
**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): **September 23, 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))
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ITEM 7.01 REGULATION FD DISCLOSURE

On September 23, 2019, Cardax, Inc. (the “Company”) issued a press release announcing the interim results of its human clinical trial with ZanthoSyn®, the Company’s astaxanthin dietary supplement.

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.

Forward-looking statements made also include, but are not limited to, statements regarding the development and potential applications of our products and product candidates, including our discussion of clinical trial interim results, which are not necessarily indicative of final results. The interim results described in this press release do not ensure that the final results of the CHASE clinical trial or other clinical trials will be positive or statistically significant or clinically meaningful. Our characterization of the CHASE clinical trial interim results in this press release as encouraging and promising and that pleiotropic effects, excellent safety, and beneficial changes in markers of cardiovascular health were demonstrated in such interim review are forward-looking statements and may not be replicated by the final results of the CHASE clinical trial or other clinical trials. The p-values reported herein are nominal p-values from non-parametric comparisons of the median between each group and placebo and no adjustments for multiple comparisons were made. There can be no assurance that we will successfully develop or commercialize our products or product candidates or that these interim results will adequately support additional intellectual property protection. In summary, our ability to predict results or the actual effects of our plans or strategies are inherently uncertain.

ITEM 9.01 FINANCIAL STATEMENT AND EXHIBITS

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated September 23, 2019 (furnished herewith)

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: September 23, 2019

CARDAX, INC.

By: /s/ David G. Watumull

David G. Watumull

Chief Executive Officer and President

Cardax Announces Interim Results from CHASE Clinical Trial

Pre-Specified Interim Review Demonstrated Beneficial Changes in Markers of Cardiovascular Health

- CRP, LDL, total cholesterol, triglycerides, oxidized LDL, and blood pressure reduced
- Interim results support excellent safety profile
- Enrollment continues

HONOLULU, Sept. 23, 2019 /PRNewswire/ — Cardax, Inc. (OTCQB:CDXI) today announced results from the pre-specified interim review of its ongoing CHASE (Cardiovascular Health Astaxanthin Supplement Evaluation) clinical trial.

The CHASE clinical trial is a double-blind, randomized, placebo-controlled clinical trial evaluating the effect of the Company's astaxanthin dietary supplement ZanthoSyn[®], on cardiovascular health, as measured by C-Reactive Protein or "CRP" levels over 12 weeks in up to 120 subjects with documented cardiovascular risk factors. Pre-specified secondary cardiovascular/inflammatory health markers, safety parameters, exploratory endpoints, and pre-specified sub-groups are also being assessed. The trial also includes an optional open-label extension through 48 weeks.

The interim results were based on data from 40 subjects administered high dose ZanthoSyn[®] (96 mg/day astaxanthin—48 mg twice a day), low dose ZanthoSyn[®] (24 mg/day astaxanthin—12 mg twice a day), or placebo. The Company believes these findings provide:

- Further mechanistic support for the Company's astaxanthin pharmaceutical development program
- Basis for additional patent filings
- Support for the cardiovascular health benefits of ZanthoSyn*

"We are encouraged by the pleiotropic effects and excellent safety demonstrated in this interim review," said Paresh Soni, M.D., Ph.D., the Company's Chief Clinical and Regulatory Strategist. "We are continuing enrollment and look forward to the final results."

Highlights from the interim review shown below are median percentage changes from baseline to week 12 unless otherwise stated. While the interim review was not powered for statistical significance, p-values less than 0.05 compared to placebo are provided.

- CRP: 28% decrease (high dose), 32% decrease (low dose), 5% decrease (placebo)
- Low-density lipoprotein cholesterol (LDL-C): 12% decrease (high dose), 7% decrease (low dose), 5% increase (placebo) (p<0.01 high dose)
- Total cholesterol: 8% decrease (high dose), 5% decrease (low dose), 4% increase (placebo) (p<0.05 high dose)
- Triglycerides: 16% decrease (high dose), 13% decrease (low dose), 6% increase (placebo)
- Oxidized LDL: 10% decrease (high dose), 3% increase (low dose), 4% increase (placebo) (p<0.05 high dose)
- Diastolic blood pressure: 5% decrease (high dose), 4% decrease (low dose), 6% increase (placebo) (p<0.05 high dose and p<0.05 low dose)
- Median astaxanthin blood levels at 12 weeks: 2,184 ng/mL (high dose), 790 ng/mL (low dose), below quantification limit of 10 ng/mL (placebo)

The interim results also underscore astaxanthin's safety profile with no safety signals observed. The CHASE Data Safety Review Board recommended that the clinical trial continue enrollment.

"These cardiovascular health findings are promising and we are grateful to all the study participants and study staff for their hard work and dedication," added David G. Watumull, Cardax President and CEO.

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About Cardax

Cardax is a development stage biopharmaceutical company primarily focused on the development of pharmaceuticals for chronic diseases driven by inflammation. The Company also has a commercial business unit that markets ZanthoSyn®, a physician recommended astaxanthin dietary supplement for inflammatory health.* CDX-101, the Company's astaxanthin pharmaceutical candidate, is being developed for cardiovascular inflammation and dyslipidemia, with a target initial indication of severe hypertriglyceridemia. CDX-301, the Company's zeaxanthin pharmaceutical candidate, is being developed for macular degeneration, with a target initial indication of Stargardt disease. The Company's pharmaceutical candidates are currently in pre-clinical development, including the planning of IND enabling studies. The safety and efficacy of the Company's pharmaceutical candidates have not been directly evaluated in clinical trials or confirmed by the FDA.

Media and Investors

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Safe Harbor – Forward Looking Statements

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*** 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.**
