is 1110 Centre Pointe Curve, Suite 101, Mendota Heights, Minnesota 55120, and telephone number is (855) 217-6361

S-8

DILUTION

The only securities that are the subject of this offering are the Warrants that are vested as of the date of the sale of the Units and the first of two contingent vests thereunder. The exercise price of the Warrants is fixed at \$1.71 per share (subject to the above-referenced adjustments in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our shares of Common Stock and also upon any distributions of assets, including cash, stock, or other property to our stockholders). The amount of dilution to the public stockholders will be the difference between the price per share you pay in this offering and the net tangible book value per share of common stock immediately after the sale of the Units.

As of June 29, 2024, we had a net tangible book value of approximately \$(19,790,000), or approximately \$(1.48) per share of Common Stock. Our net tangible book value per share represents total tangible assets, less total liabilities, divided by the number of shares of our common stock outstanding as of June 29, 2024.

S-9

PLAN OF DISTRIBUTION

We have engaged Mint Capital Advisors, Ltd. (the "placement agent") to act as our sole placement agent in connection with this offering of the Units pursuant to this prospectus supplement (limited, as noted above) and accompanying base prospectus. The terms of this offering are subject to market conditions and negotiations between us, the placement agent, and prospective investors. The engagement agreement does not give rise to any commitment by the placement agent to purchase any Units, and the placement agent will have no authority to bind us by virtue of the engagement agreement. The placement agent is not purchasing any of the Units but will assist us therewith. The placement agent may engage sub-agents or selected dealers to assist with the offering. The placement agent has no commitment to buy any of the Units referenced in this prospectus supplement and accompanying prospectus. We have entered into a unit purchase agreement directly with each investor in connection therewith, providing such investor with certain representations, warranties, and covenants from us, and we will only sell to an investor who has entered into a unit purchase agreement. We expect to deliver the Units on or about August 23, 2024, subject to satisfaction of customary closing conditions.

We have agreed to indemnify the placement agent against specified liabilities relating to or arising out of the agent's activities as placement agent.

Fees and Expenses

We have agreed to pay the placement agent in connection with this offering (i) a cash fee equal to approximately \$120,000, and (ii) accountable expenses of \$10,000. We estimate that the total expenses payable by us in connection with this offering, excluding the placement agent fees and expenses referred to above, will be approximately \$25,000.

The following table shows the per share and total cash fees we will pay to the placement agent in connection with the sale of our Units described in this prospectus supplement and the accompanying prospectus.

	<u>Debentures</u>	<u>Total</u>
Offering price	\$ 1,600,000	\$ 1,600,000
Placement agent fees	\$ 120,000	\$ 120,000
Proceeds, before expenses, to us	\$ 1,480,000	\$ 1,480,000

S-10

Other Relationships

The placement agent and its respective affiliates have engaged in, and may in the future engage in, investment banking, advisory and other commercial dealings in the ordinary course of business with us or our affiliates for which they have received and may continue to receive customary fees and commissions. However, except as disclosed in this prospectus supplement, we have no present arrangements with the placement agent for any further services.

Transfer Agent and Registrar

The transfer agent and registrar for the Common Stock is EQ BY EQUINITI, whose address is 1110 Centre Pointe Curve, Suite 101, Mendota Heights, Minnesota 55120 and telephone number is (855) 217-6361.

Listing

Our shares of Common Stock are listed on The Nasdaq Capital Market under the symbol "ALTS." We do not intend to apply for listing of the Debentures or Warrants on any securities exchange or other nationally recognized trading system.

Nasdaq Capital Market Listing

Our Common Stock is listed on The Nasdaq Capital Market under the symbol "ALTS." On August 21, 2024, the last reported sale price of our Common Stock as reported on the Nasdaq Capital Market was \$2.75 per share.

S-11

LEGAL MATTERS

Clark Hill LLP, Los Angeles, California, will provide us with opinions as to certain legal matters in connection with the shares of Common Stock offered hereby. Robert Barandes, P.C., Sagaponack, New York is counsel to the placement agent in connection with this offering.

EXPERTS

The financial statements of the Registrant as of and for the year ended December 30, 2023, incorporated by reference in this prospectus, have been audited by Hudgens, LLC, an independent registered public accounting firm, as stated in its report incorporated by reference herein, and have been incorporated in reliance upon the authority of such firm as experts in accounting and auditing. This report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

The consolidated financial statements of the Registrant as of and for the year ended December 31, 2022, incorporated by reference in this prospectus, have been audited by Frazier & Deeter, LLC, an independent registered public accounting firm, as stated in their report. Such consolidated financial statements are incorporated by reference herein, and have been incorporated in reliance upon the firm given their authority as experts in accounting and auditing. This report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

WHERE YOU CAN FIND MORE INFORMATION

This Prospectus Supplement constitutes a part of the Registration Statement. As permitted by the SEC's rules, this Prospectus Supplement and the Base Prospectus, which form a part of the Registration Statement, do not contain all the information that is included in the Registration Statement and its exhibits. You will find additional information about us in the Registration Statement and its exhibits. Any statements made in this Prospectus Supplement concerning legal documents are not necessarily complete and you should read the documents that are filed as exhibits to the Registration Statement or otherwise filed by us with the SEC for a more complete understanding of such documents or matter.

We file annual, quarterly, and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public at no cost from the SEC's website at www.sec.gov. Our corporate website is <https://alt5sigma.com>. The information on our corporate website is not incorporated by reference in this Prospectus Supplement, the Base Prospectus, or any other prospectus supplement that we file, and you should not consider it a part of this Prospectus Supplement, the Base Prospectus or any other such prospectus supplement.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this Prospectus Supplement and the Base Prospectus, and later information filed with the SEC will update and supersede this information. We incorporate by reference the documents listed below that we have previously filed with the SEC, except that information furnished under Item 2.02 or Item 7.01 of our Current Reports on Form 8-K or any other filing where we indicate that such information is being furnished and not filed under the Exchange Act, is not deemed to be filed and not incorporated by reference herein:

- our Annual Report on [Form 10-K](#) for the year ended December 30, 2023, as filed with the SEC on April 8, 2024;

- our Quarterly Reports on Form 10-Q for the fiscal quarter ended March 30, 2024, as filed with the SEC on [May 3, 2024](#), and for the fiscal quarter ended June 29, 2024, as filed with the SEC on [August 19, 2024](#);
- our Current Reports on Form 8-K (date of reports: [January 12, 2024](#), [February 8, 2024](#), [February 23, 2024](#), [March 13, 2024](#), [April 16, 2024](#), [May 6, 2024](#), [May 15, 2024](#), [May 28, 2024](#), [June 4, 2024](#), [June 21, 2024](#), and [July 15, 2024](#)), as filed with the SEC on [January 12, 2024](#), [February 8, 2024](#) with amended filing on [February 9, 2024](#), [February 28, 2024](#), [March 15, 2024](#), [April 22, 2024](#), [May 6, 2024](#), [May 21, 2024](#) with amended filing on [June 5, 2024](#), [May 31, 2024](#), [June 4, 2024](#), [June 21, 2024](#) and [July 17, 2024](#), respectively; and
- the description of our Common Stock contained in [Exhibit 4.1](#) to our Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC on April 17, 2023.

S-12

We also incorporate by reference in this Prospectus Supplement and the Base Prospectus any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date hereof but before the completion or termination of this offering (excluding any information not deemed “filed” with the SEC).

Any statements contained in a previously filed document incorporated by reference into this this Prospectus Supplement or the Base Prospectus is deemed to be modified or superseded for purposes of this this Prospectus Supplement and the Base Prospectus to the extent that a statement contained in this this Prospectus Supplement or the Base Prospectus, or in a subsequently filed document also incorporated by reference herein, modifies or supersedes that statement.

This Prospectus Supplement and the Base Prospectus may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this this Prospectus Supplement or the Base Prospectus. You should rely only on the information incorporated by reference or provided in this this Prospectus Supplement or the Base Prospectus. We have not authorized anyone else to provide you with different information. You should not assume that the information in this this Prospectus Supplement or the Base Prospectus is accurate as of any date other than the date of this this Prospectus Supplement or the date of the documents incorporated by reference in this this Prospectus Supplement or the Base Prospectus.

We will provide to each person, including any beneficial owner, to whom this this Prospectus Supplement or the Base Prospectus is delivered, upon written or oral request, at no cost to the requester, a copy of any and all of the information that is incorporated by reference in this registration statement. You may request a copy of these filings, at no cost to you, by telephoning us at (702) 997-5968 or by writing us at the following address:

ALT5 Sigma Corporation
325 E. Warm Springs Road, Suite 102
Las Vegas, Nevada 89119
Attention: Corporate Secretary

You may also access the documents incorporated by reference in this this Prospectus Supplement and the Base Prospectus through our website at <https://alt5sigma.com>. The reference to our website is an inactive textual reference only and, except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this this Prospectus Supplement, the Base Prospectus, or the registration statement of which it forms a part.

S-13



\$100,000,000.00

Common Stock
Preferred Stock
Debt Securities
Warrants
Rights
Units

We may offer and sell from time to time shares of our common stock, par value \$0.001 per share (our “Common Stock”), shares of our preferred stock, par value \$0.001 per share (our “Preferred Stock”), debt securities, warrants, rights, and units that include any of these securities. The Preferred Stock or warrants may be convertible into or exercisable for shares of our Common Stock or shares of our Preferred Stock or other of our securities registered hereunder. The debt securities may be convertible into or exchangeable for shares of our Common Stock or shares of our Preferred Stock. Our Common Stock is listed on The Nasdaq Capital Market and trades under the symbol “JAN.”

We may offer and sell these securities to or through one or more underwriters, dealers, and agents, or directly to purchasers, on a continuous or delayed basis.

The aggregate market value of our outstanding Common Stock held by non-affiliates was approximately \$274,320, based on 8,593,636 shares of outstanding Common Stock as of April 8, 2024, of which approximately 108,000 shares were held by affiliates, and based on the closing sale price of our Common Stock of \$2.54 on April 8, 2024. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities pursuant to this prospectus with a value of more than one-third of the aggregate market value of our Common Stock held by non-affiliates in any 12-month period, so long as the aggregate market value of our Common Stock held by non-affiliates is less than \$75,000,000. In the event that, subsequent to the date of this prospectus, the aggregate market value of our outstanding Common Stock held by non-affiliates equals or exceeds \$75,000,000, then the one-third limitation on sales shall not apply to additional sales made pursuant to this prospectus. During the prior 12 calendar months prior to, and including, the date of this prospectus, we have not sold any securities pursuant to General Instruction I.B.6 of Form S-3.

This prospectus describes some of the general terms that may apply to these securities and the general manner in which they may be offered. The specific terms of any securities to be offered, and the specific manner in which they may be offered, will be described in a supplement to this prospectus. You should read this prospectus and any applicable prospectus supplement carefully before you invest.

See the “Risk Factors” section of this prospectus on page 3, our filings with the SEC, and the applicable prospectus supplement for certain risks that you should consider before investing in our securities.

None of the Securities and Exchange Commission, any state securities commission, or any other regulatory body has approved or disapproved of these securities nor passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

TABLE OF CONTENTS

	<u>Page</u>
ABOUT THIS PROSPECTUS	1
AVAILABLE INFORMATION	2
INCORPORATION OF CERTAIN INFORMATION BY REFERENCE	2
FORWARD-LOOKING STATEMENTS	3
RISK FACTORS	3
BUSINESS	4
SELECTED CONSOLIDATED FINANCIAL DATA	31
DESCRIPTION OF SECURITIES WE MAY OFFER	32
DESCRIPTION OF CAPITAL STOCK	33
DESCRIPTION OF PREFERRED STOCK	36
DESCRIPTION OF DEBT SECURITIES	37
DESCRIPTION OF WARRANTS	43
DESCRIPTION OF RIGHTS	45
DESCRIPTION OF UNITS	46
USE OF PROCEEDS	46
PLAN OF DISTRIBUTION	46
LEGAL MATTERS	48
EXPERTS	48

ABOUT THIS PROSPECTUS

This document is called a prospectus and is part of a Registration Statement on Form S-3 that we have filed with the Securities and Exchange Commission (the “SEC”) using a “shelf” registration process. Under this shelf registration process, we may, from time to time, sell any combination of the securities described in this prospectus in one or more offerings in amounts that we will determine from time to time, up to a total dollar amount of \$100,000,000.00.

This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities described in this prospectus we will provide a prospectus supplement, incorporate information or document by reference into this prospectus or a related free writing prospectus or use other offering materials, as applicable, containing more specific information about the terms of the securities that are then being offered. We may also authorize one or more related free writing prospectuses to be provided to you that may contain material information relating to these offerings and securities. This prospectus, together with applicable prospectus supplements, any information or document incorporated by reference, and any related free writing prospectus or other offering materials, as applicable, we file with the SEC, includes all material information relating to these offerings and securities. We may also add, update, or change in the prospectus supplement any of the information contained in this prospectus or in the documents that we incorporate by reference into this prospectus, including, without limitation, a discussion of any risk factors or other special considerations that apply to these offerings or securities or the specific plan of distribution. If there is any inconsistency between the information in this prospectus and a prospectus supplement or information or document incorporated by reference having a later date, you should rely on the information in that prospectus supplement or incorporated information having a later date. We urge you to read carefully this prospectus, any applicable prospectus supplement, and any related free writing prospectus or other offering materials, as applicable, together with the information incorporated herein by reference as described under the heading “Incorporation of Certain Information by Reference,” before buying any of the securities being offered.

You should rely only on the information we have provided in, or incorporated by reference into, this prospectus, any applicable prospectus supplement, and any related free writing prospectus or other offering materials, as applicable. We have not authorized anyone to provide you with different information. No dealer, salesperson, or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement, any related free writing prospectus, or other offering materials, as applicable.

Neither the delivery of this prospectus nor any sale made under it implies that there has not been any change in our business or affairs or that the information in this prospectus is correct as of any date after the date of this prospectus. You should assume that the information in this prospectus, any applicable prospectus supplement, any related free writing prospectus, or other offering materials, as applicable, is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement, any related free writing prospectus, or other offering materials, as applicable, or any sale of a security.

The Registration Statement containing this prospectus, including exhibits to the Registration Statement, provides additional information about us and the securities offered under this prospectus and any prospectus supplement. We have filed and plan to continue to file other documents with the SEC that contain information about us and our business. Also, we will file legal documents that control the terms of the securities offered by this prospectus as exhibits to the reports that we file with the SEC. The Registration Statement and other reports can be read at the SEC Internet site or at the SEC offices mentioned under the heading “Available Information.”

This prospectus contains summaries of certain provisions contained in some of the documents described herein; but, reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed, or will be incorporated by reference as exhibits to the Registration Statement of which this prospectus is a part, and you may obtain copies of those documents as described below under “Available Information.”

AVAILABLE INFORMATION

We have filed with the SEC a Registration Statement on Form S-3 under the Securities Act with respect to the securities covered by this prospectus. This prospectus, which is a part of that Registration Statement, does not contain all of the information set forth in the Registration Statement or the exhibits and schedules filed therewith. For further information with respect to us and the securities covered by this prospectus, please see the Registration Statement and the exhibits filed with the Registration Statement. A copy of the Registration Statement and the exhibits filed with the Registration Statement may be inspected without charge at the Public Reference Room maintained by the SEC, located at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the Public Reference Room. The SEC also maintains an Internet website that contains reports, proxy and information statements, and other information regarding registrants that file electronically with the

SEC. The address of the website is <http://www.sec.gov>.

We are subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and, in accordance therewith, we file periodic reports, proxy statements, and other information with the SEC. Such periodic reports, proxy statements, and other information are available for inspection and copying at the Public Reference Room and website of the SEC referred to above. We maintain a website at <http://www.janone.com>. You may access our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed pursuant to Sections 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. Our website and the information contained on that site, or connected to that site, are not incorporated into and are not a part of this prospectus.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC’s rules allow us to incorporate by reference information into this prospectus. This means that we can disclose important information to you by referring you to another document. Any information referred to in this way is considered part of this prospectus from the date we file that document. Any reports filed by us with the SEC after the date of this prospectus and before the date that the offering of the securities by means of this prospectus is terminated will automatically update and, where applicable, supersede any information contained in this prospectus or incorporated by reference in this prospectus.

We incorporate by reference into this prospectus the following documents or information filed with the SEC (other than, in each case, documents or information deemed to have been furnished and not filed in accordance with SEC rules):

- Our Annual Report on [Form 10-K](#) for the year ended December 30, 2023, filed with the SEC on April 8, 2024;
- The description of our Common Stock is filed as [Exhibit 4.1](#) to our Annual Report on Form 10-K for the year ended December 28, 2019, filed with the SEC on April 6, 2020.

Additionally, all documents filed by us with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act, after (i) the date of the initial Registration Statement and prior to effectiveness of the Registration Statement and (ii) the date of this prospectus and before the termination or completion of this offering, shall be deemed to be incorporated by reference into this prospectus from the respective dates of filing of such documents, except that we do not incorporate any document or portion of a document that is “furnished” to the SEC, but not deemed “filed.” Any information that we subsequently file with the SEC that is incorporated by reference as described above will automatically update and supersede any previous information that is part of this prospectus.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon his or her written or oral request, a copy of any or all documents referred to above that have been or may be incorporated by reference into this prospectus, excluding exhibits to those documents unless they are specifically incorporated by reference into those documents. Written or telephone requests should be directed to JanOne Inc., 325 E. Warm Springs Road, Suite 102, Las Vegas, Nevada 89119, Attention: Corporate Secretary; telephone: (702) 997-5968.

2

FORWARD-LOOKING STATEMENTS

This prospectus, including the documents we incorporate by reference into it, contains forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act, the Private Securities Litigation Reform Act of 1995 (the “PSLRA”) or in releases made by the SEC. Such statements include, without limitation, statements regarding our expectations, hopes, or intentions regarding the future. Statements that are not historical fact are forward-looking statements. These forward looking statements can often be identified by their use of words such as “expect,” “believe,” “anticipate,” “outlook,” “could,” “target,” “project,” “intend,” “plan,” “seek,” “estimate,” “should,” “will,” “may,” and “assume,” as well as variations of such words and similar expressions referring to the future. These cautionary statements are being made pursuant to the Securities Act, the Exchange Act, and the PSLRA with the intention of obtaining the benefits of the “safe harbor” provisions of such laws.

The forward-looking statements contained in or incorporated by reference into this prospectus are largely based on our expectations, which reflect estimates and assumptions made by our management. These estimates and assumptions reflect our best judgment based on currently known market conditions and other factors. Although we believe such estimates and assumptions to be reasonable, they are inherently uncertain and involve certain risks and uncertainties, many of which are beyond our control. If any of those risks and uncertainties materialize, actual results could differ materially from those discussed in any such forward-looking statement. Among the factors that could cause actual results to differ materially from those discussed in forward-looking statements are those discussed under the heading “Risk Factors” below, those discussed under the heading “Risk Factors” and in other sections of our Annual Report on Form 10-K for the year ended December 30, 2023, as well as in our other reports filed from time to time with the SEC that are incorporated by reference into this prospectus. See “Available Information” and “Incorporation of Certain Information by Reference” for information about how to obtain copies of those documents.

All readers are cautioned that the forward-looking statements contained in this prospectus and in the documents incorporated by reference into this prospectus are not guarantees of future performance, and we cannot assure any reader that such statements will be realized or that the forward-looking events and circumstances will occur. Actual results may differ materially from those anticipated or implied in the forward-looking statements. All forward-looking statements in this prospectus and the documents incorporated by reference into it are made only as of the date of the document in which they are contained, based on information available to us as of the date of that document, and we caution you not to place undue reliance on forward-looking statements in light of the risks and uncertainties associated with them. Except as required by law, we undertake no obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise.

RISK FACTORS

Investing in our securities involves significant risks. You should review carefully the risks and uncertainties described under the heading “Risk Factors” contained in, or incorporated into, the applicable prospectus supplement, any related free writing prospectus, or other offering materials, as applicable, and under similar headings in the other documents that are incorporated by reference herein or therein. Each of the referenced risks and uncertainties could adversely affect our business, operating results, and financial condition, as well as adversely affect the value of an investment in our securities. When we offer and sell any securities pursuant to a prospectus supplement, we may include additional risk factors relevant to such securities in the prospectus supplement.

3

BUSINESS

General

JanOne Inc. (formerly known as Appliance Recycling Centers of America, Inc.) and subsidiaries (collectively, “we,” the “Company,” or “JanOne”) is focused on being a clinical-stage pharmaceutical company committed to finding treatments for conditions that cause severe pain and bringing drugs to market with non-addictive pain-relieving properties.

One of the Company’s goals is to reduce the need for prescriptions for dangerous opioid drugs by treating underlying diseases that cause severe pain. The Company’s first drug candidate is a treatment for Peripheral Artery Disease (“PAD”), a condition that can cause severe pain and affects over 8.5 million people in the United States. The Company

intends to champion new initiatives—digital technologies, educational advocacy, and revolutionary painkilling drugs that address what we believe is a multibillion dollar a year market—to help combat the opioid crisis, which claims tens of thousands of lives each year.

On December 28, 2022, we entered into a Purchase Agreement (the “Soin Purchase Agreement”) with Soin Therapeutics, LLC. Under the Soin Purchase Agreement, the Company acquired Soin Therapeutics and its LDN product, now known as JAN123. JAN123 is a novel formulation of 2.0 mg of LDN that results in a biphasic release of the product. The release properties of JAN123 provide for an immediate release of less than half the product with a slow, sustained release of the remaining product. Importantly, the rapid release of LDN has been reported to lead to vivid and lucid unpleasant dreams, which should be eliminated with the formulation of JAN123. Initially, a single tablet of JAN123 will be administered orally, once a day before sleep, with eventual titration up to two tablets (4 mg) before sleep.

The name of the Company, JanOne Inc., was strategically chosen to express the start of a new day in the fight against the opioid epidemic. January one is the first day of a New Year—universally considered as a day of optimism, resolution, and hope. JanOne stands by its strategic commitment to fresh thinking and innovative means to assist in ending the worst drug crisis in our nation’s history.

