NANOGEN INC
Form 8-K
August 19, 2005

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): August 12, 2005

NANOGEN, INC.

(Exact name of registrant specified in its charter)

Delaware	**000-23541**	**33-0489621**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

10398 Pacific Center Court, San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone, including area code: (858) 410-4600

(Former name and 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))

Item 8.01. Other Events.

On August 12, 2005, Nanogen received an untitled letter from the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) of the Food and Drug Administration (FDA) regarding the NanoChip® Molecular Biology Workstation, the NanoChip® Microarray, and certain of Nanogen s analyte specific reagents (ASRs).

The letter was initiated as a result of an OIVD review of information on Nanogen s website. In the letter, OIVD expressed the view that the Workstation, Microarray, and ASRs appear to be promoted to work together as an integrated system and that there are inconsistencies with the labeling and representation of intended use of our products. OVID s position in the letter is that if these products are linked together, then they are considered a medical device and subject to the requirements of a premarket approval application. A copy of the letter is posted on the FDA website at http://www.fda.gov/cdrh/oivd/letters/081105-nanogen.html.

OIVD has requested that Nanogen respond within 30 days of receipt of the letter.

We believe that our products comply with the FDA requirements and we intend to provide a response to OIVD in a timely manner.

SIGNATURES

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

NANOGEN, INC.

Date: August 18, 2005

By: /s/ Robert Saltmarsh
Name: Robert Saltmarsh
Title: Chief Financial Officer