

VERMILLION, INC.  
Form 10-Q  
November 08, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-34810

Vermillion, Inc.  
(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

12117 Bee Caves Road, Building Three, Suite 100, Austin, Texas

(Address of Principal Executive Offices)

33-0595156

(I.R.S. Employer Identification No.)

78738

(Zip Code)

(512) 519-0400

(Registrant's Telephone Number, Including Area Code)

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of October 31, 2018, the registrant had 75,382,684 shares of common stock, par value \$0.001 per share, outstanding.



VERMILLION, INC.

FORM 10-Q

For the Quarter Ended September 30, 2018

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Vermillion, OVA1 and Overa are registered trademarks of Vermillion, Inc.

## PART I - FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

Vermillion, Inc.

Condensed Consolidated Balance Sheets

(Amounts in Thousands, Except Share and Par Value Amounts)

(Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 11,760	\$ 5,539
Accounts receivable, net	656	205
Prepaid expenses and other current assets	242	459
Inventories	115	102
Total current assets	12,773	6,305
Property and equipment, net	701	1,181
Other assets	-	11
Total assets	\$ 13,474	\$ 7,497
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 495	\$ 745
Accrued liabilities	1,741	1,650
Short-term debt	188	185
Other current liabilities	-	29
Total current liabilities	2,424	2,609
Non-current liabilities:		
Long-term debt	1,340	1,481
Total liabilities	3,764	4,090
Commitments and contingencies (Note 3)		

Stockholders' equity:

Preferred stock, par value \$0.001 per share, 5,000,000 shares authorized at September 30, 2018 and December 31, 2017; none issued and outstanding at

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September 30, 2018 and December 31, 2017	-	-
Common stock, par value \$0.001 per share, 150,000,000 shares authorized at September 30, 2018 and December 31, 2017; 75,382,684 and 60,036,017 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	75	60
Additional paid-in capital	413,739	399,400
Accumulated deficit	(404,104)	(396,053)
Total stockholders' equity	9,710	3,407
Total liabilities and stockholders' equity	\$ 13,474	\$ 7,497
See accompanying notes to the unaudited condensed consolidated financial statements.		

Vermillion, Inc.

## Condensed Consolidated Statements of Operations

(Amounts in Thousands, Except Share and Per Share Amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
Product	\$ 739	\$ 657	\$ 1,979	\$ 2,195
Service	35	42	152	128
Total revenue	774	699	2,131	2,323
Cost of revenue:(1)				
Product	477	495	1,538	1,345
Service	301	284	851	855
Total cost of revenue	778	779	2,389	2,200
Gross profit (loss)	(4)	(80)	(258)	123
Operating expenses:				
Research and development(2)	129	192	425	685
Sales and marketing(3)	1,343	1,050	4,046	3,114
General and administrative(4)	1,167	1,177	3,780	3,825
Total operating expenses	2,639	2,419	8,251	7,624
Loss from operations	(2,643)	(2,499)	(8,509)	(7,501)
Interest income (expense), net	(6)	(10)	(25)	(32)
Other income (expense), net	(3)	-	(17)	(9)
Net loss	\$ (2,652)	\$ (2,509)	\$ (8,551)	\$ (7,542)
Deemed dividend on warrant repricing	-	(942)	-	(942)
Net loss attributable to common stockholders	\$ (2,652)	\$ (3,451)	\$ (8,551)	\$ (8,484)
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.04)	\$ (0.06)	\$ (0.13)	\$ (0.15)
Weighted average common shares used to compute basic and diluted net loss per common share	75,306,074	57,455,786	68,288,216	55,909,788
Non-cash stock-based compensation expense included in cost of revenue and operating expenses:				
(1) Cost of revenue	\$ 35	\$ 29	\$ 93	\$ 108
(2) Research and development	2	2	4	7
(3) Sales and marketing	14	38	85	115
(4) General and administrative	245	257	657	767

See accompanying notes to the unaudited condensed consolidated financial statements.





Vermillion, Inc.

## Condensed Consolidated Statements of Cash Flows

(Amounts in Thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (8,551)	\$ (7,542)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	527	599
Stock-based compensation expense	839	997
Loss on sale and disposal of property and equipment	11	4
Changes in operating assets and liabilities:		
Accounts receivable	49	54
Prepaid expenses and other assets	228	312
Inventories	(13)	(62)
Accounts payable, accrued liabilities and other liabilities	(159)	(401)
Deferred revenue	-	62
Net cash used in operating activities	(7,069)	(5,977)
Cash flows from investing activities:		
Purchase of property and equipment	(58)	(56)
Net cash used in investing activities	(58)	(56)
Cash flows from financing activities:		
Proceeds from private placement offering of common stock, net of issuance costs	-	5,127
Proceeds from public offering of preferred stock, net of issuance costs	4,496	-
Proceeds from public offering of common stock, net of issuance costs	8,990	-
Proceeds from exercise of common stock from exercise of warrants, net of issuance costs	-	3,577
Principal repayment of DECD loan	(138)	(136)
Repayment of capital lease obligations	(29)	(25)
Proceeds from issuance of common stock from exercise of stock options	29	-
Net cash provided by financing activities	13,348	8,543
Net increase in cash and cash equivalents	6,221	2,510
Cash and cash equivalents, beginning of period	5,539	5,242
Cash and cash equivalents, end of period	\$ 11,760	\$ 7,752
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	\$ 33	\$ 36
Supplemental disclosure of non-cash investing and financing activities:		
50,000 shares of convertible preferred stock converted to 5,000,000 shares of common stock, net of issuance costs	\$ 4,496	\$ -
Deemed dividend on warrant repricing	\$ -	\$ 942

See accompanying notes to the unaudited condensed consolidated financial statements.

Vermillion, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

## 1. ORGANIZATION, BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING AND REPORTING POLICIES

### Organization

Vermillion, Inc. (“Vermillion”; Vermillion and its wholly-owned subsidiaries are collectively referred to as the “Company,” “we” or “our”) is incorporated in the state of Delaware, and is engaged in the business of developing and commercializing diagnostic tests for gynecologic disease. The Company sells OVA1™ and Overa™ risk of malignancy tests for ovarian cancer (“OVA1” and “Overa,” respectively) through Vermillion’s wholly-owned Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) certified clinical laboratory, ASPIRA LABS, Inc. (“ASPIRA LABS”).

The Company also offers in-vitro diagnostic (“IVD”) trial services to third-party customers through its wholly-owned subsidiary, ASPIRA IVD, Inc. (“ASPIRA IVD”), which commenced operations in June 2016. ASPIRA IVD is a specialized, CLIA certified, laboratory provider dedicated to meeting the unique testing needs of IVD manufacturers seeking to commercialize high-complexity assays.

### Liquidity

The Company has incurred significant net losses and negative cash flows from operations since inception, and as a result has an accumulated deficit of approximately \$404,104,000 at September 30, 2018. The Company also expects to incur a net loss and negative cash flows from operations for the remainder of 2018. There can be no assurance that the Company will achieve or sustain profitability or positive cash flow from operations. However, management believes that the current working capital position will be sufficient to meet the Company’s working capital needs for at least the next 12 months.

As discussed in Note 4, on April 17, 2018, the Company completed two public offerings, pursuant to which certain investors purchased Vermillion common stock and Vermillion Series B convertible preferred stock for net proceeds of approximately \$13,500,000 after deducting offering expenses.

As discussed in Note 4, on August 31, 2017, certain investors exercised outstanding warrants to purchase shares of Vermillion common stock for net proceeds of approximately \$3,577,000 after deducting offering expenses.

As discussed in Note 4, on February 17, 2017, the Company completed a private placement pursuant to which certain investors purchased Vermillion common stock and warrants to purchase shares of Vermillion common stock for net proceeds of approximately \$5,127,000 after deducting offering expenses.

As discussed in Note 3, in March 2016, the Company entered into an agreement (the “Loan Agreement”) pursuant to which it may borrow up to \$4,000,000 from the State of Connecticut Department of Economic and Community Development (the “DECD”). An initial disbursement of \$2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. The remaining \$2,000,000 will be advanced if and when the Company achieves certain future milestones. The loan may be prepaid at any time without premium or penalty.

#### Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the

opinion of management of the Company, all adjustments, consisting of normal recurring adjustments necessary for the fair statement of results for the periods presented, have been included. The results of operations of any interim period are not necessarily indicative of the results of operations for the full year or any other interim period.

The unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim unaudited condensed consolidated financial statements have read or have access to the audited consolidated financial statements for the preceding fiscal year. The condensed consolidated balance sheet at December 31, 2017 included in this report has been derived from the audited consolidated financial statements at that date but does not include all the information and footnotes required by GAAP. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2017 included in Vermillion's Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 13, 2018 (the "2017 Annual Report").

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimated results.

## Significant Accounting and Reporting Policies

### Revenue Recognition

The Company accounts for revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"), which it adopted on January 1, 2018 using the modified retrospective method.

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these goods and services.

### Product Revenue

Prior to January 1, 2018, the Company recognized product revenue in accordance with the provisions of ASC 954-605, Health Care Entities - Revenue Recognition. The Company's product revenue is generated by performing diagnostic services using its OVA1 and Overa tests, and the service is completed upon the delivery of the test result to the prescribing physician. The entire transaction price is allocated to the single performance obligation contained in a

contract with a patient. Under the previous revenue recognition accounting methodology, certain product revenue was recognized upon the ultimate receipt of cash. Under ASC 606, all revenue is recognized upon completion of the OVA1 or Overa test based on estimates of amounts that will ultimately be realized. In determining the amount of revenue to be recognized for a delivered test result, the Company considers factors such as payment history and amount, payer coverage, whether there is a reimbursement contract between the payer and the Company, and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management as the collection cycle on some accounts can be as long as one year.

The Company also reviewed its patient account population and determined an appropriate distribution of patient accounts by payer (i.e., Medicare, patient pay, other third-party payer, etc.) into portfolios with similar collection experience. The Company has elected this practical expedient that, when evaluated for collectability, results in a materially consistent revenue amount for such portfolios as if each patient account were evaluated on an individual contract basis. There were no impairment losses on accounts receivable recorded during the three and nine months ended September 30, 2018.

Under the modified retrospective implementation method, the Company recorded a one-time cumulative effect adjustment at January 1, 2018 to reflect the aggregate effect of all open OVA1 and Overa tests performed prior to January 1, 2018 as if revenue had been recognized under ASC 606. The cumulative effect adjustment was

recorded increasing the opening balance of Accounts Receivable by \$500,000 in the condensed consolidated balance sheets with an offsetting reduction to Accumulated Deficit. The Company's right to receive payment on this balance is contingent only on the passage of time.

The following tables show the impact of adoption to our consolidated statement of operations and balance sheet:

#### Nine Months Ended September 30, 2018

(in thousands, except per share amounts)	Impact of changes in accounting policies		
	As Reported	Balances without adoption of ASC 606	Effect of Change Higher/(Lower)
Product revenue	\$ 1,979	\$ 1,994	\$ (15)
Operating loss	\$ (8,509)	\$ (8,494)	\$ (15)
Net loss	\$ (8,551)	\$ (8,536)	\$ (15)
Net loss per share, basic and diluted	\$ (0.13)	\$ (0.12)	\$ -

#### September 30, 2018

(in thousands)	Impact of changes in accounting policies		
	As Reported	Balances without adoption of ASC 606	Effect of Change Higher/(Lower)
Assets:			
Accounts receivable	\$ 656	\$ 171	\$ 485
Stockholders' equity:			
Accumulated deficit	\$ (404,104)	\$ (404,589)	\$ 485

ASC 606 did not have an aggregate impact on the Company's net cash provided by operating activities, but resulted in offsetting changes in certain assets and liabilities presented within net cash provided by operating activities in the Company's condensed consolidated statement of cash flows, as reflected in the above tables.

#### Other Practical Expedients



The Company does not adjust the transaction price for the effects of a significant financing component, as at contract inception, the Company expects the collection cycle to be one year or less.

The Company expenses sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses.

#### Service Revenue

The Company's service revenue is generated by performing IVD trial services for third-party customers. Application of the modified retrospective method did not impact amounts previously reported by the Company, nor did it require a cumulative effect adjustment upon adoption, as the Company's method of recognizing revenue under ASC 606 was analogous to the method utilized immediately prior to adoption. Accordingly, there is no need for the Company to disclose the amount by which each financial statement line item was affected as a result of applying the new standard and an explanation of significant changes.

Measurement of progress on contracts with customers will generally be based on the input measurement of cost incurred relative to the total expected costs to satisfy the performance obligation. The Company has not disclosed the value of unsatisfied performance obligations for all service revenue contracts with an original expected length of one year or less, which is an optional exemption that is permitted under the adoption rules. The remainder are not material to the consolidated financial statements.

#### Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (“FASB”) issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting (Topic 718), Compensation - Stock Compensation (“ASU 2016-09”). The new guidance simplifies several aspects of the accounting for share-based payments, including immediate recognition of all excess tax benefits and deficiencies in the income statement, changing the threshold to qualify for equity classification up to the employees' maximum statutory tax rates, allowing an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur, and clarifying the classification on the statement of cash flows for the excess tax benefit and employee taxes paid when an employer withholds shares for tax-withholding purposes. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016 and interim periods within that reporting period. The Company adopted this standard on January 1, 2018, and the adoption did not have a material impact on the consolidated financial statements. In June 2018, the FASB issued ASU 2018-07, Improvements to Nonemployee Share-Based Payment Accounting. This new guidance expands the scope of Topic 718 to include share-based payment transactions from acquiring goods and services from nonemployees, which was previously codified under Topic 505, where this change will modify the measurement requirements of nonemployee awards. This amendment is effective for annual periods after December 15, 2018. The Company is currently evaluating the impact of adoption of this standard.

In February 2016, the FASB issued ASU No. 2016-2, Leases (Topic 842) (“ASU 2016-2”). This guidance is intended to make leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-2 will be effective for interim and annual periods beginning after December 15, 2018. Entities are required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. Full retrospective application is prohibited and early adoption is permitted. The Company expects to adopt this standard beginning in 2019. Currently, our only significant leases are our two office leases. The Company is still evaluating the effect adoption will have on our financial statements. We expect to complete our evaluation during the fourth quarter.

In May 2014, the FASB issued ASC 606, which superseded existing revenue recognition guidance. The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The Company adopted ASC 606 effective on January 1, 2018 using the modified retrospective method. Please see the above “Revenue Recognition” section for a discussion of the Company’s revenue recognition under ASC 606.

## 2. AGREEMENTS WITH QUEST DIAGNOSTICS INCORPORATED

In March 2015, the Company entered into a commercial agreement with Quest Diagnostics, Incorporated (“Quest Diagnostics”). Pursuant to this agreement, all OVA1 U.S. testing services for Quest Diagnostics customers were transferred to Vermillion’s wholly-owned subsidiary, ASPIRA LABS, as of August 2015. Pursuant to this agreement, as amended as of March 1, 2018, Quest Diagnostics is continuing to provide blood draw and logistics support by transporting specimens from its clients to ASPIRA LABS for testing through at least March 11, 2019 in exchange for a market value fee. Per the terms of the new commercial agreement, the Company will not offer to existing or future Quest Diagnostics customers tests that Quest Diagnostics offers.

### 3. COMMITMENTS AND CONTINGENCIES

#### Development Loan

On March 22, 2016, the Company entered into the Loan Agreement with the DECD, pursuant to which the Company may borrow up to \$4,000,000 from the DECD. Proceeds from the loan were utilized primarily to fund the build-out, information technology infrastructure and other costs related to the Company's Trumbull, Connecticut facility and operations. The loan bears interest at a fixed rate of 2.0% per annum and requires equal monthly payments of principal and interest until maturity, which occurs on April 15, 2026. As security for the loan, the Company has granted the DECD a blanket security interest in the Company's personal and intellectual property. The DECD's security interest in the Company's intellectual property may be subordinated to a qualified

institutional lender. Under the terms of the Loan Agreement, as amended, the Company may be eligible for forgiveness of up to \$2,000,000 of the principal amount of the loan if the Company achieves certain job creation and retention milestones by March 1, 2021 (the “Measurement Date”). Conversely, if the Company is either unable to meet these job creation and retention milestones, namely, hiring and retaining for a consecutive two-year period 40 full-time employees with a specified average annual salary by the Measurement Date, or does not maintain the Company’s Connecticut operations for a period of 10 years, the DECD may require early repayment of a portion or all of the loan depending on job attainment as compared to the required amount plus a penalty of 5% of the total funded loan.

