

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended March 31, 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: 001-36754

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**EVOFEM BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction  
of incorporation)

12400 High Bluff Drive, Suite 600  
San Diego, CA 92130  
(Address of Principal Executive Offices)

20-8527075  
(IRS Employer  
Identification No.)

92130  
(Zip Code)

**Registrant's telephone number, including area code: (858) 550-1900**  
**Not applicable.**  
(Former name or former address, if changed since last report.)

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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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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  (Do not check if a smaller reporting company)

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

The number of shares of the registrant's common stock, \$0.0001 par value, outstanding as of April 30, 2018 was 17,763,340.

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## Table of Contents

	<b>Page</b>
	<u>1</u>
<b>PART I.</b>	
	<u>3</u>
Item 1.	<u>3</u>
	<u>4</u>
	<u>5</u>
	<u>6</u>
	<u>7</u>
Item 2.	<u>22</u>
Item 3.	<u>30</u>
Item 4.	<u>30</u>
<b>PART II.</b>	
Item 1.	<u>30</u>
Item 1A.	<u>30</u>
Item 2.	<u>61</u>
Item 3.	<u>61</u>
Item 4.	<u>62</u>
Item 5.	<u>62</u>
Item 6.	<u>82</u>
<a href="#">Signatures</a>	<u>85</u>

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## FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q (Quarterly Report) contains forward-looking statements that involve substantial risks and uncertainties. These forward-looking statements are contained principally in the sections entitled “Business,” “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, “anticipate,” “aim,” “believe,” “contemplate,” “continue,” “could,” “design,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “predict,” “poise,” “project,” “potential,” “suggest,” “should,” “strategy,” “target,” “will,” “would,” and similar expressions or phrases, or the negative of those expressions or phrases, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Although we believe we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that these statements are based on our projections of the future that are subject to known and unknown risks and uncertainties and other factors that may cause our actual results, level of activity, performance or achievements expressed or implied by these forward-looking statements, to differ. These forward-looking statements include, among other things, statements about:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operations;
- our ability to develop our lead product candidate, Amphora (L-lactic acid, citric acid, and potassium bitartrate), as a contraceptive;
- our ability to develop Amphora for additional indications;
- our ability to select and capitalize on the most scientifically, clinically or commercially promising indications or therapeutic areas for our MPT vaginal gel technology considering our limited financial resources;
- the success, cost and timing of our clinical trials;
- our dependence on third parties in the conduct of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize Amphora, our BV product candidate and any other product candidate we may seek to develop;
- the potential that results of preclinical and clinical trials indicate our current product candidates or any future product candidates we may seek to develop are unsafe or ineffective;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our current product candidates or any future product candidates we may seek to develop;
- market acceptance of our product candidates, the size and growth of the potential markets for our current product candidates and any future product candidates we may seek to develop, and our ability to serve those markets;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our MPT vaginal gel technology, our current product candidates or any other product candidates we may seek to develop;
- our reliance on licenses granted to us by third parties, our ability to preserve our rights to licenses granted to us under these license agreements and our reliance on these third-party licensors to protect the intellectual property licensed to us;

## [Table of Contents](#)

- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;
- the possibility that a third party may claim we have infringed, misappropriated or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against these claims;
- the successful development of our commercialization capabilities, including sales and marketing capabilities;
- our reliance on third-party suppliers and manufacturers;
- the success of competing therapies and products that are or become available;
- the potential for changes to current regulatory mandates requiring health insurance plans to cover FDA-cleared or approved contraceptive products without cost sharing, our ability to obtain third-party payer coverage and adequate reimbursement, and our reliance on the willingness of patients to pay out-of-pocket absent full or partial third-party payer reimbursement; and
- our ability to expand our organization to accommodate potential growth and our ability to retain and attract key personnel.

Our current product candidates are undergoing clinical development and have not been approved by the FDA or the European Commission. These product candidates have not been, nor may they ever be, approved by any regulatory agency or competent authority nor marketed anywhere in the world.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Forward-looking statements should be regarded solely as our current plans, estimates and beliefs. We have included important factors in the cautionary statements included in this Quarterly Report, particularly in Item 1A, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. You should read this Quarterly Report and the documents that we have filed as exhibits to this Quarterly Report and incorporated by reference herein completely and with the understanding that our actual future results may be materially different from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements contained in this Quarterly Report are made as of the date of this Quarterly Report, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

**PART I. FINANCIAL INFORMATION**  
**ITEM 1. Financial Statements**

**EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(Unaudited)  
(In thousands, except par value and share data)

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 5,029	\$ 1,211
Restricted cash	569	490
Prepaid and other current assets	1,608	653
<b>Total current assets</b>	<b>7,206</b>	<b>2,354</b>
Property and equipment, net	783	848
Other noncurrent assets	1,003	750
<b>Total assets</b>	<b>\$ 8,992</b>	<b>\$ 3,952</b>
<b>Liabilities, convertible preferred stock and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 13,309	\$ 8,999
Accrued expenses	12,587	12,086
Accrued compensation	1,138	2,392
Series D 2X liquidation preference	—	79,870
<b>Total current liabilities</b>	<b>27,034</b>	<b>103,347</b>
Deferred rent	92	114
Other noncurrent liabilities	158	166
<b>Total liabilities</b>	<b>27,284</b>	<b>103,627</b>
Commitments and contingencies (Note 5)		
Preferred stock, \$0.0001 par value; 5,000,000 and 57,501,624 shares authorized at March 31, 2018 and December 31, 2017, respectively:		
Series A convertible preferred stock, no shares issued and outstanding at March 31, 2018, and 12,618,279 shares issued and outstanding at December 31, 2017	—	23,848
Series B convertible preferred stock, no shares issued and outstanding at March 31, 2018, and 13,801,318 shares issued and outstanding at December 31, 2017	—	43,616
Series C-1 convertible preferred stock, no shares issued and outstanding at March 31, 2018, and 8,558,686 shares issued and outstanding at December 31, 2017	—	34,382
Series C convertible preferred stock, no shares issued and outstanding at March 31, 2018, and 5,037,784 shares issued and outstanding at December 31, 2017	—	19,469
Series D redeemable convertible preferred stock, no shares issued and outstanding at March 31, 2018, and 80 shares issued and outstanding at December 31, 2017	—	68,556
Stockholders' deficit:		
Common stock, \$0.0001 par value; 300,000,000 and 4,051,137 shares authorized at March 31, 2018 and December 31, 2017, respectively; 17,763,340 and 2,082,053 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	2	81
Additional paid-in capital	358,196	17,650
Accumulated deficit	(376,490)	(307,277)
<b>Total stockholders' deficit</b>	<b>(18,292)</b>	<b>(289,546)</b>
<b>Total liabilities, convertible preferred stock and stockholders' deficit</b>	<b>\$ 8,992</b>	<b>\$ 3,952</b>

See accompanying notes to the condensed consolidated financial statements (unaudited).

**EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)  
(In thousands, except share and per share data)

	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Operating expenses:</b>		
Research and development	\$ 11,959	\$ 1,982
General and administrative	9,027	2,931
Total operating expenses	20,986	4,913
Loss from operations	(20,986)	(4,913)
Other income (expense):		
Interest income	30	31
Other expense, net	(50)	(34)
Loss on issuance of Invesco Warrants	(47,920)	—
Change in fair value of Series D 2X liquidation preference	(130)	(350)
Total other expense, net	(48,070)	(353)
Loss before income tax	(69,056)	(5,266)
Income tax expense	—	(3)
Net loss	(69,056)	(5,269)
Accretion of Series D redeemable convertible preferred stock dividends	(66)	(888)
Net loss attributable to common stockholders	\$ (69,122)	\$ (6,157)
Net loss per share attributable to common stockholders, basic and diluted	\$ (4.62)	\$ (3.14)
Weighted-average shares used to compute net loss attributable to common stockholders, basic and diluted	14,974,458	1,959,904

See accompanying notes to condensed consolidated financial statements (unaudited).

[Table of Contents](#)

**EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**  
(Unaudited)  
(In thousands, except share data)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C-1 Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2017	12,618,279	\$23,848	13,801,318	\$43,616	8,558,686	\$34,382	5,037,784	\$19,469	80	\$68,556	81,119,014	\$ 81	\$ 17,650	\$ (307,277)	\$ (289,546)
Conversion of convertible preferred stock into Private Evofem common stock (par value \$0.001), excluding Series D (see Note 8)	(12,618,279)	(23,848)	(13,801,318)	(43,616)	(8,558,686)	(34,382)	(5,037,784)	(19,469)	—	—	40,016,067	40	121,275	—	121,315
Cancellation of restricted stock awards (see Note 10)	—	—	—	—	—	—	—	—	—	—	(4,759,091)	(5)	5	—	—
Issuance of Private Evofem common stock (par value \$0.001) upon cashless exercise of Invesco Warrants (see Note 9)	—	—	—	—	—	—	—	—	—	—	154,593,455	155	47,765	—	47,920
Exchange of 270,969,445 Private Evofem common stock (par value \$0.001) for 6,955,456 shares of Neothetics' common stock (par value \$0.0001) (see Note 3)	—	—	—	—	—	—	—	—	—	—	(264,013,989)	(270)	270	—	—
Accretion and payment of Series D dividends (see Note 8)	—	—	—	—	—	—	—	—	—	66	—	—	(66)	(157)	(223)
Conversion of Series D dividends and Series D (see Note 8)	—	—	—	—	—	—	—	—	(80)	(5,226)	6,878,989	1	5,225	—	5,226
Redemption of Series D 2X liquidation preference upon conversion of Series D (see Note 8)	—	—	—	—	—	—	—	—	—	—	—	—	80,000	—	80,000
Deemed contribution upon conversion of Series D (see Note 8)	—	—	—	—	—	—	—	—	—	(49,334)	—	—	49,334	—	49,334
Issuance of common stock and WIM Warrants (see Note 8)	—	—	—	—	—	—	—	—	—	(14,062)	3	—	14,062	—	14,062

Private placement of common stock (see Note 3)	—	—	—	—	—	—	—	—	—	—	1,614,289	—	20,000	—	20,000
Issuance of common stock-exercise of stock options	—	—	—	—	—	—	—	—	—	—	6,173	—	42	—	42
Record pre-merger Neothetics' stockholders' equity and elimination of Neothetics' historical accumulated deficit	—	—	—	—	—	—	—	—	—	—	2,308,430	—	1,946	—	1,946
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	688	—	688
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(69,056)	(69,056)
Balance at March 31, 2018	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	17,763,340	\$ 2	\$ 358,196	\$ (376,490)	\$ (18,292)

See accompanying notes to condensed consolidated financial statements (unaudited).

**EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)  
(In thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (69,056)	\$ (5,269)
Adjustments to reconcile net loss to net cash, cash equivalents and restricted cash used in operating activities:		
Loss on issuance of Invesco Warrants	47,920	—
Change in fair value of Series D 2X liquidation preference	130	350
Stock-based compensation	688	219
Depreciation and amortization	65	48
Changes in operating assets and liabilities:		
Prepaid and other assets	(574)	(95)
Accounts payable	3,964	805
Accrued expenses and other liabilities	390	(1,650)
Accrued compensation	(1,479)	(469)
Deferred rent, net of current portion	(186)	(8)
Net cash, cash equivalents and restricted cash used in operating activities	<u>(18,138)</u>	<u>(6,069)</u>
<b>Cash flows from investing activities:</b>		
Proceeds from sale of Softcup line of business	250	250
Cash acquired in connection with the Merger	1,900	—
Net cash, cash equivalents and restricted cash provided by investing activities	<u>2,150</u>	<u>250</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock	20,000	—
Proceeds from issuance of common stock- exercise of stock options	42	—
Payment of cash dividends for Series D redeemable convertible preferred stock	(157)	—
Cash paid for offering costs	—	(580)
Net cash, cash equivalents and restricted cash provided by (used in) financing activities	<u>19,885</u>	<u>(580)</u>
<b>Net change in cash, cash equivalents and restricted cash</b>	<b>3,897</b>	<b>(6,399)</b>
<b>Cash, cash equivalents and restricted cash, beginning of period</b>	<b>1,701</b>	<b>11,487</b>
<b>Cash, cash equivalents and restricted cash, end of period</b>	<b><u>\$ 5,598</u></b>	<b><u>\$ 5,088</u></b>
<b>Supplemental disclosure of noncash investing and financing activities:</b>		
Net assets acquired in connection with the Merger	\$ 46	\$ —
Deferred offering costs included in accounts payable and accrued expenses	\$ 392	\$ 16
Conversion of convertible preferred stock into common stock (excluding Series D)	\$ 121,315	\$ —
Conversion of Series D redeemable convertible preferred stock into common stock	\$ 68,622	\$ —
Redemption of Series D 2X liquidation preference upon conversion of Series D redeemable convertible preferred stock into common stock	\$ 80,000	\$ —

See accompanying notes to condensed consolidated financial statements (unaudited).

**EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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**1. Description of Business and Basis of Presentation**

***Merger***

On January 17, 2018, Neothetics, Inc., a Delaware corporation, now known as Evofem Biosciences, Inc. (the Company), completed its merger with privately-held Evofem Biosciences Operations, Inc. (Private Evofem), or the Merger, in accordance with the terms of the agreement and plan of merger and reorganization, dated October 17, 2017 (the Merger Agreement), whereby Nobelli Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Neothetics, merged with and into Private Evofem, with Private Evofem surviving as Neothetics' wholly-owned subsidiary.

In connection with the Merger, Neothetics filed a certificate of amendment to the amended and restated certificate of incorporation to, among other things, affect a 6:1 reverse stock split of its common stock (the Reverse Stock Split) and change its name from "Neothetics, Inc." to "Evofem Biosciences, Inc." Both the name change and the Reverse Stock Split were effective on January 17, 2018 (the Closing Date). Shares of the Company's common stock commenced trading on The Nasdaq Capital Market under the ticker symbol "EVFM" as of January 18, 2018. See discussions of the transactions in connection with the Merger at [Note 3- Merger Transactions](#).

Evofem Biosciences, Inc.'s operations include those of its wholly-owned subsidiaries, Evofem Inc. (Evofem Inc.), a Delaware corporation, Evofem North America, Inc., a Delaware corporation (ENA), Evofem Limited, LLC a Delaware limited liability company and Evofem Ltd., a limited company registered in England and Wales and those of its partially owned subsidiary, Evolution Pharma, a Dutch limited partnership (EP) with 99% of the outstanding partnership interests held by Evofem Inc. and 1% of the outstanding partnership interests held by Evofem Limited, LLC. Evofem Limited, LLC and Evofem Ltd. are currently inactive.

Unless otherwise noted, (i) references in this report to "Evofem" and the "Company" refer to Evofem Biosciences, Inc. and its subsidiaries following the closing of the Merger on the Closing Date, (ii) references to "Private Evofem" refer to Evofem Biosciences Operations, Inc. and its subsidiaries prior to the closing the Merger on the Closing Date, (iii) references to "Neothetics" refer to Neothetics, Inc. and its subsidiaries prior to the closing of the Merger on the Closing Date, and (iv) references to share amounts, figures (other than exchange ratios) and other information have been adjusted to reflect the Reverse Stock Split.

***Description of Business***

Evofem is a San Diego-based clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. Evofem leverages its proprietary Multi-purpose Prevention Technology (MPT) vaginal gel to develop product candidates for multiple indications, including contraception, sexually transmitted infections (STIs), and recurrent bacterial vaginosis (BV).

Evofem's MPT vaginal gel technology is an acid-buffering vaginal gel with bioadhesive properties, designed to maintain an optimal vaginal pH of 3.5 to 4.5. This vaginal pH range is inhospitable to spermatozoa, as well as certain viral and bacterial pathogens associated with STIs, and it is integral to the survival of healthy bacteria in the vagina.

Evofem's lead product candidate, Amphora® (L-lactic acid, citric acid, and potassium bitartrate) is a hormone-free, on demand, woman-controlled vaginal gel currently in a Phase 3 clinical trial as a contraceptive and in a Phase 2b/3 trial for the prevention of urogenital chlamydia in women. In addition, Evofem recently completed a Phase 1 trial of its MPT vaginal gel product candidate for the reduction of recurrent BV and is currently designing a Phase 2b/3 trial for this indication.

***Basis of Presentation and Principles and Consolidation***

Since Private Evofem was determined to be the accounting acquirer in connection with the Merger, it recorded Neothetics' assets and liabilities at fair value as of the Closing Date. Therefore, for periods prior to the Merger, the condensed consolidated financial statements were prepared on a stand-alone basis for Private Evofem and did not include the combined entities' financial position. Subsequent to the Merger, the condensed consolidated financial statements as of and for the three months ended March 31, 2018 included Neothetics' assets and liabilities.

## [Table of Contents](#)

The Company prepared the unaudited interim condensed consolidated financial statements included in this report in accordance with accounting principles generally accepted in the U.S. (GAAP) for interim financial information and the rules and regulations of the Securities and Exchange Commission (SEC) related to quarterly reports on Form 10-Q.

The Company's financial statements are presented on a consolidated basis, which include the accounts of the Company and its wholly-owned subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation. The unaudited interim condensed consolidated financial statements do not include all information and disclosures required by GAAP for annual audited financial statements and should be read in conjunction with the Private Evofem's consolidated financial statements and notes thereto for the year ended December 31, 2017 included in its Current Report on Form 8-K/A as filed with the SEC on April 6, 2018 (the 2017 Audited Financial Statements).

The unaudited interim condensed consolidated financial statements included in this report have been prepared on the same basis as the Company's audited consolidated financial statements and include all adjustments (consisting only of normal recurring adjustments) necessary for a fair statement of the financial position, results of operations, cash flows, and statement of convertible preferred stock and stockholders' deficit for periods presented. The results for the three months ended March 31, 2018 are not necessarily indicative of the results expected for the full year. The condensed consolidated balance sheet as of December 31, 2017 was derived from the 2017 Audited Financial Statements.

### ***Risks, Uncertainties and Going Concern***

The Company's principal operations have been related to research and development, including development of the Company's lead product candidate, Amphora, raising capital, recruiting personnel and establishing a corporate infrastructure. The Company has incurred operating losses and negative cash flows from operating activities since inception. As of March 31, 2018, the Company had unrestricted cash of \$5.0 million, a working capital deficit of \$19.8 million and an accumulated deficit of \$376.5 million. The Company anticipates it will continue to incur net losses into the foreseeable future.

The Company is subject to risks common to other life science companies in the development stage including, but not limited to, uncertainty of product development and commercialization, lack of marketing and sales history, development by its competitors of new technological innovations, dependence on key personnel, market acceptance of products, product liability, protection of proprietary technology, ability to raise additional financing, and compliance with U.S. Food and Drug Administration (FDA) and other government regulations. If the Company does not successfully commercialize any product candidates, it will be unable to generate recurring product revenue or achieve profitability. Management's plans to meet its short- and long-term operating cash flow requirements include obtaining additional funding.

The Company anticipates it will continue to incur net losses for the foreseeable future and incur additional costs associated with being a public company. Research and development expenses are expected to increase for the foreseeable future due to the Company's confirmatory Phase 3 clinical trial for Amphora for the prevention of pregnancy, Phase 2b/3 clinical trials for prevention of chlamydia and gonorrhea and planned clinical trials for the BV product candidate. According to management estimates, liquidity resources as of March 31, 2018 are not sufficient to maintain its planned level of operations for the next 12 months.

In addition, the uncertainties associated with the Company's ability to (i) obtain additional equity financing on terms that are favorable to Evofem, (ii) enter into collaborative agreements with strategic partners and (iii) succeed in the future operations, raise substantial doubt about the Company's ability to continue as a going concern. The financial statements have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities, in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty.

If the Company is not able to obtain the required funding in the near term, through equity financings or other means, or is unable to obtain funding on terms favorable to the Company, this will have a material adverse effect on its operations and strategic development plan for future growth. If the Company cannot successfully raise additional funding and implement its strategic development plan, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these could materially and adversely affect its liquidity, financial condition and business prospects and the Company would not be able to continue as a going concern. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on the financial statements. The Company may obtain additional financing in the future through the issuance of its common stock from other equity or debt financings or through collaborations or partnerships with other companies.

[Table of Contents](#)

## 2. Summary of Significant Accounting Policies

### *Use of Estimates*

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and the notes thereto.

On an ongoing basis, Management evaluates its estimates related to, but not limited to, the useful lives of property and equipment, the recoverability of long-lived assets, preclinical and clinical trial accruals, the measurement of the Series D 2X liquidation preference, assumptions used in estimating the fair value of warrants issued to Invesco Asset Management (the Invesco Warrants), assumptions used in estimating the fair value of stock-based compensation expense and other contingencies. The Company's assumptions regarding the measurement of the Series D 2X liquidation preference and stock-based compensation are more fully described in [Note 5 — Fair Value of Financial Instruments](#) and [Note 10 — Stock-based Compensation](#), respectively. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances and adjusts when facts and circumstances dictate. The estimates are the basis for making judgments about the carrying values of assets and liabilities and recorded expenses that are not readily apparent from other sources. As future events and their effects cannot be determined with precision, actual results may materially differ from those estimates or assumptions.