Through March 8, 2023, the Company operated its legacy businesses through its Recycling Subsidiaries, consisting of: (a) ARCA Recycling, Inc., a California corporation (“ARCA Recycling”), (b) ARCA Canada Inc., a corporation organized under the laws of Ontario, Canada (“ARCA Canada”), and (c) Customer Connexx, LLC, a Nevada limited liability company (“Connexx”). ARCA Recycling and ARCA Canada recycle major household appliances in North America by providing turnkey appliance recycling and replacement services for utilities and other sponsors of energy efficiency programs. Connexx is a company that provides call center services for recycling businesses. On March 9, 2023, we entered into a Stock Purchase Agreement (the “Recycling Purchase Agreement”) with VM7 Corporation, a Delaware corporation (“VM7”), under which it agreed to acquire all of the outstanding equity interests of the Recycling Subsidiaries. The principal of VM7 is Virland A. Johnson, our Chief Financial Officer.

The information contained in or accessible from our website is not incorporated into this Annual Report on Form 10-K (the “Form 10-K”), and it should not be considered part of this Form 10-K. We have included our website address in this Form 10-K solely as an inactive textual reference.

The Company was incorporated in Minnesota in 1983, although, through its predecessors, began operating its legacy recycling business in 1976. In 2018, the Company reincorporated in the State of Nevada. The Company’s principal office is located at 325 E. Warm Springs Road, Suite 102, Las Vegas, Nevada 89119.

Biotechnology

Overview

We are a clinical-stage biopharmaceutical company focused on becoming the leader in identifying, acquiring, licensing, developing, partnering, and commercializing novel, non-opioid, and non-addictive therapies to address the large, unmet medical need for the treatment of pain and addiction. JAN101 (formerly known as TV1001SR) is a potential treatment for PAD, a vascular disease that affects more than 8.5 million people in the U.S. and more than 60 million people worldwide. We expect to commence Phase IIb/III clinical trials for the treatment of PAD in 2025.

JAN101

Generally

JAN101, formerly known as TV1001SR, is a patented oral, sustained-release pharmaceutical composition of sodium nitrite that targets poor blood flow to the extremities, such as those with vascular complications of diabetes or PAD and treats pain. A conclusion from a round of human studies found JAN101 prevents the prevalent reports of headaches by patients treated with an immediate release formulation of sodium nitrite. In a previous study of patients with PAD, a 40 mg BID treatment with immediate release sodium nitrite led to a statistically significant reduction in reported pain, while an 80 mg BID treatment had a more pronounced effect on bioactivity and Flow Mediated Dilation, a measure of vascular function. However, a number of subjects in both treatment groups reported headaches and dizziness following treatment. Although this did not result in subjects discontinuing treatment, JAN101 was developed to overcome this side effect. JAN101 was tested in a bridging study of diabetic neuropathy subjects and, during that bridging study, the subjects did not report headaches or dizziness. Subjects in this bridging study also reported less pain following treatment and improvements in bioactivity (quantitative sensory testing, a measure of nerve function) were similar to the PAD study, where the 80 mg dosing group had the greatest improvement in Flow Mediated Dilation. The ability to alleviate pain with BID treatment of JAN101 offers promise for a new non-addictive, non-sedating treatment of chronic pain.

Clinical Studies in Humans JAN101 Attributes

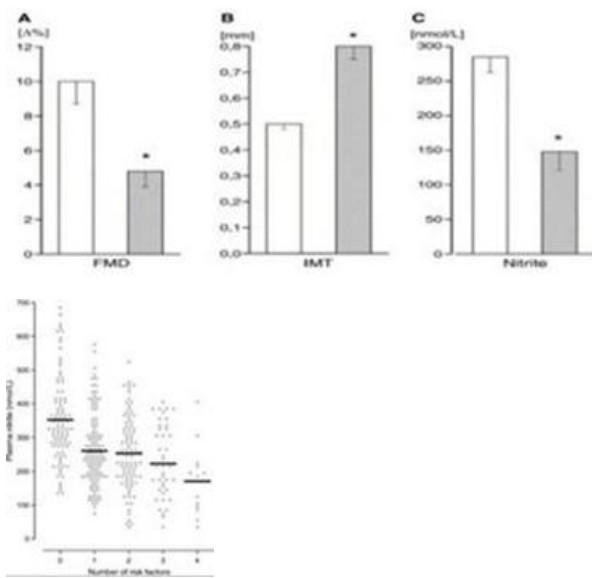
- Well-established safety profile
- Excellent bioavailability
- Lack of induced tolerance
- Non-narcotic

JAN101 does not mask pain, but instead treats the cause of pain by improving tissue and vascular function.

Benefits of Sodium Nitrite on Vascular Health

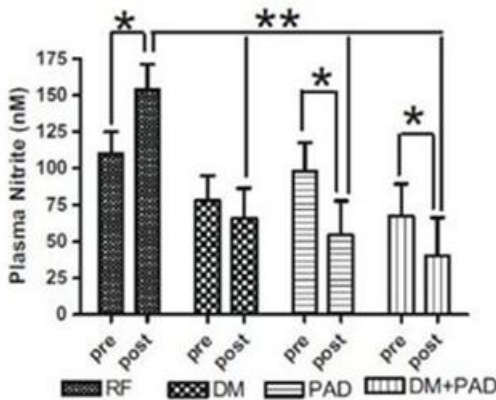
In initial research studies, sodium nitrite effectively restored ischemic tissue blood flow and was effective in a wide range of pathologies involving alterations of angiogenesis – development of new blood vessels – including diabetes, wound healing, and tissue necrosis. Beneficial effects include enhancing angiogenesis, endothelial cell proliferation, and arteriogenesis. There is also a strong association between reduced circulating nitrite levels and cardiovascular diseases in humans. We describe some of the associations and beneficial effects of sodium nitrite/nitrite below.

Plasma nitrite levels are negatively correlated to cardiovascular disease



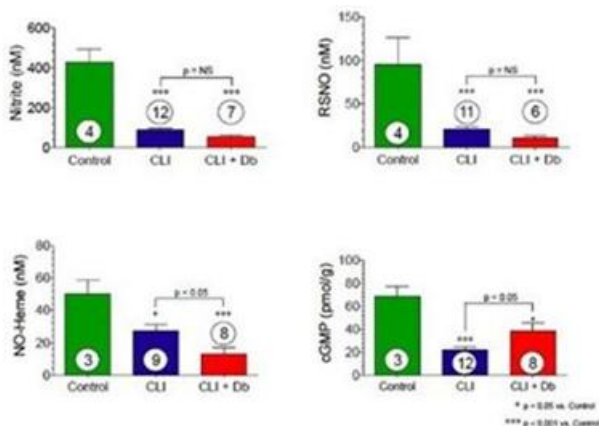
Plasma nitrite levels were inversely related to number of cardiovascular risk factors a subject had and decreased plasma nitrite was associated with decreased flow mediated vasodilation (FMD) and increased intimal medial thickness (IMT) (both are indicators of vascular pathology). Kleinbongard, et al. (2006) Free Radic Biol and Medicine 40:295-302.

Plasma nitrite levels are reduced in diabetic and PAD patients



Exercise is a well-known stimulator of endothelial nitric oxide synthase activity, an enzyme that enhances nitric oxide (NO) production, which leads to increased plasma nitrite. In the study by Allen, et al., these authors revealed that baseline plasma levels of nitrite were less in patients with diabetes mellitus (DM) or DM + PAD. Importantly, increases in plasma nitrite levels were not observed in either DM, PAD, or DM + PAD patients after supervised exercise. These data reveal that baseline nitrite availability is compromised in DM patients and that supervised exercise is unable to increase plasma nitrite levels but actually results in a decrease in nitrite, highlighting a physiological efficiency of this molecule. Allen, et al., Nitric Oxide 2009 20:231-2377.

Skeletal Muscle Nitrite and Metabolite Levels are Reduced in Critical Limb Ischemia (CLI) Patients



Skeletal muscle nitrite, nitrosothiol (RSNO), nitric oxide-heme, and cGMP are all significantly reduced in CLI (the most severe form of PAD) patients. Diabetic patients with CLI show even further nitrite reductions.

In summary, nitrite levels in various cardiovascular and vascular diseases appear to be inversely related to the severity of the disease in humans:

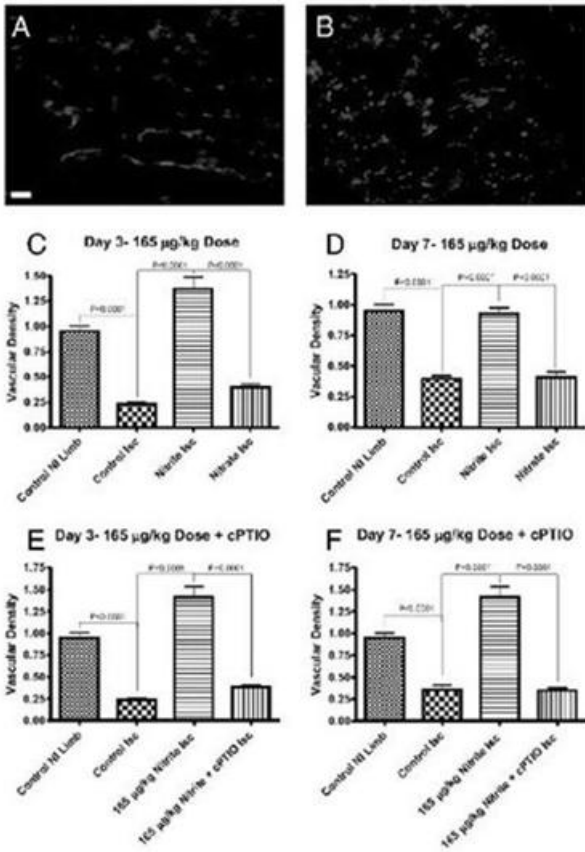
- Lower nitrite levels are associated with higher level of heart failure;
- Lower nitrite levels are observed in diabetic patients with PAD and are not compensated by exercise; and
- Nitrite levels are lower in the muscles of patients with critical limb ischemia and are further reduced in diabetic subjects with critical limb ischemia.

Given the association between low levels of circulating nitrite and human diseases, supplementation with sodium nitrite has been studied preclinically in animals. Below are summaries of some of the more important findings:

- Promotes angiogenesis
- Stimulates wound healing
- Prevents tissue necrosis

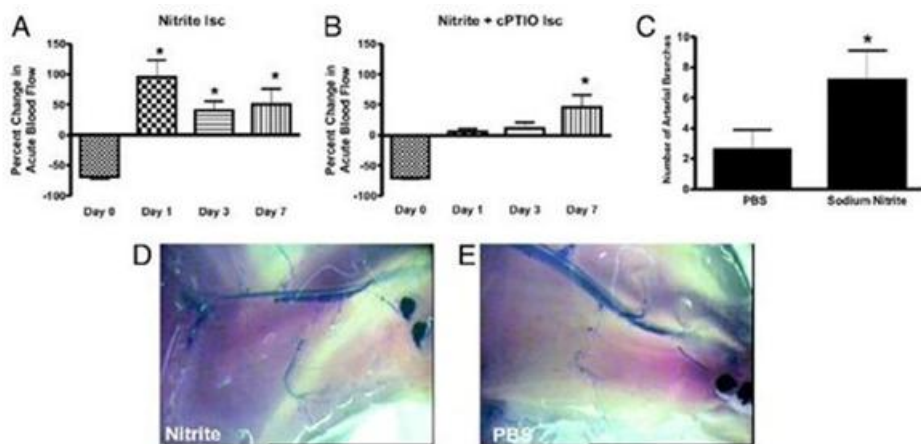
From Arya, et al.

Nitrite Therapy Selectively Increases Ischemic Tissue Vascular Density in a NO-dependent Manner



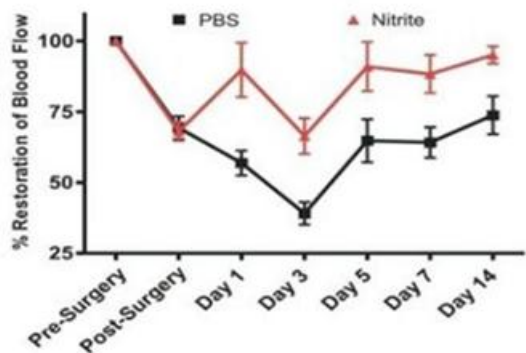
Chronic sodium nitrite therapy increases ischemic tissue vascular density in a NO-dependent manner. A and B show representative images of CD31 (red) and DAPI nuclear (blue) staining from sodium nitrite and sodium nitrate ischemic gastrocnemius muscle tissue at day 7. C and D report the vascular density of ischemic gastrocnemius muscle tissue at days 3 and 7 for 165 µg/kg sodium nitrite and nitrate treatments, respectively. E and F demonstrate the vascular density of ischemic gastrocnemius muscle tissue at days 3 and 7 from 165 µg/kg sodium nitrite plus carboxy PTIO. (Scale bar, 150 µm). n = 10 mice per treatment group. Kumar D., et al., PNAS; 2008; 105:7540-7545.

Nitrite Therapy Augments Arterial Perfusion of Ischemic Tissue



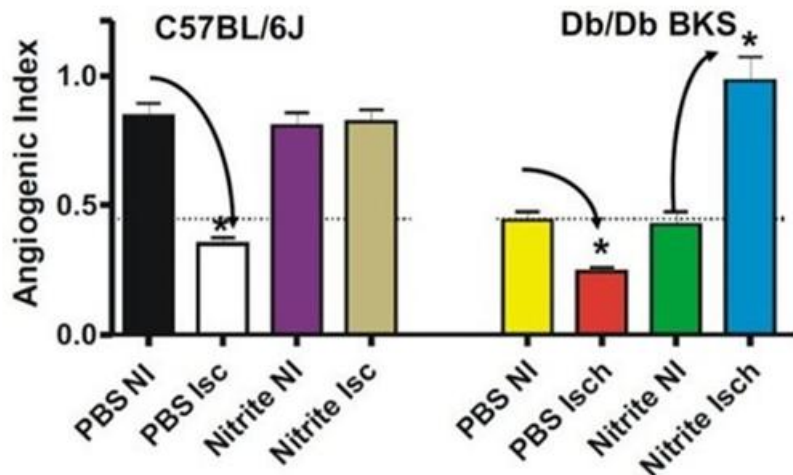
Chronic sodium nitrite therapy acutely increases ischemic tissue blood flow and stimulates arteriogenesis. A and B report 165 $\mu\text{g}/\text{kg}$ sodium nitrite-induced acute changes in blood flow of chronically ischemic tissues at various time points with or without cPTIO, respectively. C reports the number of arterial branches between PBS and nitrite therapies. D and E illustrate vascular casting of the arterial vasculature in ischemic hind limbs of day 7 nitrite or PBS-treated mice, respectively. *, $P < 0.01$ vs. sodium nitrite. $N = 10$ mice per treatment group. Kumar D., et al., PNAS;2008; 105:7540-7545.

Nitrite Therapy Restores Diabetic Ischemic Hind-Limb Blood Flow and Promotes Wound Heal



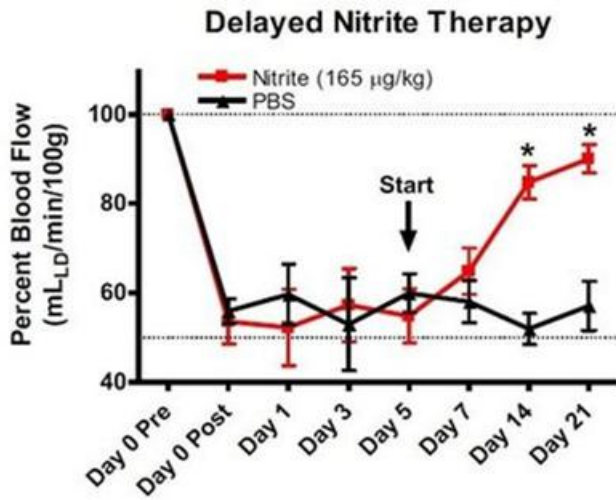
Unilateral femoral artery ligation was performed on 18-20 week old male Db/Db mice. Mice were randomized to PBS or sodium nitrite (165 $\mu\text{g}/\text{kg}$) therapy twice daily via I.P. injection. Laser doppler flowmetry was performed at the indicated time points. Increased wound dehiscence was noted in the PBS treated animals at day 7 but not in nitrite treated animals. (Bir, et al., Diabetes 2014, 63(1):270-81).

Nitrite Therapy Increases Diabetic Ischemia Induced Angiogenesis



Nitrite therapy prevented ischemia mediated endothelial cell density loss in normal C57BL/6J ischemic limbs. Nitrite therapy significantly restored endothelial cell density in ischemic limbs of diabetic mice to normal C57BL/6J levels compared to PBS therapy of non-ischemic and ischemic conditions. These data suggest that nitrite therapy may be useful in attenuating microvascular rarefaction due to loss of nitric oxide that is observed during metabolic dysfunction (Frisbee JC AJP Integr Comp Physiol 2005 289(2):R307-16; Stepp et al. Microcirculation 2007 14(4-5): 311-6).

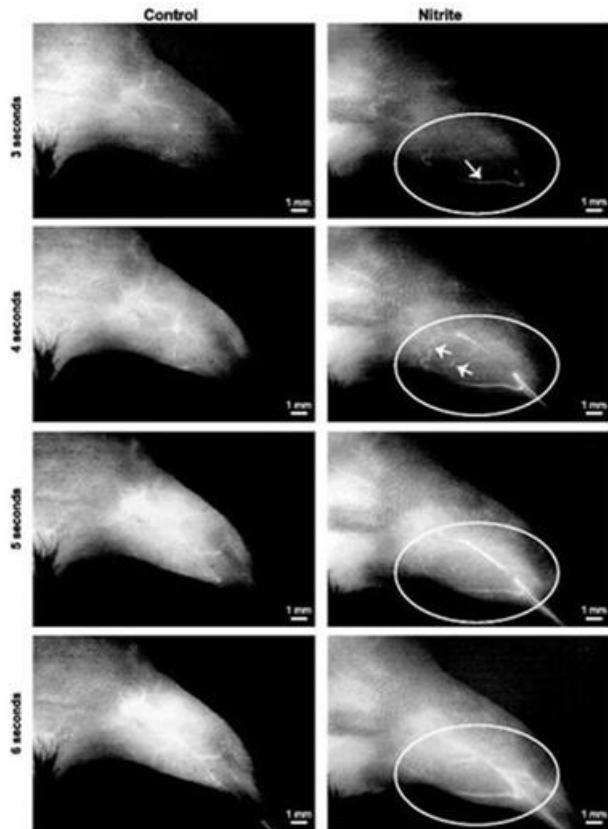
Delayed Nitrite Therapy Restores Ischemic Hind-Limb Blood Flow



Studies were performed to determine whether nitrite mediated therapy would be effective in tissue that had been left ischemic for 5 days after femoral artery ligation. Femoral artery ligation was performed in C57BL/6J mice and the animals randomized to either PBS or sodium nitrite therapy 5 days after artery ligation. Treatments were given b.i.d. via I.P. injection. Ischemic limb blood flow was measured using laser doppler flowmetry. (Bir, et al., Diabetes 2014, 63(1):270-81).

9

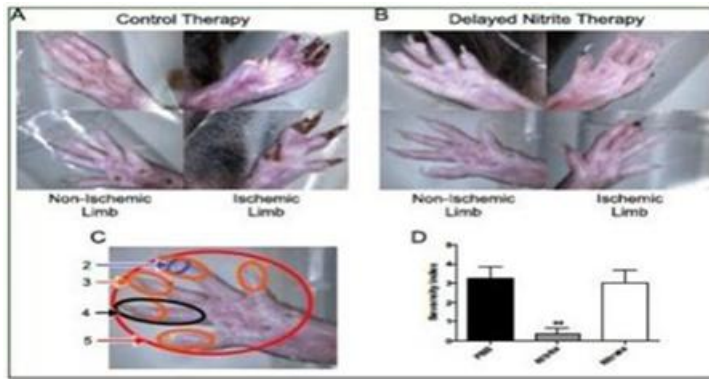
Delayed nitrite therapy increases SPY angiogram arteriogenesis



Delayed nitrite therapy increases SPY angiogram arteriogenesis. Representative temporal SPY angiogram image stills (3–6s) are shown at 11 days following ligation and 6 days after beginning therapy (either PBS or sodium nitrite). *Left*: PBS control angiogram. *Right*: sodium nitrite angiogram following injection of ICG. $n = 5$ animals per cohort. Circles identify limb anatomical regions of vascular blush, whereas arrows indicate perfused vessels that progressively occur over time.

Bir, et al., Am J Physiol Heart Circ Physiol 2012;303:H178-H188.

Nitrite Therapy Prevents Tissue Necrosis in Aged Db/Db Mice



Delayed sodium nitrite (165 ug/kg) or control PBS therapy was started 5 days post-femoral artery ligation in nine-month old Db/Db mice. Nitrite therapy significantly prevented tissue necrosis (panel B) compared to control PBS therapy (panel A). Panel D reports tissue necrosis severity as a function of degree of limb and digit involvement. Nitrite therapy, but not PBS control or sodium nitrate, significantly prevented tissue necrosis. (Bir, et al., *Diabetes* 2014, 63(1):270-81).

Nitrite and Hind Limb Ischemia Summary

Sodium nitrite has long been known to be a potent vasodilator (transiently increasing blood vessel diameter) that can lead to a drop in blood pressure when given acutely. The above studies indicate that chronic administration at low doses promotes angiogenesis, unlike one-time nitrite therapy, which does not stimulate angiogenesis. In addition, these studies and a large number of other studies not reviewed above show:

- Nitrite therapy is very specific, acting only in damaged, ischemic tissue;
- Delayed nitrite therapy effectively restores ischemic tissue blood flow;
- Nitrite therapy is effective in a wide range of pathologies involving alterations of angiogenesis including critical limb ischemia, heart failure, and tissue necrosis;
- Nitrite supplementation has had positive effects in various diabetes models, including diabetic nephropathy and diabetic wound healing;
- Beneficial effects center on enhancing angiogenesis, endothelial cell proliferation, and arteriogenesis; and
- Sustained release nitrite therapy, unlike immediate release therapy, does not lead to vasodilation or a drop in blood pressure.

