

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

FEBRUARY 8, 2005

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      (IRS Employer  
of incorporation)              File Number)      Identification No.)

13700 PROGRESS BOULEVARD  
ALACHUA, FLORIDA 32615

(Address of principal executive offices including zip code)

(386) 418-4018

Registrant's telephone number, including area code

12085 RESEARCH DRIVE, ALACHUA, FL 32615

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

ITEM 8.01 OTHER EVENTS

Today Oragenics' President, Mento Soponis, issued an open letter to shareholders as an update to the current affairs of the Company. This letter is readily accessible to the general public at Oragenics's website, [www.oragenics.com](http://www.oragenics.com) and is reproduced below.

President's Letter to Shareholders

In the interest of providing our shareholders and other interested parties with activities and developments within Oragenics, I am inaugurating a quarterly letter which will share our progress and plans for the future. Each quarter, these letters will be posted on our web site at [www.oragenics.com](http://www.oragenics.com). I hope you find this form of communication useful, and I invite your feedback.

We continue to aggressively pursue our mission, to create value through the development of innovative health solutions. Our current product opportunities offer innovative approaches to health concerns with very substantial market potential.

Replacement Therapy

Replacement Therapy is the first-of-its-kind approach to prevent a disease that affects us all to a varying extent - tooth decay. Tooth decay results when certain bacteria in the mouth produce acids that can dissolve tooth enamel. Our product will replace these disease-causing bacteria in the mouth with a virtually identical strain of the same bacteria that is unable to cause tooth decay. Our Investigational New Drug (IND) submission to the FDA received approval from the Agency late last year to undertake a Phase I clinical trial to ascertain the safety of our product.

We are now in the final preparations to begin that U.S. trial. We have engaged a

contract research organization to conduct the study for us. They are presently pre-screening potential trial subjects and expect to enroll the first trial subjects in the near future. If enrollment proceeds in a timely fashion, our expectation is to complete the trial before year end.

We also intend to initiate a Phase I clinical trial in Europe later this year in order to produce further safety data for our product and to accelerate the trials process in both Europe and the United States. Although these studies and the regulatory approval process may take as much as five years from today, we are spurred by the potential of addressing an extremely large market opportunity when Replacement Therapy achieves commercialization. Our present intention is to enter into a strategic partnership with one or more major companies within the next two years. Our partner or partners will be responsible for the pivotal clinical trial, regulatory approvals and commercialization.

#### Oral Probiotic

Our second product, the oral probiotic intended to maintain periodontal and dental health, will be ready for market introduction in Europe the first half of next year. This, too, is an innovative product that offers for the first time a means to maintain a healthy periodontal environment. We are completing a market analysis in Europe to determine product positioning and to identify the most appealing product form for consumers. We anticipate that we will sign one or more marketing partners for Europe later this year, and we expect to reach agreement with marketing partners for Asian markets as well. We estimate that product introduction into Asia may occur by 2007. This product represents potential near-term cash flow for the Company.

#### Broad Spectrum Antibiotic

Progress in the development of mutacin 1140, a broad-spectrum antibiotic, has been significant and substantial. We are near a solution to the challenge with this product, which has been to produce the molecule in quantities sufficient to conduct pre-clinical studies and ultimately satisfy commercial requirements. We believe we are near to a solution to our production challenge. Once we have established the desired level of production, we will immediately begin a focused program of pre-clinical testing with the goal of filing an IND application with the FDA within 15-18 months to begin human clinical studies.

In our laboratory studies to date, we have shown that mutacin 1140 acts against all Gram-positive bacteria. Significantly, none of the bacteria against which we have tested our antibiotic has been able to develop any resistance to the antibiotic. And remarkably, the bacterium that produces the mutacin 1140 has never been able to develop any resistance itself. We are hoping that mutacin 1140 will perform in animals and in humans with the same antibacterial effectiveness we have seen in the laboratory. If we are correct, and only future testing will tell, this product should also have very significant market potential, as resistance to currently used antibiotics is growing at a rapid rate.

#### Corporate News

On the corporate front, Dr. Jeff Hillman stepped down as Chairman of the Board to dedicate his time to the development of our products and technologies. However, he will continue to serve as a Board member. We are fortunate to gain David Gury's willingness to take a more active role with Oragenics as Chairman of the Board. Dave has extensive experience from his days as Chairman and CEO at Nabi Biopharmaceuticals in taking a company from its early development stage to a very successful and dynamic company. His advice, guidance and critical decision-making capabilities as an active Chairman of the Board will serve the Company well.

Financially, we require more capital to fund the ambitious development programs we have undertaken. In November of 2004, we began an effort to raise additional working capital. After receiving funds of nearly \$700,000 from the first three investors, we received the FDA letter lifting our clinical hold and felt compelled to stop the offering to allow the market to absorb the news of the FDA decision. We will move forward in the months ahead to fortify our financial position.

In closing, I would like to convey to you the enthusiasm and dedication every person at Oragenics applies to the work of creating value for our shareholders through the development of the special opportunities we possess. Thank you for

your support.

Sincerely,

Chuck Soponis  
President & Chief Executive Officer

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 8th day of February, 2005.

ORAGENICS, INC.  
(REGISTRANT)

BY: /s/ Mento A. Soponis

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Mento A. Soponis  
President and Chief Executive Officer