### 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

## NOVEMBER 30, 2004

Date of Report (Date of earliest event reported)

### ORAGENICS, INC.

(Exact name of registrant as specified in its charter)

FLORIDA 000-50614 59-3410522

(State or other jurisdiction (Commission of incorporation) File Number)

mission (IRS Employer mber) Identification No.)

## 12085 RESEARCH DRIVE ALACHUA, FLORIDA 32615

(Address of principal executive offices including zip code)

(386) 418-4018

Registrant's telephone number, including area code

NONE

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

ITEM 7.01 REGULATION FD DISCLOSURE

Oragenics, Inc. announced today that the FDA has lifted its clinical hold on the Company's novel treatment for prevention of dental caries.

# ITEM 9.01 FINANCIAL INFORMATION AND EXHIBITS

EXHIBIT NO. DESCRIPTION

99.1 Press Release

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### SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 30th day of November, 2004.

# ORAGENICS, INC. (REGISTRANT)

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BY: /s/ Mento A. Soponis

Mento A. Soponis President and Chief Executive Officer

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## [ORAGENICS LOGO]

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### FOR IMMEDIATE RELEASE

# FDA LIFTS CLINICAL HOLD ON ORAGENICS' NOVEL TREATMENT FOR PREVENTION OF DENTAL CARIES

# COMPANY ANTICIPATES BEGINNING PHASE I STUDY OF REPLACEMENT THERAPY IN EARLY 2005

ALACHUA, FL (NOVEMBER 30, 2004): Oragenics, Inc. (AMEX:ONI) reported today that the U.S. Food and Drug Administration (FDA) has agreed to lift the clinical hold on the company's Replacement Therapy for the treatment of dental caries. The FDA's clearance to proceed with a Phase I safety trial came following the agency's completed review of the study's clinical design and the unanimous vote of the Recombinant DNA Advisory Committee (RAC) on March 15, 2004 that the first human clinical study of Oragenics Replacement Therapy be carried out under the protocol proposed by the company. The FDA had placed Oragenics' original Investigational New Drug application (IND) on clinical hold in May 2003, pending further review of the study design.

"We are extremely pleased to reach agreement with the FDA on a clinical protocol that adequately addresses the potential safety questions posed by the first human clinical trial of our novel Replacement Therapy," said Chuck Soponis, Oragenics' president and chief executive officer. "We anticipate initiating Phase I human clinical safety testing of our Replacement Therapy early in 2005."

## ABOUT REPLACEMENT THERAPY

Replacement Therapy is a single, painless topical treatment that could in theory offer life-long protection from most tooth decay. Tooth decay is caused by lactic acid produced by a bacterium in the mouth called Streptococcus mutans. Oragenics' Replacement Therapy employs a patented, genetically modified strain of S. mutans that does not produce this decay-producing acid. When applied to a person's teeth by a dentist, this engineered bacterium displaces the resident acid-producing bacterium, providing potentially life-long protection against most dental decay. Replacement therapy is the result of 25 years of research by Oragenics' founder and chief scientific officer, Jeffrey Hillman, DMD, PhD, a noted molecular geneticist and expert on oral microbiology. Oragenics plans to complete Phase I safety testing for Replacement Therapy and to partner with a major healthcare products or pharmaceutical firm prior to initiating later stages of clinical development.

-- More --

### FDA LIFTS CLINICAL HOLD ON TRIAL OF ORAGENICS' NOVEL TREATMENT FOR PREVENTION OF DENTAL CARIES PAGE 2

## ABOUT ORAGENICS

Oragenics, Inc. is an emerging biotechnology company focused on the development and licensure of innovative products and technologies for improving human health. The company's lead product is a novel oral rinse for the prevention of tooth decay, which is anticipated to enter clinical trials in early 2005. The company is also developing a novel antibiotic with broad-spectrum activity against gram-positive bacteria and a probiotic product aimed at maintaining oral health. The company is headquartered in Alachua, Florida. For more information about Oragenics, please consult the company's website at www.oragenics.com. SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995: This release includes forward-looking statements which reflect Oragenics' current views with respect to future events and financial performance. These forward-looking statements are based on management's beliefs and assumptions and information currently available. The words "believe", "expect", "anticipate", "intend", "estimate", "project" and similar expressions which do not relate solely to historical matters identify forward-looking statements. Investors should be cautious in relying on forward-looking statements because they are subject to a variety of risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed in any such forward-looking statements. These factors include, but are not limited to (1) the ability to successfully complete development and commercialization of Oragenics' Replacement Therapy for prevention of tooth decay, novel antibiotic, and probiotic product for oral health; (2) the ability to obtain substantial additional funding; (3) the ability to develop and commercialize products before competitors;)4) the ability to develop commercial products with the in-licensed technology; and (5)) other factors detailed from time to time in filings with the Securities and Exchange Commission. We expressly disclaim any responsibility to update forward-looking statements.

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