JAN101

JAN 101 is designed to treat diseases associated with poor vascular function. The following table summarizes our current product candidate:

Therapeutic Area	Drug	Pre-IND	Phase 1	Phase 2a	Phase 2b	Phase 3
Peripheral Artery Disease						
Pain	JAN101					

Pain

Pain is a protective reaction that alerts the body to the presence of actual or potential tissue damage so that necessary corrective responses can be mounted. The National Institutes of Health (the "NIH") defines chronic pain as pain that persists beyond the normal healing time of an injury or that persists longer than three months. It is estimated that chronic pain affects 100 million individuals in the United States and over 1.5 billion people worldwide; thus, more people suffer from chronic pain than diabetes, heart disease, and cancer combined (Cowen Therapeutic Categories Outlook, March 2019). Chronic pain exacts a tremendous cost in terms of direct treatment and rehabilitation expenditures, lost worker productivity, prevalent addiction to opioid-based drugs, and emotional and financial burden for patients and their families. According to an Institute of Medicine of the National Academies report, pain is a significant public health problem in the United States that costs society between \$560 billion and \$635 billion annually. Despite the magnitude of the pain problem, innovation in the development of therapeutic solutions has been largely absent. Since 2010, there have been 20 approvals by the FDA for the treatment of pain, of which 12 were opioid variants, one was an extended-release generic corticosteroid, five were variants of aspirin, and two were variants of other existing drugs. We are developing a novel product candidate designed to overcome the limitations of current treatment options for patients with PAD who suffer from chronic pain. According to a research study by Stanford University, more than 24% of patients with PAD are at risk of high opioid use. By treating pain at the source and presenting patients and physicians with better and safer treatment alternatives, we expect to minimize opioids at the prescription pad. Given the properties of JAN101, we have made the strategic decision to focus initially on pain associated with PAD by treating the underlying cause of PAD.

Peripheral artery disease

Peripheral artery disease ("PAD") is a general term for conditions in which arterial blood flow to the limbs is partially blocked. When there is less blood present in the extremities relative to demand, muscle pain and fatigue result, especially in the calf, which is also known as "intermittent claudication." In many patients, pain and fatigue are relieved through rest. Roughly half of patients with PAD are asymptomatic. The most common cause of PAD / intermittent claudication is atherosclerosis. Diabetes, chronic kidney disease, hypertension, and smoking are all risk factors that can increase the likelihood of PAD. In atherosclerosis, fat deposits (plaques) build up along arterial walls, resulting in a reduction in blood flow in the legs. This same process can cause strokes if the arteries leading up to the brain are affected.

Because of the high rate of asymptomatic patients, prevalence figures vary widely. Some estimate that up to 200 million people worldwide have PAD, ranging from asymptomatic disease to severe. Prevalence increases as a function of patient age, rising sharply after the age of 60. Thus, in countries with an aging population, it is expected that the prevalence of PAD will only increase. There is also a strong ethnic and racial component to PAD prevalence, which may be due to cultural differences in diet and exercise, along with genetic differences. Some suggest a prevalence of eight to 12 million in the United States alone, with roughly one-third experiencing pain when walking, which improves upon resting. The diagnosis of PAD usually begins with patient complaints of pain in the extremities. If the patient is already being treated or monitored for

diabetes or other risk factors, then the physician will check for a weak or absent pulse in the extremity. Decreased blood pressure, poor wound healing, and whooshing sounds (via stethoscope) in the legs are also tell-tale signs of PAD / intermittent claudication. Angiograms, electrocardiograms, and ultrasounds can also be used to image and confirm the diagnosis.

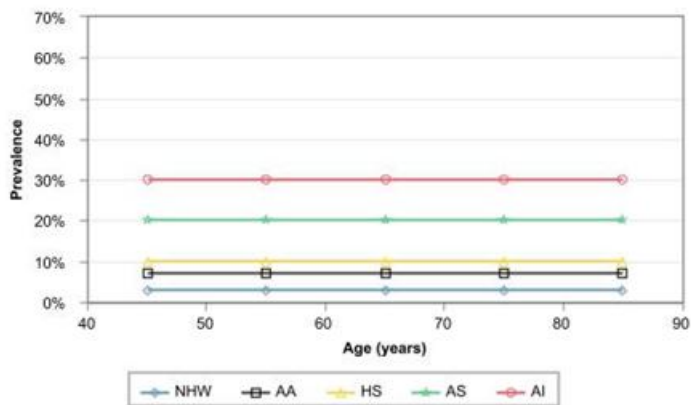


Figure 1: Ethnic-specific prevalence of PAD in men in the US, by age. NHW = Non-Hispanic Whites, AA = African American, HS = Hispanics, AS = Asian Americans, AI = American Indians. Source: (Criqui, 2015)

The non-drug treatment of PAD / intermittent claudication may be divided into four general categories:

- *Lifestyle* – Primarily changes in diet and smoking cessation.
- *Exercise* – Patients who walk, cycle, stretch, or swim can experience marked improvement. Formal programs involving treadmills and track walking (usually three to five times per week) are frequently provided to patients. However, if the pain is triggered by exercise (claudication) and is significant, it can discourage the patient from exercise.
- *Angioplasty* – A procedure by which the affected artery is stretched with a balloon-like device. This procedure has limited effectiveness and is reserved for severely blocked arteries.
- *Bypass Surgery* – Arteries that are beyond angioplasty can be bypassed entirely. This procedure is typically reserved for cases where the blockage is considered very long (~10 centimeters) and nearly complete.

The underlying condition is not addressed by surgery. Surgical approaches will not, in the long run, improve exercise capacity and walking distance. Only exercise itself, coupled with lifestyle changes and drug approaches, has this benefit.

Prescription drugs for the treatment of the underlying PAD may be divided into multiple categories, depending on the underlying condition and severity:

- *Cholesterol-Lowering Agents* – Statins and bile acid sequestrants.

- *Antiplatelet Medications* – Aspirin and related drugs, such as clopidogrel. Cilostazol also has antiplatelet properties.
- *Antihypertensives* – Patients with underlying high blood pressure can and will receive any number of medications to reduce blood pressure, such as ACE inhibitors and diuretics.
- *Diabetes Therapies* – While a substantial portion of PAD patients may have pre-diabetes or fulminant diabetes, it is unknown if aggressive treatment of diabetes has a positive effect on PAD.
- *Pain* – To our knowledge, no drugs are specifically indicated for PAD-associated pain. Pentoxifylline, for example, is indicated “...for the treatment of patients with intermittent claudication on the basis of chronic occlusive arterial disease of the limbs.” (Sanofi-Aventis U.S. LLC, 2010). However, the evidence supporting the effectiveness of pentoxifylline is mixed. Short-term courses of NSAIDs, such as ibuprofen, may be used, provided the patient is not on another anticoagulant, like aspirin. Non-drug pain relievers, such as TENS and massage therapy, may also be used in these patients. Opioids may also be used, which creates a risk for addiction and potential misuse at the medicine cabinet by family members.

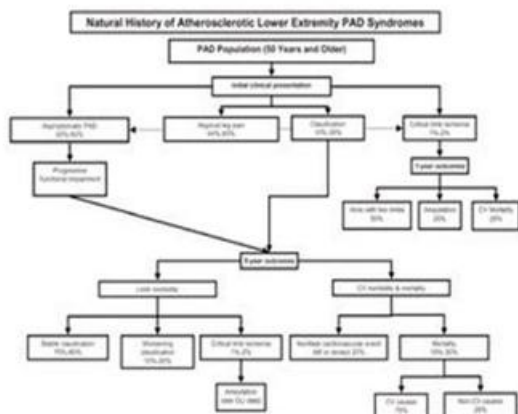


Figure 2: Natural history of PAD. Source: (Hirsch, 2006).

The lack of any truly effective treatment of PAD, along with encouraging early trial results using JAN101 on both improving vascular function and reducing pain in PAD patients, has created an opportunity potentially to treat this large unmet medical need. By improving vascular function, JAN101 has the potential to reduce associated pain and improve PAD patients' quality of life.

Our Strategy

Our focus is to develop and commercialize novel, non-opioid, and non-addictive therapies to address, safely and effectively, the significant unmet medical need of chronic pain or treat conditions that cause pain. The principal elements of our strategy to achieve this mission are the following:

- **License, acquire, develop, and create novel, non-opioid and non-addictive therapies by leveraging our understanding of pain biology to address the large and growing problem of pain.** While innovation in medical sciences has led to exciting new treatment options in many disease areas, pain has seen limited innovation in recent years. We have a deep understanding of the pathophysiology of pain and diseases that cause pain. We intend to leverage this understanding to bring innovation in the pain treatment paradigm through targeted acquisitions of companies or assets in development. Our advisors and doctors have years of collective experience in leadership positions at institutions and substantial scientific experience and understand the complexity of designing and executing clinical trials for and developing therapies.
- **Advance the development of JAN101, designed for the treatment of patients with PAD and pain associated with the disease.** There are limited therapeutic options available for patients with PAD and we believe that JAN101 has the potential to transform the standard of care to a twice-a-day pill to improve moderate-to-severe PAD substantially.
- **Leverage clinical activity of JAN101 possibly to expand into new indications.** The Company is in discussion with multiple researchers about expanding JAN101's use into other indications. JanOne will provide the researchers previously manufactured clinical supplies of JAN101 for use in their clinical trials.
- **Advance JAN101 through clinical development and pursue development of additional product candidates through acquisitions.** Our objective is to build a well-balanced, multi-asset portfolio targeting the large population of patients with chronic and acute pain. To achieve this, in addition to JAN101, we intend to pursue partnerships, licensing agreements, and potential acquisitions of other pharma companies. We continue our search for assets with indications where we believe they could have meaningful impact and address the large unmet medical need. In addition, we may choose to selectively in-license or acquire complementary product candidates by leveraging the insights, network, and experience of our team.

13

- **Maximize the commercial potential of all our product candidates.** We currently intend to retain all commercial rights to JAN101 in the United States and selectively partner outside of the United States. Because we believe that PAD is an attractive market for many major pharmaceutical companies, we may sub-license or partner certain indications if we believe it may enhance stockholder value. As we continue to build and develop our product portfolio, we may opportunistically pursue strategic partnerships that maximize the value of our pipeline while seeking to develop other indications.
- **Leverage our management team background and expertise.** We have assembled a team with extensive experience described above.

Chronic Pain

The NIH defines chronic pain as pain that persists either beyond the normal healing time of an injury or longer than three months. We believe that chronic pain represents a significant public health crisis. It is estimated that chronic pain affects 100 million individuals in the United States and over 1.5 billion people worldwide; thus, more people suffer from chronic pain than diabetes, heart disease, and cancer combined (Cowen Therapeutic Categories Outlook, March 2019). Chronic pain exacts a tremendous cost in terms of direct treatment and rehabilitation expenditures, lost worker productivity, prevalent addiction to opioid-based drugs, and emotional and financial burden for patients and their families. According to an Institute of Medicine of the National Academies report, pain is a significant public health problem in the United States that costs society between \$560 billion and \$635 billion annually. Chronic pain is the leading cause of long-term disability in the United States, and approximately 23 million adults in the United States experience severe pain over a three-month period. Globally, the prevalence of chronic pain is even larger, with over one billion people worldwide affected each year. Common types of chronic pain include those of neuropathic and inflammatory origin and may involve the skin, muscles, joints, bones, tendons, ligaments, and other soft tissues. Chronic pain is associated with a variety of clinical conditions including, but not limited to, arthritis, spinal conditions, cancer, fibromyalgia, diabetes, surgical recovery, visceral injury, and general trauma.

Pain is a necessary protective reaction that alerts the body to the presence of actual or potential tissue damage so that necessary corrective responses can be mounted. Pain is signaled by specialized cells in the peripheral nervous system called nociceptors, or pain-sensing fibers. These pain-sensing fibers normally transmit information about stimuli that approach or exceed harmful intensity from different locations in the body to the brain, which registers this information as a sensation of pain. In the case of tissue injury due to trauma or infection, pain accompanies the associated inflammation, persists for the duration of the inflammatory response, and aids healing by inhibiting use of the affected body part.

Pain also can modify the central nervous system, such that the brain becomes sensitized and registers more pain with less provocation. This is called central sensitization. When central sensitization occurs, the nervous system goes through a process called wind-up and gets regulated in a persistent state of high reactivity. This persistent, or up-regulated, state of reactivity lowers the threshold for what triggers the sensation of pain and can result in the sensation of pain even after the initial injury might have healed.

When there is dysfunction in pain signaling, injury to the nervous system, or an unhealed injury, pain becomes no longer just a symptom, but a disease in itself.

Current Therapeutic Approaches to Treating Chronic Pain and Their Limitations

NSAIDs

Some of the most widely used therapies to treat chronic inflammatory pain are non-steroidal anti-inflammatory drugs ("NSAIDs"). NSAIDs can have significant side effects that include gastrointestinal bleeding, gastritis, high blood pressure, fluid retention, kidney problems, heart problems, and rashes. On April 7, 2005, the FDA announced a decision to require boxed warnings of potential cardiovascular risk for all NSAIDs.

Corticosteroids

Corticosteroids, or steroids, also possess anti-inflammatory properties and are commonly used in the practice of pain management, either systemically or locally, depending on the condition. Steroids work by decreasing inflammation and reducing the activity of the immune system. While steroids are commonly used, they may have numerous and serious side effects. These side effects may include allergic or hypersensitivity reactions, increased risk for infection, adrenal insufficiency, diabetes or decreased glucose tolerance, hypertension, loss of bone density, and loss of joint cartilage volume. In addition, steroids should not be administered when there is an infection present because steroids can inhibit the body's natural infection-fighting immune response. Also, if a joint is already damaged or is subject to chronic deterioration, intra-articular, or IA steroid injections are not likely to provide any long-term restorative benefit. For the above reasons, IA steroid injections are generally recommended to be administered no more often than every six weeks and not more than three to four times per year.

Opioids

Opioids are some of the most widely prescribed therapeutics for chronic and acute pain, and sales of these drugs have quadrupled between 1999 and 2010. According to a National Survey on Drug Use and Health report, in 2016 more than one-third of adult Americans were prescribed opioids and 230 million opioid prescriptions were written that year in the United States. Opioids act by binding to specific receptors located on neurons in both the central and peripheral nervous system throughout the body including in the brain, spinal cord, and other nervous tissue. Although they can be effective in providing pain relief, the increased medical use of opioids has been accompanied by an increase in the abuse and misuse of prescription opioids. In addition, for most patients, chronic opioid use is a poor option due to an intolerance to the many side effects, including nausea, vomiting, drowsiness, and constipation, and the propensity for opioids to become less effective with long-term use. According to the Centers for Disease Control and Prevention (the “CDC”), almost two million individuals abused or were dependent on prescription opioids in 2014. CDC figures show that the number of opioid-related overdose deaths has quadrupled between 1999 and 2010, and currently approximately 40% of opioid overdose deaths in the United States involve a prescription opioid. This increase in prescription opioid-related deaths in the United States prompted former President Trump to declare the opioid crisis a national Public Health Emergency in October 2017. Opioid abuse has become an epidemic in the United States, ranking as the nation’s second most prevalent illegal drug problem. These major issues create the need to find new approaches to treating chronic pain.

Our Approach to Treating PAD and Chronic Pain

The unmet medical need for treating PAD and chronic pain reflects the historic failure to develop novel classes of analgesics with comparable or greater efficacy, an acceptable level of adverse effects and a lower abuse liability than those currently available. Some of the reasons for this include the heterogeneity of chronic pain and its related conditions, and the complexity and diversity of the underlying pathophysiological mechanisms for pain. However, recent advances in the understanding of the neurobiology of pain are beginning to offer opportunities to identify new drug targets and develop new therapeutic strategies.

We have taken an innovative and targeted approach to identifying treatments for chronic pain that leverages our understanding of the pathophysiology of pain. Pain is variable. For example, it can be inflammatory or neuropathic in nature, and it may be localized to a specific area of the body or it may be generalized throughout. We believe that the most effective way to treat chronic pain is through therapies that specifically target the origin of the pain signal. We strive to maximize JAN 101’s potential based on its unique mechanism of action related to the origin of the pain signal.

A Randomized, Double-Blind Study of the Effects of a Sustained Release Formulation of Sodium Nitrite (SR-nitrite) on Patients with Diabetic Neuropathy

Background: Sodium nitrite has been reported to be effective in reducing chronic peripheral pain.

Objectives: To evaluate the safety and efficacy of 40 and 80 mg, BID, of an oral sustained-release formulation of sodium nitrite (SR-nitrite) in patients suffering from diabetic neuropathy, and to determine whether SR-nitrite would reduce the frequency of headaches reported previously by subjects receiving the same doses of an immediate release formulation. Study Design: Phase II, single-center, randomized, double-blind, placebo-controlled clinical trial. Setting: The Ohio Pain Clinic and Kettering Medical Center.

Methods: Twenty-four patients were randomized to 40 mg or 80 mg SR-nitrite or placebo twice daily for 12 weeks. The primary objective was to determine whether headaches would be reduced using SR-nitrite. The primary efficacy endpoint was the mean difference in the change of the Neuropathic Pain Symptom Inventory (NPSI) pain score from baseline to that reported after 12 weeks of treatment. Secondary endpoints included changes from baseline for the Brief Pain Inventory (BPI) Scale, the RAND 36 questionnaire, Short-Form McGill Questionnaire, daily patient reported score for neuropathic pain, changes in HbA1c, PulseOx, and quantitative sensory testing.

Results: The number of subjects reporting adverse events and the number of adverse events did not change with dose. There were no reports of treatment-related headaches. Although no significant differences were identified in patient responses to the questionnaires, a trend was observed. In the NPSI assessment, patients in the 40 mg and 80 mg dosing groups reported a 12.7% and 22.0% reduction in pain, respectively, compared to an 8.4% reduction by patients in the placebo group. A trend was also observed with the BPI total severity score. However, the 40 mg dosing group reported the greatest reduction in pain using the McGill Pain index and via patient logs of daily pain scores, where the mean of pain scores reported by subjects in the 40 mg group dropped by day 41 and generally stayed lower than the mean of scores reported by subjects in either of the other two groups. Patients in the 80 mg SR-nitrite group had an improvement in both Nerve Sensory Conductance and Nerve Sensory Velocity. No changes were observed in HbA1c levels or PulseOx.

Limitations: Small sample size.

Conclusion: Sustained release sodium nitrite prevents the prevalent reports of headaches by patients treated with an immediate release formulation of sodium nitrite. In a previous study of patients with peripheral arterial disease (PAD), 40 mg BID treatment led to a statistically significant reduction in reported pain. Similar trends were observed at the end of the trial period for most of the pain questionnaires used in the study. The 80 mg BID treatment had the more pronounced effect on bioactivity (quantitative sensory testing), which was similar to the PAD study, where this dosing group had the greatest improvement in Flow Mediated Dilatation. The ability to alleviate pain with BID treatment of SR-nitrite offers promise for a new non-addictive, non-sedating treatment of chronic pain and warrants further study.

Microcirculatory injury, which is common in diabetic patients, can lead to a number of problems. Prominent among these is diabetic peripheral neuropathy (DPN). About 10% of patients will have evidence of DPN at the time they are initially evaluated, and almost 50% of diabetic patients will ultimately develop DPN. Of diabetic patients with DPN, 40% to 50% suffer from chronic pain, as well as paresthesia, sensory loss, and weakness, and have at least an eight-fold increased risk of undergoing a distal lower extremity amputation compared to similar non-diabetics. Endothelial cells play an important part in the regulation of microcirculation, as they maintain vascular tone by secreting both vasodilators and vasoconstrictors. A central feature of diabetic microvascular disease (MVD) is endothelial dysfunction, which, in turn, plays an important role in the development and progression of DPN. The pathophysiological factors leading to endothelial dysfunction in diabetes include chronic hyperglycemia and protein glycosylation, insulin resistance, inflammation, and increased oxidative stress. Studies have now shown a close relationship between endothelial dysfunction and diminished nitric oxide (NO) bioavailability. Endogenously produced NO has a half-life measured in seconds, and is rapidly oxidized to nitrite (NO₂⁻) and nitrate (NO₃⁻) end-products, the latter of which is biologically inert. In the presence of microcirculatory ischemia and endothelial cell dysfunction, however, endogenous NO production by eNOS is much more limited. In such circumstances, circulating NO₂ can be non-enzymatically reduced to increase NO availability. In addition to serving as a circulating NO reservoir, nitrite itself has also been shown to have direct and potent vasodilatory effects in vitro and in vivo. The findings that NO₂⁻ mediates vasodilatation, both directly and through NO generation, has led to growing interest in the potential effectiveness of nitrite as a therapeutic agent in conditions associated with DPN and endothelial dysfunction. Such conditions include diabetic microvascular disease, DPN, and retinopathy, in which low levels of NO and NO₂⁻, as well as elevated levels of nitrate (NO₃⁻), suggest that the complete oxidation of NO occurs during diabetes with insufficient NO₂⁻ reserves to restore NO bioavailability. Previous human studies with an oral formulation of NaNO₂ have shown that administration twice daily improves vascular function. In the peripheral arterial disease study, subjects who received the lower dose of NaNO₂ reported a significant reduction in pain. Although side effects were minimal, headaches and dizziness were reported by a large number of subjects, likely due to the rapid release of NaNO₂ leading to vasodilation. An oral, sustained-release formulation of NaNO₂ (SR-nitrite) was developed in an attempt to overcome these problems and was tested in a porcine model of metabolic syndrome with critical limb ischemia. SR-nitrite-treated animals showed increased myocardial NO bioavailability, diminished oxidative stress, and cytoprotection in ischemic tissue. Importantly, 24-hour telemetry recordings of blood pressure showed no evidence of vasodilation. In the above study, we hypothesized that the SR-nitrite would reduce or eliminate headaches reported in patients following administration of the immediate release formulation. Given the promising results on reducing pain in diabetic patients with PAD reported in the previous study, patients with diabetic neuropathy were utilized in this study to determine whether any trends in reducing pain could be observed. The study design was a randomized, placebo controlled, double-blind phase II study was carried out to investigate the safety and potential biological activity of multiple doses of an oral, sustained-release formulation of sodium nitrite (SR-nitrite; TheraVasc Inc., Cleveland, OH, USA), BID in doses of 40 mg and 80 mg over a 12-week treatment period, in human subjects with diabetes and neuropathic pain in the lower extremities and feet. The trial was approved by the Copernicus Group Institutional Review Board and listed on ClinicalTrials.gov: www.clinicaltrials.gov/ct2/show/NCT02412852. The study was funded by TheraVasc Inc. (“TheraVasc”).

