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

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **January 25, 2019**

CARDAX, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

333-181719

(Commission
File Number)

45-4484428

(IRS Employer
Identification No.)

2800 Woodlawn Drive, Suite 129, Honolulu, Hawaii 96822

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(808) 457-1400**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a -12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d -2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e -4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 7.01 REGULATION FD DISCLOSURE.

On January 25, 2019, Cardax, Inc. (the “Company”), issued a 2019 summary and update that provides certain information about its strategy and platform.

In accordance with General Instruction B.2 of Form 8-K, the information set forth herein and in Exhibit 99.1 hereto is deemed to be “furnished” and shall not be deemed to be “filed” for purposes of the Exchange Act. The information set forth in Item 7.01 of this Current Report on Form 8-K shall not be deemed an admission as to the materiality of any information in this Current Report on Form 8-K that is required to be disclosed solely to satisfy the requirements of Regulation FD.

Safe Harbor

This release may contain certain forward-looking statements regarding our prospective performance and strategies within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995, and are including this statement for purposes of said safe harbor provisions. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, and expectations of our company, are generally identified by use of words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “project,” “seek,” “strive,” “try,” or future or conditional verbs such as “could,” “may,” “should,” “will,” “would,” or similar expressions. Our ability to predict results or the actual effects of our plans or strategies is inherently uncertain. Accordingly, actual results may differ materially from anticipated results. Some of the factors that could cause our actual results to differ from our expectations or beliefs include, without limitation, the risks discussed from time to time in our filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Except as required by applicable law or regulation, we undertake no obligation to update these forward-looking statements to reflect events or circumstances that occur after the date on which such statements were made.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
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99.1	<u>2019 Summary and Update, dated January 25, 2019 (furnished herewith)</u>
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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: January 25, 2019

CARDAX, INC.

By: /s/ David G. Watumull

David G. Watumull

Chief Executive Officer and President



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2019 SUMMARY AND UPDATE

January 2019

CERTAIN DISCLAIMERS

There are statements in this presentation that are not historical facts. These “forward-looking statements” can be identified by use of terminology such as “anticipate,” “believe,” “estimate,” “expect,” “hope,” “intend,” “may,” “plan,” “positioned,” “project,” “propose,” “should,” “strategy,” “will,” “would,” or any similar expressions. You should be aware that these forward-looking statements are subject to risks and uncertainties that are beyond our control. For a discussion of these risks and their potential impact to the information provided in this presentation, you should read the information that we have filed with the Securities and Exchange Commission, including the reports filed pursuant to the Securities Exchange Act of 1934, as amended, especially the risks discussed under the section entitled “Risk Factors” included in such reports. In light of these numerous risks and uncertainties, we cannot provide any assurance that the results and events contemplated by our forward-looking statements contained in this presentation will in fact transpire. You are cautioned to not place undue reliance on these forward-looking statements, which speak only as of their dates. We do not undertake any obligation to update or revise any forward-looking statements.

Unless otherwise indicated, information contained in this presentation concerning our company, our business, the services we provide and intend to provide, our industry and our general expectations concerning our industry are based on management estimates. Such estimates are derived from publicly available information released by third party sources, as well as data from our internal research, and reflect assumptions made by us based on such data and our knowledge of the industry, which we believe to be reasonable. However, we cannot provide any assurance that these assumptions or estimates will be accurate or events that we expect will in fact transpire.

Various third-party brands and logos depicted in this presentation are registered and common law trademarks of their respective owners and are used solely for illustrative and comparative purposes. The Company and its products have not been approved, sponsored, or endorsed by these entities, with which the Company has no affiliation, relationship, or arrangement. Quotes used in this presentation by unaffiliated persons do not indicate any endorsement or recommendation by any such person.

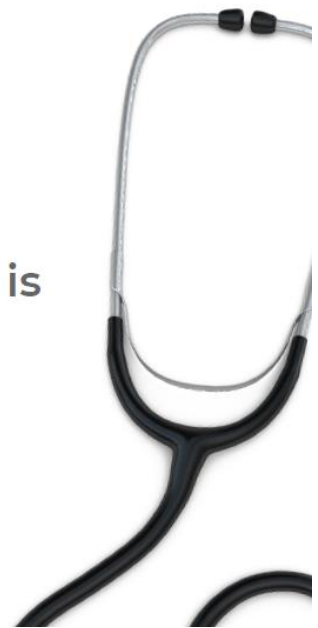
No securities are being offered by Cardax through this presentation. If you would like additional information, please contact Cardax.

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



PHYSICIANS AGREE:

The key to health and longevity is
INFLAMMATORY HEALTH



Why not manage inflammatory health with other leading anti-inflammatories?