### *Segment Reporting*

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

### *Concentrations of Credit Risk*

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and restricted cash. Deposits in the Company's checking and time deposit accounts are maintained in federally insured financial institutions in excess of federally insured limits. The Company invests in funds through a major U.S. bank and is exposed to credit risk in the event of default to the extent of amounts recorded on the consolidated balance sheets.

The Company has not experienced any losses in such accounts and believes it is not exposed to significant concentrations of credit risk on its cash, cash equivalents and restricted cash balances due to the financial position of the depository institutions in which these deposits are held.

### *Significant Accounting Policies*

The Company's significant accounting policies are more fully described in Note 2 to the 2017 Audited Financial Statements. There have been no changes to the significant accounting policies during the first three months of fiscal year 2018.

### *Cash, Cash Equivalents and Restricted Cash*

Cash and cash equivalents consists of readily available cash in checking and money market accounts. Restricted cash consists of cash held in monthly time deposit accounts, which are collateral for the Company's credit cards and facility leases.

The following table provides a reconciliation of cash, cash equivalents and restricted cash, reported within the condensed consolidated statements of cash flows (in thousands):

	Three Months Ended March 31,	
	2018	2017
Cash and cash equivalents	\$ 5,029	\$ 4,553
Restricted cash	569	535
Total cash, cash equivalents and restricted cash presented in the condensed consolidated statements of cash flows	<u>\$ 5,598</u>	<u>\$ 5,088</u>

### Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, potentially dilutive securities are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore, basic and diluted net loss per share were the same for all periods presented. Potentially dilutive securities excluded from the calculation of diluted net loss per share are summarized in the table below. For the three months ended March 31, 2017, the shares in the table have been adjusted to reflect the conversion of Series A, B, C-1, and C convertible preferred stock and Series D redeemable convertible preferred stock (Series D) into the common stock as fully described in [Note 8 - Convertible Preferred Stock](#), and the Reverse Stock Split.

	Three Months Ended March 31,	
	2018	2017
Convertible preferred stock	—	1,027,079
Series D redeemable convertible preferred stock	—	5,159,240
Unvested restricted common stock subject to repurchase	—	122,149
Unvested restricted stock units	—	2,566
Options to purchase common stock	398,960	161,626
Warrants to purchase common stock	2,011,875	—
Total	2,410,835	6,472,660

### Recently Adopted Accounting Pronouncements

The Company qualifies as an “emerging growth company” (EGC) pursuant to the provisions of the Jumpstart Our Business Startups (JOBS) Act. Section 7(a)(2)(B) of the Securities Act of 1933, as amended, permits EGCs to defer compliance with new or revised accounting standards until non-issuers are required to comply with such standards. However, the Company elected not to take advantage of the extended transition period for implementation of new or revised financial accounting standards, and as a result, the Company will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* (ASU No. 2014-09), which amends the existing accounting standards for revenue recognition. ASU No. 2014-09 is based on principles that govern the recognition of revenue at an amount an entity expects to be entitled when products are transferred to customers. The new standard as amended by ASU No. 2015-14, ASU No. 2016-10 and ASU No. 2016-12 was effective for the Company beginning January 1, 2018. The Company adopted the new standard using the full retrospective approach, which did not have an impact on the Company’s financial position or results of operations as the Company is pre-revenue and does not anticipate generating any significant revenue prior to 2020.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* (ASU No. 2017-09), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. ASU No. 2017-09 was effective for the Company beginning January 1, 2018. The adoption of this new standard did not have a material impact on the Company’s financial position or results of operations.

### Recently Issued Accounting Pronouncements — Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (ASU No. 2016-02), which changes the presentation of assets and liabilities relating to leases. The core principle of ASU No. 2016-02 is that a lessee should recognize the assets and liabilities that arise from leases. All leases create an asset and a liability for the lessee in accordance with FASB Concepts Statement No. 6, *Elements of Financial Statements*, and, therefore, recognition of those lease assets and lease liabilities represents an improvement over previous GAAP, which did not require lease assets and lease liabilities to be recognized for most leases. The new standard as amended by ASU No. 2018-01 will be effective for the Company beginning

January 1, 2019. The Company's 2015 Lease will expire in 2020 (see [Note 6 — Commitments and Contingencies](#) for details of the 2015 Lease) and be subject to the provisions of this new standard. The Company is in the process of assessing the impact of the new standard on its consolidated financial statements.

### 3. Merger Transactions

As described in [Note 1- Description of Business and Basis of Presentation](#), Private Evofem merged with Neothetics effective on the Closing Date. The Merger was accounted for as a reverse recapitalization with Private Evofem treated as the accounting acquirer pursuant to Accounting Standards Codification (ASC) 805- *Business Combinations*. Under reverse recapitalization accounting, the accounting acquirer shall measure the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree at their acquisition-date fair values.

The following transactions were completed with the Merger and recorded by the Company:

- Recorded Neothetics' assets, liabilities and stockholders' equity at fair value as of the Closing Date, including \$1.9 million cash and cash equivalents, \$0.5 million prepaids and other current assets, \$0.4 million current and noncurrent liabilities and \$1.9 million common stock (Neothetics had 2,308,430 shares of common stock outstanding as of the Closing Date on a post-split basis at par value of \$0.0001 per share) and additional paid-in capital (including the reclassification of Neothetics' historical accumulated deficit into additional paid-in capital);
- Converted each share of Private Evofem's capital stock including its Series A convertible preferred stock, Series B convertible preferred stock, Series C-1 convertible preferred stock and Series C convertible preferred stock into Private Evofem's common stock on a one-for-one basis for an aggregate of 40,016,067 shares. Upon such conversion, reclassified the net proceeds from Private Evofem's issuance of these preferred stocks to common stock at Private Evofem's par value and additional paid-in capital, net of par value;
- Cancelled 4,759,091 shares of Private Evofem's unvested restricted common stock at Private Evofem's par value on a pre-split basis;
- Issued the Invesco Warrants for the purchase up to an aggregate of 155,081,982 shares of Private Evofem's common stock, which were immediately net exercised on a cashless basis for 154,593,455 shares of Private Evofem's common stock;
- Exchanged 270,969,445 shares of Private Evofem's common stock for 41,732,794 shares of Neothetics' common stock on a pre-split basis at the common stock exchange ratio of 0.1540 (or 6,955,456 shares on a post-split basis). These shares, together with the shares converted from the 80 shares of Private Evofem Series D discussed below, accounted for an aggregate 87% ownership in Neothetics upon closing of the Merger;
- Converted 80 shares of Private Evofem's Series D into 41,273,941 shares of Neothetics' common stock on a pre-split basis (or 6,878,989 on a post-split basis), including:
  - i. Adjustment for the final change in fair value of Private Evofem's Series D 2X liquidation preference;
  - ii. Redemption of the Series D 2X liquidation preference upon conversion;
  - iii. Private Evofem's Series D Warrant Rights were assumed by Neothetics and exchanged for three shares of the Company's common stock and warrants for the purchase of 2,000,000 shares of the Company's common stock (the WIM Warrants). The Company recorded the fair value of the WIM Warrants and related capital contribution upon issuance of the WIM Warrants; and
  - iv. Recording cash dividends between January 6, 2018 and the Closing Date, which was paid upon closing of the Merger to WIM.
- Sold 1,614,289 shares of the Company's common stock in a private placement for gross proceeds of \$20.0 million;
- Neothetics affected the Reverse Stock Split, and thus the Company adjusted common stock and additional paid-in capital associated with shares issued in connection with the Merger due to the 6:1 reverse stock split; and
- Neothetics assumed Private Evofem's 2012 Equity Incentive Plan and each outstanding stock option issued thereunder was converted into the right to purchase the number of shares of Neothetics' common stock equal to approximately

[Table of Contents](#)

0.1540, as adjusted for the Reverse Stock Split multiplied by the number of shares of Private Evofem's common stock issuable upon exercise of the option to purchase shares of Private Evofem's common stock.

#### 4. Balance Sheet Details

##### *Prepaid and Other Current Assets*

Prepaid and other current assets consist of the following (in thousands):

	<b>March 31, 2018</b>	<b>December 31, 2017</b>
Flex note receivable (1)	\$ 250	\$ 250
Other receivable from related parties	202	17
Clinical supplies	96	119
Insurance	306	96
Rent	99	63
Research and development costs	134	30
Deferred offering costs	392	—
Other	129	78
Total	<u>\$ 1,608</u>	<u>\$ 653</u>

(1) In June 2016, Private Evofem's board of directors committed to a plan to sell its Softcup line of business (Softcup) and re-direct its available cash resources to further develop Amphora. In July 2016, the Company entered into an Asset Purchase Agreement with The Flex Company (Flex), whereby Flex would acquire certain assets and assume certain liabilities associated with Softcup. Total consideration for the Softcup sale was \$1.9 million, with \$0.6 million received in cash at closing and the remaining \$1.3 million due and payable under a note in favor of the Company (the Flex Note) through January 1, 2021 (the Maturity Date). The Flex Note bears simple interest at a rate of 5.0% per annum on the remaining principal amount outstanding. An annual principal payment of approximately \$0.3 million and the annual accrued and unpaid interest are payable each January 1, beginning in 2017 through the Maturity Date.

The Flex Note is secured by the Softcup assets and has been recorded at present value. The Company's incremental borrowing rate and the stated interest rate of the Flex Note are materially consistent.

##### *Property and Equipment, Net*

Property and equipment, net, consists of the following (in thousands):

	<b>Useful Life</b>	<b>March 31, 2018</b>	<b>December 31, 2017</b>
Research equipment	5 years	\$ 639	\$ 639
Computer equipment and software	3 years	6	6
Office furniture	5 years	205	205
Leasehold improvements	5 years or less	340	340
		<u>1,190</u>	<u>1,190</u>
Less: accumulated depreciation and amortization		(407)	(342)
Total, net		<u>\$ 783</u>	<u>\$ 848</u>

Depreciation expense was \$65,000 and \$48,000 for the three months ended March 31, 2018 and 2017, respectively.

##### *Other Noncurrent Assets*

Other noncurrent assets consist of the following (in thousands):

[Table of Contents](#)

	March 31, 2018	December 31, 2017
Flex note receivable, net of current portion	\$ 500	\$ 750
Deferred expense	503	—
<b>Total</b>	<b>\$ 1,003</b>	<b>\$ 750</b>

**Accrued Expenses**

Accrued expenses consist of the following (in thousands):

	March 31, 2018	December 31, 2017
Clinical studies	\$ 9,474	\$ 8,789
Sublicense fees	2,000	2,000
Abandoned initial public offering costs	186	135
Board of directors' fees and related expenses	173	247
Legal and other professional fees	437	727
Other	317	188
<b>Total</b>	<b>\$ 12,587</b>	<b>\$ 12,086</b>

**5. Fair Value of Financial Instruments**

The fair values of the Company's assets and liabilities, including the money market fund and Series D 2X liquidation preference, measured on a recurring basis are summarized in the following tables, as applicable (in thousands):

	March 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund (1)	\$ 612	\$ 612	\$ —	\$ —
<b>Total assets</b>	<b>\$ 612</b>	<b>\$ 612</b>	<b>\$ —</b>	<b>\$ —</b>

(1) Included as a component of cash and cash equivalents on the accompany condensed consolidated balance sheet.