JAN101—Regulatory Strategy

Sodium nitrite has been previously approved as one of the active components of cyanide poisoning antidote. This means the approval path for JAN101 is through a 505(b)(2) (“NDA”), which we intend to pursue.

JAN101—Commercial Strategy

We currently intend to use third-party providers and manufacturers to support the commercialization JAN101, if we are successful in obtaining FDA approval. We believe that we can promote JAN101 to the patients suffering from PAD in a cost effective manner. We anticipate our commercial operation will include outside sales management, outside sales support, distribution support, and an internal marketing group. Additional requisite capabilities will include focused management of key accounts, such as managed-care organizations, group purchasing organizations, and government accounts. We intend selectively to partner with third parties with vast experience in the space, as we have been partnering for every aspect of development.

Competition

The biotechnology and pharmaceutical industries are characterized by extensive research and development efforts, rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. We are currently focused on the development and commercialization of our asset pipeline of novel, non-opioid, and non-addictive therapies for PAD. The number of patients suffering from chronic PAD is large and growing. While we believe that JAN 101 and our Chief Scientific Officer’s development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including pharmaceutical, biotechnology, and specialty pharmaceutical companies that market or develop therapeutics to treat chronic pain. Academic research institutions, governmental agencies, as well as public and private institutions are also potential sources of competitive products and technologies. Our competitors may have significantly greater financial resources, robust drug pipelines, established presence in the market, and expertise in research and development, manufacturing, pre-clinical and clinical testing, obtaining regulatory approvals and reimbursement, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified clinical, regulatory, scientific, sales, marketing, and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. The key competitive factors affecting the success of JAN 101 (as well as other subsequent product candidates), if and when approved, is likely to be its efficacy, durability, safety, price, and the availability of reimbursement from government and other third-party payors.

Significant competition exists in the PAD pain field. Although we believe our approach to developing novel treatments for pain is unique from most other existing or investigational therapies, such as NSAIDs, corticosteroids, and opioids, we will need to compete with all currently available and future therapies within the indications where our development is focused. With respect to JAN101, the main classes of marketed products that are available for the treatment of PAD pain include NSAIDs and opioids. Furthermore, numerous monoclonal antibodies targeting nerve growth factor, or NGF inhibitors, are in clinical development, including two product candidates in Phase III.

There are a number of companies developing or marketing therapies for the treatment and management of pain that may compete with JAN 101, including many major pharmaceutical and biotechnology companies.

Intellectual Property

Our success depends in large part upon our ability to obtain and maintain proprietary protection for our products and technologies, and to operate without infringing or otherwise violating the proprietary rights of others. We endeavor to protect our products using a combination of intellectual property protections and available government regulatory and marketing exclusivities afforded to new medicines. For example, we endeavor to protect our products by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. We also use other forms of protection, such as confidential information, trade secrets, and know-how, and trademarks to protect our intellectual property, particularly where we do not believe patent protection is appropriate or obtainable.

The proprietary nature of, and protection for, JAN 101, processes, and know-how are important to our business. Our policy is to pursue, maintain, and defend intellectual property rights, and to protect the technology, inventions, and improvements that are commercially important to our business.

Trade Secrets and Other Proprietary Information

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, we have developed methods for more efficient manufacture of sustained released sodium nitrite tablets. We seek to protect our proprietary information, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, and commercial partners.

License Agreement

On November 19, 2019, we entered into a Patent and Know How License Agreement (the “License Agreement”) with UAB Research Foundation (“UABRF”), TheraPAD, and the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College, acting on behalf of LSU Health Shreveport, together with UABRF and TheraPAD collectively, the “Licensors”). Under the License Agreement, the Licensors have agreed to grant to JanOne an exclusive, worldwide license, including the right to sublicense, to the Licensors’ patent rights and know-how related to the Licensors’ sustained release formulation of sodium nitrite. Under the License Agreement, we have agreed to pay a non-refundable upfront license fee and certain milestone payments upon the achievement of certain milestones of up to approximately \$6.5 million and certain royalty payments and annual license maintenance fees. The License Agreement requires us to use commercially reasonable efforts to develop and commercialize JAN101.

Soin Therapeutics

JanOne acquired Soin Therapeutics, a company focused on the development of a novel formulation of low-dose naltrexone (“LDN”) for the treatment of chronic regional pain syndrome (“CRPS”) in 2022. CRPS is a rare pain disorder, characterized by a complex set of symptoms, affecting approximately 200,000 patients annually in the US. There are currently no approved treatments for patients with CRPS. Prior to the acquisition, Soin Therapeutics received Orphan Drug Designation for the product, which provides a variety of incentives for developing the product in this indication.

JAN123

Generally

JAN123 is a novel formulation of 2.0 mg of LDN that results in a biphasic release of the product. The release properties of JAN123 provide for an immediate release of less than half the product with a slow, sustained release of the remaining product. Importantly, the rapid release of LDN has been reported to lead to vivid and lucid unpleasant

dreams, which should be eliminated with the formulation of JAN123. Initially, a single tablet of JAN123 will be administered orally, once a day before sleep, with eventual titration up to two tablets (4 mg) before sleep.

Naltrexone

Naltrexone was first synthesized in 1965 and approved by the FDA for the oral treatment of opioid dependence in 1984, with the brand name Trexan. Later it was approved for the oral treatment of alcohol dependence in 1995, when the brand name was changed by DuPont to ReVia. A depot formulation for intramuscular injection was approved by the FDA under the brand name Vivitrol for alcohol dependence in 2006 and opioid dependence in 2010. Typical oral doses are 50 to 100 mg daily, with a once-monthly intramuscular formulation also available. At these doses, Naltrexone has been shown to function as a nonselective opioid antagonist with a high affinity for μ opioid receptors, which decreases addiction cravings (Schumacher, Basbaum et al. 2017, Opioid Agonists & Antagonists. Basic & Clinical Pharmacology, 14e. B. G. Katzung. New York, NY, McGraw-Hill Education). However, there is a risk that patients who are non-compliant with oral naltrexone may experience opioid intoxication simply by skipping doses of naltrexone. Oral bioavailability is also variable from patient to patient, largely due to first-pass metabolism. Thus, naltrexone is pharmacologically effective, but may be ineffective in a real world setting without counseling and strong patient support (Minozzi, 2011, Oral naltrexone maintenance treatment for opioid dependence. Chechra Database Syst Rev(4), CD001333). There are also multiple generic Naltrexone tablets available on the market for oral administration.

Low-Dose Naltrexone (LDN)

Compared to the standard dose, LDN is defined as a daily dose of Naltrexone of 1 to 5 mg, which is 10- to 100-fold lower than the dose used to manage substance use disorders (LDN Research Trust, Toljan and Vrooman 2018, Low-Dose Naltrexone (LDN)-Review of Therapeutic Utilization. Med Sci (Basel) 6(4)). Off-label uses of Naltrexone at lower doses have been explored based on a different mechanism of action for the treatment of inflammatory, rheumatologic, and neurologic conditions. These include multiple sclerosis, fibromyalgia, Crohn disease, chronic fatigue syndrome (CFS), and, more recently, CRPS. At the low doses used for these conditions, Naltrexone is thought to act as an immune modulator. Some speculate that this effect is related to reduced neuroinflammation in the case of disorders like CFS (Cant, Dalglish et al. 2017, Naltrexone Inhibits IL-6 and TNF α Production in Human Immune Cell Subsets following Stimulation with Ligands for Intracellular Toll-Like Receptors. Front Immunol 8: 809).

Evidence suggests that, at low doses, Naltrexone antagonizes TLR4 on activated glial cells without the previously mentioned function as a μ -opioid receptor antagonist (Chopra and Cooper 2013, Treatment of Complex Regional Pain Syndrome (CRPS) using low-dose naltrexone LDN. J Neuroimmune Pharmacol 8(3): 470-476.). TLR4 has been shown to be a key mediator of microglial activation, which has been identified as a causal mechanism of neuropathic pain in CRPS. Microglial activation is associated with the release of pro-inflammatory cytokines, reactive oxygen species, and prostaglandins, which amplify the inflammatory response (Carniglia, Ramirez et al. 2017, Neuropeptides and Microglial Activation in Inflammation, Pain, and Neurodegenerative Diseases. Mediators of Inflammation 2017: 5048616). Thus, LDN presents a promising therapeutic avenue for the treatment of CRPS, a condition in which TLR4 upregulation is a primary pathway, through attenuation of glial activation and direct targeting of TLR4 activity (Del Valle, Schwartzman et al. 2009, Spinal cord histopathological alterations in a patient with longstanding complex regional pain syndrome. Brain Behav Immun 23(1): 85-91. By downregulating the inflammatory cytokine release, LDN should be beneficial for CRPS patients.

CRPS patients suffer from severe debilitating pain, and even light touch or benign stimulation elicits extreme amounts of pain. Microglial cells and glial cells oftentimes are involved in this pain-signaling pathway. By reducing glial cell activation, Low-dose Naltrexone can treat this pain syndrome. Another potential mechanism of action of LDN treatment on pain is a paradoxical upregulation of opioid signaling. It is noted that, when taken at bedtime, the short-acting low-dose Naltrexone binds to receptors, which leads to a brief blockade of opioid receptors between 2 and 4 a.m. This blockade is believed to upregulate vital life elements of the body and cause an increase in endorphin and enkephalin production. This increase in endorphins and enkephalins will likely cause a decrease in pain that the patient experiences overall. Therefore, LDN leads to transient opioid receptor blockade, which triggers a positive feedback mechanism that increases the production of endogenous opioids (endogenous endorphins and enkephalins) and opioid signaling (Ludwig, Zagon et al. 2017, Serum [Met(5)]-enkephalin levels are reduced in multiple sclerosis and restored by low-dose naltrexone. Exp Biol Med (Maywood) 242(15): 1524-1533; Toljan and Vrooman 2018, Low-Dose Naltrexone (LDN)-Review of Therapeutic Utilization. Med Sci (Basel) 6(4)). Together, these mechanisms may work to alleviate pain associated with CRPS.

Interestingly, low-dose Naltrexone also has effects on the peripheral nervous system. In the peripheral nervous system, it was found that low-dose Naltrexone can modulate T and B lymphocyte production. And it was noticed that low-dose Naltrexone could reduce interleukin 6, interleukin 12, and tumor necrosis factor alpha in the periphery regarding peripheral nervous systems. CRPS patients often have an increase in inflammatory cytokines and may often note an increase in interleukin 6, 12, and tumor necrosis factor alpha. By reducing these inflammatory cytokines back to a normal state, it is predicted that low-dose Naltrexone could treat the actual disease state of CRPS.

In summary, low-dose Naltrexone has a very specific mechanism of action that will distinctly treat CRPS through inhibition of inflammatory cytokines, glial cell activation, neuroinflammation, and increase of endogenous enkephalins and endorphins. In other words, low-dose Naltrexone is not just treating the symptoms with this medication but also treating the underlying disease state and process specific to CRPS.

Chronic Regional Pain Syndrome (CRPS)

CRPS, also termed reflex sympathetic dystrophy (RSD), is a chronic, orphan neurologic condition that typically affects the extremities after trauma or nerve injury, and can cause severe pain. As the most common and prominent symptom of CRPS, the pain is often deep inside the limbs with a burning, stinging, or tearing sensation. Sensory changes are also common and may include increased sensitivity to painful stimuli, feeling pain from stimuli that are usually non-painful, and in some instances, sensory loss (e.g., numbness). In addition to pain, patients commonly experience an affected extremity that is warm, red, and swollen, at least initially. As CRPS progresses, it becomes refractory to sympathetic nerve blocks, conventional analgesics, anticonvulsants, and antidepressants.

CRPS is a rare neurologic disease. It is a painful progressive condition and is listed in the rare disease database of the National Organization for Rare Disorders (NORD). CRPS is subdivided into two categories: type I and type II CRPS. In CRPS type I, there are no nerve injuries or lesions identified. CRPS type I is also known as "reflex sympathetic dystrophy," and it comprises about 90 percent of all cases of CRPS. CRPS type II (causalgia), on the other hand, is diagnosed when there is evidence of nerve damage. As described in the NORD, it was found that CRPS type I developed in 5.46 persons out of every 100,000 per year and the incidence rate of CRPS type 2 was 0.82 persons out of every 100,000 per year, giving rise to a combined incidence rate for both CRPS types I and II of 6.28 per 100,000 person-years (Sandroni, Benrud-Larson et al. 2003, Complex regional pain syndrome type I: incidence and prevalence in Olmsted county, a population-based study. Pain 103(1-2): 199-207; Goh, Chidambaram et al. 2017, Complex regional pain syndrome: a recent update. Burns Trauma 5:2.).

The underlying cause of CRPS is not well understood. In most cases, it occurs after an illness or injury that did not directly damage the nerves in the affected area (Type I). In some cases, it occurs after a specific nerve injury (Type II). The exact trigger of CRPS after an injury is not known, but it may be due to abnormal interactions between the central and peripheral nervous systems and/or inappropriate inflammatory responses. There are multiple factors that may contribute to CRPS development, including immobilization, alterations to the nervous system of the body, and inflammation. Genetic factors and psychological factors, such as anxiety, depression, and anger, may also contribute to the symptoms of CRPS. However, there is no evidence that CRPS is a disease that can be caused by genetic factors alone, and the role of psychological factors in CRPS development remains unproven.

CRPS is treated by approaching it from different areas: physical therapy (PT), occupational therapy (OT), medications for pain management, neuromodulation through implantable devices, and/or nerve blocks targeting the sympathetic chain. Neridronate and zoledronate D,L-lysine monohydrate (ZLM) has been designated as an orphan drugs for the treatment of CRPS in 2013 and 2015, respectively. However, neither of them has been approved. Thus, there is no current FDA-approved drug for CRPS.

Clinical Studies of LDN on CRPS

LDN has been widely used for chronic pain and inflammatory condition and has been shown to alleviate symptoms of pain in patients with chronic pain. A number of case studies have also reported positive effects for LDN in the treatment of CRPS. Chopra et al. reported 2 patient case studies with CRPS who experienced significantly less pain with 4.5 mg daily LDN treatment (Chopra and Cooper 2013, Treatment of Complex Regional Pain Syndrome (CRPS) using low-dose naltrexone (LDN). *J Neuroimmune Pharmacol* 8(3): 470-476). The remission of pain and dystonic spasms in Case 1, as well as remission of all CRPS symptoms (including fixed dystonia) in Case 2, provide evidence that a multi-modal interventional approach, which includes low-dose Naltrexone (a known glial attenuator), should be considered as a treatment option for the treatment of CRPS patients, particularly those patients with dystonic movement disorders. In another CRPS case study, Sturn and Collin found alleviation of pain symptoms as early as 2 days after beginning LDN therapy, with significantly less pain at 4 weeks (Sturn and Collin 2016, Low-Dose Naltrexone: A New Therapy Option for Complex Regional Pain Syndrome Type I Patients. *Int J Pharm Compd* 20(3): 197-201). Weinstock et al. reported alleviation of pain symptoms within one month of LDN treatment, with complete remission of CRPS leg symptoms by 16 months (Weinstock, Myers et al. 2016, Identification and Treatment of New Inflammatory Triggers for Complex Regional Pain Syndrome: Small Intestinal Bacterial Overgrowth and Obstructive Sleep Apnea. *AA Case Rep* 6(9): 272-276). In a recent case study, an CRPS patient was able to discontinue gabapentin and amitriptyline via the use of LDN, while simultaneously achieving superior pain relief (Soin, 2021, Management of pediatric complex regional pain syndrome with low-dose naltrexone. *Pain Medicine Case Reports*, 5(3), 109-113). LDN has been reported to have benefits related to other symptoms of chronic pain syndromes as well, including dystonic spasms, CRPS flares, energy, sleep disturbances, and mood.

Systematic literature review of LDN use showed that the most commonly reported AEs with LDN use were dizziness, vomiting, nausea, and vivid dreams (Soin et al. 2021, Low-Dose Naltrexone Use for Patients with Chronic Regional Pain Syndrome: A Systematic Literature Review. *Pain Physician* 24(4): E393-E406.). Other reported AEs included headaches, abdominal pain, gastrointestinal issues, peripheral edema, restlessness, falls, somnolence, irritability, hematological abnormalities, urinary infection, difficulty concentrating, anxiety, sleepiness, hot flashes/sweating, tachycardia, depression, muscle and joint pain, fatigue, tinnitus, heartburn, dry mouth, and joint pain. Another systematic review also evaluated occurrence of adverse events (AEs) and serious adverse events (SAEs) with LDN use and found that only mild AEs reported among the included studies (89 studies), including nausea, vomiting, and dizziness (Bolton, Hodkinson et al. 2019, Serious adverse events reported in placebo randomized controlled trials of oral naltrexone: a systematic review and meta-analysis. *BMC Med* 17(1): 10). Although 119 patients reported at least one SAE in the naltrexone study arm, meta-analysis found no difference between occurrence of SAEs in naltrexone and placebo groups. Furthermore, secondary analysis found only 6 AEs that were statistically significant: decreased appetite, dizziness, nausea, sleepiness, sweating, and vomiting.

Efficacy of low-dose naltrexone treatment on CRPS

<u>Author (year)</u>	<u>Symptoms</u>	<u>Symptoms alleviated</u>	<u>Time to alleviation of symptoms</u>	<u>Dose</u>	<u>AEs and SAEs</u>
Chopra et al. (2013)	swelling, allodynia, color change, temperature change, some weakness, blisters, skin ulceration, dystonic spasms, dysesthesia	Dystonic spasms, CRPS flares, energy, pain tolerance, sleep disturbances, pain, mood	< 2 months	4.5 mg/day	None
Sturn et al. (2016)	Pain	Pain	2 days	1.5 mg	None
Weinstock et al. (2016)	Severe leg pain, episodic pain in arms and nose, asymmetric and shiny skin with fluctuating temperature changes, color change, edema, IBS, atypical chest pain and fatigue, edema, blue discoloration, tenderness, joint hypermobility with EDS diagnosis	Leg and bowel symptoms; all CRPS pain, bowel symptoms, and fatigue	< 1 month	4.5 mg/day	None

Orphan Drug Designation

An orphan disease is a rare disease affecting fewer than 200,000 people in the US. It is often a serious or fatal condition for which there are no effective therapies. In 1983, the Orphan Drug Act was passed to incentivize companies to develop drugs for patients with rare diseases. Orphan drug designation provides incentives to companies, including:

- Tax credits for qualifies clinical trials
- Exemption from user fees
- Potential for seven years of market exclusivity after approval

In addition, given the small number of patients with a disease and the severity of the disease, approvals are often granted with fewer and smaller trials, saving costs and time. JAN123 was granted Orphan Status for the treatment of CRPS.

Clinical Development Plan

LDN can be rapidly developed in the US via the 505(b)(2) regulatory pathway. This pathway is used for candidates that contain drugs that are already approved but come in a dosage form or delivery system that is different than the original, approved product. In this case, JAN123 fits these criteria perfectly. LDN has the added benefit of being developed at a much lower dose (< 5 milligrams) compared to approved naltrexone products, which are 50 milligrams per tablet. Therefore, it is likely that product development will consist of the following general steps:

- Manufacturing and approval of clinical batches of LDN tablets prior to clinical studies;
- Phase I pharmacokinetic study(ies) to confirm the release profile of LDN; and
- A single Phase III study to demonstrate efficacy in CRPS.

A protocol synopsis of the development plan is presented below:

Title of study	Phase I: The Pharmacokinetics of LDN in the fed and fasted state of a Single Oral Dose of LDN, 4 mg Phase III: Double-Blind Placebo-Controlled Trial of Low-Dose Naltrexone to Treat Complex Regional Pain Syndrome (CRPS)
Clinical Phase	Phase I: The Pharmacokinetics of LDN in the fed and fasted state Phase III: Registration/Efficacy Study to hopefully facilitate an NDA application for the use of low-dose naltrexone to treat CRPS

Objectives: Phase I: To determine pharmacokinetics of single oral low-dose naltrexone in healthy participants in fasting and fed state
Phase3: The primary objective is to assess the efficacy of low-dose naltrexone in treating complex regional pain syndrome symptoms (CRPS).
We plan to conduct a double-blind, randomized, placebo-controlled trial to treat CRPS using low-dose naltrexone.

For Efficacy:

- 1- Assess daily NRS (numerical pain scale 0 – 10) scores through the 3-month study
- 2- Study the possible changes or improvement in the Brief Pain Inventory (BPI) and Oswestry Disability Index (ODI) over the three-month study

For Safety:

We will also monitor safety labs on enrollment and termination of the study. However, we would like to point out that this drug has been available and FDA approved at much higher doses (50 – 150mg or higher) orally with a long-standing proven safety track record. The drug has been available with multiple different embodiments, route of administration and at much higher doses for quite a long time and the safety of the drug has already been extensively established and published.

Investigational product JAN123

Study Design Phase 1: Single-center, dual-arm, cross-over, open-label study

Phase 3: Study Description

We plan to conduct a randomized, double blind placebo controlled trial to treat Complex Regional Pain Syndrome. The study duration will be three months long. Patients in the treatment group will receive a single tablet for the first month of a 2mg dose of Naltrexone. Then, after 1 month, the patient will take 2 tablets for a total of 4mg for months 2 and 3. Study conclusion will be after 3 months.

Patients in the placebo group will take a single tablet for 1 month followed by 2 tablets for month 2 and 3.

A total number of 200 patients with a 1:1 randomization will used. Since CRPS is an orphan disease, we will likely have to use a total of 25 clinical sites or more to be able to adequately recruit the study.

Safety labs will be completed prior to first dose and upon study completion.

For clinical efficacy, we will be assessing daily NRS (1-10) pain scores, a brief pain inventory (BPI) at enrollment and at months 1, 2, and 3 (study completion) and Oswestry Disability Index (ODI) at enrollment and at months 1, 2, and 3 (study completion). Statistically significant improvement in pain scores or any scales in the BPI or ODI are desired outcomes.