An initial disbursement of \$2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. The remaining \$2,000,000 will be advanced if and when the Company achieves certain other future milestones. The loan may be prepaid at any time without premium or penalty.

### Operating Leases

The Company leases facilities to support its business of discovering, developing and commercializing diagnostic tests in the fields of gynecologic disease. The Company’s principal facility, including the CLIA laboratory used by ASPIRA LABS, is located in Austin, Texas, and the CLIA laboratory used by ASPIRA IVD is located in Trumbull, Connecticut. The Austin, Texas lease includes an aggregate annual base rent of \$86,000 and annual estimated common area charges, taxes and insurance of \$46,000 and expires on January 31, 2019.

In October 2015, the Company entered into a lease agreement for a facility in Trumbull, Connecticut. The lease required initial payments for the buildout of leasehold improvements to the office space, which were approximately \$596,000. The term of the lease is five years beginning after the initial date of occupancy in January 2016 and a rent abatement period of five months. The lease includes an aggregate annual base rent of \$32,000 and annual estimated common area charges, taxes and insurance of \$95,000.

Building rent for the three months ended September 30, 2018 and 2017 totaled \$66,000 for each period. Building rent for the nine months ended September 30, 2018 and 2017 totaled \$199,000 and \$189,000, respectively.

### Non-cancelable Royalty Obligations

The Company is a party to an amended research collaboration agreement with The Johns Hopkins University School of Medicine under which the Company licenses certain of its intellectual property. Under the terms of the amended research collaboration agreement, Vermillion is required to pay the greater of 4% royalties on net sales of diagnostic

tests using the assigned patents or annual minimum royalties of \$57,500. Royalty expense for the three months ended September 30, 2018 and 2017 totalled \$30,000 for each period. Royalty expense for the nine months ended September 30, 2018 and 2017 totalled \$78,000 and \$94,000, respectively.

#### 4. STOCKHOLDERS' EQUITY

##### 2018 Offerings

On April 13, 2018, the Company entered into two underwriting agreements (each, an "Underwriting Agreement") with Piper Jaffray & Co., as the sole underwriter (the "Underwriter"), in connection with separate but concurrent public offerings of the Company's securities.

Pursuant to the first Underwriting Agreement, the Company agreed to issue and sell an aggregate of 10,000,000 shares of Vermillion common stock, par value \$0.001 per share, offered by the Underwriter in a public offering at a price to the public of \$1.00 per share (the "Common Stock Offering"). Under this Underwriting Agreement, the Company granted the Underwriter an option to purchase up to an additional 1,500,000 shares of Vermillion common stock at the public offering price, less underwriting discounts and commissions, to cover over-allotments, if any. The Underwriter did not exercise this option. The Common Stock Offering closed on April 17, 2018 and resulted in proceeds, net of 7% underwriting costs and other offering costs, to the Company of \$8,992,000.

Pursuant to the second Underwriting Agreement, the Company agreed to issue and sell an aggregate of 50,000 shares of Vermillion Series B Convertible Preferred Stock, par value \$0.001 per share, offered by the Underwriter in a public offering at a price to the public of \$100.00 per share (the “Series B Offering”). The Series B Offering closed on April 17, 2018 and resulted in proceeds, net of 7% underwriting costs and other offering costs, to the Company of \$4,496,000.

Upon obtaining Company stockholder approval at the annual meeting of Company stockholders on June 21, 2018, each of the 50,000 shares of Vermillion Series B Convertible Preferred Stock was automatically converted into shares of Vermillion common stock, at a conversion rate of 100 shares of Vermillion common stock per one share of Vermillion Series B Convertible Preferred Stock, including shares issuable pursuant to customary anti-dilution provisions.

#### 2017 Warrant Repricing and Exercise

In December 2014, the Company issued warrants to purchase up to an aggregate of 4,166,659 shares of Vermillion common stock at an exercise price of \$2.00 per share in conjunction with a December 2014 private placement of Vermillion common stock.

On August 31, 2017, certain holders of these warrants exercised warrants to purchase 3,796,818 shares of Vermillion common stock in consideration for the Company agreeing to reduce the exercise price to \$1.00 per share of Vermillion common stock. The remaining 369,841 unexercised warrants expired by their original terms on December 23, 2017.

The Company issued 3,796,818 shares of Vermillion common stock and received \$3,796,818 in aggregate gross proceeds (approximately \$3,577,000 net of transaction costs). The incremental non-cash fair value of approximately \$942,000 from the modification of the warrants was calculated using the Black-Scholes model and recorded as a deemed dividend to the warrant holders within stockholders’ equity.

#### 2017 Private Placement

On February 17, 2017, the Company completed a private placement pursuant to which certain investors purchased 3,747,125 shares of Vermillion common stock at a price of \$1.40 per share. Vermillion also issued warrants to purchase shares of Vermillion common stock at a price of \$0.125 per warrant share in the private placement. Net proceeds of the private placement were approximately \$5,127,000 after deducting offering expenses. The warrants are exercisable for 2,810,338 shares of Vermillion common stock at \$1.80 per share. The warrants expire on the fifth anniversary of the date of issuance or, if earlier, five business days after Vermillion delivers notice that the closing price per share of its common stock exceeded the exercise price for 20 consecutive trading days during the exercise period.

The sale of common stock and issuance of warrants qualified for equity treatment under GAAP. The respective values of the warrants and common stock were calculated using their relative fair values and classified under common stock and additional paid-in capital. The value ascribed to the warrants is \$804,000 and to the common stock is approximately \$4,296,000.

#### 2010 Stock Incentive Plan

The Company's employees, directors, and consultants are eligible to receive awards under the Vermillion, Inc. Second Amended and Restated 2010 Stock Incentive Plan (the "2010 Plan"). The 2010 Plan permits the granting of a variety of awards, including stock options, share appreciation rights, restricted shares, restricted share units, unrestricted shares, deferred share units, performance and cash-settled awards, and dividend equivalent rights. The 2010 Plan provides for issuance of up to 12,122,983 shares of Vermillion common stock, subject to adjustment as provided in the 2010 Plan.

#### Stock-Based Compensation

During the three months ended September 30, 2018, the Company awarded Vermillion's non-employee directors an aggregate of 27,871 shares of restricted stock under the 2010 Plan having a fair value of approximately \$35,000. The vesting of these shares of restricted stock is as follows: 32% on September 1, 2018, and 68% on December 1, 2018. The Company also awarded a certain consultant 16,816 shares of restricted stock under the 2010 Plan having a fair value of approximately \$13,000.

During the nine months ended September 30, 2018, the Company awarded Vermillion's non-employee directors an aggregate of 398,400 shares of restricted stock under the 2010 Plan having a fair value of approximately \$442,000. The vesting of these shares of restricted stock is as follows: 50% on June 1, 2018, 25% on September 1, 2018 and 25% on December 1, 2018. 35,000 of those shares of restricted stock were forfeited upon the departure of a board member in June. The Company also awarded certain consultants 23,350 shares of restricted stock under the 2010 Plan having a fair value of approximately \$23,000.

During the nine months ended September 30, 2018, the Company granted certain officers and employees options to purchase an aggregate of 934,000 shares of Vermillion common stock with an exercise price of \$1.11 per share and 125,000 shares of Vermillion common stock with an exercise price of \$0.90 per share. These stock options vest 25% on each of the four anniversaries of the vesting commencement date for each such stock option.

The allocation of employee stock-based compensation expense by functional area for the three and nine months ended September 30, 2018 and 2017 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2018	2017	2018	2017
Cost of revenue	\$ 22	\$ 21	\$ 69	\$ 61
Research and development	2	-	4	5
Sales and marketing	14	38	95	108
General and administrative	233	216	727	630
Total	\$ 271	\$ 275	\$ 895	\$ 804



## 5. LOSS PER SHARE

The Company calculates basic loss per share using the weighted average number of shares of Vermillion common stock outstanding during the period. Because the Company is in a net loss position, diluted loss per share is calculated using the weighted average number of shares of Vermillion common stock outstanding and excludes the effects of 7,414,053 and 7,971,860 potential shares of Vermillion common stock as of September 30, 2018 and 2017, respectively, that are anti-dilutive. Potential shares of Vermillion common stock include incremental shares of Vermillion common stock issuable upon the exercise of outstanding warrants, stock options and unvested restricted stock units.

