# 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): **December 5, 2017**

# CARDAX, INC.
(Exact name of registrant as specified in its charter)

| **Delaware** | **333-181719** | **45-4484428** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (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 [X]

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 December 5, 2017, Cardax, Inc. (the "Company") issued a press release refuting false and baseless allegations made by a competitive trade group Natural Algae Astaxanthin Association (" NAXA") in a "citizen" petition that NAXA recently filed with the Food and Drug Administration.

In accordance with General Instruction B.2 of Form 8-K, the information set forth herein and in Exhibit 99.1 hereto are 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**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated December 5, 2017 (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: December 5, 2017

**CARDAX, INC.**

By: */s/ David G. Watumull*
David G. Watumull
Chief Executive Officer and President

**Cardax Refutes Allegations by Competitive Trade Group, NAXA**

Cardax also Demands that NAXA Immediately Stop Making "Reckless and Unsupported" Statements
that Misinform Consumers and Create Market Confusion

HONOLULU, December 5, 2017 /PRNewswire/ — Cardax, Inc. (OTCQB: CDXI) today refuted numerous false and baseless allegations made by the Natural Algae Astaxanthin Association ("NAXA") in a "citizen" petition that it recently filed with the Food and Drug Administration ("FDA"). NAXA is a small trade group with four members: Cyanotech Corporation (manufacturer of BioAstin®), Algatechnologies, Algae Health Sciences, Inc., and Alphy Biotech – each of which markets astaxanthin products made from poorly characterized microalgal extracts in direct competition with Cardax's premium astaxanthin dietary supplement, ZanthoSyn®.

ZanthoSyn®, Cardax's premium astaxanthin dietary supplement for inflammatory health and longevity, is supported by more than 1,500 peer reviewed papers and 50 proof-of-concept human clinical studies, and the product carries a GRAS ("Generally Recognized as Safe") safety designation in accordance with FDA regulations. Moreover, ZanthoSyn® offers superior purity and absorption advantages compared to microalgal astaxanthin.*

"We are fully confident in the anti-inflammatory health benefits, safety, and regulatory status of ZanthoSyn®. NAXA's allegations are simply spurious and do not present a good faith, scientifically credible assessment of the facts," said David G. Watumull, Cardax CEO. "We have developed our strong regulatory position with leading FDA regulatory consultants who held senior positions at the FDA, and are confident that ZanthoSyn® fully complies with all FDA regulations. Facts do matter, and the public should not be swayed by NAXA's false and baseless claims that misinform the consumer. We believe that NAXA's efforts are simply a transparent attempt to attack our successful product offering, and that these efforts to create market confusion are being driven by our competitors. Accordingly, we have demanded that NAXA immediately stop making such reckless and unsupported statements."

"Promoting the health and well being of our consumers is and always will be the paramount focus of Cardax," Watumull added. "In the meantime, we will take every prudent step to strongly defend the integrity of ZanthoSyn® and protect our fast growing company from these meritless attacks. Cardax will not let this thinly-veiled PR stunt divert our focus from continuing to grow the ZanthoSyn® sales and marketing program nationwide."

Below are Cardax's responses to the baseless allegations contained in NAXA's November 27, 2017 petition to the FDA:

1. The astaxanthin in ZanthoSyn® is Generally Recognized as Safe ("GRAS").

   The astaxanthin in ZanthoSyn® is AstaSana™, a synthetic astaxanthin ingredient manufactured by DSM Nutritional Products ("DSM"), which is part of Koninklijke DSM N.V., a Dutch multinational health, nutrition, and materials company with more than 20,000 employees in 50 countries. DSM self-affirmed GRAS for AstaSana™ in 2015 (see DSM Astaxanthin GRAS Press Release). Contrary to NAXA's claims, Cardax does not rely on the GRAS designations from any of the microalgal astaxanthin manufacturers.

2. The astaxanthin in ZanthoSyn® has robust safety data.

   The astaxanthin in ZanthoSyn® (AstaSana™ from DSM) has been extensively safety-tested and these data are publicly available (see DSM Astaxanthin Short Safety Summary). We believe that the astaxanthin in ZanthoSyn® has been more extensively safety-tested than microalgal astaxanthin. The DSM Astaxanthin Short Safety Summary also supports the labeled ZanthoSyn® astaxanthin dosage.