	December 31, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Series D 2X liquidation preference	\$ (79,870)	\$ —	\$ —	\$ (79,870)
<b>Total liabilities</b>	<b>\$ (79,870)</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ (79,870)</b>

Series D 2X liquidation preference is stated at fair value and is considered a Level 3 input because the fair value measurement is based, in part, on significant inputs not observed in the market. The Company determined the fair value of Series D 2X liquidation preference as described below.

The following table summarizes the changes in Level 3 financial liabilities measured at fair value on a recurring basis for the three months ended March 31, 2018 (in thousands):

	Series D 2X Liquidation Preference Liability	
Balance at December 31, 2017	\$	79,870
Change in fair value of Series D 2X liquidation preference		130
Redemption of Series D 2X liquidation preference upon conversion of Series D		(80,000)
<b>Balance at March 31, 2018</b>	<b>\$</b>	<b>—</b>

### *Series D 2X Liquidation Preference*

As described in the Note 2 to the 2017 Audited Financial Statements, the Company's issuance of Series D resulted in the identification of an embedded derivative that required bifurcation and liability accounting at fair value. See the *Series D Redeemable Convertible Preferred Stock* discussion in [Note 8 — Convertible Preferred Stock](#) for the terms of the Series D.

In connection with the Merger, Private Evofem converted 80 shares of Series D into Neothetics' common stock. To determine the final fair value of the Series D 2X liquidation preference, the Company utilized a hybrid valuation model that considers the probability of achieving certain exit scenarios, the Company's cost of capital, the estimated period the Series D 2X liquidation preference would be outstanding, consideration received for the instrument with the Series D 2X liquidation preference and at what price and changes, if any, in the fair value of the underlying instrument to the Series D 2X liquidation preference. The valuations resulted in a concluded fair value of the Series D 2X liquidation preference of \$80.0 million as of the Closing Date, which was reclassified from a Series D 2X liquidation preference to additional paid-in capital upon the conversion into Neothetics' common stock.

The change in fair value of the Series D 2X liquidation preference for the three months ended March 31, 2018 and 2017 was \$0.1 million and \$0.4 million, respectively.

## **6. Commitments and Contingencies**

### *Operating Leases*

In November 2009, Private Evofem entered into a lease for office space under a noncancelable lease agreement that expired in March 2017 (the UTC Lease), as amended. Through January 2015, Private Evofem shared this office space with Cosmederm Biosciences, Inc. (Cosmederm) when Private Evofem assigned its rights and obligations under the UTC Lease to Cosmederm. Effective February 27, 2017, Private Evofem entered into a lease termination agreement (the UTC Lease Termination) with Cosmederm and the landlord for the UTC Lease. In March 2017, Private Evofem paid \$55,000 of an early termination fee directly to Cosmederm who remitted the fee to the landlord, and derecognized the security deposit receivable from the landlord and payable to Cosmederm. Upon execution of the UTC Lease Termination, Private Evofem was relieved of all obligations under the UTC Lease.

Effective January 30, 2015, Private Evofem entered into a sublease for office space under a noncancelable lease agreement that expires in March 2020 (the 2015 Lease). The sublease provides for two renewal periods of five years each, but the sub-lessor is not expected to renew its lease. In lieu of paying a security deposit directly to the sub-lessor, the Company maintains a time deposit in favor of the sub-lessor (the Deposit), which is included in restricted cash in the condensed consolidated balance sheets. During months 13 through 58 of the 2015 Lease term, subject to certain restrictions, approximately \$5,000 of the Deposit may be released each month through November 2019 and approximately \$66,000 of the Deposit may be released each month between December 2019 and March 2020. As of March 31, 2018 and December 31, 2017, restricted cash maintained as collateral for the Company's Deposit was \$0.4 million for both periods.

Concurrent with the execution of the 2015 Lease, Private Evofem entered a sublease with WomanCare Global Trading, Inc. (WCGT) whereby WCGT agreed to sublease approximately 25% (subject to annual adjustment), as amended, of the Company's office space (the WCG Sublease). The Company remains the primary obligor under the WCG Sublease and records all sublease income as a reduction of rent expense in the condensed consolidated statements of operations. WCGT paid an initial security deposit of approximately \$0.3 million (the WCG Security Deposit). During months 13 through 58 of the 2015 Lease term, subject to certain restrictions, approximately \$2,500 of the WCG Security Deposit is creditable against monthly rent payments through November 2019 and approximately \$33,000 of the WCG Security Deposit is creditable against rent payments each month between December 2019 and March 2020. As of March 31, 2018 and December 31, 2017, the WCG Security Deposit totaled approximately \$0.2 million for both periods, which was included in accrued expenses and other noncurrent liabilities in the condensed consolidated balance sheets. During the three months ended March 31, 2017, sublease payments received from WCGT totaled \$28,000. There were no sublease payments received from WCGT during the three months ended during March 31, 2018.

On January 20, 2015, Neothetics entered into a non-cancelable operating lease with LJ Gateway Office LLC (LJ Gateway Lease) for its facilities, which expires in March 2020. In connection with the LJ Gateway Lease, Neothetics issued a stand-by letter of credit in lieu of a security deposit. On January 31, 2017, Neothetics entered into an Eleventh Amendment to the LJ Gateway Lease (the Lease Amendment), which provided Neothetics with additional office space located at Suite No. 250. Concurrent with the Lease Amendment, Neothetics entered into a sublease providing for the sublease of additional office space (Suite 270). Upon the occurrence of the sublessor retaining possession of the original premises in February 2017, the sublessor received rent abatement for months one, three, and four as well as a discount of 50% off the base rent for months five

## [Table of Contents](#)

through nine. The sublessor paid Neothetics a base rent of \$27,768 for the second month's rent and \$30,317 security deposit. The base rent will increase by three percent on each annual anniversary. The Company has recorded the rental income collected or accrued under the sublease as a reduction of rent expense. As of March 31, 2018 and December 31, 2017, restricted cash maintained as collateral for LJ Gateway Lease's security deposit was \$0.1 million for both periods.

In December 2017, Neothetics entered into the Twelfth Amendment to the LJ Gateway Lease, whereby upon the mutual execution and delivery of a new lease between LJ Gateway Office LLC's affiliate and the sublessor and upon the occurrence of the sublessor vacating their subleased space, LJ Gateway Office LLC and Neothetics agreed that the LJ Gateway Lease with respect to the Suite 270 office space shall be terminated. As of March 31, 2018, the sublease had not been terminated.

Rent expense was \$0.2 million for each of the three months ended March 31, 2018 and 2017. Rent expense is recognized on a straight-line basis over the term of the lease. Accordingly, rent expense recognized in excess of rent paid is accounted for as deferred rent in the condensed consolidated balance sheets, of which the current portion is included in accrued expenses in the condensed consolidated balance sheets.

As of March 31, 2018, future minimum lease commitments under the above mentioned operating leases, together with sublease income, are as follows (in thousands):

	<b>Operating Leases</b>	<b>Sublease Income</b>	<b>Net</b>
Year ending December 31, 2018	\$ 872	\$ (398)	\$ 474
Year ending December 31, 2019	1,208	(547)	661
Year ending December 31, 2020	311	(140)	171
Total	<u>\$ 2,391</u>	<u>\$ (1,085)</u>	<u>\$ 1,306</u>

### *Contingencies*

From time to time the Company may be involved in various lawsuits, legal proceedings or claims that arise in the ordinary course of business. There were no claims or actions pending against the Company as of March 31, 2018 and December 31, 2017, which Management believes would have, individually or in the aggregate, a material adverse effect on its business, liquidity, financial position, results of operations or cash flows. However, litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm the Company's business.

### *Intellectual Property Rights*

In 2014, Private Evofem entered into an amended and restated license agreement with Rush University (the Rush License Agreement) pursuant to which Rush University granted Private Evofem an exclusive, worldwide license of certain patents and know-how, related to its MPT vaginal gel authorizing Private Evofem to make, distribute and commercialize products and processes for any and all therapeutic, prophylactic and/or diagnostic uses, including, without limitation, use for female vaginal health and/or contraception.

The Company may be obligated to pay an earned royalty based upon a percentage of net sales in the range of mid-single digits. Commencing on January 1 of year three after a product has received regulatory approval and has been introduced to market, the Company may become obligated to pay minimum annual royalties, to the extent the earned royalty or sublicensing fees, as applicable, do not exceed the minimum annual royalties.

In October 2015, the Company's subsidiaries, ENA and EP entered into separate sublicense agreements (the Sublicenses) with WomanCare Global Trading CIC (WGCIC) for a contraceptive vaginal ring. In August 2016, ENA, EP and WGCIC entered into a side letter to modify the timing of the 2016 and 2017 payments due under the Sublicenses. On an aggregate basis, consideration under the Sublicenses consisted of (i) payments or potential payments to the licensor of (a) an upfront payment of \$10.0 million, (b) potential regulatory and commercial milestone payments up to \$32.0 million, (c) potential royalty payments on net product sales and (d) potential royalty payments on net sales of an equivalent generic product and (ii) \$5.0 million in annual sublicense fees through October 1, 2019 to WGCIC. In December 2016, under the terms of the Sublicenses, ENA and EP provided 90-days written notice of termination of the Sublicenses to WGCIC, which period concluded on March 28, 2017.

As of March 31, 2018 and December 31, 2017, the Company had accrued sublicense fees of approximately \$2.0 million for both periods, which are included in accrued expenses in the condensed consolidated balance sheets. The Company is responsible for making interest payments to WomanCare Global International (WCGI) for unpaid sublicense fees. As of March

31, 2018 and December 31, 2017, accrued interest expense on unpaid sublicense fees totaled \$0.1 million for both periods. See [Note 7 – Related-party Transactions](#) for a summary of the Company's transactions with WCGCIC and WCGI and related entities.