## 6. RELATED PARTY TRANSACTIONS

On December 18, 2017, the Company entered into a consulting agreement for a term of up to five months with the Company's former Senior Vice President, Finance and Chief Accounting Officer. Pursuant to the terms of the consulting agreement through May 15, 2018, the consultant provided accounting and finance services related to the transition of financial leadership. The Company agreed to pay \$150 per hour for such consulting services. The consultant also remained eligible for payout under the Company's 2017 Corporate Incentive Plan after he satisfactorily met certain performance obligations as outlined in the consulting agreement. During the nine months ended September 30, 2018, the consultant was paid an aggregate of \$53,925 for services provided pursuant to the consulting

agreement.

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## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995.

These statements involve a number of risks and uncertainties. Words such as “may,” “expects,” “intends,” “anticipates,” “believes,” “estimates,” “plans,” “seeks,” “could,” “should,” “continue,” “will,” “potential,” “projects” and similar expressions to identify such forward-looking statements. Readers are cautioned that these forward-looking statements speak only as of the date on which this Quarterly Report on Form 10-Q is filed with the Securities and Exchange Commission (the “SEC”), and, except as required by law, Vermillion, Inc. (“Vermillion” and, together with its subsidiaries, the “Company,” “we,” “our,” or “us”) does not assume any obligation to update, amend or clarify them to reflect events, new information or circumstances occurring after such date.

Examples of forward-looking statements regarding our business include the following:

- projections or expectations regarding our future test volumes, revenue, cost of revenue, operating expenses, cash flow, results of operations and financial condition;
- our plan to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders;
- our planned business strategy and the anticipated timing of the implementation thereof;
- plans with respect to our market expansion and growth, including plans to market OVA1 and Overa outside the United States;
- plans to develop new algorithms and molecular diagnostic tests;
- plans to develop a product or tool combining an OVA1 with results of a symptom index;
- plans to establish our own payer coverage for Overa and expand coverage for OVA1;
  - intentions to address clinical questions related to early disease detection, treatment response, monitoring of disease progression, prognosis and other issues in the fields of oncology and women's health;
- plans to leverage infrastructure and enhance our pipeline of future technologies by fostering relationships with in vitro diagnostic (“IVD”) companies;
- plans with respect to ASPIRA IVD, Inc. (“ASPIRA IVD”);
- expected service revenue
- our planned focus on the execution of five core strategic business drivers in ovarian cancer diagnostics and specialized laboratory services to address unmet medical needs for women faced with gynecologic disease and other conditions and the continued development of our business;
- anticipated efficacy of our products, product development activities and product innovations;
- expected competition in the markets in which we compete;
- plans with respect to ASPIRA LABS, Inc. (“ASPIRA LABS”);
- expectations regarding future services provided by Quest Diagnostics Incorporated (“Quest Diagnostics”);
- plans to expand our ovarian cancer franchise beyond OVA1, including with respect to Overa, OVA1/Overa Reflex, and DxA1 and DxA2;
- plans regarding the commercialization of Overa;



- plans to decentralize OVA1 testing to physician offices and healthcare systems;
- plans to develop informatics products and develop and perform laboratory developed tests (“LDTs”);
- plans with respect to the Company’s pelvic mass registry, including anticipated sources of funding;
- anticipated effects on reimbursement for OVA1 from changes to Novitas Solutions’ administrative requirements;
- expectations regarding the Company’s approach of monitoring and combining multiple protein biomarkers to create diagnostic tests to aid physicians considering treatment options for patients with complex diseases, and the Company’s future development of new In Vitro Diagnostic Multivariate Index Assays (IVDMIA);
- expectations regarding existing and future collaborations and partnerships, including OVA1 and Overa distribution agreements;
- plans regarding future publications;
- our continued ability to comply with applicable governmental regulations, expectations regarding pending regulatory submissions and plans to seek regulatory approvals for our tests outside the United States;
- our ability to obtain and maintain the regulatory approvals required to market Overa in other countries;
- our continued ability to expand and protect our intellectual property portfolio;
  - anticipated liquidity and capital requirements;
- anticipated future losses and our ability to continue as a going concern;
- expectations regarding the second disbursement from our financing arrangement, as amended, with the State of Connecticut Department of Economic and Community Development (the “DECD”);
- expected expenditures, including the expected increase in expenses related to sales and marketing of OVA1 and Overa in 2018;
- our ability to use our net operating loss carryforwards;
- anticipated future tax liability under U.S. federal and state income tax legislation;
- expected market adoption of our diagnostic tests, including OVA1 and Overa;
- expectations regarding our ability to launch new products we develop, license, co-market or acquire;
- expectations regarding raising capital and the amount of financing anticipated to be required to fund our planned operations; and
- expectations regarding reimbursement for our products, and our ability to obtain such reimbursement, from third-party payers such as private insurance companies and government insurance plans.

Forward-looking statements are subject to significant risks and uncertainties, including those discussed in Part I, Item 1A “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2017 (our “2017 Annual Report”), that could cause actual results to differ materially from those projected in such forward-looking statements due to various factors, including our ability to increase the volume of OVA1 or Overa sales; our ability to market our test through sales channels other than Quest Diagnostics including ASPIRA LABS; failures by third-party payers to reimburse OVA1 or Overa or changes or variances in reimbursement rates; our ability to secure additional capital on acceptable terms to execute our business plan; our ability to commercialize OVA1 or Overa both within and outside the United States; in the event that we succeed in commercializing OVA1 or Overa outside the United States, the political, economic and other conditions affecting other countries (including foreign exchange rates); our ability to continue developing certain existing technologies; our ability to develop and commercialize additional diagnostic products and achieve market acceptance with respect to these products; our ability to compete successfully; our ability to obtain any regulatory approval required for our future diagnostic products; our or our suppliers’ ability to comply with Food and Drug Administration (“FDA”) requirements for production, marketing

and post-market monitoring of our products; additional costs that may be required to make further improvements to our manufacturing operations; our ability to maintain sufficient or acceptable supplies of immunoassay kits from our suppliers; our ability to continue to develop, protect and promote our proprietary technologies; our ability to use intellectual property directed to diagnose biomarkers; our ability to successfully defend our proprietary technology against third parties; future litigation against us, including infringement of intellectual property and product liability exposure; our ability to retain key employees; business interruptions; legislative actions resulting in higher compliance costs; changes in healthcare policy; our ability to comply with environmental laws; our ability to generate sufficient demand for ASPiRA LABS' services to cover its operating costs; our ability to comply with the additional laws and regulations that apply to us in connection with the operation of ASPiRA LABS; our ability to comply with FDA regulations that relate to our products and to obtain any FDA clearance or approval required to develop and perform LDTs; ASPiRA IVD's lack of operating history; ASPiRA IVD's ability to generate and maintain business; fluctuations over time with respect to ASPiRA IVD's operating results; ASPiRA IVD's ability to enter into profitable contracts; ASPiRA IVD's ability to maintain effective information systems without significant interruption; ASPiRA IVD's ability to perform its services in compliance with contractual requirements, regulatory standards and ethical considerations; our ability to integrate and achieve anticipated results from any acquisitions or strategic alliances; and our ability to comply with continued listing requirements of The Nasdaq Capital Market.

## Overview

Our vision is to drive the advancement of women's health by providing innovative methods to detect, monitor and manage the treatment of both benign and malignant gynecologic disease, with our primary focus being diseases of the female pelvic cavity.

We have expanded our corporate strategy with the goal of transforming Vermillion from a technology license company to a diagnostic service and bio-analytic solutions provider. Our plan is to broaden our commercial focus from ovarian cancer to differential diagnosis of women with a range of gynecological disorders. Our strategy is being deployed in three phases. The three phases are a rebuild phase, which was completed in the third quarter of 2015, a transformation phase, which is now virtually complete except for continuing expansion of payer coverage, and a market expansion and growth phase, which we began in 2017.