3. ZanthoSyn® does not need a New Dietary Ingredient ("NDI") notification.

Synthetic copies of natural substances that are present in the human diet as food additives (including those that are self-affirmed as GRAS for direct addition to food) may be used as dietary ingredients in dietary supplements without New Dietary Ingredient (NDI) notification, in accordance with FDA regulations (see FDA Official Clarifies Agency's Position on NDI Filing Exemption). The astaxanthin in ZanthoSyn® (AstaSana™ from DSM) has been present in the human diet for over 20 years, having been approved by the FDA in 1995 for use in the feed of animals to be consumed by humans; AstaSana™ was also self-affirmed GRAS for use in human food in 2015. Therefore, it is suitable for use as a dietary ingredient in dietary supplements without NDI notification.

4. The ZanthoSyn® label correctly states that astaxanthin is "clinically studied".

Astaxanthin has been clinically studied and the active ingredient in ZanthoSyn® is astaxanthin. Both ZanthoSyn® and microalgal astaxanthin deliver astaxanthin to the bloodstream. Cardax demonstrated in a human clinical study that ZanthoSyn® is more orally bioavailable than BioAstin® (microalgal astaxanthin), as measured by the levels of astaxanthin in the blood stream (see ZanthoSyn® Absorption Human Clinical Study). ZanthoSyn® does have a different isomeric mix than microalgal astaxanthin: microalgal astaxanthin consists mostly of the 3S,3'S optical isomer of astaxanthin and ZanthoSyn® is a mixture of 3S,3'S, 3R,3'R, and the meso forms of astaxanthin. All of these isomers are found in nature, and there is no credible scientific evidence that there is any meaningful biological difference between these astaxanthin isomers, from either a safety or efficacy standpoint.

5. ZanthoSyn®'s "anti-inflammatory" structure/function claims are fully compliant with FDA regulations.

The FDA is very clear that the phrase "anti-inflammatory" is permitted, provided it is in context with a structure/function claim. (Please see FDA Guidance on Structure Function Claims and refer to the specific guidance regarding an anti-inflammatory claim in Criterion 5: "…claiming to be […] an anti-inflammatory […] will not be a disease claim if there is context that makes clear that the intended effect of the product is on structure/function and not disease.") Cardax provides the appropriate structure/function context in ZanthoSyn®'s product labeling and sales materials.

Hypocritically, NAXA's own website (as of December 1, 2017) refers to astaxanthin as an anti-inflammatory for various health applications and even references disease application. Similarly, the website of Cyanotech's Nutrex Hawaii subsidiary also refers to astaxanthin as having anti-inflammatory properties (as of December 1, 2017).

6. ZanthoSyn® is endorsed by physicians.

Prominent physicians and other healthcare professionals recommend ZanthoSyn® to their patients based on the underlying science of astaxanthin and the superior purity and absorption advantages of ZanthoSyn® compared to microalgal astaxanthin. Cardax has conducted intensive educational meetings on ZanthoSyn®/astaxanthin with more than 250 physicians and other healthcare professionals —many of whom are using ZanthoSyn® themselves.

**About Cardax**

Cardax devotes substantially all of its efforts to developing and commercializing dietary supplements. Cardax is initially focusing on astaxanthin, which is a powerful and safe naturally occurring anti-inflammatory that supports health and longevity.* The safety and efficacy of Cardax's products have not been directly evaluated in clinical trials or confirmed by the FDA.

**About ZanthoSyn®**

ZanthoSyn® is a physician recommended anti-inflammatory supplement for health and longevity that features astaxanthin with optimal absorption and purity. ZanthoSyn® contains astaxanthin, which is Generally Recognized as Safe (GRAS) according to FDA regulations.

**About Astaxanthin**

Astaxanthin is a clinically studied compound with safe anti-inflammatory activity that supports joint health, cardiovascular health, metabolic health, liver health, and longevity.*

**Media and Investors**

Janice Kam
1-808-457-1400
press@cardaxpharma.com

**Safe Harbor**

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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.**