## 7. Related-party Transactions

### *Consulting Agreements*

Effective April 1, 2016, Private Evofem entered into a one-year consulting agreement (the 2016 Consulting Agreement) with Thomas Lynch, the chairman of the Company's board of directors. Pursuant to the 2016 Consulting Agreement, Mr. Lynch provides consulting services with respect to investor relations and business development activities as requested from time to time. Pursuant to the 2016 Consulting Agreement, Mr. Lynch (i) received a stock option for the purchase of 150,000 shares of the Private Evofem's common stock with an exercise price of \$1.19 per share on a pre-split basis, which vest over a one-year period, through March 1, 2017, and (ii) was issued a restricted stock unit for the rights to 100,000 shares of the Private Evofem's common stock (RSU) on a pre-split basis. Upon completion of the Merger, Mr. Lynch's vested stock option was converted into an option to purchase up to 3,850 shares of the Company's common stock with an exercise price of \$46.36 per share. In addition upon closing of the Merger, Mr. Lynch agreed to cancel all of his unvested restricted stock units received pursuant to the 2016 Consulting Agreement. See *Restricted Stock Units* discussion in [Note 10 — Stock-based Compensation](#) for the accounting treatment for Mr. Lynch's restricted stock units.

In August 2017, Private Evofem and Mr. Lynch entered into a two-year consulting agreement (the 2017 Consulting Agreement), which was effective as of April 1, 2017. This 2017 Consulting Agreement provides for (i) annual compensation of \$0.4 million, including \$0.1 million related to his board services and (ii) a stock option for the purchase of 250,000 shares of Private Evofem's common stock on a pre-split basis that vests quarterly through March 31, 2018, which remained unissued at the time of the Merger. On March 12, 2018, the Company issued a stock option for the purchase of 225,000 shares of the Company's common stock in lieu of the unissued stock option pursuant to the 2017 Consulting Agreement, of which 125,000 shares vest on the grant date and the remaining shares shall vest in a series of twelve successive equal monthly installments upon completion of each additional month of service measured from April 1, 2018. The option was awarded in connection with Mr. Lynch's consulting services for the Company for the fiscal year 2017 and 2018. This option was granted out of the share reserve increases approved by the board of directors under the 2014 Plan. This increase was approved at the Company's annual meeting held on May 8, 2018. See "Contingent Options" discussion in [Note 10 - Stock-based Compensation](#). During the three months ended March 31, 2018, compensation paid to Mr. Lynch under the 2017 Consulting Agreement was \$0.5 million. As of March 31, 2018, accrued compensation owed to Mr. Lynch totaled approximately \$0.1 million, of which approximately \$58,000 relates to his board services during 2018.

### *Transactions with WCGI and Related Entities (collectively WCG entities)*

In 2009, Sandra Pelletier founded WomanCare Global International, a non-profit organization registered in England and Wales (WCGI) and became WCGI's chief executive officer. In February 2013, Private Evofem and WCGI formed an alliance (the WCGI Alliance) and Ms. Pelletier also became Private Evofem's chief executive officer. Concurrent with the forming of the WCGI Alliance, Private Evofem and WCGI entered into (i) a service agreement to which the companies shared resources and employees and (ii) a three-year grant agreement under which the Private Evofem provided funding of \$4.0 million per year to WCGI.

As more fully described in [Note 6 — Commitments and Contingencies](#), (i) effective in February 2015, Private Evofem and WCGT, a WCGI subsidiary, entered into a sublease for office space and (ii) in October 2015, (a) Private Evofem through its wholly-owned subsidiaries entered into two sublicense agreements, whereby Private Evofem was responsible for paying \$5.0 million in annual sublicense fees, net of amounts paid under the grant agreement during 2015, to WCGCIC, also a WCGI affiliate, and (b) the service and grant agreements were cancelled. Sublicense fees are included in research and development expenses in the condensed consolidated statements of operations.

In early 2015, Private Evofem became the corporate sponsor of WCGI's "Then Who Will" educational campaign, which ended in late 2017. During the three months ended March 31, 2017, corporate support payments to vendors performing services for the "Then Who Will" campaign on behalf of WCGI totaled approximately \$0.1 million, which were included in general and administrative expenses in the condensed consolidated statements of operations. There were no such payments during the three months ended March 31, 2018.

## [Table of Contents](#)

Effective January 2016, Private Evofem and WCGI entered into a shared-services agreement (the SSA), which replaced the prior service agreement. Under the terms of the SSA, Private Evofem and WCGI cross charge the other company's services provided by each entity on behalf of the other. The SSA also allows for netting of due to and due from shared-services fees. Through December 31, 2016, Ms. Pelletier was being paid directly by each WCGI and Private Evofem. As of January 1, 2017, Ms. Pelletier was no longer paid directly by WCGI and was subject to Private Evofem's SSA. During the three months ended March 31, 2018 and 2017, services provided under the SSA on behalf of WCGI totaled approximately \$0.1 million and \$0.3 million, respectively. As of March 31, 2018 and December 31, 2017, net shared-services due to the Company totaled approximately \$67,000 and \$13,000, respectively.

The following table summarizes receivables, payables, payments and expenses related to the Company's transactions with WCGI related entities as of and for the three months ended March 31, (in thousands):

	2018		2017	
Receivables	\$	109	\$	130
Payables	\$	2,107	\$	2,009
Payments	\$	—	\$	1,011
Interest expense	\$	31	\$	6

### *Transactions with WCG Cares*

In 2013, WCG Cares, a 501(c)(3) nonprofit organization was incorporated under the laws of the State of California. Its primary purpose is to directly engage in and/or fund the development and implementation of programs that promote reproductive health, education, research and increased access to high-quality, innovative and affordable reproductive healthcare and healthcare products around the world. Since November 2017, Ms. Pelletier has served as the Chair of the Board of WCG Cares and served as the Chief Executive Officer and President of WCG Cares from 2013 until November 2017. Mr. Justin J. File and Dr. Kelly Culwell also serve as WCG Cares' Chief Financial Officer and Chief Medical Officer, respectively (see shared-services agreement discussion below).

The Company agreed to be a corporate sponsor of WCG Cares' U.S. education campaign, the Tryst Network, which officially launched in February 2018. The Company paid WCG Cares \$0.3 million in March 2018 as part of its corporate sponsorship of the Tryst Network. As of March 31, 2018 and December 31, 2017, accrued Tryst-related costs totaled \$0.2 million for both periods.

In March 2018, the Company and WCG Cares entered a shared-services agreement (the Cares Shared Services Agreement). Under the terms of the Cares Shared Services Agreement, the Company and WCG Cares cross charge services provided by each entity (or its subsidiaries) on behalf of the other. The Cares Shared Services Agreement also allows for netting of due to and due from shared-services fees. As of March 31, 2018, net shared-services due to the Company totaled approximately \$20,000.

### *Variable Interest Entity Considerations*

Due to shared management and numerous agreements between the Company and WCGI and the Company and WCG Cares, management reviewed its relationship with both WCGI and its subsidiaries and WCG Cares in accordance with the authoritative guidance for variable interest entities within ASC 810 — *Consolidation*. The Company concluded that due to WCGI's and WCG Cares' status as not-for-profit entities, the scope exception from qualifying as a variable interest entity was met and, therefore, the Company is not required to consolidate WCGI or WCG Cares.

## **8. Convertible Preferred Stock**

Immediately prior to the Merger, as more fully described in [Note 1 - Description of Business and Basis of Presentation](#), each share of Private Evofem's capital stock (other than Private Evofem's Series D), including its Series A convertible preferred stock, Series B convertible preferred stock, Series C-1 convertible preferred stock and Series C convertible preferred stock was converted to Private Evofem's common stock on a one-for-one basis for an aggregate of 40,016,067 shares. Immediately following the Merger, Private Evofem's common stock was then exchanged for approximately 0.1540 shares of Neothetics' common stock. In addition, each share of Private Evofem's Series D was converted into approximately 515,924 shares of Neothetics' common stock for an aggregate of 41,273,941 shares. As of March 31, 2018, no shares of convertible preferred stock were issued and outstanding.

## [Table of Contents](#)

Dividends on the Series D were payable (i) upon conversion, (ii) redemption or (iii) liquidation. As such, although the Company's board of directors has not declared dividends, the Company accrues dividends on the Series D. Upon closing of the Merger, the Company paid cash dividends of \$0.2 million for the accrued dividends only for the period of January 6, 2018 to the Closing Date and the accrued and unpaid dividends of \$5.2 million as of December 31, 2017 were reclassified to additional paid-in capital upon conversion of 80 shares of Series D into common stock.

The designated, issued and outstanding shares of convertible preferred stock, by series, as of December 31, 2017 were as follows (aggregate liquidation amount and proceeds, net of issuance costs, in thousands):

	Shares Designated	Original Issue Price	Shares Issued and Outstanding	Common Stock Equivalents (1)	Aggregate Liquidation Amount	Proceeds, Net of Issuance Costs
Series A	12,768,492	\$ 1.9579445	12,618,279	12,618,279	\$ 24,706	\$ 23,848
Series B	31,034,696	\$ 3.2222	13,801,318	13,801,318	44,471	43,616
Series C-1	8,660,572	\$ 3.97	8,558,686	8,558,686	33,978	34,382
Series C	5,037,784	\$ 3.97	5,037,784	5,037,784	20,000	19,469
Series D (2)(3)	80	\$ 500,000	80		85,160	39,739
Total	57,501,624		40,016,147		\$ 208,315	\$ 161,054

- (1) The Series D shares were convertible into shares in the next equity financing (either preferred or common) at a 50% discount to the fair value price per share of the shares to be issued in the next financing, therefore, the Series D common stock equivalents and the totals for common stock equivalents have been left blank.
- (2) Aggregate liquidation amount included accrued and unpaid dividends of \$5.2 million as of December 31, 2017.
- (3) Proceeds, net of issuance costs, included \$35.0 million in cash and \$5.0 million from the conversion of the Amended Cosmederm Note (see more discussions below) less issuance costs of approximately \$0.3 million. This line excluded the Series D 2X liquidation preference net issuance price of \$18.2 million, the loss on the issuance of Series D of \$35.2 million, loss on extinguishment of related-party note payable of \$6.7 million and accrued Series D dividends of \$5.2 million.

Private Evofem and Cosmederm entered a promissory note during 2015, which was amended in July 2016 in conjunction with the Private Evofem's Series D financing (the Amended Cosmederm Note). Cosmederm assigned the Amended Cosmederm Note with the then outstanding principal balance of \$10.0 million to WIM. As a condition to closing the Private Evofem's Series D, WIM immediately converted \$5.0 million of the Amended Cosmederm Note into 10 shares of the Private Evofem's Series D and cancelled the remaining \$5.0 million.

### *Series D*

In July 2016, Private Evofem entered into a Series D purchase agreement with WIM, which was subsequently amended in July 2017 to increase the number of authorized preferred stock for issuance (as amended, the Series D SPA). The Series D SPA authorized the issuance and sale of an aggregate of 80 shares of Series D, which was sold at an issuance price per share of \$500,000. WIM also received the right to receive warrant shares to be determined in the next equity financing (Warrant Rights). See *Warrant Rights* discussion below.