During the first phase, we expanded our leadership team by hiring several new senior leaders including a chief executive officer. In addition, we expanded our commercial strategy, reestablished medical and advisory support, rebuilt our patient advocacy strategy and established a billing system and a payer strategy outside of our relationship with Quest Diagnostics. During the second phase, we completed the process of obtaining licensure of ASPiRA LABS in all of the states that require licenses, and are in the process of establishing our own payer coverage for OVA1, Multivariate Index Assay (MIA), and our second-generation OVA1 test, trademarked Overa, Multivariate Index Assay, 2nd Generation (MIA2G). Overa has been launched on a targeted basis. In October, we launched OVA1+, which is designed to improve accuracy and reduce false positives by nearly 40% by leveraging the strengths of OVA1's sensitivity and Overa's specificity. In the third phase, we plan to fully commercialize OVA1 and Overa by utilizing the full national licensure of ASPiRA LABS, select laboratories for distribution, decentralized OVA1 testing to physician offices and healthcare systems, managed care coverage in select markets, our sales force and existing customer base. Unlike OVA1, Overa uses a global testing platform, which will allow Overa to be deployed internationally. We initiated the targeted launch of Overa in October 2016 with two key accounts converting from OVA1 to Overa. In October 2015, we announced registration of the CE mark for and clearance to market Overa in the European Union. We also plan to develop an LDT product series, which we refer to internally as Diagnostic

Algorithms #1 (“DxA1”) and Diagnostic Algorithms #2 (“DxA2”). We anticipate that DxA1 and DxA2 will include not only biomarkers, but also clinical risk factors, other diagnostics and patient history data in order to boost predictive value. During the third quarter, we reorganized and reinvested in a stronger sales and marketing team in order to better position our new commercial offerings.

We are dedicated to the discovery, development and commercialization of novel high-value diagnostic and bio-analytical solutions that help physicians diagnose, treat and improve outcomes for women. Our tests are intended to detect, characterize and stage disease, and to help guide decisions regarding patient treatment, which may include decisions to refer patients to specialists, to perform additional testing, or to assist in monitoring response to therapy. A distinctive feature of our approach is to combine multiple biomarkers, other modalities and diagnostics, clinical risk factors and patient data into a single, reportable index score that has higher diagnostic

accuracy than its constituents. We concentrate on our development of novel diagnostic tests for gynecologic disease, with an initial focus on ovarian cancer. We also intend to address clinical questions related to early disease detection, treatment response, monitoring of disease progression, prognosis and others through collaborations with leading academic and research institutions.

Our initial product, OVA1, is an FDA-cleared blood test designed to, in addition to a physician's clinical assessment of a woman with a pelvic mass, identify women who are at high risk of having a malignant ovarian tumor prior to planned surgery. We have launched on a targeted basis a second-generation biomarker panel known as Overa, which is intended to maintain our product's high sensitivity while improving specificity. We received FDA clearance for Overa in March 2016. Overa uses the Roche cobas 4000, 6000 and 8000 platforms.

In June 2014, Vermillion launched ASPIRA LABS, a Clinical Laboratory Improvements Amendments of 1988 ("CLIA") certified national laboratory based in Austin, Texas, which specializes in applying biomarker-based technologies to address critical needs in the management of gynecologic cancers and disease. ASPIRA LABS provides expert diagnostic services using a state-of-the-art biomarker-based diagnostic algorithm to aid in clinical decision making and advance personalized treatment plans. The lab currently processes our OVA1 and Overa tests, and we plan to develop and perform LDTs at ASPIRA LABS in the future. ASPIRA LABS holds a CLIA Certificate of Registration and a state laboratory license in California, Florida, Maryland, New York, Pennsylvania and Rhode Island. The Centers for Medicare & Medicaid Services issued a provider number to ASPIRA LABS in March 2015.

In 2016, we created a new service within the ASPIRA channel strategy, "an ASPIRA IVD Services Program". In April 2016, we formed ASPIRA IVD to offer IVD trial services to third-party customers. ASPIRA IVD is a specialized laboratory provider dedicated to meeting the unique testing needs of IVD manufacturers seeking to commercialize high-complexity assays. ASPIRA IVD was built around a core of laboratory expertise and an FDA-compliant quality system, and strives to deliver accurate and reliable results to its third-party customers suitable for FDA submission. ASPIRA IVD received a CLIA laboratory license in June 2016 and commenced operations in the second quarter of 2016.

#### Strategy:

We are focused on the execution of five core strategic business drivers in ovarian cancer diagnostics and specialized laboratory services to build long-term value for our investors:

- Maximizing the existing OVA1 opportunity in the United States by taking the lead in payer coverage and commercialization of OVA1. This strategy included the launch of a CLIA certified clinical laboratory, ASPIRA LABS, in June 2014;
- Expanding the distribution platform beyond the U.S. by launching Overa, a next generation biomarker panel, while building the clinical utility and health economics foundation of both OVA1 and Overa, which we believe may allow for better domestic market penetration and international expansion (FDA clearance for Overa was received in March 2016);
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- Leveraging our existing database and specimen bank while building the largest specimen and data repository of gynecologic pelvic mass patients worldwide;
- Expanding our product offerings to additional pelvic disease conditions such as endometriosis and polycystic ovarian syndrome by adding additional gynecologic bio-analytic solutions involving biomarkers, other modalities (e.g., imaging), clinical risk factors and patient data to aid diagnosis and risk stratification of women presenting with a pelvic mass disease; and
- Expanding our customer offerings with the launch of our ASPIRA IVD laboratory services.

We believe that these business drivers will contribute significantly to addressing unmet medical needs for women faced with gynecologic disease and other conditions and the continued development of our business.

OVA1 addresses a clear clinical need, namely the pre-surgical identification of women who are at risk of having a malignant ovarian tumor. Numerous studies have documented the benefit of referral of these women to gynecologic oncologists for their initial surgery. Prior to the clearance of OVA1, no blood test had been cleared by the FDA for physicians to use in the pre-surgical management of ovarian adnexal masses. OVA1 is a qualitative serum test that utilizes five well-established biomarkers and proprietary software cleared as part of the OVA1 510(k) to determine the likelihood of malignancy in women over age 18, with a pelvic mass for whom surgery is planned. OVA1 should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of OVA1 carries the risk of unnecessary testing, surgery and delayed diagnosis. OVA1 was developed through large pre-clinical studies in collaboration with numerous academic medical centers encompassing over 2,500 clinical samples. OVA1 was fully validated in a prospective multi-center clinical trial encompassing 27 sites reflective of the diverse nature of the clinical centers at which ovarian adnexal masses are evaluated.

In the United States, revenue for diagnostic tests comes from several sources, including third-party payers such as insurance companies, government healthcare programs, such as Medicare and Medicaid, client bill accounts and patients. Novitas Solutions, the Medicare contractor, covers and reimburses for OVA1 tests performed in certain states, including Texas. Because OVA1 tests are exclusively performed at ASPIRA LABS in Texas this local coverage determination from Novitas Solutions essentially provides national coverage for patients enrolled in Medicare as well as Medicare Advantage health plans. ASPIRA LABS also bills third-party commercial and other government payers as well as client bill accounts and patients for OVA1.

In October 2016, we launched our pelvic mass specimen and data repository and began the collection of Institutional Review Board patient consents for collection and cataloging of serum samples for future research purposes.

In November 2016, The American College of Obstetricians and Gynecologists ("ACOG") issued Practice Bulletin Number 174 which included OVA1 as a "Multivariate Index Assay". This bulletin outlines ACOG's "new" clinical management guidelines for adnexal mass management.

These new clinical management guidelines replace the July 2007 version, Practice Bulletin 83. Practice Bulletins summarize current information on techniques and clinical management issues for the practice of obstetrics and gynecology. Practice Bulletins are evidence-based documents, and recommendations are based on the evidence. This is also the only clinical management tool used for adnexal masses. Guidelines do not exist for adnexal masses, only Practice Bulletins. Guidelines do exist, however, for ovarian cancer management.

The Practice Bulletin recommends that obstetricians and gynecologists evaluating women with adnexal masses who do not meet Level A criteria of a low risk transvaginal ultrasound should proceed with Level B clinical guidelines. Level B guidelines state that the physician may use risk assessment tools such as existing CA125 technology or OVA1 ("Multivariate Index Assay") as listed in the bulletin. Based on this, OVA1 has now achieved parity with CA125 as a Level B recommendation for the management of adnexal masses.