Because of the risk of dangerous

SIDE EFFECTS

associated with chronic use



Because of the risk of dangerous

SIDE EFFECTS

associated with chronic use

HEART
ATTACKS

GI BLEEDS

STROKES

LIVER
DAMAGE

IMMUNE
COMPROMISE

and more...

There's NO anti-inflammatory that's safe for
CHRONIC USE

UNTIL NOW



CARDAX HIGHLIGHTS

- Cardax is a public company (OTCQB:CDXI)
 - We were founded in 2006 in Honolulu, Hawaii
 - We are a biopharmaceutical company uniquely focused on xanthophyll carotenoids: powerful antioxidant and anti-inflammatory agents — without the toxicity issues of other products
 - We have invested over \$40 million on research and product development of new chemical entities and applications related to xanthophyll carotenoids
 - In late 2016 we introduced our first commercial product, ZanthoSyn® (astaxanthin) capsules, into the nutritional market with impressive revenue growth and penetration
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OUR STRATEGY

To be the world leaders in
pharmaceutical and
nutritional applications of
xanthophyll carotenoids

- Focus on health applications of nature-identical synthetic xanthophyll carotenoids
 - Leverage our platform for commercial success
 - Previous safety and human POC studies with the active ingredient of CDX-101, our lead pharmaceutical candidate, may allow us to move directly into Phase III if permitted by the FDA
 - Final CMC development for CDX-101 is underway
 - CDX-101's active ingredient reduced important cardiovascular risk factors of inflammation (CRP) and triglycerides in human POC studies and animal models
 - CDX-101 also has potential in the treatment of arthritis and liver disease
 - We filed a request for orphan drug designation with the US FDA for CDX-301, our lead orphan drug candidate
 - We launched a nutritional brand to generate cash flow to fund continued pharmaceutical development
-

OUR MANAGEMENT TEAM

- **David G. Watumull** – *Chief Executive Officer and President*
Co-founder and co-inventor of our products.
 - **Dr. Gilbert Rishton** – *Chief Science Officer*
Formerly with Amgen's drug discovery group for Sensipar.
 - **David M. Watumull** – *Chief Operating Officer*
18 years of experience in xanthophyll carotenoid product development and commercialization.
 - **Dr. Timothy King** – *Vice President, Research*
Formerly with Fred Hutchinson Cancer Research Center and has over 20 years of experience with xanthophyll carotenoid applications in medicine.
 - **Randall Mau** – *Vice President, Medical & Business Relations*
Formerly with Pfizer's sales and marketing team for 18 years.
 - **Gilbert Shin** – *Vice President, Retail Sales & Marketing*
Formerly with GNC for 20 years, ending as a regional sales director.
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OUR BOARD OF DIRECTORS & CHIEF ADVISORS



- **George W. Bickerstaff** – *Chairman*
Former Chief Financial Officer of Novartis Pharma.
 - **David G. Watumull** – *Director*
Chief Executive Officer and President of Cardax.
 - **Dr. Terence A. Kelly** – *Director*
Former research executive with Boehringer Ingelheim.
 - **Michele Galen** – *Director*
Former communications executive with Shire and Novartis.
 - **Dr. Makarand Jawadekar** – *Director*
Former research executive with Pfizer.
 - **Elona Kogan** – *Director*
Biotech business executive most recently at Ariad Pharma.
 - **Dr. Deepak Bhatt** – *SAB Chairman*
Harvard Medical School / BWH. PI of REDUCE-IT clinical trial.
 - **Dr. Fred D. Sancilio** – *Senior Advisor*
40 years of drug development experience.
 - **Dr. Paresh Soni** – *Senior Advisor*
Former Amarin head of development.
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CARDAX PLATFORM

- **CDX-101 (*astaxanthin Rx*)**: targets systemic inflammation at source; pre-clinical studies indicate efficacy in treating cardiovascular risk factors including inflammation and triglycerides; positioned to move directly into Phase III following CMC
 - **CDX-301 (*zeaxanthin Rx*)**: protects retina against blue light and oxidative damage; currently awaiting orphan drug designation from the US FDA as treatment for Stargardt Disease in children
 - **ZanthoSyn® (*astaxanthin supplement*)**: commercial nutritional product for inflammatory health; utilizes a proprietary delivery technology for astaxanthin that enhances bioavailability 2.85x versus other formulations
-

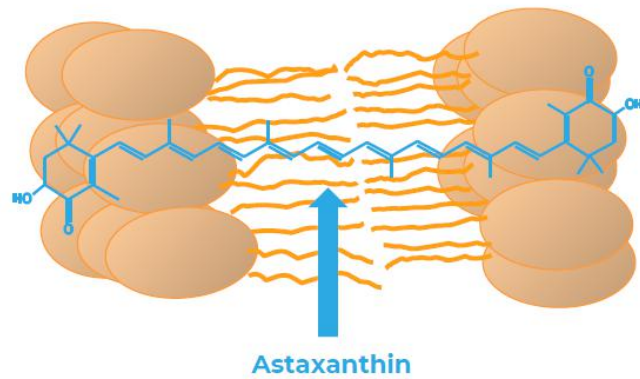
MECHANISM OF ACTION

Astaxanthin spans mitochondrial membrane

Reduces pathological activation of inflammatory pathways by modulating oxidative stress in mitochondria