### *Warrant Rights*

The Warrant Rights issued in connection with the issuance of Series D in 2016 and 2017 were convertible into warrants to purchase up to that number of equity securities to be issued in the next equity financing of Private Evofem equal to (i) seventy-five percent (75.0%) of the purchase price paid for the Series D (or \$30.0 million), divided by (ii) the per share price of the equity securities issued to the new investors in such next equity financing. The exercise price of the warrants will equal the per share price of the equity securities to be issued in the next equity financing and the warrants were to expire seven years from the closing of such next equity financing. The Warrant Rights are inseparable from the Series D. As of December 31, 2017, Private Evofem had not completed a next equity financing and, therefore, the Warrant Rights remained outstanding.

Additionally, Private Evofem determined that since the exercise price of the warrants to be received by WIM is equal to the fair value of the shares for which the warrant would have become exercisable at issuance, there was *de minimis* value associated with the Warrant Rights and, therefore, Private Evofem did not record a warrant liability for the Warrant Rights as of December 31, 2017.

## [Table of Contents](#)

Upon completion of the Merger, Private Evofem's Series D Warrant Rights were assumed by Neothetics and exchanged for an aggregate of three shares of the Company's common stock and the WIM Warrants to purchase up to 2,000,000 shares of the Company's common stock and the three shares issued in connection with the WIM Warrants may not be separately transferred. The WIM Warrants will become exercisable on January 17, 2019 and shall remain exercisable until the earlier of January 18, 2022 or immediately prior to the completion of an acceleration event, as defined, and have an exercise price of \$8.35 per share.

The Company determined that the WIM Warrants are free standing financial instruments and equity classified in accordance with ASC 480—*Distinguish Liabilities from Equity*. To determine the fair value of the WIM Warrants, the Company utilized the Black-Scholes-Merton (BSM) option-pricing model, where the warrants exercise price was determined based on a Monte Carlo simulation. The valuations resulted in a concluded fair value of the WIM Warrants of \$14.1 million as of January 18, 2018, which was recorded as additional paid-in capital in the condensed consolidated balance sheet.

### **9. Stockholders' Deficit**

#### *Warrants*

As of March 31, 2018, warrants to purchase 2,011,875 shares of the Company's common stock remain outstanding at a weighted average exercise price of \$8.62 per share. These warrants include WIM Warrants to purchase up to 2,000,000 shares of common stock as described in [Note 8- Convertible Preferred Stock](#), which will become exercisable on January 17, 2019, and two warrants to purchase 11,875 shares of common stock that were issued prior to the Merger, which were exercisable as of March 31, 2018.

#### *Common Stock*

Effective January 17, 2018 and in connection with the Merger, the Company amended and restated its certificate of incorporation, under which the Company is authorized to issue up to 300,000,000 shares of common stock, \$0.0001 par value per share, and 5,000,000 shares of preferred stock, \$0.0001 par value per share.

On January 17, 2018, immediately prior to the closing of the Merger, Private Evofem issued the Invesco Warrants for the purchase up to an aggregate of 155,081,982 shares of the Private Evofem's common stock, par value \$0.001 per share, which were immediately net exercised on a cashless basis for 154,593,455 shares of Private Evofem's common stock. These shares of Private Evofem's common stock were then converted into the right to receive shares of Neothetics' common stock upon completion of the Merger at the common stock exchange ratio of 0.1540, subject to adjustment for the Reverse Stock Split. The Company determined that the Invesco Warrants are free standing financial instruments and equity classified in accordance with ASC 480—*Distinguish Liabilities from Equity*. The Company had an external valuation completed as of January 17, 2018 with a concluded fair value of \$47.9 million using the BSM option-pricing model, which was recorded as a loss on the issuance of Invesco Warrants within other income (expense) in the condensed consolidated statement of operations, with corresponding entries to common stock par value for the shares issued and additional paid-in capital in the condensed consolidated balance sheet. See [Note 3- Merger Transactions](#) for more descriptions of the transactions completed in connection with the Merger.

#### *At the Market Program*

On December 1, 2015, Neothetics entered into a Controlled Equity Offering Sales Agreement (Sales Agreement) with Cantor Fitzgerald, as a sales agent pursuant to which Neothetics may offer and sell from time to time, through Cantor Fitzgerald shares of Neothetics' common stock, par value \$0.0001 per share, having an aggregate offering price of up to \$20.0 million. The minimum share price for this Controlled Equity Offering is selected at the discretion of the board of directors. Through March 31, 2018, no shares of common stock have been sold pursuant to this Sales Agreement.

#### *Common Stock Reserved for Future Issuance*

Common stock reserved for future issuance is as follows in common equivalent shares as of March 31, 2018:

[Table of Contents](#)

Common stock issuable upon the exercise of stock options outstanding	398,960
Common stock issuable upon the exercise of common stock warrants	2,011,875
Common stock available for future issuance under the 2014 ESPP	118,825
Common stock available for future issuance under the 2014 Plan	458,586
Total common stock reserved for future issuance	<u>2,988,246</u>

## 10. Stock-based Compensation

### *Equity Incentive Plans*

In September 2012, Private Evofem adopted the 2012 Equity Incentive Plan (the 2012 Plan) that provides for the issuance of restricted stock awards, restricted stock units, or non-qualified and incentive common stock options to its employees, non-employee directors and consultants, from its authorized shares. In general, the options expire ten years from the date of grant and generally vest either (i) over a four-year period, with 25% exercisable at the end of one year from the employee's hire date and the balance vesting ratably thereafter or (ii) over a three-year period, with 25% exercisable at the grant date and the balance vesting ratably thereafter. Upon completion of the Merger, Private Evofem's 2012 Plan was assumed by Neothetics and awards outstanding under the 2012 Plan became awards for Neothetics' common stock. Effective as of the Merger, no further awards may be issued under the 2012 Plan.

On September 15, 2014, Neothetics' board of directors adopted, and stockholders approved, the Equity Incentive Plan (the 2014 Plan). As of March 31, 2018, there were 458,586 shares available to grant under the 2014 Plan. On March 9, 2018, the Company's board of directors approved, subject to stockholder approval, and recommended its stockholders approve at the annual meeting held on May 8, 2018, the amendment and restatement of the 2014 Plan (the Amended and Restated 2014 Plan), that, among other things, would increase the number of authorized shares under the 2014 Plan from 749,305 to an aggregate of 5,300,000 shares. Such stockholder approval was obtained on May 8, 2018.

### *Stock Options*

The following table summarizes stock-based compensation expense related to stock options granted to employees and non-employee directors included in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2018	2017
Research and development	\$ 230	\$ 47
General and administrative	458	172
Total	<u>\$ 688</u>	<u>\$ 219</u>

There were 3,136,030 and 6,645 stock options granted during the three months ended March 31, 2018 and 2017, respectively. The stock options granted in March 2018 to purchase up to an aggregate of 3,136,030 shares of common stock were granted out of the share reserve increase approved by the board of directors under the Amended and Restated 2014 Plan on March 11, 2018, and were subject to the Company obtaining the requisite stockholder approval (the "Contingent Options"). Such stockholder approval of the Amended and Restated 2014 Plan was obtained on May 8, 2018.

In connection with the Merger, all Neothetics' remaining employees were terminated without cause and Neothetics entered into Separation and Release Agreements with these employees. The Separation and Release Agreements entitled employees full acceleration of all unvested stock options granted under the 2014 Plan and extension of the exercise period for all options held by employees to the earlier of (i) the expiration of the stock option pursuant to its terms or (ii) March 31, 2019. The Company applied share-based payment modification accounting in accordance with ASC 718 — *Compensation — Stock Compensation* and determined the incremental value of the modification to the awards resulting from the extension of the exercise period was \$0.2 million.

As of March 31, 2018, unrecognized stock-based compensation expense for employees and non-employee directors stock options was approximately \$1.4 million, which the Company expects to recognize over a weighted-average remaining period of 1.9 years, assuming all unvested options become fully vested.

### *Summary of Assumptions*

## [Table of Contents](#)

The fair value of stock-based compensation for stock options granted to employees, non-employee directors and consultants was estimated on the date of grant using the BSM option pricing model based on the following weighted-average assumptions for options granted during the three months ended March 31, 2017. No fair value of stock-based compensation was estimated for the Contingent Options granted during the three months ended March 31, 2018 in accordance with ASC 718 — *Compensation — Stock Compensation*.

	<b>Three Months Ended March 31, 2017</b>
Expected volatility	90.9%
Risk-free interest rate	2.2%
Expected dividend yield	—%
Expected term (years)	5.8

*Expected volatility.* The expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry.

*Risk-free interest rate.* The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the stock option grants.

*Expected dividend yield.* The expected dividend yield assumption is based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends.

*Expected term.* The expected term represents the period options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determines the expected term assumption using the practical expedient as provided for under ASC 718 — *Compensation — Stock Compensation*, which is the midpoint between the requisite service period and the contractual term of the option.

### ***Restricted Stock Awards***

In September 2016, under the 2012 Equity Incentive Plan, Private Evofem issued an aggregate of 4,759,091 shares of restricted stock on a pre-split basis to members of management (the RSAs) with vesting terms subject to the completion of an initial public offering (IPO) by Private Evofem. Upon closing of the Merger, as more fully described in [Note 1 – Description of Business and Basis of Presentation](#), the members of management agreed to cancel their restricted stock awards. As a result, all 4,759,091 shares of unvested RSAs on a pre-split basis were cancelled during the three months ended March 31, 2018, and there was no unrecognized stock-based compensation expense related to the RSAs.

### ***Restricted Stock Units***

In October 2016, as previously described in [Note 7 — Related-party Transactions](#), Private Evofem issued a restricted stock unit for the right to 100,000 shares of Private Evofem’s common stock on a pre-split basis to the chairman of the Company’s board of directors (the RSUs). Upon closing of the Merger, the chairman agreed to cancel his RSUs. As a result, all 100,000 shares of unvested RSUs on a pre-split basis were cancelled during the three months ended March 31, 2018, and there was no unrecognized stock-based compensation expense related to the RSUs.

### ***Employee Stock Purchase Plan***

In November 2014, the Neothetics adopted the 2014 Employee Stock Purchase Plan (the ESPP), which enables eligible employees to purchase shares of its common stock using their after-tax payroll deductions of up to 15% of their eligible compensation, subject to certain restrictions.