In December 2016, we received an FDA Clarification Letter regarding OVA1 and Overa. This letter was in reference to the September 7, 2016 FDA Safety Communication advising women and their physicians against the use of ovarian cancer screening tests for asymptomatic women.

In order to avoid any confusion, as well as to document the FDA position on OVA1 and Overa, Jeffrey Shuren, M.D., J.D., Director for the Center for Devices and Radiological Health at the FDA, sent a letter to Vermillion, dated December 21, 2016. In the letter, Dr. Shuren stated:

We agree that this safety communication does not apply to Vermillion's FDA-cleared tests, OVA1 (MIA) and Overa (MIA2G), which are not screening tests for ovarian cancer.

FDA cleared OVA1 (MIA) and Overa (MIA2G) as aids to further assess the likelihood that malignancy is present when the physician's independent clinical and radiological evaluation does not indicate malignancy. The intended uses of the two assays are the same—to help physicians more reliably identify which patients would benefit from consultation with or referral to a

gynecologic oncologist. OVA1 (MIA) and Overa (MIA2G) are indicated for women who present with an adnexal mass.

In March 2015, we entered into a new commercial agreement with Quest Diagnostics. Pursuant to this agreement, all OVA1 U.S. testing services for Quest Diagnostics customers were transferred to Vermillion's wholly-owned subsidiary, ASPIRA LABS, as of August 10, 2015. Pursuant to this agreement, as amended as of March 1, 2018, Quest Diagnostics is continuing to provide blood draw and logistics support by transporting specimens from its clients to ASPIRA LABS for testing through at least March 11, 2019 in exchange for a market value fee. Per the terms of the new commercial agreement, the Company will not offer to existing or future Quest Diagnostics customers tests that Quest Diagnostics offers.

In 2016, we continued to make progress with increased payer positive medical policies and in network agreements for a total of over 80 million covered lives.

In the first half of 2017, ASPIRA IVD services landed two top pharmaceutical trial service agreements including one enrollment study.

In July 2017, ASPIRA LABS expanded its patient advocacy program nationally to assist patients with proactive benefit checks, with over 90% resulting in OVA1 utilization.

In September 2017, the preliminary Protecting Access to Medicare Act of 2014 ("PAMA") price for OVA1 and Overa was published by the Center for Medicare and Medicaid Service. The preliminary OVA1 rate is based on the median of private payer payments we submitted as part of the market-based payment reforms mandated through PAMA. The Overa price was benchmarked to the only proteomic test currently on the fee schedule, which uses biomarkers and an algorithm to produce a prognostic score. Under the new fee schedule effective January 1, 2018, the price for OVA1 (MIA) (code 81503) is \$897 and the price for Overa is \$950.

In 2018, we have continued to make progress with increased payer positive medical policies and in network agreements. As of September 30, 2018, we had 131 million covered lives and 112 million lives under contract agreement.

In October 2018, ASPIRA LABS launched OVA1®+, a new clinical pathway which combines the strengths of OVA1® and Overa®. The new offering improves accuracy and reduces false positives by nearly 40%.

As of the fourth quarter of 2018, we have launched our new platform and cloud service for decentralizing OVA1 testing. The platform and web service will allow other facilities to perform OVA1 and calculate OVA1 scores locally, enabling increased reach and access in the markets we serve.

#### Recent Developments

On April 17, 2018, the Company completed two underwritten public offerings, pursuant to which certain investors purchased 10,000,000 shares of Vermillion common stock, par value \$0.001 per share, for \$1.00 per share (the “Common Stock Offering”) and 50,000 shares of Vermillion Series B convertible preferred stock, par value \$0.001 per share, for \$100.00 per share (the “Series B Offering” and, together with the Common Stock Offering, the “Offerings”) for net proceeds of approximately \$13,500,000 after deducting offering expenses.

Upon obtaining Company stockholder approval at the annual meeting of Company stockholders on June 21, 2018, each of the 50,000 shares of Vermillion Series B Convertible Preferred Stock was automatically converted into shares of Vermillion common stock, at a conversion rate of 100 shares of Vermillion common stock per one share of Vermillion Series B Convertible Preferred Stock, including shares issuable pursuant to customary anti-dilution provisions.

On July 24, 2018, the Company received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market notifying the Company that, for the preceding 30 consecutive business days, the closing bid price for the Company’s common stock was below the minimum \$1.00 per share requirement for continued

inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). The Company has the opportunity to regain compliance or produce a plan to regain compliance. However, there can be no assurance that the Company will regain compliance.

Effective August 17, 2018, the Company appointed Nancy G. Coccozza to its board of directors.

#### Critical Accounting Policies and Estimates

Prior to January 1, 2018, we recognized product revenue in accordance with the provisions of ASC 954-605, Health Care Entities - Revenue Recognition. Our product revenue is generated by performing diagnostic services using its OVA1 and Overa tests, and the service is completed upon the delivery of test result to the prescribing physician. Under the previous revenue recognition accounting methodology, certain product revenue was recognized upon the ultimate receipt of cash. Under ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"), all revenue is recognized upon completion of the OVA1 or Overa test based on estimates of amounts that will ultimately be realized. In determining the amount to accrue for a delivered test result, we consider factors such as historical payment history and amount, payer coverage, whether there is a reimbursement contract between the payer and us, and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management. We also reviewed our patient account population and determined an appropriate distribution of patient accounts by payer (i.e., Medicare, patient pay, other third-party payer, etc.) into portfolios with similar collection experience. When evaluated for collectability, this results in a materially consistent revenue amount for such portfolios as if each patient account were evaluated on an individual contract basis.

Under the modified retrospective implementation method, we recorded a one-time cumulative effect adjustment at January 1, 2018 to reflect the aggregate effect of all OVA1 and Overa tests performed prior to January 1, 2018 as of revenue had been recognized under ASC 606. The cumulative effect adjustment was recorded increasing the opening balance of Accounts Receivable by \$500,000 in the condensed consolidated balance sheets with an offsetting reduction to Accumulated Deficit.

## Results of Operations - Three Months Ended September 30, 2018 Compared to Three Months Ended September 30, 2017

The selected summary financial and operating data of the Company for the three months ended September 30, 2018 and 2017 were as follows:

(dollars in thousands)	Three Months Ended September 30,		Increase (Decrease)	
	2018	2017	Amount	%
Revenue:				
Product	\$ 739	\$ 657	\$ 82	12
Service	35	42	(7)	(17)
Total revenue	774	699	75	11
Cost of revenue:				
Product	477	495	(18)	(4)
Service	301	284	17	6
Total cost of revenue	778	779	(1)	(0)
Gross profit (loss)	(4)	(80)	76	(95)
Operating expenses:				
Research and development	129	192	(63)	(33)
Sales and marketing	1,343	1,050	293	28
General and administrative	1,167	1,177	(10)	(1)
Total operating expenses	2,639	2,419	220	9
Loss from operations	(2,643)	(2,499)	(144)	6
Interest income (expense), net	(6)	(10)	4	(40)
Other income (expense), net	(3)	-	(3)	-
Net loss	(2,652)	(2,509)	(143)	6
Deemed dividend on warrant repricing		(942)	942	
Net loss attributable to common stockholders	\$ (2,652)	\$ (3,451)	\$ 799	6

**Product Revenue.** Product revenue was \$739,000 for the three months ended September 30, 2018 compared to \$657,000 for the same period in 2017. Effective January 1, 2018, revenue for ASPIRA LABS is being recognized when the OVA1 test is being performed based on estimates of what we expect to ultimately realize. The 12% product revenue increase is due to a slight increase in our tests performed, as well as an increase in price per test.

The number of OVA1 tests performed increased 1% to approximately 1,981 OVA1 tests during the three months ended September 30, 2018 compared to approximately 1,954 OVA1 tests for the same period in 2017. We expect the test volume to improve over the remainder of the year as we increase our sales and marketing investments.

**Service Revenue.** Service revenue was \$35,000 for the three months ended September 30, 2018 compared to \$42,000 for the same period in 2017. Service revenue varies from quarter to quarter based on the stages of ongoing customer projects. Revenue for ASPIRA IVD is being recognized once certain revenue recognition criteria have been met (see Note 1 to the financial statements included in Part I, Item I of this Form 10-Q). Due to the existing pipeline, we expect service revenue to increase slightly in the fourth quarter of 2018.

