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VERMILLION, INC. Form 8-K September 15, 2009

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): September 15, 2009 (September 11, 2009)

Vermillion, Inc. (Exact name of registrant as specified in its charter)

Commission File Number: 000-31617

Delaware (State or other jurisdiction of incorporation) 33-059-5156 (IRS Employer Identification No.)

47350 Fremont Blvd., Fremont, CA 94538 (Address of principal executive offices, including zip code) 510.226.2800

(Registrant s telephone number, including area code) (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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 September 11, 2009 Vermillion, Inc. (the Company) issued a press release announcing that the U.S. Food and Drug Administration (the FDA) had cleared the OVA1 Test for use in helping physicians determine if a woman is at risk for a malignant pelvic mass. The press release issued by the Company is attached as Exhibit 99.1 and is incorporated by reference herein.

Forward-Looking Statements

Certain matters discussed in this Current Report on Form 8-K and the exhibits hereto contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. These forward-looking statements may relate to, among other things, expectations of the business environment in which the Company operates and projections of future performance. These forward-looking statements are based upon current management s expectations and may therefore involve risks and uncertainties. A variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. There are no guarantees that the Company will succeed in its efforts to commercialize its ovarian cancer diagnostic tests in 2009 or during any other period of time. Factors that could cause actual results to materially differ include but are not limited to: (1) uncertainty in obtaining intellectual property protection for inventions made by the Company; (2) unproven ability of the Company to discover, develop, and commercialize diagnostic products based on findings from its disease association studies; (3) inability of the Company to discover or identify new protein biomarkers and use such information to develop ovarian cancer diagnostic products; (4) uncertainty as to whether the Company will be able to obtain any required regulatory approval of its future diagnostic products; (5) uncertainty of market acceptance of its products, including the risk that its products will not be competitive with products offered by other companies, or that users will not be entitled to receive adequate reimbursement for its products from third party payors such as private insurance companies and government insurance plans; (6) the impact of the Company s Chapter 11 filing, which may disrupt and distract the Company s management or result in unanticipated expenses or increases to estimated expenses; and (7) other factors that might be described from time to time in the Company s filings with the Securities and Exchange Commission. All information in this Form 8-K is as of the date of filing, and Vermillion expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements to reflect any change in Vermillion s expectations or any change in events, conditions or circumstances on which any such statement is based, unless required by law.

Item 9.01. Financial Statements and Exhibits.

- (d) Exhibit No. Description.
 - 99.1 Press Release dated September 11, 2009.

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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.

Vermillion, Inc.

Date: September 15, 2009 By: /s/ Gail S. Page

Gail S. Page

Executive Chair of the Board of

Directors

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EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release dated September 11, 2009.