The ESPP initially authorized the issuance of 28,333 shares of common stock pursuant to purchase rights granted to employees. The number of shares of common stock reserved for issuance automatically increased on January 1, 2015 and will continue to increase on each January 1 thereafter through January 1, 2024, by the smaller of (a) 1.0% of the total issued and outstanding shares on the preceding December 31, and (b) a number of shares determined by the board of directors of Neothetics. The ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended (the Code).

## [Table of Contents](#)

The fair value of shares issued to employees under the ESPP is estimated using a BSM option-pricing model, which requires the use of subjective and complex assumptions, including (a) the expected stock price volatility, (b) the calculation of the expected term of the award, (c) the risk-free interest rate and (d) the expected dividend yield.

Following completion of the Merger, there was no enrollment in the ESPP. During the three months ended March 31, 2018 and 2017, there were no shares of common stock purchased under the ESPP.

## **ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The terms “we,” “us,” “our,” “Evoform” or the “Company” refer collectively to Evoform Biosciences, Inc. and its wholly-owned subsidiaries, unless otherwise stated. All information presented in this report is based on our fiscal year. Unless otherwise stated, references to particular years, quarters, months or periods refer to our fiscal years ending December 31 and the associated quarters, months and periods of those fiscal years.*

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the corresponding notes included elsewhere in this report. For additional context with which to understand our financial condition and results of operations, see the audited consolidated financial statements and accompanying notes contained therein as of December 31, 2017 and 2016 and related notes in our Current Report on Form 8-K/A as filed with the SEC on April 6, 2018 (the 2017 Audited Financial Statements). This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth under Item 1A of this Quarterly Report. Unless otherwise defined in this section, the defined terms in this section have the meanings set forth in the 2017 Audited Financial Statements.*

### **Overview**

We are a San Diego-based clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women’s sexual and reproductive health. We are currently developing product candidates for contraception, sexually transmitted infections (STIs), and bacterial vaginosis (BV).

Our lead product candidate, Amphora (L-lactic acid, citric acid, and potassium bitartrate) is currently being developed for three potential indications: as a contraceptive, for the prevention of urogenital *chlamydia trachomatis* infection (chlamydia) in women and for the prevention of urogenital *Neisseria gonorrhoeae* infection (gonorrhea) in women. Amphora is in a confirmatory Phase 3 clinical trial for contraception and in a Phase 2b/3 clinical trial for prevention of chlamydia.

Our confirmatory, Phase 3 clinical trial for Amphora as a contraceptive is an open-label, single-arm trial in 1,400 women in the United States. We expect to report top-line results from this trial in the first quarter of 2019 and, if positive, to resubmit the New Drug Application (NDA) to the United States Food and Drug Administration (FDA) shortly thereafter. Subject to acceptance and timely approval of the NDA by the FDA, we plan to commercialize Amphora in early 2020.

We are also conducting a Phase 2b/3 clinical trial of Amphora for the prevention of certain STIs in women. The primary endpoint of this trial is prevention of chlamydia and the secondary endpoint is prevention of gonorrhea. We envision our STI program as developing label expansion opportunities to further differentiate Amphora from other contraceptive products in the market.

In addition, we are advancing a second Multi-purpose Prevention Technology (MPT) vaginal gel product candidate for the treatment of recurrent BV. In a recently completed Phase 1 dose-finding trial for this product candidate, the highest dose formulation of our BV product candidate (5-gram) reduced vaginal pH for up to seven days following a single administration.

Since inception, we have devoted substantially all our efforts on developing product candidates leveraging our MPT vaginal gel technology, including conducting preclinical and clinical trials and providing general and administrative support for these operations. We do not have any approved products and have not generated any revenue from product sales. Although our lead product candidate, Amphora, is in a later stage of clinical development, it has not yet been approved for use as a contraceptive or any other targeted indications. Additionally, Amphora and our BV product candidate are still in early stage clinical development for the prevention of certain STIs and for recurrent BV, respectively. We do not currently expect to generate any significant revenues prior to 2020. To finance our current strategic plans, including the conduct of ongoing and future clinical trials, further research and development and anticipated pre-commercialization activities in 2019, we will require significant additional capital. Assuming we have sufficient liquidity, we will incur significantly higher costs in the foreseeable future.

## *Merger*

As described in [Note 1- Description of Business and Basis of Presentation](#), on January 17, 2018 (the Closing Date), Neothetics, now known as Evofem Biosciences, Inc., completed its merger with privately-held Evofem Biosciences Operations, Inc. (Private Evofem), or the Merger; in accordance with the terms of the agreement and plan of merger and reorganization, dated October 17, 2017. Since Private Evofem was determined to be the accounting acquirer in connection with the Merger, it recorded Neothetics' assets and liabilities at fair value as of the Closing Date. To reflect the close of the Merger, we recorded the following items:

- Recorded the issuance of 154,593,455 shares of Private Evofem's common stock upon the cashless exercise of warrants (the Invesco Warrants) issued to funds affiliated with Invesco Ltd., immediately prior to the closing of the Merger and recognized the fair value of the Invesco Warrants upon issuance.
- Reclassified the net proceeds from Private Evofem's issuance of an aggregate of 40,016,067 shares of Private Evofem's convertible preferred stock to common stock and additional paid-in capital, net of par value, upon conversion to Private Evofem common stock immediately prior to the closing of the Merger.
- Recognized the exchange of 270,969,445 shares of Private Evofem common stock and 80 shares of Private Evofem Series D redeemable convertible preferred stock (Series D) outstanding immediately prior to the closing of the Merger for 83,006,735 shares of Neothetics' common stock in exchange for 87% ownership in Neothetics upon closing of the Merger.
- Adjusted for the final change in fair value of Private Evofem's Series D 2X liquidation preference and reclassified the Series D 2X liquidation preference upon conversion of 80 shares of Private Evofem's Series D to additional paid-in capital.
- Recorded the fair value of the warrants issued to funds affiliated with Woodford Investment Management Ltd to purchase up to 2,000,000 shares of the Company's common stock (the WIM Warrants) and related capital contribution upon issuance of the WIM Warrants.
- Recorded cash dividends between January 6, 2018 and the Closing Date, paid upon closing of the Merger to WIM.
- Recorded \$20.0 million in proceeds from the sale of our common stock in a private placement completed immediately after the closing of the Merger (the Private Placement).
- Adjusted common stock and additional paid-in capital associated with shares issued in the Merger and Private Placement due to the 6:1 reverse stock split.

We historically have funded our operations primarily through sales of our common stock, convertible preferred stock, related-party advances and a note payable from Cosmederm Biosciences, Inc.

## Financial Operations Overview

### Revenue

To date, we have not generated any revenue from our lead product candidate, Amphora. We do not expect to generate any revenue from any product candidates we develop unless and until we obtain regulatory approval and commercialize our products or enter into collaborative agreements with third parties. In the future, if Amphora is approved for commercial sale in the United States, we may generate revenue from product sales. Outside of the United States, we expect to out-license commercialization rights to Amphora to global pharmaceutical companies or other qualified potential partners or enter collaborations for the commercialization and distribution of Amphora, from which we may generate licensing revenue. We do not expect to commercialize Amphora before 2020, if ever.

### Operating Expenses

#### Research and development expenses

Our research and development expenses primarily consist of costs associated with the preclinical and clinical development of our product candidates. Our research and development expenses include:

- external development expenses incurred under arrangements with third parties, such as fees paid to contract research organizations (CROs) relating to its clinical trials, costs of acquiring and evaluating clinical trial data such as investigator grants, patient screening fees, laboratory work and statistical compilation and analysis, and fees paid to consultants and its scientific advisory board;
- costs to acquire, develop and manufacture clinical trial materials, including fees paid to contract manufactures;
- payments related to licensed products and technologies;
- costs related to compliance with drug development regulatory requirements;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, and research and other supplies.

We expense internal and third-party research and development as incurred.

The following table summarizes research and development expenses by product candidate (in thousands):

	Three Months Ended March 31,	
	2018	2017
Third-party development costs:		
Amphora, as a contraceptive	\$ 9,484	\$ 955
Chlamydia/Gonorrhea	534	21
Bacterial vaginosis	211	205
Total third-party development costs	10,229	1,181
Other unallocated internal research and development costs	1,730	801
Total research and development expenses	\$ 11,959	\$ 1,982

Completion dates and costs for our clinical development programs can vary significantly for each current and any future product candidates and are difficult to predict. Therefore, we cannot estimate with any degree of certainty the aggregate costs we will incur regarding the development of our product candidates. We anticipate we will make determinations as to which programs and product candidates to pursue as well as the most appropriate funding allocations for each program and product candidate on an ongoing basis in response to the results of ongoing and future clinical trials, regulatory developments, and our

## [Table of Contents](#)

ongoing assessments as to each current or future product candidates' commercial potential. We will need to raise substantial additional capital in the future to complete clinical development for our current and future product candidates. We may enter into collaborative agreements in the future to conduct clinical trials and gain regulatory approval of our product candidates, particularly in markets outside of the United States. We cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and overall capital requirements.

The costs of clinical trials may vary significantly over the life of a program owing to the following:

- per patient trial costs;
- the number of sites included in the trials;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

### *General and administrative expenses*

Our general and administrative expenses consist primarily of salaries, benefits, travel, business development expense and stock-based compensation expense, and other related costs for our employees and consultants in executive, administrative, finance and human resource functions. Other general and administrative expenses include facility-related costs not otherwise included in research and development and professional fees for accounting, auditing, tax and legal fees, and other costs associated with obtaining and maintaining our patent portfolio, and conducting commercial assessments for our product candidates.

We expect our general and administrative expenses to increase as we hire additional personnel to support the growth of our business and as a result of being a publicly-traded company.

### ***Other Income (Expense)***

Other income (expense) consists primarily of loss on issuance of Invesco Warrants, and the change in fair value of the Series D 2X liquidation preference, which for each share of Series D is equal to two times the issuance price per share of Series D, plus accrued and unpaid dividends, and became payable upon the closing of the Merger.

Loss on issuance of Invesco Warrants was recognized upon issuance of warrants to Invesco as they were determined as free-standing equity-classified financial instruments and were immediately exercised on January 17, 2018.

The Series D 2X liquidation preference expired at the Closing Date, at which time the final fair value of the Series D 2X liquidation preference was estimated. The final change in fair value of the Series D 2X liquidation preference of \$0.1 million was recognized within change in fair value of the Series D 2X liquidation preference within the condensed consolidated statements of operations. Additionally, the Series D 2X liquidation preference was reclassified to additional paid-in capital within the condensed consolidated balance sheets. Prior to the closing of the Merger, the Series D 2X liquidation preference was revalued at each reporting date and changes in fair value were recognized as increases in or decreases to other income (expense).