Treatment Regimen and Route of Administration Study Drugs are as follows:

Phase I: Single Oral dose of JAN123, 4 mg given on separate days with and without food separated by a washout period of no less than 7 days

Phase III: Patients will be dosed with either the low-dose naltrexone or placebo for three months. Initially for the first month patients will take 1 tablet at bedtime (typically in the evenings) for the first month and then increase to 2 tablets for month 2 and 3. Specifically the Naltrexone will be 2mg tablets, such that for the first month with the 1 tablet per day the patient will be on 2mg doses and subsequently increase to 2 tablets in the evening for a total of 4mg.

Duration of treatment: Phase I: One day for each dose. Two doses of 2 mg each, in total, separated by a washout period of no less than 7 days.

Phase III: This will be a 3 month trial or approximately 90 days. Upon enrollment, patients will be on either low-dose naltrexone or placebo for 90 days.

Participant duration is expected to be 121 days, and at the conclusion of the study (approximately day 90 post-treatment) patients will come in for a final site visit to complete remaining surveys and within 7 days of completion the patients will obtain final safety labs which are anticipated to be a complete blood count and a comprehensive metabolic panel. Since Naltrexone is non-opioid based and does not have withdrawal issues, patients can immediately discontinue the therapy without concerns. As referenced earlier, the safety of Naltrexone orally is already well established and our tested doses are low.

Number of Centers Phase 1: Single Center Clinical Trial

Phase 3: Multicenter Clinical Trial

Likely 25 total sites. Keeping in mind this is an Orphan Disease state and recruitment may be quite difficult, we feel the need to have 25 clinical sites to enroll 200 patients.

Clinical sites will be likely Pain Management Centers, both academic and private practice facilities that have access to patients who suffer from CRPS and also include local PIs who have the skill set and ability to properly diagnose CRPS.

Local or regional clinical trial coordinators will be assigned to each site as well.

Enrolling participants are those who meet the diagnosis criteria of CRPS. Typically CRPS is diagnosed using the Budapest Criteria. Age range of 18 - 65 for enrollment, negative pregnancy test, and stable therapy for 3 months.

Subjects: Phase I: Adult male and female healthy subjects, 18-65 years of age, satisfying all inclusion and exclusion criteria.

Phase III: Patients diagnosed with CRPS (Complex Regional Pain Syndrome), Adult male and female patients, 18-65 years of age.

Number of Subjects

Phase I: 10 patients

Phase III: 200 patients

Endpoints

Phase I: Primary Outcome Measure:

PK profile for low-dose naltrexone (Time Frame: Day 1: predose and at multiple time points after low-dose naltrexone administration).

- C_{max} (Maximum observed plasma concentration)
- T_{max} (Time to reach maximum plasma concentration)
- AUC_{0-t} (Area under the plasma concentration-time curve from 0 hour to the time of the last quantifiable concentration)
- AUC_{0-inf} (Area under the plasma concentration-time curve from 0 hour extrapolated to infinity)
- CL/F (Oral clearance)

Phase 3:

Primary Outcome Measure: Improvement in NRS pain scores over a 3-month time period.

Secondary Outcome Measure: Improvement in Brief Pain Inventory and Oswestry Disability Index (ODI) or other verified pain scales.

End of Study will occur upon completion of the 90-day trial of the low-dose naltrexone or placebo. It is expected that patients will complete all required surveys and testing requirements of the study. Through March 8, 2023, the Company operated its legacy businesses, ARCA Recycling, Inc. (“ARCA Recycling”), ARCA Canada Inc. (“ARCA Canada”), and Customer Connexx, LLC (“Connexx”), in its Recycling segment. ARCA Recycling and ARCA Canada recycle major household appliances in North America by providing turnkey appliance recycling and replacement services for utilities and other sponsors of energy efficiency programs. Connexx is a company that provides call center services for recycling businesses. On March 9, 2023, we entered into a Stock Purchase Agreement with VM7 Corporation, a Delaware corporation, under which the Buyer agreed to acquire all of the outstanding equity interests of (a) ARCA Recycling, Inc., a California corporation, (b) Customer Connexx LLC, a Nevada limited liability company, and (c) ARCA Canada Inc., a corporation organized under the laws of Ontario, Canada. The principal of the Buyer is Virland A. Johnson, our Chief Financial Officer

Early termination is also a possible way to end the study due to issues such as side effects, adverse events, or patient desire to withdraw from the study, among other reasons.

Safety Assessments

Standard clinical evaluation and objective measures will be employed to monitor and assess safety during the conduct of the trial. Furthermore, the results of safety assessments will be used during the trial to monitor and protect the safety of enrolled subjects. Strict subject and study stopping criteria will be implemented to protect the subject’s well-being.

Intellectual Property

The composition of Naltrexone is off-patent and generic versions of the drug are available at 50 mg doses. LDN has been routinely compounded in compounding pharmacies and used clinically off-label. However, the 4.5 mg compounded tablets are associated with sleep disturbances, manifested in vivid and lucid unpleasant dreams. For these reasons, JAN-123 was developed as a biphasic release, orally available tablet to reduce the likelihood of unpleasant dreams. A provisional patent was filed in December 2020 and converted to a PCT application in November 2021 (Pub. No. US 2022/0202807 A1). US Patent number 11,752,143 B2 issued on September 12, 2023. The issued claims in this patent cover the use of the biphasic LDN formulation for treatment of patients with chronic pain. In addition, claims are made to the titration of the LDN for treating chronic pain. While there is no guarantee that the pending applications or future pending claims will issue, the issued US patent will provide protection of JAN123 through 2040 and the Orphan Drug Designation provides 7 years of market exclusivity after drug approval in the event that there are any challenges to this patent.

Trade Secrets and Other Proprietary Information

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, we have developed methods for more efficient manufacture of the biphasic LDN. We seek to protect our proprietary information, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, and commercial partners.

Soin Purchase Agreement

On December 28, 2022, we entered into a Purchase Agreement (the “Soin Purchase Agreement”) with Soin Therapeutics, LLC. Under the Soin Purchase Agreement, JanOne acquired Soin Therapeutics and its LDN product, now known as JAN123. This all-stock transaction has a value of \$13M, with up to an additional \$17M depending on revenues generated by the product, for a total value of up to \$30M. The transaction includes restrictions on the maximum number of shares of preferred stock and common stock that can be issued to or transferred by Soin Therapeutics at any given time.

Our Team

Tony Giordano, Ph.D., our Chief Scientific Officer, joined the Company in December 2019 from the Cleveland Clinic, the No.2 rated hospital in the country, where he served as Senior Director of Special Projects in the Business Development group. Dr. Giordano has extensive experience in drug development, having served as Vice President or President of seven different biotechnology companies he co-founded, including companies developing platform technologies, a cancer vaccine, and Alzheimer’s Disease and cardiovascular therapies. He has managed numerous clinical trials and the launch of a medical food product. Dr. Giordano has also served as an Associate Professor and Assistant Dean of Research and Business Development at LSU Health Sciences Center in Shreveport, Louisiana (“LSU Health Shreveport”), at which he led the licensing efforts at the campus and at Abbott Labs, where, in addition to serving as a Senior Research Scientist, he was involved in technology assessment activities. Dr. Giordano has a Ph.D. focused in Molecular Genetics from The Ohio State University and completed Fellowships at the NIH National Cancer Institute and the NIH National Institute of Aging.

In November 2019, we formed a Scientific Board of Advisors (the “SBA”) and the following doctors and scientists currently are members of our SBA:

Chris Kevil, Ph.D., Chair of the Scientific Board of Advisors –Dr. Kevil, an internationally known expert in vascular pathophysiology, PAD, and nitric oxide biology, discovered the role of sodium nitrite in promoting angiogenesis that led to the development of TV1001, now known as JAN101. Dr. Kevil earned his Ph.D. from LSU Health Shreveport in Molecular and Cellular Physiology, followed by a fellowship at the University of Alabama at Birmingham (UAB) with an emphasis on redox pathophysiology. Returning to LSU Health Shreveport in the Department of Pathology, he established cutting edge research programs regarding redox biology regulation of peripheral vascular

diseases. This led to ground-breaking insights on how glutathione, nitrite/nitric oxide, and hydrogen sulfide regulate vascular health during ischemia.

Edgar Ross, MD – Dr. Ross is the current Director of the Pain Management Center at Brigham and Women’s Hospital and a professor of anesthesia at Harvard Medical School. Dr. Ross is recognized as Castle Connolly’s America’s top doctors for the fifth year in a row. In addition to serving as chairman of Pfizer’s partnership on pain, Dr. Ross also has served as a member of the Blue Cross and Blue Shield Opioid Prescribing Policy Committee.

John Cooke, MD, Ph.D. – Dr. Cooke is the Chair of the Department of Cardiovascular Sciences at the Houston Methodist Research Institute, Director of the Center for Cardiovascular Regeneration, and Medical Director of the RNA Therapeutics Program in the Houston Methodist DeBakey Heart & Vascular Center in Houston, Texas. He trained in cardiovascular medicine and obtained a Ph.D. in physiology at the Mayo Clinic. He was recruited to Harvard Medical School as an assistant professor of medicine. In 1990, he was recruited to Stanford University to spearhead its program in vascular biology and medicine, and was appointed professor in the Division of Cardiovascular Medicine at Stanford University School of Medicine, and associate director of the Stanford Cardiovascular Institute until his recruitment to Houston Methodist in 2013. Dr. Cooke has published over 500 research papers, position papers, reviews, book chapters, and patents in the arena of vascular medicine and biology with over 30,000 citations. He has served on national and international committees that deal with cardiovascular diseases, including the American Heart Association, American College of Cardiology, Society for Vascular Medicine, and the National Heart, Lung and Blood Institute. He has served as president of the Society for Vascular Medicine, as a director of the American Board of Vascular Medicine, and as an associate editor of Vascular Medicine.

Joshua Beckman, MD – Dr. Beckman is the Director of Vascular Medicine and the Gayle and Paul Stoffel Distinguished Chair in Cardiology at UT Southwestern Medical Center. Prior to this, he founded and is director of the Section of Vascular Medicine in the Division of Cardiovascular and is Professor of Medicine at Vanderbilt University Medical Center. The overriding theme linking all of his career activities is vascular function in health and disease. Dr. Beckman’s primary research focuses on the mechanisms by which diabetes mellitus impairs vascular function. Secondary investigations involve studying the effect on endothelial function of non-diabetes-related insulin resistance, androgen deprivation, and vascular function in venous bypass grafts. Dr. Beckman has been involved in numerous clinical studies and has published over 300 research papers with over 30,000 citations. In addition to a number of other journals, Dr. Beckman serves in editorial roles at *Vascular Medicine* and *Circulation*, two of the premier journals in the cardiovascular space.

Nicolas Goeders, Ph.D. – Dr. Goeders is a Professor and Head of the Department of Pharmacology, Toxicology and Neuroscience at LSU Health Shreveport. He has conducted addiction research for the past 30 years and is regarded as one of the world’s leaders on the role for stress in substance abuse disorder. His work has helped to determine the mechanisms responsible for how stress contributes to relapse to drug use. He has published over 100 manuscripts, has written 15 book chapters, and was issued five patents, one of which is a drug currently in clinical development. Dr. Goeders also serves as the Executive Director of the Louisiana Addiction Research Center.

Commercial Operations

We currently do not have any marketing and sales organization. We have retained global rights to JAN-101 and JAN123, and, if either of them or one of our potential subsequent product candidates is approved by the FDA to market in the United States, we expect that our sales force will be supported by sales management, internal sales support, an outside marketing group, and distribution support. We intend to invest in our commercial capabilities prudently by focusing our marketing efforts on the physician subspecialties that treat patients with PAD. These physicians include, but are not limited to, pain management specialists, rheumatologist, surgeons, and sports medicine physicians. We will also evaluate licensing and partnering with third parties to help us reach other sales channels and geographic markets inside and outside of the United States.

Government Regulation

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing, and distribution of drugs, such as those we are developing. These agencies, and other federal, state, and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling, and export and import of product candidates.

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the “FDCA”) and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, the approval process, or thereafter, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA’s refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests, animal studies, and formulation studies in compliance with the FDA’s good laboratory practice (“GLP”), regulations;
- submission to the FDA of an Investigational New Drug Application (“IND”), which must become effective before human clinical trials may begin;
- approval by an institutional research board (“IRB”) at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice (“GCP”) requirements to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of a new drug application (NDA);
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices (“cGMP”) requirements and to assure that the facilities, methods, and controls are adequate to preserve the drug’s identity, strength, quality, and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a risk evaluation and mitigation strategy (“REMS”), and the potential requirement to conduct post-approval studies.

Pre-clinical Studies

Pre-clinical studies include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, and any available clinical data or literature, among other things, to the FDA as part of an IND. Some pre-clinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Clinical holds also may be imposed by the FDA at any time before or during clinical trials, due to safety concerns about on-going or proposed clinical trials, or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. Through the 505(b)2 regulatory path, the FDA allows a sponsor to rely on well documented, published studies to support the clinical development of the product. The FDA has indicated that it will accept published data in support of the Company's development program for JAN101 but prior to filing an NDA would require the Company to complete developmental and reproductive toxicology studies.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on their www.clinicaltrials.gov website. The information contained in, or accessible through, this website does not constitute a part of this Annual Report. We have included this website address solely as an inactive, textual reference.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase I: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, and excretion and, if possible, to gain an early indication of its effectiveness.
- Phase II: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to evaluate the efficacy of the product for specific targeted diseases preliminarily, and to determine dosage tolerance and optimal dosage.
- Phase III: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate sufficient data statistically to evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase IV clinical trials as a condition of approval of an NDA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase II, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase II clinical trial to discuss Phase II clinical results and present plans for the pivotal Phase III clinical trials that they believe will support approval of the new drug. JanOne submitted briefing materials in 2021 describing the previous research and development activities and planned clinical trials. The Company is now working to implement suggestions by the FDA to be ready to submit a protocol amendment in late 2024.

Concurrently with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of product candidates and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and non-clinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

United States Review and Approval Process

The results of product development, pre-clinical, and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act (the "PDUFA"), guidelines that are currently in effect, the FDA has a goal of 10 months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates, and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee; but, it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that

the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional Phase III trial or other significant and time-consuming requirements related to clinical trials, non-clinical studies, or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA that addresses all of the deficiencies identified in the letter, or withdraw the application. Even if such additional data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase IV clinical testing, which involves clinical trials designed to assess a drug's safety and effectiveness further after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products that already have been commercialized. The FDA may also place other conditions on approval, including the requirement for REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription, or dispensing of products. Marketing approval may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

The Food and Drug Administration Safety and Innovation Act (the "FDASIA") made permanent the Pediatric Research Equity Act (the "PREA"), which requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or the FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including Fast Track Designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a Fast Track Designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of 10 months under current PDUFA guidelines. Under the new PDUFA agreement, these six- and 10-month review periods are measured from the "filing" date, rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for Fast Track Designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials that establish that the drug product has an effect (i) on a surrogate endpoint that is reasonably likely to predict clinical benefit or (ii) on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, including taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the FDASIA, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our initial (or subsequent) product candidates, as appropriate.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user program fee requirements for any marketed products.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase IV clinical trials, and surveillance to assess further and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from

cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval of a drug or medical device is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs or devices may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have promoted off-label uses improperly may be subject to significant liability.

The Hatch-Waxman Amendments

The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, added two pathways for FDA drug approval. First, the Hatch-Waxman amendments to the FDCA authorized the FDA to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference from the data owner. The applicant may rely upon the FDA's findings of safety and efficacy for an approved product that acts as the "listed drug." The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the listed drug. The FDA may then approve a new product candidate for all, or some, of the label indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Second, the Hatch-Waxman amendments to the FDCA also established a statutory procedure for submission and FDA review and approval of abbreviated new drug applications ("ANDAs") for generic versions of branded drugs previously approved by the FDA (such previously approved drugs are referred to as "listed drugs"). An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications, and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Pre-market applications for generic drugs are termed abbreviated because they generally do not include pre-clinical and clinical data to demonstrate safety and effectiveness. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. The bioequivalence studies for orally administered, systemically available drug products assess the rate and extent to which the active pharmaceutical ingredient (the "API") is absorbed into the bloodstream from the drug product and becomes available at the site of action. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the listed drug. For some drugs, other means of demonstrating bioequivalence may be required by the FDA, especially where rate and/or extent of absorption are difficult or impossible to measure. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not bioequivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA that references a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the referenced NDA holder and patent owners assert a patent challenge directed to one of the Orange Book-listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired.

Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or a NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

United States Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any therapeutic product candidate for which we may seek regulatory approval. Sales in the United States will depend in part on the availability of adequate financial coverage and reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE, and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our initial or subsequent therapeutic product candidates can be subject to challenge, reduction, or denial by payors.

The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our initial or subsequent product candidates to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug product candidates, restrict or regulate post-approval activities, and affect the profitable sale of drug product candidates.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Affordable Care Act, formally known as the Patient Protection and Affordable Care Act (the "ACA"), was enacted by Congress, and signed into law by the President. It substantially changed the methods by which healthcare is financed by both the government and private insurers, and significantly impacted the United States pharmaceutical industry. The ACA, among other things: (i) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid-managed care organizations; (ii) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (iii) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; (iv) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; (v) expanded the eligibility criteria for Medicaid programs; (vi) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (vii) established a Center for Medicare & Medicaid Innovation to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, former President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high-cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of two percent per fiscal year and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

United States Healthcare Fraud and Abuse Laws and Compliance Requirements

Federal and state healthcare laws and regulations restrict business practices in the pharmaceutical industry. The United States laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving, offering, or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- the federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals, or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the federal Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which among other things, requires certain manufacturers of drugs, devices, and biologics that are reimbursable by a federal healthcare program to report annually to the United States Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and
- similar federal laws and state law equivalents of each of the above federal laws.

Regulation Outside of the United States

To the extent that our initial or subsequent product candidates, if and when approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

In order to market our future products in the European Economic Area (the "EEA") and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization (an "MA"). There are two types of Marketing Authorizations:

- the Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency (the “EMA”) and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy products, and medicinal products containing a new active substance indicated for the treatment certain diseases, such as AIDS, cancer, neurodegenerative disorders, diabetes, and auto-immune and viral diseases. The Centralized Procedure is optional for products that contain a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific, or technical innovation or that are in the interest of public health in the EU; and
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, a National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above-described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy.

Data and Marketing Exclusivity

In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The 10-year market exclusivity period can be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications that, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. In Japan, medicinal products approved for administration to a patient via a new route of administration qualify for six years of market exclusivity.

Clinical Trials

Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization (the “ICH”) guidelines on GCPs. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the European Union, it must appoint an entity within the European Union to act as its legal representative. The sponsor must purchase a clinical trial insurance policy and, in most EU countries, the sponsor is liable to provide “no fault” compensation to any study subject injured in the clinical trial.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority, and a positive opinion from an IEC. The application for a clinical trial authorization must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier that contains information about the manufacture and quality of the medicinal product under investigation. Currently, clinical trial authorization applications must be submitted to the competent authority in each EU Member State in which the trial will be conducted. Under the new Clinical Trials Regulation (Regulation (EU) No 536/2014), which took effect on January 31, 2022, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with cGMP. Other national and European Union-wide regulatory requirements also apply.

Recycling

We started our business in 1976 as a used appliance retailer that reconditioned old appliances to sell in our stores. Under contracts with national and regional retailers of new appliances, we collected the replaced appliance from the retailer’s customer’s residence when one of their stores delivered a new appliance. Any old appliances that we could not sell in our stores were sold to scrap metal processors. In the late 1980s, stricter environmental regulations began to affect the disposal of unwanted appliances and we were no longer able to take appliances that contained hazardous components to scrap metal processors. At that time, we began to develop systems and equipment to remove the harmful materials so that metal processors would accept the appliance shells for processing. We then offered our services for disposing of appliances in an environmentally sound manner to appliance manufacturers and retailers, waste hauling companies, rental property managers, local governments, and the public. In 1989, we began contracting with electric utility companies to provide turnkey appliance recycling services to support their energy conservation efforts. Since that time, through March 8, 2023, we provided our services to approximately 400 utilities and other providers of energy efficiency programs throughout North America.

Through March 8, 2023, when we disposed of our recycling business, we had contracts to recycle, or to replace and recycle, major household appliances for approximately 100 utilities and other providers of energy efficiency services across North America. We operate 17 recycling centers in the United States and Canada to process and recycle old appliances according to all federal, state, provincial, and local rules, and regulations. We used United States Environmental Protection Agency (the “EPA”) Responsible Appliance Disposal (“RAD”) Program-compliant methods to remove and manage hazardous components and materials properly, including CFC refrigerants, mercury, polyurethane foam insulation, and recyclable materials, such as ferrous and nonferrous metals, plastics, and glass. During our operations of the recycling business, all of our facilities complied with licensing and permitting requirements, and employees who process appliances receive extensive safety and hazardous materials training.

Our wholly-owned Recycling Subsidiaries in our Recycling segment included ARCA Recycling and ARCA Canada, which recycle major household appliances in North America by providing turnkey appliance recycling and replacement services for utilities and other sponsors of energy efficiency programs, and Connexx, which provides call center services for the recycling segment.

Disposition of our Recycling Business

On March 19, 2023, the Company entered into a Stock Purchase Agreement (the “Recycling Purchase Agreement”) with VM7 Corporation (“VM7”), under which it agreed to acquire all of the outstanding equity interests of the Recycling Subsidiaries, consisting of: (a) ARCA Recycling, (b) ARCA Canada, and (c) Connexx. The principal of VM7 is Virland A. Johnson, our Chief Financial Officer. The sale of all of the outstanding equity interests of the Recycling Subsidiaries to VM7 under the Recycling Purchase Agreement (the “Disposition Transaction”) was consummated simultaneously with the execution of the Recycling Purchase Agreement. Our Board of Directors unanimously approved the Recycling Purchase Agreement and the Disposition Transaction.

