

NEOGENOMICS INC
Form 8-K
February 19, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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)

February 19, 2014

NEOGENOMICS, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction

of incorporation)

001-35756
(Commission

File Number)

74-2897368
(I.R.S. Employer

Identification No.)

12701 Commonwealth Drive, Suite 9, Fort Myers,

Florida
(Address of principal executive offices)

(239) 768-0600

33913
(Zip Code)

(Registrant's telephone number, including area code)

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:

- .. 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.

In December 2013, the Centers for Medicare and Medicaid Services (CMS) issued new guidance through their National Correct Coding Initiative (NCCI) Policy Manual⁽¹⁾ (the "NCCI Manual") which could potentially change how laboratories account for the quantity of FISH probes being billed to CMS. A newly added Section K, Paragraph 9 of this NCCI Manual directly contradicts previously issued guidance contained in Section J, Paragraph 6 regarding FISH testing, which had established the current practice of reporting and billing one unit of service for each reportable FISH probe⁽²⁾.

According to the new guideline in Paragraph K(9), if two or more probes are applied to a sample at the same time, a single unit of service is now to be billed, because the two probes are part of the same "probe staining procedure". Although the definition of "probe staining" is not clear, it appears that the intent is for CMS to reimburse \$0 for a second, third or fourth FISH probe contained in the same vial of reagent. As the cost of reagents from suppliers is substantially greater when multiple probes are incorporated, and technician and pathologist time required to perform and analyze the test is significantly greater when multiple probes are involved, the effect of this guideline may be significant.

NeoGenomics, like other laboratory providers, may choose not to perform FISH tests if costs exceed expenses. NeoGenomics believes FISH is an essential test to inform whether cancer is present, define the subtype of cancer, and help Physicians decide how to effectively treat the disease. In the event the language in Paragraph K(9) of the NCCI Manual is not clarified or changed, it would have the effect of reducing reimbursement for a number of the Company's FISH testing services that utilize multiple FISH probes that have been pre-mixed into the same vial of reagents by the probe suppliers.

NeoGenomics has contacted Medicare carriers, FISH probe suppliers, reimbursement experts and competitors in the lab industry and there seems to be universal confusion about this new guideline. This new policy was promulgated to the laboratory industry without any notice or the opportunity to comment and has an effective date of January 1, 2014. NeoGenomics has written a letter to the Medical Director of the NCCI as well as CMS, requesting clarification on this issue, but it has not yet received a response or had an opportunity to discuss its concerns. A copy of this letter can be accessed through the homepage of the Company's website by clicking on the button marked "Recent NCCI Edits".

While the Company is hopeful that the NCCI and CMS will reconsider their current stance, in the event they do not, NeoGenomics would be forced to alter its billing practices for the affected FISH testing services or reconsider providing the affected FISH services for Medicare beneficiaries.

While NeoGenomics is still determining the impacts that might arise from a negative resolution of the NCCI FISH edit issue, the Company preliminarily estimates that it may result in a reduction of approximately \$3 million of revenue and \$0.04 per share of net income for the full year 2014, and a reduction of approximately \$1.0 million of revenue and \$0.02 per share of net income for the first quarter of 2014.

- (1) See NCCI Policy Manual for Medicare Services Effective January 1, 2014, Chapter X Pathology/Laboratory Services CPT Codes 80000 89999, Section K (Medically Unlikely Edits), Paragraph 9, which states:

The unit of service for in situ hybridization reported as CPT codes 88365, 88367, or 88368 is each probe staining procedure per specimen. If a single probe staining procedure for one or more probes is performed on multiple blocks from a surgical specimen, multiple slides from a cytologic specimen, or multiple slides from a hematologic specimen, only one unit of service may be reported for each separate specimen. Physicians should not report more than one unit of service for CPT codes 88365, 88367, or 88368 per specimen for a probe staining procedure even if it contains multiple separately interpretable probes.

- (2) See NCCI Manual, Section J, Paragraph 6, which states:

Beginning January 1, 2005, quantitative or semi-quantitative in situ hybridization (tissue or cellular) performed by computer-assisted technology should be reported as CPT code 88367 when performed by a physician (limited to M.D./D.O.). Beginning January 1, 2005, quantitative or semi-quantitative in situ hybridization (tissue or cellular) performed by manual methods should be reported as CPT code 88368 when performed by a physician (limited to M.D./D.O.). ..Only one unit of service may be reported for CPT code 88365, 88367 or 88368 for each reportable probe.

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.

NEOGENOMICS, INC.

By: /s/ George Cardoza
George Cardoza
Chief Financial Officer

Date: February 19, 2014

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