Cost of Revenue - Product. Cost of product revenue was \$477,000 for the three months ended September 30, 2018 compared to \$495,000 for the same period in 2017, representing a decrease of 4% due primarily to decreases in depreciation and lab supply costs, offset by postage costs due to new kits, as well as Quest project management fees incurred in 2018. We expect the cost of product revenue to remain consistent in the fourth quarter of 2018 compared to the third quarter of 2018.



**Cost of Revenue - Service.** Cost of service revenue was \$301,000 for the three months ended September 30, 2018 compared to \$284,000 for the same period in 2017. The 6% increase related primarily to lab supplies purchased in connection with larger projects in the third quarter of 2018. We expect the cost of service revenue to fluctuate consistent with service revenue to some extent; however, due to the fixed nature of the costs, we expect the fourth quarter costs to be largely consistent with those of the third quarter.

**Research and Development Expenses.** Research and development expenses represent costs incurred to develop our technology and carry out clinical studies, and include personnel-related expenses, regulatory costs, reagents and supplies used in research and development laboratory work, infrastructure expenses, contract services and other outside costs. Research and development expenses for the three months ended September 30, 2018 decreased \$63,000, or 33%, compared to the same period in 2017. This decrease was primarily due to a reduction in consulting expenses. We expect research and development expenses to increase slightly from the third to the fourth quarter of 2018 due to the completion of ongoing studies and publications.

**Sales and Marketing Expenses.** Our sales and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses, and infrastructure expenses. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding OVA1 and Overa. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation, and dissemination of scientific and health economic publications. Sales and marketing expenses for the three months ended September 30, 2018 increased \$293,000, or 28%, compared to the same period in 2017. This increase was primarily due to increased headcount and personnel-related expenses and increased consulting costs in the third quarter of 2018 compared to 2017. We expect sales and marketing expenses to increase modestly over the remainder of 2018 as we focus efforts on the commercialization of OVA1 and Overa.

**General and Administrative Expenses.** General and administrative expenses consist primarily of personnel-related expenses, professional fees and other costs, including legal, finance and accounting expenses and other infrastructure expenses. General and administrative expenses for the three months ended September 30, 2018 decreased by \$10,000, or 1%, compared to the same period in 2017. We expect general and administrative expenses to remain consistent with the third quarter in the fourth quarter of 2018.

## Results of Operations - Nine Months Ended September 30, 2018 Compared to Nine Months Ended September 30, 2017

The selected summary financial and operating data of the Company for the nine months ended September 30, 2018 and 2017 were as follows:

(dollars in thousands)	Nine Months Ended September 30,		Increase (Decrease)	
	2018	2017	Amount	%
Revenue:				
Product	\$ 1,979	\$ 2,195	\$ (216)	(10)
Service	152	128	24	19
Total revenue	2,131	2,323	(192)	(8)
Cost of revenue:				
Product	1,538	1,345	193	14
Service	851	855	(4)	(0)
Total cost of revenue	2,389	2,200	189	9
Gross profit (loss)	(258)	123	(381)	(310)
Operating expenses:				
Research and development	425	685	(260)	(38)
Sales and marketing	4,046	3,114	932	30
General and administrative	3,780	3,825	(45)	(1)
Total operating expenses	8,251	7,624	627	8
Loss from operations	(8,509)	(7,501)	(1,008)	13
Interest income (expense), net	(25)	(32)	7	(22)
Other income (expense), net	(17)	(9)	(8)	89
Net loss	(8,551)	(7,542)	(1,009)	13
Deemed dividend on warrant repricing		(942)	942	
Net loss attributable to common stockholders	\$ (8,551)	\$ (8,484)	\$ (67)	13

**Product Revenue.** Product revenue was \$1,979,000 for the nine months ended September 30, 2018 compared to \$2,195,000 for the same period in 2017. Effective January 1, 2018, revenue for ASPIRA LABS is being recognized when the OVA1 test is being performed based on estimates of what we expect to ultimately realize. The 10% product revenue decrease is due to a decrease in our tests performed, especially those for client bill customers.

The number of OVA1 tests performed decreased 15% to approximately 5,683 OVA1 tests during the nine months ended September 30, 2018 compared to approximately 6,665 OVA1 tests for the same period in 2017. The volume decrease was primarily due to the previously announced loss of a client bill customer in July 2017, which was concentrated in uncovered territories (territories not covered by an ASPIRA sales representative).

**Service Revenue.** Service revenue was \$152,000 for the nine months ended September 30, 2018 compared to \$128,000 for the same period in 2017. Service revenue varies based on the stages of ongoing customer projects. Revenue for ASPIRA IVD is being recognized once certain revenue recognition criteria have been met (see Note 1 to

the financial statements included in Part I, Item I of this Form 10-Q).

Cost of Revenue - Product. Cost of product revenue was \$1,538,000 for the nine months ended September 30, 2018 compared to \$1,345,000 for the same period in 2017, representing an increase of 14% due primarily to some equipment maintenance costs, increased postage costs as well as Quest project management fees incurred in 2018.

Cost of Revenue - Service. Cost of service revenue was \$851,000 for the nine months ended September 30, 2018, which was nearly flat compared to \$855,000 in costs for the same period in 2017.

**Research and Development Expenses.** Research and development expenses represent costs incurred to develop our technology and carry out clinical studies, and include personnel-related expenses, regulatory costs, reagents and supplies used in research and development laboratory work, infrastructure expenses, contract services and other outside costs. Research and development expenses for the nine months ended September 30, 2018 decreased \$260,000, or 38%, compared to the same period in 2017. This decrease was primarily due to a reduction in consulting expenses.

**Sales and Marketing Expenses.** Our sales and marketing expenses consist primarily of personnel-related expenses, education and promotional expenses, and infrastructure expenses. These expenses include the costs of educating physicians, laboratory personnel and other healthcare professionals regarding OVA1 and Overa. Sales and marketing expenses also include the costs of sponsoring continuing medical education, medical meeting participation, and dissemination of scientific and health economic publications. Sales and marketing expenses for the nine months ended September 30, 2018 increased \$932,000, or 30%, compared to the same period in 2017. This increase was primarily due to increased headcount and personnel-related expenses, one-time costs for Chief Operating Officer severance and increased consulting costs in 2018 compared to 2017.

**General and Administrative Expenses.** General and administrative expenses consist primarily of personnel-related expenses, professional fees and other costs, including legal, finance and accounting expenses and other infrastructure expenses. General and administrative expenses for the nine months ended September 30, 2018 decreased by \$45,000, or 1%, compared to the same period in 2017. The decrease was primarily due to the remeasurement of consultant stock options in 2018 and reduced headcount, partially offset by increased consulting fees in 2018.

## Liquidity and Capital Resources

We plan to continue to expend resources selling and marketing OVA1 and Overa, operating our IVD trial services business and developing additional diagnostic tests and service capabilities.

We have incurred significant net losses and negative cash flows from operations since inception. At September 30, 2018, we had an accumulated deficit of \$404,104,000 and stockholders' equity of \$9,710,000. As of September 30, 2018, we had \$11,760,000 of cash and cash equivalents and \$2,424,000 of current liabilities. Working capital was \$10,349,000 and \$3,696,000 at September 30, 2018 and December 31, 2017, respectively.

On April 17, 2018, the Company completed the Offerings pursuant to which certain investors purchased shares of Vermillion common stock and shares of Vermillion Series B Convertible Preferred Stock for net proceeds of approximately \$13,500,000 after deducting offering expenses.

On August 31, 2017, certain holders exercised warrants to purchase 3,796,818 shares of Vermillion common stock (which warrants were issued in conjunction with a December 2014 private placement of Vermillion common stock) in consideration for the Company agreeing to reduce the exercise price from \$2.00 to \$1.00 per share of Vermillion common stock. As a result, the Company issued 3,796,818 shares of Vermillion common stock and received \$3,797,000 in aggregate gross proceeds (approximately \$3,577,000 net of transaction costs).

On February 17, 2017, the Company completed a private placement pursuant to which certain investors purchased Vermillion common stock and warrants to purchase shares of Vermillion common stock for net proceeds of approximately \$5,127,000 after deducting offering expenses.

