VERMILLION, INC.
Form 8-K
July 17, 2015
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): July 14, 2015

Vermillion, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	001-34810	33-059-5156
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

12117 Bee Caves Road Building Three, Suite 100, Austin, TX 78738

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (512) 519-0400

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 1.01. Entry into a Material Definitive Agreement.

On July 14, 2015, Vermillion, Inc. (the "Company") entered into an underwriting agreement (the "Underwriting Agreement") with Canaccord Genuity Inc., as representative of the several underwriters named therein (collectively, the "Underwriters"), in connection with the underwritten public offering and sale of 8,350,000 shares of the Company's common stock, par value $0.001 per share ("Common Stock"), at a price to the public of $1.96 per share (the "Offering"). Pursuant to the Underwriting Agreement, the Company granted the Underwriters a 30-day option to purchase up to an additional 1,252,500 shares of Common Stock solely to cover over-allotments. On July 16, 2015, the Underwriters exercised their option in full. The Offering, including the purchase of an additional 1,252,500 shares of Common Stock pursuant to the exercise of the over-allotment option, is expected to close on July 17, 2015, subject to the satisfaction of customary closing conditions.

The Offering is being made pursuant to the prospectus supplement dated July 14, 2015 and filed with the Securities and Exchange Commission (the "SEC") on July 14, 2015, to the prospectus dated October 2, 2014, filed with the SEC on October 1, 2014, as part of Amendment No. 1 to the Company's Registration Statement on Form S-3 (File No. 333-198734).

The Underwriting Agreement contains customary representations, warranties and covenants by the Company, as well as customary indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended.

The foregoing description of the Underwriting Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Underwriting Agreement, which is filed as Exhibit 1.1 to this report and is incorporated herein by reference. A copy of the opinion of Sidley Austin LLP, counsel to the Company, regarding the legality of the shares of Common Stock issued and sold in the offering is filed as Exhibit 5.1 hereto.

Item 8.01. Other Events.

The Company is also filing this report to update its previously disclosed risk factors. The risk factors set forth below update certain of the risk factors contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014 and the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015. Stockholders should also refer to the risks described under the caption "Risk Factors" in the Company's most recent Annual Report on Form 10-K and any subsequently filed Quarterly Reports on Form 10-Q. Unless otherwise mentioned or unless the context requires otherwise, all references in these risk factors to "we," "our," "us" or similar references mean the Company and its subsidiaries.

If we or our suppliers fail to comply with FDA requirements for production, marketing and post-market monitoring of our products, we may not be able to market our products and services and may be subject to stringent penalties, product restrictions or recall; further improvements to our manufacturing operations may be required that could entail additional costs.

The commercialization of our products could be delayed, halted or prevented by applicable FDA regulations. If the FDA were to view any of our actions as non-compliant, it could initiate enforcement actions, such as a warning letter and possible imposition of penalties. For instance, we are subject to a number of FDA requirements, including compliance with the FDA's Quality System Regulations "QSR" requirements, which establish extensive requirements for quality assurance and control as well as manufacturing procedures. Failure to comply with these regulations could result in enforcement actions for us or our potential suppliers. Adverse FDA actions in any of these areas could significantly increase our expenses and reduce our revenue. We will need to undertake steps to maintain our operations in line with the FDA's QSR requirements. Some components of OVA1 are manufactured by other

companies and we are required to ensure that, to the extent that we incorporate those components into our finished OVA1 test, we use those components in compliance with QSR. Any failure to do so would have an adverse effect on our ability to commercialize OVA1. Our suppliers' manufacturing facilities, since they manufacture finished kits that we use in OVA1, are subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies. Our facility also is subject to FDA inspection. We or

our suppliers may not satisfy such regulatory requirements, and any such failure to do so may adversely affect our business, financial condition and results of operations.

In the future, we plan to develop and perform LDTs at ASPiRA LABS. If the FDA finalizes its October 3, 2014 draft guidance documents that outline the FDA's proposal to actively regulate LDTs, we may need to obtain a 510(k) clearance or pre-market approval ("PMA") for our future LDTs, and there is no guarantee that we would ever procure the needed FDA clearance or approval. We also would need to comply with ongoing regulatory requirements.

We intend to develop and perform LDTs at ASPiRA LABS. The FDA has historically exercised enforcement discretion and not required approvals or clearances for LDTs. However, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs.

According to the draft guidance documents, all laboratories with LDTs—except for those only performing forensic testing or certain LDTs for transplantation—would need to comply with some basic statutory requirements, regardless of the risks of the tests, including adverse event reporting, corrections and removals reporting and registration and listing or notification.

In addition, "high" and "moderate" risk tests not subject to an exemption will need to be the subject of a PMA or 510(k) submitted to the FDA in a phased-in manner. High-risk tests are those that are classified as Class III devices. Within those high-risk devices, the FDA identifies the "highest risk devices" as (1) LDTs with the same intended use as an approved or cleared companion diagnostic; (2) LDTs with the same intended use as an FDA-approved Class III device; and (3) certain LDTs for determining safety and effectiveness of blood or blood products. Moderate-risk tests are those that are classified as Class II devices.

The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. It is unclear at this time when, or if, the draft guidance documents will be finalized, and, if so, how the final framework might differ from the proposal. In addition, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance documents for tests that are on the market at the time the guidance documents are finalized.

Legislative proposals addressing the FDA's oversight of LDTs have been previously introduced, and we expect that new legislative proposals will be introduced from time to time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate LDTs as medical devices is difficult to predict.

Even before the FDA finalizes such guidance documents, the FDA may assert that a test that we believe to be an LDT is not an LDT and could require us to seek clearance or approval to offer such tests for clinical use. If the FDA pre-market review or approval is required for any of the future LDTs we may develop, we may be forced to stop selling our tests or be required to modify claims or make such other changes while we work to obtain FDA clearance or approval. Our business would be negatively affected until such review is completed and clearance to market or approval is obtained.

If pre-market review is required by the FDA or if we decide to voluntarily pursue FDA pre-market review of our future LDTs, there can be no assurance that any tests we develop in the future will be cleared or approved on a timely basis, if at all. Obtaining FDA clearance or approval for diagnostics can be expensive, time consuming and uncertain, and for higher-risk devices generally takes several years and requires detailed and comprehensive scientific and clinical data. In addition, medical devices are subject to ongoing FDA obligations and continued regulatory oversight and review. Ongoing compliance with FDA regulations for those tests would increase the cost of conducting our business and subject us to heightened regulation by the FDA and penalties for failure to comply with these

requirements.

Forward-Looking Statements

The foregoing contains forward-looking statements, as that term is defined in the Private Litigation Reform Act of 1995, that involve significant risks and uncertainties. These forward-looking statements are based on the Company's expectations as of the date of this report. 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. The Company expressly

disclaims any obligation to update, amend or clarify any forward-looking statements to reflect events, new information or circumstances occurring after the date of this press release, except as required by law.

Item 9.01Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.Description.

1.1Underwriting Agreement, dated July 14, 2015, between Vermillion, Inc. and Canaccord Genuity Inc., as representative of the several underwriters named therein

5.1Opinion of Sidley Austin LLP

23.1Consent of Sidley Austin LLP (included in Exhibit 5.1)

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: July 17, 2015 By:/s/ Eric J. Schoen

Name: Eric J. Schoen

Title: Vice President, Finance and

Chief Accounting Officer

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