The economic aspects of the Disposition Transaction are: (i) we reduced the liabilities on our consolidated balance sheets by approximately \$17.6 million (excluding those related to the California Business Fee and Tax Division, as discussed below); (ii) we will receive not less than \$24.0 million in aggregate monthly payments from VM7, which payments are subject to potential increase due to the Recycling Subsidiaries’ future performance; and (iii) during the next five years, we may request that VM7 prepay aggregate monthly payments in the aggregate amount of \$1 million. We also received one thousand dollars for the equity of each of the Recycling Subsidiaries at the closing. Each monthly payment is to be the greater of (a) \$140,000 (or \$100,000 for each January and February during the 15-year payment period) or (b) a monthly percentage-based payment, which is an amount calculated as follows: (i) 5% of the Recycling Subsidiaries’ aggregate gross revenues up to \$2,000,000 for the relevant month, plus (ii) 4% of the Recycling Subsidiaries’ aggregate gross revenues between \$2,000,000 and \$3,000,000 for the relevant month, plus (iii) 3% of the Recycling Subsidiaries aggregate gross revenues over \$3,000,000 for the relevant month. VM7 will receive credit toward the payment of the first monthly payment (March of 2023) for any payments, distributions, or

cash dividends paid by any of the Recycling Subsidiaries to the Company on or after March 19, 2023.

VM7 may prepay, at any time and in total, the estimated aggregate of the future monthly payments. That amount will be an amount equal to the then-present value of the estimated future monthly payments, discounted at the rate of 5% per annum (the “Prepayment Price”). Furthermore, VM7 will be required to pay the Prepayment Price upon the earliest of (i) Mr. Johnson holding less than 75% of the capital stock of VM7, (ii) VM7 selling substantially all of its assets, (iii) VM7 holding less than 50% of the capital stock of the Recycling Subsidiaries, or (iv) the Recycling Subsidiaries selling substantially all of their respective assets. Upon payment of the Prepayment Price, VM7 will have no further purchase price payment obligations to the Company.

Additional terms of the Disposition Transaction are: (i) we have the right to appoint one member of VM7’s board of directors until the sooner of VM7 having paid the Prepayment Price or having tendered all of the monthly payments; (ii) Mr. Johnson’s annual salary as Chief Executive Officer of VM7 shall be \$400,000, prorated, for the remainder of the 2023 calendar year, and then adjusted annually to an amount equal to 1% of the Recycling Subsidiaries’ aggregate gross revenues, until the sooner of VM7 having paid the Prepayment Price or having tendered all of the monthly payments; and (iii) we will receive additional payments from VM7 (that are not related to the on-going monthly payments) that relate to certain taxing agency issues. Upon settlement of the continuing dispute between ARCA Recycling and the California Business Fee and Tax Division (as to which settlement, there can be no assurance), ARCA Recycling will pay to us 50% of the amount of the reduction between the current assessment and any such settlement. The payment will be memorialized by a three-year promissory note with interest at five percent per annum. The first payment under the note will be on the last day of VM7’s fiscal year in which the settlement occurs and the remaining payments each year thereafter. If ARCA Recycling receives a refund from the agency for payments previously made, it shall pay to us an amount equivalent to 25% of such refund after reduction for the legal fees payable to counsel for this proceeding. ARCA Recycling and Connexx are due to receive from the Internal Revenue Service two payments in the aggregate amount of approximately \$931,000 in connection with the Employee Retention Credit provisions of the Coronavirus Aid, Relief, and Economic Security Act and the Taxpayer Certainty and Disaster Tax Relief Act of 2020. Those payments are to be tendered to us within 10 days of receipt by ARCA Recycling or Connexx.

To secure VM7’s obligations under the Recycling Purchase Agreement and pursuant to a Stock and Membership Interests Pledge Agreement dated March 19, 2023 (the “Pledge Agreement”), Mr. Johnson pledged to us all of the capital stock in VM7 (“VM7’s Capital Stock”) and VM7 pledged to us all of the equity interests of the Recycling Subsidiaries (the “Subject Securities”). Under the terms of the Pledge Agreement, upon an Event of Default (as defined in the Pledge Agreement), among other remedies in our favor, we may foreclose on any or all of VM7’s Capital Stock and the Subject Securities. We may also cause the ownership of VM7’s Capital Stock and of the Subject Securities to be transferred to us automatically, pursuant to an irrevocable transfer entered in our favor, as referenced in the Pledge Agreement. In the event of an automatic transfer, all of the monthly payments previously made by VM7 pursuant to the terms of the Recycling Purchase Agreement will then be characterized as contributions to the capital of the Company without dilution of the Company’s capital stock.

The parties have made customary representations, warranties, covenants, and indemnities in connection with the Disposition Transaction.

The Recycling Purchase Agreement contains certain representations and warranties that the parties made to each other as of the date of the Recycling Purchase Agreement or such other date as explicitly referenced therein. The representations and warranties were made solely for purposes of the Recycling Purchase Agreement and (i) are subject to limitations agreed by the parties in negotiating the terms and conditions thereof, (ii) may not be accurate or complete as of any specified date, (iii) will be qualified by the underlying disclosure schedules, (iv) may be subject to a contractual standard of materiality different from those generally applicable to investors, and (v) may have been used for the purpose of allocating risk among the parties thereto, rather than for establishing any matters as facts. Information concerning the subject matter of the representations and warranties may change after March 8, 2023, and subsequent information may or may not be fully reflected in JanOne’s public disclosures. For the foregoing reasons, the representations and warranties contained in the Recycling Purchase Agreement should not be relied upon as statements of factual information.

Subsequent to the closing of the Disposition Transaction, VM7 determined that, after expending significant amounts of time and resources, it was unable to obtain sufficient equity or debt financing to continue the operations of the Recycling Subsidiaries. Accordingly, we were advised that the operations of the Recycling Subsidiaries were wound down and, ultimately, ceased. Because we did not receive all of the economic benefits of the Disposition Transaction and understand that we will not receive any future benefits of the Disposition Transaction, we determined to fully impair the approximately \$5.3 million carrying value of the Disposition Transaction on our balance sheet. We also determined not to exercise any of our remedies under the Recycling Purchase Agreement so that we could maintain our focus on our clinical-stage biopharmaceutical activities.

Technology

During the year ended January 1, 2022, the Company took a full write-down of the unamortized portion of the GeoTraq intangible asset of approximately \$9.8 million, and then on May 24, 2022, the Company entered into an Asset Purchase Agreement with SPYR Technologies Inc., pursuant to which the Company sold to SPYR substantially all the assets and assigned none of the liabilities of the Company’s wholly-owned subsidiary, GeoTraq Inc. The aggregate purchase price for the GeoTraq assets was \$13.5 million, payable in cash and shares of SPYR’s capital stock. As of the closing of the transaction on May 24, 2022, SPYR issued to the Company 30,000,000 shares of its common stock at \$0.03 per share, and delivered a five-year Promissory Note in the initial principal amount of \$12.6 million. The Promissory Note bears simple interest at the rate of 8% per annum, provides quarterly interest payments due the first day of each calendar quarter, and may be prepaid at any time without penalty. Quarterly interest payments may be made in cash or in shares of SPYR’s restricted common stock or preferred stock. The Promissory Note matures on May 23, 2027.

Employees

As of April 8, 2024, the Company had five employees, all of whom were full-time.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth selected consolidated financial data for the periods ended or as of the dates indicated. Such historical consolidated financial data should be read in conjunction with the information set forth in our [Annual Report on Form 10-K for the year ended December 30, 2023](#) filed with the SEC on April 8, 2024, and incorporated herein by reference.

The statement of operations data presented below for each of the years ended December 30, 2023 and December 31, 2022, and the balance sheet data as of December 30, 2023 and December 31, 2022, are derived from the audited “Consolidated Financial Statements” contained in our Annual Report on Form 10-K for the year ended December 30, 2023. Our historical results are not necessarily indicative of the results to be expected for any future periods.

(in thousands, except per share)

	For the 52-Week Period Ended	
	December 30, 2023	December 31, 2022
Revenues	\$ —	\$ —
Cost of revenues	—	—
Gross profit	—	—

Operating expenses:		
Sales, general and administrative expenses	4,746	3,149
Impairment expense	15,100	—
Total operating expenses	19,486	3,149
Operating loss	(19,486)	(3,149)
Other income		
Interest expense, net	2,250	468
Gain on litigation settlement	—	1,950
Gain on reversal of contingent liabilities	—	637
Unrealized loss on marketable securities	(926)	(631)
Other income, net	998	2,124
Total other income, net	2,322	4,548
(Loss) Income before income taxes	(17,524)	1,399
Income tax benefit	(429)	(6,621)
Net (loss) income from continuing operations	(17,095)	8,020
Income from discontinued operations	10,254	5,081
Income tax provision for discontinued operations	971	2,109
Net income from discontinued operations	9,283	2,972
Net (Loss) income	\$ (7,812)	\$ 10,992
Income (Loss) per share:		
Net (loss) income per share from continuing operations, basic and diluted	\$ 4.27	\$ 2.55
Net income per share from discontinued operations, basic	\$ 2.32	\$ 0.94
Net income per share from discontinued operations, diluted	\$ 2.09	\$ 0.94
Net (loss) income per share, basic and diluted	\$ (1.95)	\$ 3.49
Weighted average common shares outstanding:		
Basic	4,005,334	3,150,230
Diluted	4,444,361	3,150,230
Net income	\$ (7,812)	\$ 10,992
Effect of foreign currency translation adjustments	\$ —	\$ (4)
Total other comprehensive loss, net of tax	\$ —	\$ (4)
Comprehensive (loss) income	\$ (7,812)	\$ 10,988

	December 30, 2023	December 31, 2022
Balance Sheet Data		
Total assets	\$ 18,847	\$ 46,756
Current liabilities	5,905	23,938
Total liabilities	7,285	29,939
Mezzanine equity	14,510	14,510
Total stockholders' equity	(3,308)	2,307
Total liabilities, mezzanine equity, and stockholders' equity	\$ 18,487	\$ 46,756

31

DESCRIPTION OF SECURITIES WE MAY OFFER

We may issue from time to time, in one or more offerings the following securities:

- shares of Common Stock;
- shares of Preferred Stock, which may be convertible into shares of Common Stock;
- debt securities, which may be senior or subordinated and may be convertible into or exchangeable for shares of Common Stock or shares of Preferred Stock;
- warrants exercisable for debt securities, shares of Common Stock, or shares of Preferred Stock;
- rights to purchase any of such securities; and
- units composed of our debt securities, shares of Common Stock, shares of Preferred Stock, and warrants, in any combination.

This prospectus contains a summary of the material general terms of the various securities that we may offer. The specific terms of the securities will be described in a prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, which may be in addition to or different from the general terms summarized in this prospectus. Where applicable, the prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials will also describe any material United States federal income tax considerations relating to the securities offered and indicate whether the securities offered are or will be listed on any securities exchange. The summaries contained in this prospectus and in any prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, may not contain all of the information that you would find useful. Accordingly, you should read the actual documents relating to any securities sold pursuant to this prospectus. See “Available Information” and “Incorporation of Certain Information by Reference” for information about how to obtain copies of those documents.

The terms of any particular offering, the initial offering price, and the net proceeds to us will be contained in the prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, relating to such offering.

32

DESCRIPTION OF CAPITAL STOCK

The following summary of terms of our Common Stock and our Preferred Stock is based upon our Articles of Incorporation (our “Charter”) and Bylaws (our “Bylaws”), currently in effect, and under Chapter 78 of the Nevada Revised Statutes (the “NRS”). This summary is not complete and is subject to, and qualified in its entirety by reference to, our Charter and our Bylaws. For a complete description of the terms and provisions of our Common Stock, please refer to our Charter and Bylaws, which are filed as

exhibits to Registration Statement of which this prospectus forms a part. Throughout this section, references to “we,” “our,” and “us” refer to JanOne Inc. and its subsidiaries. We encourage you to carefully read these documents and the applicable provisions of the NRS.

General

Our authorized capital stock consists of 200,000,000 shares of Common Stock, par value \$0.001 per share, and 2,000,000 shares of Preferred Stock, par value \$0.001 per share, of which 259,729 shares are designated as Series A-1 Convertible Preferred Stock (our “Series A-1 Preferred Stock”), and 200,000 shares are designated as Series S Convertible Preferred Stock (our “Series S Preferred Stock”), which have a stated value of \$300.00 per share (the “Stated Value”).

As of April 8, 2024, we had 8,593,636 shares of our Common Stock issued and outstanding, 156,630 shares of our Series A-1 Preferred Stock issued and outstanding, and 100,000 shares of our Series S Preferred Stock issued and outstanding.

The authorized and unissued shares of Common Stock and Preferred Stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may then be listed. Unless approval of our stockholders is so required, our Board of Directors (our “Board”) does not currently intend to seek stockholder approval for the issuance and sale of our Common Stock.

All of our issued and outstanding shares of our capital stock are fully paid and non-assessable.

Common Stock

Voting, Dividend, and Liquidation Rights

Each holder of our Common Stock is entitled to one vote for each share issued and outstanding held on all matters to be voted upon by the stockholders. Each holder of our Series A-1 Preferred Stock is entitled to 17 votes for each share issued and outstanding held on all matters to be voted upon by the stockholders. Each holder of our Series S Preferred Stock is entitled to one vote for each share issued and outstanding held on all matters to be voted upon by the stockholders. Our Charter does not provide for cumulative voting in the election of directors. Subject to the rights of the holders of the Series A-1 Preferred Stock to their preferential dividend in accordance with the provisions of our Charter, the holders of shares of our Common Stock and Series A-1 Preferred Stock (on an as-if-converted to Common Stock basis in accordance with the terms of our Charter) will be entitled to such cash dividends as may be declared from time to time by our Board from funds available therefor. Upon liquidation, dissolution, or winding up of the Company, and after all liquidation preferences payable to any series of Preferred Stock entitled thereto have been satisfied, our remaining assets shall be distributed to all holders of Common Stock and any similarly situated stockholders who are not entitled to any liquidation preference or, if there be an insufficient amount to pay all such stockholders, then ratably among such holders.

Preemptive, Conversion, or Other Rights

Our shares of Common Stock do not have any preemptive, conversion, or redemption rights. Our shares of Series A-1 Preferred Stock do not have any preemptive or redemption rights and each share of which is convertible into 20 shares of our Common Stock. Our shares of Series S Preferred do not have any preemptive or redemption rights and, subject to the provisions of the Certificate of Designation in respect of the Series S Preferred Stock, each share of which is convertible into shares of our Common Stock at a conversion price of \$1.66 per share.

Stockholder Action; Special Meetings

Stockholders’ actions can only be taken at an annual or special meeting of our stockholders. Our Bylaws provide that special meetings of the stockholders may be called at any time only by (i) our Chief Executive Officer, (ii) two of the members of the Board, or (iii) upon a written request of stockholders holding 10% or more of the capital stock entitled to vote.

Board of Directors; Removal; Vacancies

Our Bylaws specify that the number of directors is to be determined by a majority vote of the Board. Our Board is currently composed of four directors. We do not have a classified Board. Pursuant to our Bylaws and the NRS, a director serves until the regular meeting next following or closely coinciding with the expiration of his or her term of office and until his or her successor has been elected and qualified, or until his or her earlier death, removal, or resignation.

Newly created directorships resulting from an increase in the number of directors and vacancies occurring on our Board for any reason may be filled by a vote of a majority of the directors then in office, although less than a quorum exists. A director that is appointed or elected to fill a vacancy shall hold office for the remaining term of his or her predecessor.

Limitation of Liability and Indemnification

Our Charter provides that none of our directors and officers shall be personally liable to us or our stockholders for damages for breach of fiduciary duty as a director or officer, except for liability for (i) acts or omissions that involve intentional misconduct, fraud, or knowing violation of law or (ii) for authorizing any distribution in violation of Section 78.300 of the NRS. Our Bylaws provide that any officer or director who is made a party or witness to an action, suit, or proceeding, whether civil, criminal, administrative, or investigative, by reason of the fact that he or she is or was one of our directors or officers or serving at our request as a director, officer, employee, or agent, shall be indemnified and held harmless by us to the fullest extent authorized by the NRS. The right to indemnification shall include the right of advancement of expenses to the extent permitted under the NRS.

Listing and Transfer Agent

Our common stock is listed on The Nasdaq Capital Market under the symbol “JAN.” The transfer agent and registrar for our common stock is EQ Shareowner Services.

Series A-1 Convertible Preferred Stock

Dividends

We cannot declare, pay, or set aside any dividends on shares of any other class or series of our capital stock unless (in addition to the obtaining of any consents required by our Articles of Incorporation) the holders of the Series A-1 Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend in the aggregate amount of \$1.00, regardless of the number of then-issued and outstanding shares of Series A-1 Preferred Stock. Any remaining dividends allocated by the Board of Directors shall be distributed in an equal amount per share to the holders of outstanding Common Stock and Series A-1 Preferred Stock (on an as-if-converted to Common Stock basis pursuant to the Conversion Ratio as defined below).

Conversion

Each share of Series A-1 Preferred Stock has the right to be converted into 20 shares of Common Stock of the Company.

Redemption

The shares of Series A-1 Preferred Stock have no redemption rights.

Preemptive Rights

Holders of shares of Series A-1 Preferred Stock are not entitled to any preemptive rights in respect to any securities of the Company, except as set forth in the Series A-1 Certificate of Designation or any other document agreed to by us.

Voting Rights

Each holder of a share of Series A-1 Preferred Stock has that number of votes as is determined by multiplying (i) the number of shares of Series A Preferred Stock held by such holder and (ii) 17. The holders of Series A-1 Preferred Stock vote together with all other classes and series of Common Stock and Preferred Stock of the Company as a single class on all actions to be taken by the holders of Common Stock of the Company, except to the extent that voting as a separate class or series is required by law.

Protective Provisions

Without first obtaining the affirmative approval of a majority of the holders of the shares of Series A-1 Preferred Stock, we may not directly or indirectly (i) increase or decrease (other than by redemption or conversion) the total number of authorized shares of Series A-1 Preferred Stock; (ii) effect an exchange, reclassification, or cancellation of all or a part of the Series A-1 Preferred Stock, but excluding a stock split or reverse stock split or combination of the Common Stock or preferred stock; (iii) effect an exchange, or create a right of exchange, of all or part of the shares of another class of shares into shares of Series A-1 Preferred Stock; or (iv) alter or change the rights, preferences, or privileges of the shares of Series A-1 Preferred Stock so as to affect adversely the shares of such series, including the rights set forth in the Series A-1 Certificate of Designation; *provided, however*, that we may, without any vote of the holders of shares of the Series A-1 Preferred Stock, make technical, corrective, administrative, or similar changes to the Series A-1 Certificate of Designation that do not, individually or in the aggregate, materially adversely affect the rights or preferences of the holders of shares of the Series A-1 Preferred Stock.

Series S Convertible Preferred Stock

On December 28, 2022 the Company acquired Soin Therapeutics LLC, a Delaware limited liability company (“STLLC”) by way of merger. In connection with this transaction, with a potential value of up to \$30 million, the Company tendered 100,000 shares of the Company’s Series S Convertible Preferred Stock to Amol Sooin, M.D., the sole stockholder of STLLC (“Dr. Sooin”).

Dividends

The shares of Series S Preferred Stock have no dividend rights.

Conversion

Dr. Sooin may convert up to \$10 million of value of the Series S Preferred Stock into shares of the Company’s Common Stock from and after the sooner of (y) the issuance by the FDA of New Drug Approval for low-dose naltrexone for treating pain or (z) 10 years from the closing of the acquisition of STLLC. Further, during the 10-year period following the closing, Dr. Sooin may convert up to an additional \$17 million of value of shares of Series S Preferred Stock at a rate of five percent of the gross revenues that the Company receives in connection with sales or license revenue from STLLC-related products.

Dr. Sooin further agreed to certain restrictions on the maximum number of shares of Series S Preferred Stock that he may ultimately keep or that he may convert into shares of our Common Stock or sell into the public markets at any given time: (i) Dr. Sooin may not convert shares of Series S Preferred Stock into shares of the Company’s Common Stock in an amount such that, upon any such conversion, he beneficially own shares of the Company’s Common Stock in excess of 4.99% of the Company’s then-outstanding Common Stock and (ii) during the five-year period that commences on the date that Dr. Sooin is first eligible to convert any shares of Series S Preferred Stock into shares of the Company’s Common Stock, he will not dispose of any of such shares into the public markets in an amount that exceeds five percent of the daily trading volume of the Company’s common stock during any trading day.

In lieu of Dr. Sooin exercising his initial conversion rights in respect of up to \$3 million in value of his Series S Preferred Stock, Dr. Sooin and we agreed that we will tender to him \$3 million in three payments: the first payment of \$100,000 was made in March 2024, the second payment in the amount of \$100,000 is due on July 31, 2024, and the third payment of \$2,800,000 is due on December 31, 2024.

Redemption

The shares of Series S Preferred Stock have no redemption rights.

Preemptive Rights

Holders of shares of Series S Preferred Stock are not entitled to any preemptive rights in respect to any securities of the Company, except as set forth in the Series S Certificate of Designation or any other document agreed to by us.

Voting Rights

Each share of Series S Preferred Stock has one vote. The holders of Series S Preferred Stock vote together with all other classes and series of Common Stock and Preferred Stock of the Company as a single class on all actions to be taken by the holders of Common Stock of the Company, except to the extent that voting as a separate class or series is required by law.

Liquidation Preference

Upon a voluntary or involuntary liquidation, dissolution or winding up of the Company, the Holders of Series S Preferred Stock have preferential rights to holders of junior securities and shall be entitled to payments in an amount equal to the Stated Value for each share of Series S Preferred Stock that is eligible to be converted into the Company’s Common Stock at such time, if any.

Protective Provisions

Without first obtaining the affirmative approval of a majority of the holders of the shares of Series S Preferred Stock, we may not directly or indirectly (i) increase or decrease (other than by redemption or conversion) the total number of authorized shares of Series S Preferred Stock; (ii) effect an exchange, reclassification, or cancellation of all or a part of the Series S Preferred Stock, but excluding a stock split or reverse stock split or combination of the Common Stock or preferred stock; (iii) effect an exchange, or create

a right of exchange, of all or part of the shares of another class of shares into shares of Series S Preferred Stock; or (iv) alter or change the rights, preferences, or privileges of the shares of Series S Preferred Stock so as to affect adversely the shares of such series, including the rights set forth in the Series S Certificate of Designation; *provided, however*, that we may, without any vote of the holders of shares of the Series S Preferred Stock, make technical, corrective, administrative, or similar changes to the Series S Certificate of Designation that do not, individually or in the aggregate, materially adversely affect the rights or preferences of the holders of shares of the Series S Preferred Stock.