Does not inhibit normal function

MITOCHONDRIAL HEALTH



Focusing on the source of inflammation

ANTI-INFLAMMATORY ACTIVITY

Astaxanthin acts upon the molecular targets of existing anti-inflammatories:

- Anti-IL-1 β (Ilaris)
- COX-2 (Celebrex)
- PGE2 (aspirin)
- TNF- α (Humira, Remicade, Enbrel)
- NF-k β (steroids)

HUMAN STUDIES

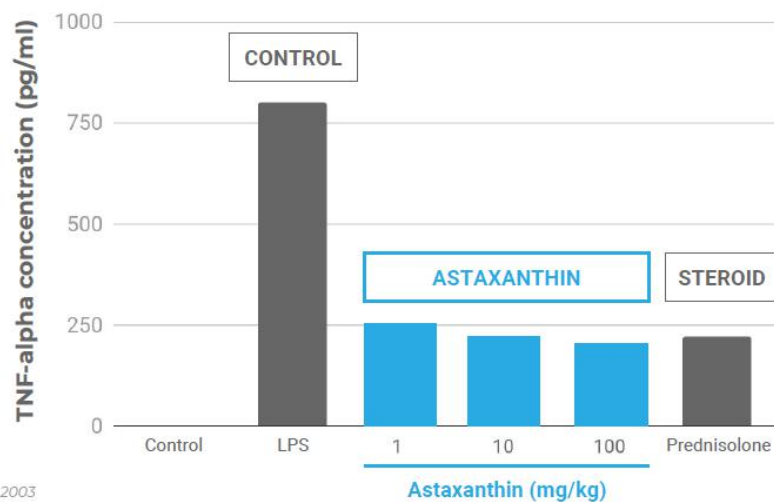
- **TNF- α** significantly reduced (-30%, p=0.0022)
- **CRP** significantly reduced (-20%, p<0.05, two studies)
- **Oxidative stress** significantly reduced (MDA, IsoP, SOD, TAC increased)

ANIMAL STUDIES

- Inflammatory markers reduced in various model systems
 - **TNF- α , IL-1 β , IL-6, CRP, NF-k β , PGE-2, iNOS, MCP-1, ERK, JNK, COX-2**
 - **TNF- α** reduced equivalent to equal dose of prednisolone
- Pathway inhibition (**NF-k β**) and activation (**PI3K/AKT, adiponectin**)
- **Oxidative stress** reduced in mitochondria

REDUCTION OF TNF- α IN INFLAMMATORY ANIMAL MODEL = TO PREDNISOLONE

Effect of astaxanthin on TNF- α concentrations in the aqueous humor. The aqueous humor was collected 24 hours after LPS treatment. Each value represents the mean \pm SD (n=8). The dose of prednisolone was 10 mg/kg. p<0.01, compared with the LPS group.



Ohgami et al. Ophth. Invest. Vis. Sci. 44(6):2694-2701, 2003

PRE-CLINICAL RESULTS

With earlier generation of CDX-101
(same active ingredient)

- **Reduced re-thrombosis** by 84% in a canine model of myocardial infarction
 - **Reduced triglycerides** by 72% in ApoE(-/-) mice and lower total cholesterol and aortic arch atherosclerosis in LDLR(-/-) mice
 - **Reduced elevated liver enzymes** and attenuated pathohistological alterations in mice with alcohol-induced hepatic stress
 - **Increased FOXO3 gene expression** by 90% in mice. The protective FOXO3 allele (G allele) is associated with longevity.
-