On March 22, 2016, we entered into the Loan Agreement pursuant to which we may borrow up to \$4,000,000 from the DECD. Proceeds from the loan were utilized primarily to fund the build-out, information technology infrastructure and other costs related to our Trumbull, Connecticut facility and operations. The loan bears interest at a fixed rate of 2.0% per annum and requires equal monthly payments of principal and interest until maturity, which occurs on April 15, 2026. As security for the loan, we have granted the DECD a blanket security interest in our personal and intellectual property. The DECD's security interest in our intellectual property may be subordinated to a qualified institutional lender. Under the terms of the agreement, as amended, we may be eligible for forgiveness of up to \$2,000,000 of the principal amount of the loan if we achieve certain job creation and

retention milestones measured by March 1, 2021 (the “Measurement Date”). Conversely, if we are either unable to meet these job creation and retention milestones, namely, hiring and retaining for a consecutive two-year period 40 full-time employees with a specified average annual salary by the Measurement Date or do not maintain our Connecticut operations for a period of 10 years, the DECD may require early repayment of a portion or all of the loan depending on job attainment as compared to the required amount plus a penalty of 5% of the total funded loan. An initial disbursement of \$2,000,000 was made to the Company on April 15, 2016 under the Loan Agreement. The remaining \$2,000,000 will be advanced if and when the Company achieves certain other future milestones. The loan may be prepaid at any time without premium or penalty.

We expect to incur a net loss and negative cash flows from operations in the remainder of 2018. Our management believes that successful achievement of our business objectives may require additional financing.

The Company expects to raise capital, if necessary, through a variety of sources, which may include the exercise of common stock warrants, equity offerings, debt financing, collaborations, licensing arrangements, grants and government funding and strategic alliances. However, additional funding may not be available when needed or on terms acceptable to the Company. If the Company is unable to obtain additional capital, it may not be able to continue sales and marketing, research and development, or other operations on the scope or scale of current activity and that could have a material adverse effect on the Company’s business, results of operations and financial condition.

Net cash used in operating activities was \$7,069,000 for the nine months ended September 30, 2018, resulting primarily from the net loss reported of \$8,551,000, partially offset by depreciation and amortization of \$527,000, stock compensation expense of \$839,000, and changes in prepaid expenses of \$228,000.

Net cash used in operating activities was \$5,977,000 for the nine months ended September 30, 2017, resulting primarily from the net loss reported of \$7,542,000 and changes in accounts payable, accrued and other liabilities of \$401,000 partially offset by stock compensation expense of \$997,000, depreciation and amortization of \$599,000 and prepaid expenses of \$312,000.

Net cash used in investing activities was \$58,000 and \$56,000 for the nine months ended September 30, 2018 and 2017, respectively, which consisted of property and equipment purchases.

Net cash provided by financing activities was \$13,348,000 for the nine months ended September 30, 2018, resulting primarily from the proceeds from the sale of Vermillion preferred stock of \$4,496,000 and of Vermillion common stock of \$8,990,000 in our April 2018 public offering.

Net cash provided by financing activities was \$8,543,000 for the nine months ended September 30, 2017, which consisted primarily of proceeds from the sale of Vermillion common stock in our February 2017 private placement,

net of issuance costs, as well as proceeds from the exercise of common stock warrants, net of issuance costs.

Our future liquidity and capital requirements will depend upon many factors, including, among others:

- resources devoted to sales, marketing and distribution capabilities;
  - the rate of OVA1 and Overa product adoption by physicians and patients;
- the insurance payer community's acceptance of and reimbursement for OVA1 and Overa;
- the successful targeted launch of Overa;
- resources devoted to our IVD trials laboratory and services;
- the revenue generated by our IVD trial services business;

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- our plans to acquire or invest in other products, technologies and businesses; and
- the market price of our common stock.

We have significant net operating loss (“NOL”) carryforwards as of September 30, 2018 for which a full valuation allowance has been provided due to our history of operating losses. Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions may restrict our ability to use our NOL credit carryforwards due to ownership change limitations occurring in the past or that could occur in the future. These ownership changes may also limit the amount of NOL credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively.

New tax legislation, commonly referred to as the Tax Cuts and Jobs Act (H.R. 1), was enacted on December 22, 2017. ASC740, Accounting for Income Taxes, requires companies to recognize the effect of tax law changes in the period of enactment even though the effective date for most provisions is for tax years beginning after December 31, 2017. Since our federal deferred tax asset was fully offset by a valuation allowance, the reduction in the U.S. corporate income tax rate to 21% did not materially affect our financial statements. Significant provisions that are not yet effective but may impact income taxes in future years include: the repeal of the corporate Alternative Minimum Tax, the limitation on the current deductibility of net interest expense in excess of 30% of adjusted taxable income for levered balance sheets, a limitation on utilization of net operating losses generated after tax year 2017 to 80% of taxable income, the unlimited carryforward of net operating losses generated after tax year 2017, temporary 100% expensing of certain business assets, additional limitations on certain general and administrative expenses, and changes in determining the excessive compensation limitation. Currently, we do not anticipate paying cash federal income taxes in the near term due to any of the legislative changes, primarily due to the availability of our net operating loss carryforwards. Future interpretations relating to the recently enacted U.S. federal income tax legislation which vary from our current interpretation and possible changes to state tax laws in response to the recently enacted federal legislation may have a significant effect on this projection.

#### Off-Balance Sheet Arrangements

As of September 30, 2018, we had no off-balance sheet arrangements that are reasonably likely to have a current or future material effect on our condensed consolidated financial condition, results of operations, liquidity, capital expenditures or capital resources.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Per Item 305(e) of Regulation S-K, the information called for by this Item 3 is not required.

### ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.



Our senior management is responsible for establishing and maintaining a system of disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer’s management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management, including our Chief Executive Officer and Chief Financial Officer, performed an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2018. Based on this evaluation, our Chief Executive Officer and

Chief Financial Officer have concluded that as of September 30, 2018, our disclosure controls and procedures were effective.

Changes in internal controls over financial reporting.

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

### ITEM 1.LEGAL PROCEEDINGS

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially and adversely affect our results of operations, cash flows and financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors. While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of September 30, 2018, that, in the opinion of management, will have a material adverse effect on our financial position, results of operations or cash flows.

### ITEM 1A. RISK FACTORS

There have been no material changes to our risk factors from those disclosed under “Risk Factors” in Part I, Item 1A of our 2017 Annual Report, as supplemented by the risk factor disclosed under “Risk Factors” in Part II, Item 1A of our quarterly report on Form 10-Q for the quarter ended June 30, 2018, filed with the SEC on August 9, 2018. The risks and uncertainties described in our 2017 Annual Report, as supplemented, are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect our business, financial condition or results of operations.

ITEM 6. EXHIBITS The following exhibits are filed or incorporated by reference with this report as indicated below:

Exhibit Number	Exhibit Description	Incorporated by Reference			Filing Date	Filed Herewith
		Form	File No.	Exhibit		
<u>3.1</u>	<u>Fourth Amended and Restated Certificate of Incorporation of Vermillion, Inc. dated January 22, 2010</u>	8-K	000-31617	3.1	January 25, 2010	
<u>3.2</u>	<u>Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation, effective June 19, 2014</u>	10-Q	001-34810	3.2	August 14, 2014	
<u>3.3</u>	<u>Certificate of Designations, Preferences and Rights of Series B Convertible Preferred Stock</u>	8-K	001-34810	4.1	April 17, 2018	
<u>3.4</u>	<u>Fifth Amended and Restated Bylaws of Vermillion, Inc., effective June 19, 2014</u>	10-Q	001-34810	3.3	August 14, 2014	
<u>31.1</u>	<u>Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>					√
<u>31.2</u>	<u>Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>					√
<u>32.1</u>	<u>Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>					(1)
101	Interactive Data Files					√

(1) Furnished herewith

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 thereunto duly authorized.

Vermillion, Inc.

Date: November 8, 2018 /s/ Valerie B. Palmieri  
Valerie B. Palmieri

President and Chief Executive Officer

(Duly Authorized Officer and

Principal Executive Officer)

Date: November 8, 2018 /s/ Robert Beechey  
Robert Beechey

Chief Financial Officer

(Duly Authorized Officer, Principal Financial Officer

and Principal Accounting Officer)