Anti-Takeover Effects of Certain Provisions of our Charter, our Bylaws, and the NRS

Certain provisions of the NRS and our Charter and Bylaws could make more difficult the acquisition of us by means of a tender offer or otherwise, and the removal of incumbent officers and directors. These provisions are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of us.

Advance Notice of Stockholder Proposals

Stockholder proposals must be submitted to the Chairman of our Board, our Chief Executive Officer, our President, or our Secretary not less than 120 days before the one-year anniversary of the date on which we released our proxy statement in connection with the previous year's annual meeting of stockholders. In the event that our annual meeting date has been changed by more than 30 days from the date of the prior year's annual meeting, written proposals must be submitted within a reasonable time before we begin to print and mail our proxy materials. To be in proper form, a stockholder's written proposal must be in compliance with Rule 14a-8 under the Exchange Act and must include: (i) a brief description of the business desired to be brought before the annual meeting and the reasons for conducting such business at the annual meeting, (ii) the name and record address of such stockholder, (iii) the class or series and number of shares of our capital stock that are owned beneficially or of record by such stockholder, (iv) a description of all arrangements or understandings between such stockholder and any other person or persons (including their names) in connection with the proposal of such business by such stockholder and any material interest of such stockholder in such business, and (v) a representation that such stockholder intends to appear in person or by proxy at the annual meeting to bring such business before the meeting. This provision could make it more difficult for stockholders to submit proposals for consideration and nominees for director at an annual meeting of our stockholders.

Business Combinations

The "business combination" provisions of Sections 78.411 to 78.444, inclusive, of the NRS prohibit a Nevada corporation with at least 200 stockholders (at least 100 of whom are stockholders of record and residents of the State of Nevada) from engaging in various "combination" transactions with any interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the transaction is approved by the entity's board of directors prior to the date the interested stockholder obtained such status; or after the expiration of the three-year period, unless:

- the transaction is approved by the entity's board of directors or a majority of the voting power held by disinterested stockholders of the entity, or
- if the consideration to be paid by the interested stockholder is at least equal to the highest of: (a) the highest price per share paid by the interested stockholder within the three years immediately preceding the date of the announcement of the combination or in the transaction in which it became an interested stockholder, whichever is higher, (b) the market value per share of common stock on the date of announcement of the combination and the date the interested stockholder acquired the shares, whichever is higher, or (c) for holders of preferred stock, the highest liquidation value of the preferred stock, if it is higher.

A "combination" is defined to include mergers or consolidations or any sale, lease exchange, mortgage, pledge, transfer, or other disposition, in one transaction or a series of transactions, with an "interested stockholder" having: (a) an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation, (b) an aggregate market value equal to 5% or more of the aggregate market value of all outstanding shares of the corporation, or (c) 10% or more of the earning power or net income of the corporation.

In general, an "interested stockholder" is a person who, together with affiliates and associates, owns (or within three years, did own) 10% or more of an entity's voting stock. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Acquisitions of Controlling Interest

Nevada's "acquisition of controlling interest" statutes (NRS 78.378 through 78.3793, inclusive) contain provisions governing the acquisition of a controlling interest in certain Nevada corporations. These "control share" laws provide generally that any person who acquires a "controlling interest" in certain Nevada corporations may be denied voting rights, unless a majority of the disinterested stockholders of the corporation elects to restore such voting rights. These laws would apply to us as of a particular date if we were to have 200 or more stockholders of record (at least 100 of whom have addresses in Nevada appearing on our stock ledger at all times during the 90 days immediately preceding that date) and do business in the State of Nevada directly or through an affiliated corporation, unless our Charter or Bylaws in effect on the tenth day after the acquisition of a controlling interest provide otherwise. These laws provide that a person acquires a "controlling interest" whenever a person acquires shares of a subject corporation that, but for the application of these provisions of the NRS, would enable that person to exercise (1) one-fifth or more, but less than one-third, (2) one-third or more, but less than a majority, or (3) a majority or more of all of the voting power of that corporation in the election of its directors. Once an acquirer crosses one of these thresholds, shares that it acquired in the transaction that took it over the threshold and shares that it acquired within the 90 days immediately preceding the date when it acquired or offered to acquire a controlling interest become "control shares" to which the voting restrictions described above apply.

DESCRIPTION OF PREFERRED STOCK

Shares of our Preferred Stock may be issued in one or more series, and our Board is authorized to determine the designation and to fix the number of shares of each series. Our Board is further authorized to fix and determine the dividend rate, premium or redemption rates, conversion rights, voting rights, preferences, privileges, restrictions, and other variations granted to or imposed upon any wholly unissued series of our Preferred Stock.

Prior to the issuance of shares of a series of Preferred Stock, our Board will adopt resolutions and file a certificate of designation with the Secretary of State of the State of Nevada. The certificate of designation will fix for each series the designation and number of shares and the rights, preferences, privileges, and restrictions of the shares including, but not limited to, the following:

- the voting rights, if any, of the Preferred Stock;
- any rights and terms of redemption;
- the dividend rate(s), period(s), and/or payment date(s) or method(s) of calculation applicable to the Preferred Stock;
- whether dividends are cumulative or non-cumulative and, if cumulative, the date from which dividends on the Preferred Stock will accumulate;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon the liquidation, dissolution, or winding up of our affairs;

- the terms and conditions, if applicable, upon which the Preferred Stock will be convertible into Common Stock, another series of Preferred Stock, or any other class of securities, including the conversion price (or manner of calculation) and conversion period;
- the provision for redemption, if applicable, of the Preferred Stock;
- the provisions for a sinking fund, if any, for the Preferred Stock;
- the liquidation preferences, if any, for the Preferred Stock;
- any limitations on the issuance of any class or series of Preferred Stock ranking senior to or on a parity with the class or series of Preferred Stock as to dividend rights and rights upon liquidation, dissolution, or winding up of our affairs; and
- any other specific terms, preferences, rights, limitations, or restrictions of the Preferred Stock.

In addition to the terms listed above, we will set forth in a prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, the following terms relating to the series of Preferred Stock being offered:

- the number of shares of the preferred stock offered, the liquidation preference per share, the conversion rights, and the offering price of the Preferred Stock;
- the procedures for any auction and remarketing, if any, for the Preferred Stock;
- any listing of the Preferred Stock on any securities exchange; and
- a discussion of any material and/or special United States federal income tax considerations applicable to the Preferred Stock.

DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we include in any applicable prospectus supplements or any related free writing prospectus or other offering materials, as applicable, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future debt securities we may offer pursuant to this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. If we so indicate in a prospectus supplement, the terms of any debt securities offered under such prospectus supplement may differ from the terms we describe below, and to the extent the terms set forth in a prospectus supplement differ from the terms described below, the terms set forth in the prospectus supplement or any related free writing prospectus or other offering materials, as applicable, shall control.

We may sell from time to time, in one or more offerings under this prospectus, debt securities, in one or more series. These debt securities that we may issue include senior debt securities, senior subordinated debt securities, subordinated debt securities, convertible debt securities, and exchangeable debt securities. We will issue any such senior debt securities under a senior indenture that we will enter into with a trustee to be named in the senior indenture. We will issue any such subordinated debt securities under a subordinated indenture, which we will enter into with a trustee to be named in the subordinated indenture. We use the term “indentures” to refer to either the senior indenture or the subordinated indenture, as applicable. The indentures will be qualified under the Trust Indenture Act of 1939, as amended (the “Trust Indenture Act”), as in effect on the date of the indenture. We use the term “debenture trustee” to refer to either the trustee under the senior indenture or the trustee under the subordinated indenture, as applicable.

The following summary description, together with the additional information we may include in any applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, does not purport to be complete and is subject to, and qualified in its entirety by reference to, the form of indenture filed as an exhibit to the Registration Statement of which the prospectus is a part, as it may be supplemented, amended, or modified from time to time, as well as the notes and supplemental agreement relating to each series of debt securities that will be incorporated by reference as exhibits to the Registration Statement that includes the prospectus or as exhibits to a Current Report on Form 8-K if we offer debt securities.

General

The indenture does not limit the amount of debt securities that may be issued thereunder, and each indenture provides that the specific terms of any series of debt securities shall be set forth in, or determined pursuant to, an authorizing resolution and/or a supplemental indenture, if any, relating to such series.

We may issue the debt securities issued under the indentures as “discount securities,” which means they may be sold at a discount below their stated principal amount. These debt securities, as well as other debt securities that are not issued at a discount, may be issued with “original issue discount,” or “OID,” for U.S. federal income tax purposes because of interest payment and other characteristics or terms of the debt securities. Material U.S. federal income tax considerations applicable to debt securities issued with OID will be described in more detail in any applicable prospectus supplement.

We will describe in the applicable prospectus supplement, the related free writing prospectus, or other offering materials, as applicable, the terms of the series of debt securities being offered, including:

- the title or designation;
- the aggregate principal amount and any limit on the aggregate principal amount that may be issued;
- the maturity date or dates on which principal will be payable;
- the form of the debt securities of the series;
- the applicability of any guarantees;
- whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;
- whether the debt securities rank as senior debt, senior subordinated debt, subordinated debt, or any combination thereof, and the terms of any subordination;

- if the price (expressed as a percentage of the aggregate principal amount thereof) at which such debt securities will be issued is a price other than the principal amount thereof, the portion of the principal amount thereof payable upon declaration of acceleration of the maturity thereof, or, if applicable, the portion of the principal amount of such debt securities that is convertible into another security or the method by which any such portion shall be determined;

- the interest rate or rates, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable, and the regular record dates for interest payment dates or the method for determining such dates;
- our right, if any, to defer payment of interest and the maximum length of any such deferral period;
- if applicable, the date or dates after which, or the period or periods during which, and the price or prices at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;
- the date or dates, if any, on which, and the price or prices at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;
- the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof;
- the place or places where payments will be payable;
- whether the debt securities of that series shall be issued in whole or in part in the form of a global security or securities, the terms and conditions, if any, upon which such global security or securities may be exchanged in whole or in part for other individual securities; and the depository for such global security or securities;
- whether the indenture will restrict our ability to pay dividends or will require us to maintain any asset ratios or reserves;
- if, other than the full principal amount thereof, the portion of the principal amount of debt securities of the series that shall be payable upon declaration of acceleration of the maturity thereof;
- whether we will be restricted from incurring any additional indebtedness;
- additions to or changes in the events of default with respect to the securities and any change in the right of the trustee or the holders to declare the principal, premium, if any, and interest, if any, with respect to such securities to be due and payable;
- additions to or changes in the provisions relating to satisfaction and discharge of the indenture;
- additions to or changes in the provisions relating to the modification of the indenture both with and without the consent of holders of debt securities issued under the indenture;
- whether interest will be payable in cash or additional debt securities at our or the holders' option and the terms and conditions upon which the election may be made;
- the terms and conditions, if any, upon which we will pay amounts in addition to the stated interest, premium, if any, and principal amounts of the debt securities of the series to any holder that is not a "United States person" for federal tax purposes;
- any restrictions on transfer, sale, or assignment of the debt securities of the series;
- a discussion on any material or special U.S. federal income tax considerations applicable to a series of debt securities; and
- any other specific terms, preferences, rights, or limitations of, or restrictions on, the debt securities, any other additions or changes in the provisions of the indenture, and any terms that may be required by us or advisable under applicable laws or regulations.

We may issue debt securities that provide for an amount less than their stated principal amount to be due and payable upon declaration of acceleration of their maturity pursuant to the terms of the indenture. We will provide you with information on the federal income tax considerations and other special consideration applicable to any of these debt securities in the applicable prospectus supplement, related free writing prospectus, or other offering materials, as applicable.

Conversion or Exchange Rights

We will set forth in the applicable prospectus supplement, related free writing prospectus, or other offering materials, as applicable, the terms on which a series of debt securities may be convertible into or exchangeable for shares of our Common Stock, shares of our Preferred Stock, or other securities. We will include provisions as to settlement upon conversion or exchange and whether conversion or exchange is mandatory, at the option of the holder, or at our option. We may include provisions pursuant to which the number of shares of our Common Stock, shares of our Preferred Stock, or our other securities that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger, or Sale; No Protection in Event of a Change of Control or Highly Leveraged Transaction

Unless we provide otherwise in the prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, applicable to a particular series of debt securities, the indenture will contain covenant that restricts our ability to merge or consolidate, or sell, convey, transfer, or otherwise dispose of our assets as an entirety or substantially as an entirety, unless we are the surviving corporation or the successor to or acquirer of such assets (other than a subsidiary of ours) expressly assumes all of our obligations under the indenture or the debt securities, as appropriate. In addition, we cannot complete such a transaction unless immediately after completing the transaction, no event of default under the indenture, and no event that, after notice or lapse of time or both, would become an event of default under the indenture, has occurred and is continuing.

Unless we provide otherwise in the prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable to a particular series of debt securities, the debt securities will not contain any provisions that may afford holders of the debt securities protection in the event we have a change of control or in the event of a highly leveraged transaction (whether or not such transaction results in a change of control), which could adversely affect holders of debt securities.

Events of Default Under the Indentures

Unless we provide otherwise in the prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable to a particular series of debt securities, the following are events of default under the indentures with respect to any series of debt securities that we may issue:

- if we fail to pay interest when due and our failure continues for a period of 90 days; *provided, however*, that a valid extension of an interest payment period by us in accordance with the terms of any indenture supplement thereto shall not constitute a default in the payment of interest for this purpose;

- if we fail to pay the principal of, or premium, if any, on any series of debt securities as and when the same shall become due and payable whether at maturity, upon redemption, by declaration or otherwise, or in any payment required by any sinking or analogous fund established with respect to such series; *provided, however*, that a valid extension of the maturity of such debt securities in accordance with the terms of any indenture supplement thereto shall not constitute a default in the payment of principal or premium, if any;
- if we fail to observe or perform any other covenant or agreement contained in the debt securities or the indenture, other than a covenant specifically relating to another series of debt securities, and our failure continues for 90 days after we receive written notice of such failure, requiring the same to be remedied and stating that such is a notice of default thereunder, from the trustee or holders of at least 25% in aggregate principal amount of the outstanding debt securities of the applicable series; and
- if specified events of bankruptcy, insolvency, or reorganization occur as to us.

No event of default with respect to a particular series of debt securities (except as to certain events of bankruptcy, insolvency, or reorganization) necessarily constitutes an event of default with respect to any other series of debt securities. The occurrence of an event of default may constitute an event of default under any bank credit agreements we may have in existence from time to time. In addition, the occurrence of certain events of default or acceleration under the indenture may constitute an event of default under certain of our other indebtedness outstanding from time to time.

If an event of default with respect to debt securities of any series at the time outstanding occurs and is continuing, then the trustee or the holders of at least 25% in principal amount of the outstanding debt securities of that series may, by a notice in writing to us (and to the debenture trustee if given by the holders), declare to be due and payable immediately the principal (or, if the debt securities of that series are discount securities, that portion of the principal amount as may be specified in the terms of that series) of and premium and accrued and unpaid interest, if any, on all debt securities of that series. Before a judgment or decree for payment of the money due has been obtained with respect to debt securities of any series, the holders of a majority in principal amount of the outstanding debt securities of that series (or, at a meeting of holders of such series at which a quorum is present, the holders of a majority in principal amount of the debt securities of such series represented at such meeting) may rescind and annul the acceleration if all events of default, other than the non-payment of accelerated principal, premium, if any, and interest, if any, with respect to debt securities of that series, have been cured or waived as provided in the applicable indenture (including payments or deposits in respect of principal, premium or interest that had become due other than as a result of such acceleration). We refer you to the prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, relating to any series of debt securities that are discount securities for the particular provisions relating to acceleration of a portion of the principal amount of such discount securities upon the occurrence of an event of default.

Subject to the terms of the indentures, if an event of default under an indenture shall occur and be continuing, the debenture trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the debenture trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method, and place of conducting any proceeding for any remedy available to the debenture trustee, or exercising any trust or power conferred on the debenture trustee, with respect to the debt securities of that series, provided, that:

- the direction so given by the holder is not in conflict with any law or the applicable indenture; and
- subject to its duties under the Trust Indenture Act, the debenture trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will only have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies if:

- the holder previously has given written notice to the debenture trustee of a continuing event of default with respect to that series;
- the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made written request, and such holders have offered reasonable indemnity to the debenture trustee to institute the proceeding as trustee; and
- the debenture trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series (or at a meeting of holders of such series at which a quorum is present, the holders of a majority in principal amount of the debt securities of such series represented at such meeting) other conflicting directions within 60 days after the notice, request, and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the applicable debenture trustee regarding our compliance with specified covenants in the applicable indenture.

Modification of Indentures; Waiver

We and the debenture trustee may change the applicable indenture without the consent of any holders with respect to specific matters, including:

- to evidence the succession of another corporation to us and the assumption by any such successor of our covenants in such indenture and in the debt securities issued thereunder;
- to add to our covenants or to surrender any right or power conferred on us pursuant to the indenture;
- to establish the form and terms of debt securities issued thereunder;
- to evidence and provide for a successor trustee under such indenture with respect to one or more series of debt securities issued thereunder or to provide for or facilitate the administration of the trusts under such indenture by more than one trustee;
- to cure any ambiguity, to correct or supplement any provision in the indenture that may be defective or inconsistent with any other provision of the indenture or to make any other provisions with respect to matters or questions arising under such indenture; provided that no such action adversely affects the interests of the holders of any series of debt securities issued thereunder in any material respect;
- to add to, delete from, or revise the conditions, limitations, and restrictions on the authorized amount, terms, or purposes of issue, authentication, and delivery of securities under the indenture;
- to add any additional events of default with respect to all or any series of debt securities;
- to supplement any of the provisions of the indenture as may be necessary to permit or facilitate the defeasance and discharge of any series of debt securities, provided that such action does not adversely affect the interests of any holder of an outstanding debt security of such series or any other security in any material respect;
- to make provisions with respect to the conversion or exchange rights of holders of debt securities of any series;

- to pledge to the trustee as security for the debt securities of any series any property or assets;
- to add guarantees in respect of the debt securities of one or more series;
- to change or eliminate any of the provisions of the indenture, provided that any such change or elimination becomes effective only when there is no security of any series outstanding created prior to the execution of such supplemental indenture that is entitled to the benefit of such provision;
- to provide for certificated securities in addition to or in place of global securities;
- to qualify such indenture under the Trust Indenture Act;
- with respect to the debt securities of any series, to conform the text of the indenture or the debt securities of such series to any provision of the description thereof in our offering memorandum or prospectus relating to the initial offering of such debt securities, to the extent that such provision, in our good faith judgment, was intended to be a verbatim recitation of a provision of the indenture or such securities; or
- to make any other change that does not adversely affect the rights of holders of any series of debt securities issued thereunder in any material respect.

In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the debenture trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series (or, at a meeting of holders of such series at which a quorum is present, the holders of a majority in principal amount of the debt securities of such series represented at such meeting) that is affected. However, the debenture trustee and we may make the following changes only with the consent of each holder of any outstanding debt security affected:

- extending the fixed maturity of the series of debt securities;
- reducing the principal amount, reducing the rate of, or extending the time of payment of interest, or any premium payable upon the redemption of any debt securities;
- reducing the principal amount of discount securities payable upon acceleration of maturity;
- making the principal of or premium or interest on any debt security payable in currency other than that stated in the debt security;
- impair the right to institute suit for the enforcement of any payment on any debt security when due;
- if applicable, adversely affect the right of a holder to confer or exchange a debt security; or
- reducing the percentage of debt securities, the holders of which are required to consent to any amendment or waiver.

Except for certain specified provisions, the holders of at least a majority in principal amount of the outstanding debt securities of any series (or, at a meeting of holders of such series at which a quorum is present, the holders of a majority in principal amount of the debt securities of such series represented at such meeting) may on behalf of the holders of all debt securities of that series waive our compliance with provisions of the indenture. The holders of a majority in principal amount of the outstanding debt securities of any series may, on behalf of the holders of all the debt securities of such series, waive any past default under the indenture with respect to that series and its consequences, except a default in the payment of the principal of, premium, or any interest on any debt security of that series or in respect of a covenant or provision, which cannot be modified or amended without the consent of the holder of each outstanding debt security of the series affected; *provided, however*, that the holders of a majority in principal amount of the outstanding debt securities of any series may rescind an acceleration and its consequences, including any related payment default that resulted from the acceleration.

Discharge, Defeasance, and Covenant Defeasance

We can discharge or decrease our obligations under the indenture as stated below.

We may discharge obligations to holders of any series of debt securities that have not already been delivered to the trustee for cancellation and that have either become due and payable or are by their terms to become due and payable, or are scheduled for redemption, within one year. We may effect a discharge by irrevocably depositing with the trustee cash or government obligations, as trust funds, in an amount certified to be enough to pay, when due, whether at maturity, upon redemption or otherwise, the principal of, and any premium and interest on, the debt securities and any mandatory sinking fund payments.

Unless otherwise provided in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, we may also discharge any and all of our obligations to holders of any series of debt securities at any time, which we refer to as defeasance. We may also be released from the obligations imposed by any covenants of any outstanding series of debt securities and provisions of the indenture, and we may omit to comply with those covenants without creating an event of default under the trust declaration, which we refer to as covenant defeasance. We may effect defeasance and covenant defeasance only if, among other things:

- we irrevocably deposit with the trustee cash or government obligations denominated in the currency of the debt securities, as trust funds, in an amount certified to be enough to pay at maturity, or upon redemption, the principal (including any mandatory sinking fund payments) of, and any premium and interest on, all outstanding debt securities of the series; and
- we deliver to the trustee an opinion of counsel from a nationally recognized law firm to the effect that the holders of the series of debt securities will not recognize income, gain or loss for U.S. federal income tax purposes as a result of the defeasance or covenant defeasance and that defeasance or covenant defeasance will not otherwise alter the holders' U.S. federal income tax treatment of principal, and any premium and interest payments on, the series of debt securities.

In the case of a defeasance by us, the opinion we deliver must be based on a ruling of the Internal Revenue Service issued, or a change in U.S. federal income tax law occurring, after the date of the indenture, since such a result would not occur under the U.S. federal income tax laws in effect on that date.