CARDAX PLATFORM



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-

CDX-301

Macular Protection Against
Photo-Oxidative Damage

- **CDX-301 delivers zeaxanthin, a xanthophyll carotenoid found in the human macula**
 - **Indication: Stargardt Disease**
 - Genetic disease impacting the macula – primarily of children
 - Macular degeneration normally begins in childhood for those having this disease
 - Designated by FDA as an orphan disease (<200,000 patients) in the United States
 - Earlier generation of CDX-301 (same active ingredient) has shown potential effectiveness in the treatment of Stargardt Disease in pre-clinical studies
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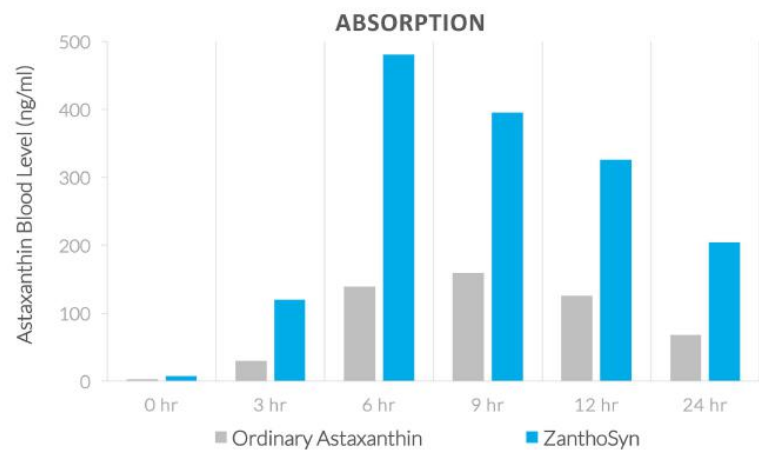
CARDAX PLATFORM

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-

ZANTHOSYN® ASTAXANTHIN ABSORPTION

- AUC: 2.85-fold greater
 - $p=0.013$
- C_{max} = 3.0-fold greater
 - $p=0.013$
- Coefficient of variation
 - ZanthoSyn = 27%
 - Ordinary asta = 62%
- T_{max} = 6 hours
- No adverse events

cardax



ZanthoSyn

SUPERIOR ABSORPTION

- 2.85x better absorption vs. ordinary astaxanthin

SUPERIOR PURITY

- Precision & purity (cGMP)
- No aftertaste or smell

SUPERIOR SAFETY

- Generally Recognized as Safe according to FDA regulations



ZANTHOSYN® REVENUE HISTORY

Year-Over-Year
Quarterly Growth



ZANTHOSYN® CLINICAL TRIAL (ongoing)

TARGETING CARDIOVASCULAR INFLAMMATORY HEALTH

- Supports sales & marketing
- Serves as POC for Rx
- Patent(s) pending

CHASE Trial

Cardiovascular Health: Astaxanthin Supplement Evaluation

- **Randomized, double-blind, placebo controlled, GCP**
- **Subjects:** Up to 360 (*largest astaxanthin trial ever reported*)
 - Cardiovascular risk factors
 - C-reactive protein (CRP) > 2 mg/L
 - Standard of care
- **Primary Endpoint:** Cardiovascular inflammatory health as measured by CRP (change from baseline)
- **Other Endpoints:** Triglycerides, LDL, HDL, inflammatory markers, FOXO3 (anti-aging gene)
- **Duration:** 12 weeks with optional 48 week open label extension
- **Top Tier Leaders:** Jon Ruckle, MD (PI of 350+ clinical trials); Deepak Bhatt, MD, PI of REDUCE-IT clinical trial with Amarin, head of interventional cardiology at BWH/Harvard Medical School

INTELLECTUAL PROPERTY

- **Cardax IP consists of 28 issued patents**
 - 14 patents issued in the United States
 - 14 patents issued in Europe, China, India, Japan, and Hong Kong
 - 3 patent applications pending in United States, Europe, and Brazil
 - **Cardax IP includes:**
 - **Issued composition of matter patents** covering thousands of xanthophyll carotenoid derivatives
 - **Issued use patents** covering hundreds of indications
 - **Additional patents pending**
-

MARKET OPPORTUNITY

*www.bizjournals.com/prnewswire/press_releases/2018/03/16/1041315



- **Global sales of drugs for inflammatory diseases exceed \$25 billion annually***
 - CDX-101 (astaxanthin Rx), our lead pharmaceutical candidate, may address CV risk factors such as CRP (a measure of inflammation) and elevated triglycerides
 - ZanthoSyn® (astaxanthin supplement), our OTC nutritional product, addresses inflammatory health without prescription
- **Stargardt Disease impacts approximately 40,000 patients in the United States**
 - CDX-301 (zeaxanthin Rx), our orphan drug candidate, has a market potential exceeding \$200 million annually
 - CDX-301 may be eligible for a Pediatric Review Voucher potentially worth in excess of \$100M upon FDA approval

IN SUMMARY

- Cardax is a public biopharmaceutical company with a unique platform of xanthophyll carotenoids targeting inflammation and oxidative stress without side effects
 - Robust IP, pre-clinical results, clinical data, and efficient development pathways support transformative market opportunities
 - Our short and mid-term goals: file INDs and then NDAs for two xanthophyll carotenoids
 - CDX-101 (astaxanthin Rx) for hypertriglyceridemia and then cardiovascular inflammation
 - CDX-301 (zeaxanthin Rx) for Stargardt Disease
 - Our model includes growing revenue from our nutritional brand, ZanthoSyn® (astaxanthin supplement)
-



THANK YOU