Although we may discharge or decrease our obligations under the indenture as described in the two preceding paragraphs, we may not avoid, among other things, our duty to register the transfer or exchange of any series of debt securities, to replace any temporary, mutilated, destroyed, lost, or stolen series of debt securities or to maintain an office or agency in respect of any series of debt securities.

Registered Global Securities and Book Entry System

The debt securities of a series may be issued in whole or in part in book-entry form and will be represented by one or more fully registered global securities. We will deposit any registered global securities with a depository or with a nominee for a depository identified in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials and registered in the name of such depository or nominee. In such case, we will issue one or more

registered global securities denominated in an amount equal to the aggregate principal amount of all of the debt securities of the series to be issued and represented by such registered global security or securities. This means that we will not issue certificates to each holder.

Unless and until it is exchanged in whole or in part for debt securities in definitive registered form, a registered global security may not be transferred except as a whole:

- by the depository for the registered global security to its nominee;
- by a nominee of the depository to the depository or another nominee of the depository; or
- by the depository or its nominee to a successor of the depository or a nominee of the successor.

The prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, relating to a series of debt securities will describe the specific terms of the depository arrangement involving any portion of the series represented by a registered global security. We anticipate that the following provisions will apply to all depository arrangements for debt securities:

- ownership of beneficial interests in a registered global security will be limited to persons that have accounts with the depository for such registered global security, these persons being referred to as “participants,” or persons that may hold interests through participants;
- upon the issuance of a registered global security, the depository for the registered global security will credit, on its book-entry registration and transfer system, the participants’ accounts with the respective principal amounts of the debt securities represented by the registered global security beneficially owned by the participants;
- any dealers, underwriters, or agents participating in the distribution of the debt securities will designate the accounts to be credited; and
- ownership of beneficial interest in the registered global security will be shown on, and the transfer of the ownership interest will be effected only through, records maintained by the depository for the registered global security for interests of participants, and on the records of participants for interests of persons holding through participants.

The laws of some states may require that specified purchasers of securities take physical delivery of the securities in definitive form. These laws may limit the ability of those persons to own, transfer, or pledge beneficial interests in registered global securities.

So long as the depository for a registered global security, or its nominee, is the registered owner of the registered global security, the depository or such nominee, as the case may be, will be considered the sole owner or holder of the debt securities represented by the registered global security for all purposes under the indenture. Except as stated below, owners of beneficial interests in a registered global security:

- will not be entitled to have the debt securities represented by a registered global security registered in their names;
- will not receive or be entitled to receive physical delivery of the debt securities in the definitive form; and
- will not be considered the owners or holders of the debt securities under the relevant indenture.

Accordingly, each person owning a beneficial interest in a registered global security must rely on the procedures of the depository for the registered global security and, if the person is not a participant, on the procedures of a participant through which the person owns its interest, to exercise any rights of a holder under the indenture.

We understand that, under existing industry practices, if we request any action of holders or if an owner of a beneficial interest in a registered global security desires to give or take any action that a holder is entitled to give or take under the indenture, the depository for the registered global security would authorize the participants holding the relevant beneficial interests to give or take the action, and the participants would authorize beneficial owners owning through the participants to give or take the action or would otherwise act upon the instructions of beneficial owners holding through them.

We will make payments of principal and premium, if any, and interest, if any, on debt securities represented by a registered global security registered in the name of a depository or its nominee to the depository or its nominee, as the case may be, as the registered owners of the registered global security. Neither we nor the trustee, or any other agent of ours or the trustee will be responsible or liable for any aspect of the records relating to, or payments made on account of, beneficial ownership interests in the registered global security or for maintaining, supervising, or reviewing any records relating to the beneficial ownership interests.

We expect that the depository for any debt securities represented by a registered global security, upon receipt of any payments of principal and premium, if any, and interest, if any, in respect of the registered global security, will immediately credit participants’ accounts with payments in amounts proportionate to their respective beneficial interests in the registered global security as shown on the records of the depository. We also expect that standing customer instructions and customary practices will govern payments by participants to owners of beneficial interests in the registered global security held through the participants, as is now the case with the securities held for the accounts of customers in bearer form or registered in “street name.” We also expect that any of these payments will be the responsibility of the participants.

If the depository for any debt securities represented by a registered global security is at any time unwilling or unable to continue as depository or stops being a clearing agency registered under the Exchange Act, we will appoint an eligible successor depository. If we fail to appoint an eligible successor depository within 90 days, we will issue the debt securities in definitive form in exchange for the registered global security. In addition, we may at any time and in our sole discretion decide not to have any of the debt securities of a series represented by one or more registered global securities. In that event, we will issue debt securities of the series in a definitive form in exchange for all of the registered global securities representing the debt securities. The trustee will register any debt securities issued in definitive form in exchange for a registered global security in the name or names as the depository, based upon instructions from its participants, shall instruct the trustee.

Information Concerning the Debenture Trustee

The debenture trustee, other than during the occurrence and continuance of an event of default under the applicable indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the debenture trustee under such indenture must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the debenture trustee is under no obligation to exercise any of the powers given it by the indentures at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses, and liabilities that it might incur.

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering

materials, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless we otherwise indicate in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, we will make interest payments by check which we will mail to the holder. Unless we otherwise indicate in a prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, we will designate the corporate trust office of the debenture trustee as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the debenture trustee for the payment of the principal of or any premium or interest on any debt securities which remains unclaimed at the end of two years after such principal, premium, or interest has become due and payable will be repaid to us, and the holder of the security thereafter may look only to us for payment thereof.

Governing Law

The indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act is applicable.

Subordination of Subordinated Debt Securities

Our obligations pursuant to any subordinated debt securities will be unsecured and will be subordinate and junior in priority of payment to certain of our other indebtedness to the extent described in a prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable.

Outstanding Debt Securities

As of April 8, 2024, we had the following debt securities outstanding:

- [Form of Fourth Amendment to Secured Revolving Line of Credit Promissory Note, amendment dated February 7, 2024, issued to Isaac Capital Group LLC \[filed as Exhibit 10.101 to the Company's Form 10-K filed April 8, 2024 \(File No. 0-19621\) and incorporated herein by reference\].](#)
- [Form of First Amendment to Promissory Note in favor of Live Ventures Incorporated, dated February 7, 2024 \[filed as Exhibit 10.102 to the Company's Form 10-K filed April 8, 2024 \(File No. 0-19621\) and incorporated herein by reference\].](#)
- [Form of Promissory Note in favor of Isaac Capital Group LLC, dated February 7, 2024 \[filed as Exhibit 10.103 to the Company's Form 10-K filed April 8, 2024 \(File No. 0-19621\) and incorporated herein by reference\].](#)
- [Form of Promissory Note in favor of Live Ventures Incorporated, dated February 7, 2024 \[filed as Exhibit 10.104 to the Company's Form 10-K filed April 8, 2024 \(File No. 0-19621\) and incorporated herein by reference\].](#)
- [Form of Promissory Note in favor of Jon Isaac, dated March 4, 2024 \[filed as Exhibit 10.106 to the Company's Form 10-K filed April 8, 2024 \(File No. 0-19621\) and incorporated herein by reference\].](#)

DESCRIPTION OF WARRANTS

General

We may issue warrants to purchase debt securities, shares of our Common Stock, shares of our Preferred Stock, or any combination of these securities. We may issue the warrants independently or together with any underlying securities, and the warrants may be attached or separate from the underlying securities. We may also issue a series of warrants under a separate warrant agreement to be entered into between a warrant agent and us. The warrant agent will act solely as our agent in connection with the warrants of such series and will not assume any obligation or relationship of agency for or with holders or beneficial owners of warrants.

The following description is a summary of selected provisions relating to the warrants that we may issue. The summary is not complete. When warrants are offered in the future, a prospectus supplement, information, or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, will explain the particular terms of those securities and the extent to which these general provisions may apply. The specific terms of the warrants as described in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials will supplement and, if applicable, may modify or replace the general terms described in this section.

This summary and any description of warrants in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials is subject to and is qualified in its entirety by reference to all the provisions of any specific warrant document or agreement, which we will file with the SEC for incorporation by reference into this prospectus. See "Available Information" and "Incorporation of Certain Information by Reference" for information on how to obtain a copy of a warrant document when it is filed.

When we refer to a series of warrants, we mean all warrants issued as part of the same series under the applicable warrant agreement.

Terms

The applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials may describe the terms of any warrants that we may offer, including but not limited to the following:

- the title of the warrants;
- the total number of warrants;
- the price or prices at which the warrants will be issued;
- the currency or currencies that investors may use to pay for the warrants;
- the date on which the right to exercise the warrants will commence and the date on which the right will expire;
- whether the warrants will be issued in registered form or bearer form;
- information with respect to book-entry procedures, if any;

- if applicable, the minimum or maximum amount of warrants that may be exercised at any one time;
- if applicable, the designation and terms of the underlying securities with which the warrants are issued and the number of warrants issued with each underlying security;
- if applicable, the date on and after which the warrants and the related underlying securities will be separately transferable;
- if applicable, a discussion of material United States federal income tax considerations;
- if applicable, the terms of redemption of the warrants;
- the identity of the warrant agent, if any;
- the procedures and conditions relating to the exercise of the warrants; and
- any other terms of the warrants, including terms, procedures, and limitations relating to the exchange and exercise of the warrants.

Warrant Agreements

We may issue the warrants in one or more series under one or more warrant agreements, each to be entered into between a bank, trust company, or other financial institution as warrant agent, and us. We may add, replace, or terminate warrant agents from time to time. We may also choose to act as our own warrant agent or may choose one of our subsidiaries to do so.

The warrant agent under a warrant agreement will act solely as our agent in connection with the warrants issued under that agreement. The warrant agent will not assume any obligation or relationship of agency or trust for or with any holders of those warrants. Any holder of warrants may, without the consent of any other person, enforce by appropriate legal action, on its own behalf, its right to exercise those warrants in accordance with their terms. Until the warrant is properly exercised, no holder of any warrant will be entitled to any rights of a holder of the warrant property purchasable upon exercise of the warrant.

Form, Exchange, and Transfer

We may issue the warrants in registered form or bearer form. Warrants issued in registered form, *i.e.*, book-entry form, will be represented by a global security registered in the name of a depository, which will be the holder of all the warrants represented by the global security. Those investors who own beneficial interests in a global warrant will do so through participants in the depository's system, and the rights of these indirect owners will be governed solely by the applicable procedures of the depository and its participants. In addition, we may issue warrants in non-global form, *i.e.*, bearer form. If any warrants are issued in non-global form, warrant certificates may be exchanged for new warrant certificates of different denominations, and holders may exchange, transfer, or exercise their warrants at the warrant agent's office or any other office indicated in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials.

Prior to the exercise of their warrants, holders of warrants exercisable for debt securities will not have any of the rights of holders of the debt securities purchasable upon such exercise and will not be entitled to payments of principal (or premium, if any) or interest, if any, on the debt securities purchasable upon such exercise. Prior to the exercise of their warrants, holders of warrants exercisable for shares of Common Stock or shares of Preferred Stock will not have any rights of holders of the shares of Common Stock or the shares of Preferred Stock purchasable upon such exercise and will not be entitled to dividend payments, if any, or voting rights of the shares of Common Stock or the shares of Preferred Stock purchasable upon such exercise.

Exercise of Warrants

A warrant will entitle the holder to purchase for cash an amount of securities at an exercise price that will be stated in, or that will be determinable as described in, the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials. Warrants may be exercised at any time from the initial exercise date and time through and including the close of business on the expiration date set forth in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials. After the close of business on the expiration date, unexercised warrants will become void. Warrants may be redeemed as set forth in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials.

Warrants may be exercised as set forth in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials. Upon receipt of payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, we will forward, as soon as practicable, the securities purchasable upon such exercise. If less than all of the warrants represented by such warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

DESCRIPTION OF RIGHTS

We may issue rights to purchase our debt securities, shares of our Common Stock, or shares of our Preferred Stock. These rights may be issued independently or together with any other security offered hereby and may or may not be transferable by the stockholder receiving the rights in such offering. In connection with any offering of such rights, we may enter into a standby arrangement with one or more underwriters or other purchasers pursuant to which the underwriters or other purchasers may be required to purchase any securities remaining unsubscribed for after such offering.

Each series of rights will be issued under a separate rights agreement that we will enter with a bank or trust company, as rights agent, all of which will be set forth in the relevant offering material. The rights agent will act solely as our agent in connection with the certificates relating to the rights and will not assume any obligation or relationship of agency or trust with any holders of rights certificates or beneficial owners of rights.

The following description is a summary of selected provisions relating to rights that we may offer. The summary is not complete. When rights are offered in the future, a prospectus supplement, information, or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, will explain the particular terms of those securities and the extent to which these general provisions may apply. The specific terms of the rights as described in a prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, will supplement and, if applicable, may modify or replace the general terms described in this section.

This summary and any description of rights in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials is subject to and is qualified in its entirety by reference to the rights agreement and the rights certificates. We will file each of these documents, as applicable, with the SEC and incorporate them by reference as an exhibit to the Registration Statement of which this prospectus is a part on or before the time we issue a series of rights. See "Available Information" and "Incorporation of Certain Documents by Reference" above for information on how to obtain a copy of a document when it is filed.

The applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials may describe:

- in the case of a distribution of rights to our stockholders, the date of determining the stockholders entitled to the rights distribution;
- in the case of a distribution of rights to our stockholders, the number of rights issued or to be issued to each stockholder;
- the exercise price payable for the underlying debt securities, shares of our Common Stock or shares of our Preferred Stock upon the exercise of the rights;
- the number and terms of the underlying debt securities, shares of our Common Stock or shares of our Preferred Stock that may be purchased per each right;
- the extent to which the rights are transferable;
- the date on which the holder’s ability to exercise the rights shall commence, and the date on which the rights shall expire;
- the extent to which the rights may include an over-subscription privilege with respect to unsubscribed securities;
- if applicable, the material terms of any standby underwriting or purchase arrangement entered into by us in connection with the offering of such rights; and
- any other terms of the rights, including, but not limited to, the terms, procedures, conditions, and limitations relating to the exchange and exercise of the rights.

The provisions described in this section, as well as those described under “—Description of Debt Securities” and “—Description of Capital Stock” above, will apply, as applicable, to any rights we offer.

DESCRIPTION OF UNITS

General

We may issue units composed of (i) our debt securities, (ii) shares of our Common Stock, (iii) shares of our Preferred Stock, (iv) warrants to purchase our debt securities, shares of our Common Stock, or shares of our Preferred Stock or any combination of these securities, and (v) rights to purchase our debt securities, shares of our Common Stock, or shares of our Preferred Stock in any combination. We will issue each unit so that the holder of the unit is also the holder of each security included in the unit. As a result, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

The following description is a summary of selected provisions relating to units that we may offer. The summary is not complete. When units are offered in the future, a prospectus supplement, information, or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, will explain the particular terms of those securities and the extent to which these general provisions may apply. The specific terms of the units as described in a prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, will supplement and, if applicable, may modify or replace the general terms described in this section.

This summary and any description of units in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials is subject to and is qualified in its entirety by reference to the unit agreement, collateral arrangements, and depositary arrangements, if applicable. We will file these documents with the SEC for incorporation by reference into this prospectus, as applicable. See “Available Information” and “Incorporation of Certain Information by Reference” for information on how to obtain a copy of a document when it is filed.

The applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials may describe:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions for the issuance, payment, settlement, transfer, or exchange of the units or of the securities composing the units;
- whether the units will be issued in fully registered or global form; and
- any other terms of the units.

The applicable provisions described in this section, as well as those described under “Description of Debt Securities,” “Description of Capital Stock” and “Description of Warrants,” will apply to each unit and to each security included in each unit, respectively.

USE OF PROCEEDS

Unless otherwise indicated in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, we intend to use the net proceeds from the sale of securities for general corporate purposes, which may include capital expenditures, working capital and general and administrative expenses.

PLAN OF DISTRIBUTION

We may sell the securities through underwriters or dealers, through agents, directly to one or more purchasers, through a rights offering, or otherwise. We will describe the terms of the offering of the securities in a prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, including:

- the name or names of any underwriters, if any;
- the purchase price of the securities and the proceeds we will receive from the sale;
- any underwriting discounts and other items constituting underwriters’ compensation;
- any public offering price;
- any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

Only underwriters we name in the prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as

The distribution of securities may be effected, from time to time, in one or more transactions, including:

- block transactions (which may involve crosses) and transactions on The Nasdaq Capital Market or any other organized market on which the securities may be traded;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its own account pursuant to a prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable;
- ordinary brokerage transactions and transactions in which a broker-dealer solicits purchasers;
- sales “at the market” to or through a market maker or into an existing trading market, on an exchange or otherwise; and
- sales in other ways not involving market makers or established trading markets, including direct sales to purchasers.

The securities may be sold at a fixed price or prices, which may be changed, or at market prices prevailing at the time of sale, at prices relating to the prevailing market prices, or at negotiated prices. The consideration may be cash or another form negotiated by the parties. Agents, underwriters, or broker-dealers may be paid compensation for offering and selling the securities. That compensation may be in the form of discounts, concessions, or commissions to be received from us or from the purchasers of the securities. Dealers and agents participating in the distribution of the securities may be deemed to be underwriters and compensation received by them on resale of the securities may be deemed to be underwriting discounts and commissions under the Securities Act. If such dealers or agents were deemed to be underwriters, they may be subject to statutory liabilities under the Securities Act.

We may also make direct sales through subscription rights distributed to our existing stockholders on a pro rata basis, which may or may not be transferable. In any distribution of subscription rights to our stockholders, if all of the underlying securities are not subscribed for, we may then sell the unsubscribed securities directly to third parties or may engage the services of one or more underwriters, dealers, or agents, including standby underwriters, to sell the unsubscribed securities to third parties.

Some or all of the securities that we offer through this prospectus may be new issues of securities with no established trading market. Any underwriters to whom we sell our securities for public offering and sale may make a market in those securities, but they will not be obligated to do so and they may discontinue any market making at any time without notice. Accordingly, we cannot assure you of the liquidity of, or continued trading markets for, any securities that we offer.

Agents may, from time to time, solicit offers to purchase the securities. If required, we will name in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus or other offering materials, as applicable, any agent involved in the offer or sale of the securities and set forth any compensation payable to the agent. Unless otherwise indicated, any agent will be acting on a best efforts basis for the period of its appointment. Any agent selling the securities covered by this prospectus may be deemed to be an underwriter, as that term is defined in the Securities Act, of the securities.

If underwriters are used in an offering, securities will be acquired by the underwriters for their own account and may be resold, from time to time, in one or more transactions, including negotiated transactions, at a fixed public offering price, or at varying prices determined at the time of sale, or under delayed delivery contracts or other contractual commitments. Securities may be offered to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. If an underwriter or underwriters are used in the sale of securities, an underwriting agreement will be executed with the underwriter or underwriters at the time an agreement for the sale is reached. The applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials will set forth the managing underwriter or underwriters, as well as any other underwriter or underwriters, with respect to a particular underwritten offering of securities, and will set forth the terms of the transactions, including compensation of the underwriters and dealers and the public offering price, if applicable. The prospectus, and the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials will be used by the underwriters to resell the securities.

If a dealer is used in the sale of the securities, we or an underwriter will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. To the extent required, we will set forth in the prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, the name of the dealer and the terms of the transactions.

We may directly solicit offers to purchase the securities and may make sales of securities directly to institutional investors or others. These persons may be deemed to be underwriters within the meaning of the Securities Act with respect to any resale of the securities. To the extent required, the prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, will describe the terms of any such sales, including the terms of any bidding or auction process, if used.

Agents, underwriters, and dealers may be entitled under agreements that may be entered into with us to indemnification against specified liabilities, including liabilities incurred under the Securities Act, or to contribution to payments they may be required to make in respect of such liabilities. If required, the prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials, as applicable, will describe the terms and conditions of such indemnification or contribution. Some of the agents, underwriters or dealers, or their affiliates may be customers of, engage in transactions with or perform services for us, our subsidiaries, or affiliates in the ordinary course of business.

Under the securities laws of some states, the securities offered by this prospectus may be sold in those states only through registered or licensed brokers or dealers.

Any person participating in the distribution of Common Stock registered under the Registration Statement that includes this prospectus will be subject to applicable provisions of the Exchange Act, and the applicable SEC rules and regulations, including, among others, Regulation M, which may limit the timing of purchases and sales of any of our Common Stock by any such person. Furthermore, Regulation M may restrict the ability of any person engaged in the distribution of our Common Stock to engage in market-making activities with respect to our Common Stock. These restrictions may affect the marketability of our Common Stock and the ability of any person or entity to engage in market-making activities with respect to our Common Stock.

Certain persons participating in an offering may engage in over-allotment, stabilizing transactions, short-covering transactions, and penalty bids in accordance with Regulation M under the Exchange Act that stabilize, maintain, or otherwise affect the price of the offered securities. If any such activities occur, they will be described in the applicable prospectus supplement, information or document incorporated by reference, related free writing prospectus, or other offering materials.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution.

All securities we offer other than shares of Common Stock will be new issues of securities with no established trading market. Any underwriters may make a market in these securities but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, Clark Hill PLC, Los Angeles, California, will provide opinions regarding the validity of any securities offered by this prospectus. Clark Hill PLC may also provide opinions regarding certain other matters. The legality of the securities for any underwriters, dealers, or agents will be passed upon by counsel as may be specified in the applicable prospectus supplement.

EXPERTS

The financial statements of the Registrant as of and for the year ended December 30, 2023, incorporated by reference in this prospectus, have been audited by Hudgens, LLC, an independent registered public accounting firm, as stated in its report incorporated by reference herein, and have been incorporated in reliance upon the authority of such firm as experts in accounting and auditing. This report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

The consolidated financial statements of the Registrant as of and for the year ended December 31, 2022, incorporated by reference in this prospectus, have been audited by Frazier & Deeter, LLC, an independent registered public accounting firm, as stated in their report. Such consolidated financial statements are incorporated by reference herein, and have been incorporated in reliance upon the firm given their authority as experts in accounting and auditing. This report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.



Up to \$5,000,000

Common Stock

PROSPECTUS SUPPLEMENT

H.C. Wainwright & Co.

The date of this prospectus supplement is June 21, 2024.