**Results of Operations**

Three Months Ended March 31, 2018 Compared to Three Months Ended March 31, 2017 (in thousands):

**Research and development expenses**

	Three Months Ended March 31,		2018 vs. 2017	
	2018	2017	\$ Change	% Change
Research and development	\$ 11,959	\$ 1,982	\$ 9,977	503%

The overall increase in research and development expenses was primarily due to a \$9.1 million increase in clinical trial costs related to our confirmatory Phase 3 clinical trial for Amphora for the prevention of pregnancy and our Phase 2b/3 clinical trial for prevention of chlamydia, both of which commenced enrollment in the second half of 2017, a \$0.5 million increase in personnel costs primarily due to an increase in headcount, an increase in stock-based compensation due to the acceleration of vesting and the associated incremental value of that modification to the stock options granted to a Neothetics' employee, and a \$0.3 million increase in costs incurred for outside services.

**General and administrative expenses**

	Three Months Ended March 31,		2018 vs. 2017	
	2018	2017	\$ Change	% Change
General and administrative	\$ 9,027	\$ 2,931	\$ 6,096	208%

The overall increase in general and administrative expenses was primarily driven by a \$4.5 million increase in professional services and personnel costs mainly attributable to the one-time costs associated with the Merger, a \$0.8 million increase in personnel costs including a \$0.3 million increase in stock-based compensation due to the acceleration of vesting for stock options granted to Private Evofem's non-employees directors and Neothetics' employees and the incremental value of the modification to the stock options granted to Neothetics' employees, and the recognition of \$0.3 million in costs incurred as part of our corporate sponsorship of the Tryst Network during the three months ended March 31, 2018. These increases were partially offset by a \$0.3 million decrease in public relations and market research related expenses.

**Loss on issuance of Invesco Warrants**

	Three Months Ended March 31,		2018 vs. 2017	
	2018	2017	\$ Change	% Change
Loss on issuance of Invesco Warrants	\$ (47,920)	\$ —	\$ (47,920)	100%

As described in [Note 9- Stockholders' Deficit](#), the Company issued the Invesco Warrants immediately prior to the Closing Date with the Company recognizing the fair value of the warrants as a loss on issuance for the three months ended March 31, 2018. No such loss was recorded for the three months ended March 31, 2017.

**Change in fair value of Series D 2X liquidation preference**

	Three Months Ended March 31,		2018 vs. 2017	
	2018	2017	\$ Change	% Change
Change in fair value of Series D 2X liquidation preference	\$ (130)	\$ (350)	\$ 220	(63)%

As described in [Note 5- Fair Value of Financial Instruments](#), in connection with the Merger the Company recognized a change in fair value of the Series D 2X liquidation preference upon a final valuation before conversion of all 80 shares issued and outstanding Series D into Neothetics' common stock. The valuation model utilized considers the probability of achieving certain exit scenarios, the Company's cost of capital, the estimated period the Series D 2X liquidation preference would be outstanding, consideration received for the instrument with the Series D 2X liquidation preference and at what price and changes, if any, in the fair value of the underlying instrument to the Series D 2X liquidation preference. The variance in change in fair value of represents changes in assumptions in the valuation model.

## Liquidity and Capital Resources

### Overview

We have incurred losses and negative cash flows from operating activities since inception. As of March 31, 2018, we had \$5.0 million in unrestricted cash, a working capital deficit of \$19.8 million and an accumulated deficit of \$376.5 million.

We anticipate we will continue to incur net losses for the foreseeable future and incur additional costs associated with being a public company. We expect our research and development expenses will increase for the foreseeable future due to our confirmatory Phase 3 clinical trial for Amphora for the prevention of pregnancy, our Phase 2b/3 clinical trials for prevention of chlamydia and gonorrhea. According to management estimates, liquidity resources as of March 31, 2018 are not sufficient to maintain our planned level of operations for the next 12 months. In addition, the uncertainties associated with our ability to (i) obtain additional equity financing on terms that are favorable to us, (ii) enter into collaborative agreements with strategic partners and (iii) succeed in our future operations, raise substantial doubt about our ability to continue as a going concern.

The opinion of our independent registered public accounting firm on our audited financial statements as of and for the years ended December 31, 2017 and 2016 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. Our unaudited condensed consolidated financial statements as of and for the three months ended March 31, 2018 and 2017 appearing in this Quarterly Report on Form 10-Q do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue our operations.

If we are not able to obtain the required funding in the near term, through equity financings or other means, or are not able to obtain funding on terms favorable to us, it will have a material adverse effect on our operations and strategic development plan for future growth. If we cannot successfully raise additional funding and implement our strategic development plan, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these could materially and adversely affect our liquidity, financial condition and business prospects and we would not be able to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements. We may obtain additional financing in the future through the issuance of our common stock from other equity or debt financings or through collaborations or partnerships with other companies.

### At the Market Program

On December 1, 2015, the Company entered into a Controlled Equity Offering Sales Agreement (the Sales Agreement) with Cantor Fitzgerald, as a sales agent pursuant to which the Company may offer and sell from time to time, through Cantor Fitzgerald shares of our common stock, par value \$0.0001 per share, having an aggregate offering price of up to \$20.0 million. The minimum share price for any Sales Agreement is selected at the discretion of the board of directors. No shares of common stock were sold pursuant to this Sales Agreement during the three months ended March 31, 2018.

### Summary Statement of Cash Flows

The following table sets forth a summary of the net cash flow activity for each of the periods set forth below (in thousands):

	Three Months Ended March 31,		2018 vs. 2017
	2018	2017	% Change
Net cash, cash equivalents and restricted cash used in operating activities	\$ (18,138)	\$ (6,069)	199 %
Net cash, cash equivalents and restricted cash provided by investing activities	2,150	250	760 %
Net cash, cash equivalents and restricted cash provided by (used in) financing activities	19,885	(580)	(3,528)%
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 3,897	\$ (6,399)	(161)%

*Cash Flows from Operating Activities.* Since inception, the primary use of cash, cash equivalents and restricted cash was to fund further development of our lead product candidate, Amphora, as a contraceptive, as well as potential other indications and to support general and administrative operations.

## [Table of Contents](#)

*Cash Flows from Investing Activities.* Net cash, cash equivalents and restricted cash provided by investing activities for the three months ended March 31, 2018 increased by \$1.9 million compared to the same period in 2017 primarily due to cash acquired from Neothetics in connection with the Merger as described in [Note 1- Description of Business and Basis of Presentation](#).

*Cash Flows from Financing Activities.* During the three months ended March 31, 2018, the primary source of cash, cash equivalents and restricted cash was the sale of 1,614,289 shares of the Company's common stock for gross proceeds of \$20.0 million in a private placement transaction, offset by \$0.2 million payment of Series D dividends upon conversion of Series D into Neothetics' common stock. During the three months ended March 31, 2017, net cash and restricted cash used was for the payments of deferred financing costs associated with our abandoned IPO.

### ***Operating and Capital Expenditure Requirements***

Our future capital requirements are difficult to forecast. We expect to incur additional capital expenditures for serialization equipment to be utilized in the manufacturing of Amphora prior to commercialization, but cannot adequately predict the cost of the equipment in the future or other potential capital expenditure requirements, if any.

We expect research and development expenses to increase substantially for the foreseeable future as we advance Amphora as a contraceptive, pursue expanded indications for Amphora and advance our BV product candidate through additional clinical development programs. In addition, we expect to incur costs as we make improvements to our manufacturing process. The process of conducting preclinical and clinical trials necessary to obtain regulatory approval is costly and time consuming and we may never succeed in achieving regulatory approval for any of our product candidates. The probability of success for each product candidate will be affected by numerous factors, including preclinical data, clinical trial data, competition, manufacturing capability and commercial viability. We are responsible for all research and development costs for our programs.

We expect general and administrative expenses to increase as we hire additional personnel to support commercialization of our product candidates, if any. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with stock exchange listing and SEC requirements, director's and officer's liability insurance premiums, and investor relations-related expenses.

When we believe regulatory approval of a product candidate appears likely, we expect to incur significant costs as we establish a sales and marketing infrastructure for distribution, promotion and sales of our products.

### **Off-Balance Sheet Arrangements**

As of March 31, 2018 and December 31, 2017, we do not have any off-balance sheet arrangements, as such term is defined under Item 303 of Regulation S-K, that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

### **Other Matters**

#### ***Recently Issued Accounting Pronouncements***

For information with respect to recent accounting pronouncements, see [Note 2 — Summary of Significant Accounting Policies](#) to our condensed consolidated financial statements appearing in Part I, Item 1 of this report.

#### ***Critical Accounting Policies***

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the applicable periods. Management bases its estimates, assumptions and judgments, on historical experience and on various other factors it believes to be reasonable under the circumstances. Different estimates, assumptions and judgments may change the estimated used in the preparation of our consolidated financial statements, which, in turn, could materially change our results from those reported. Management evaluates its estimates, assumptions and judgments on an ongoing basis. However, if our assumptions change, we may need to

## [Table of Contents](#)

revise our estimates, or take other corrective actions, either of which may also have a material adverse effect on our consolidated statements of operations, liquidity and financial condition. We believe the following critical accounting policies involve significant areas where management applies estimates, assumptions and judgments in the preparation of our consolidated financial statements. See Note 2 to our 2017 Audited Financial Statements for our additional accounting policies.

### *Clinical Trial Accruals*

As part of the process of preparing our financial statements, we are required to estimate expenses resulting from our obligations under contracts with vendors, CROs and consultants and under clinical site agreements relating to conducting our clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by recording those expenses in the period in which services are performed and efforts are expended. We account for these expenses according to the progress of the clinical trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models and discussions with applicable personnel and outside service providers as to the progress of clinical trials. During a clinical trial, we adjust the clinical expense recognition if actual results differ from estimates. We make estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical trial accruals are partially dependent upon accurate reporting by CROs and other third-party vendors. Although we do not expect estimates to differ materially from actual amounts, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any reporting period. For the three months ended March 31, 2018 and 2017, there were no material adjustments to our prior period estimates of accrued expenses for clinical trials.

### *Determining Fair Value of Stock Options*

The fair value of the shares of our common stock underlying stock-based awards are estimated on each grant date by our board of directors. Prior to completion of the Merger, to determine the fair value of the common stock underlying option grants, the board of directors considered, among other things, valuations of our common stock prepared by an unrelated valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Given the absence of a public trading market for our common stock prior to completion of the Merger, the BOD exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; progress of our R&D efforts; our operating and financial performance, including levels of available capital resources; the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock; sales of our convertible preferred stock; the valuation of publicly traded companies in our industry, equity market conditions affecting comparable public companies and the lack of marketability of our common stock. We obtained valuations on at least an annual basis or when we determined significant value generating or diminishing internal and/or external events have occurred, which would significantly increase or decrease the fair value of the common stock underlying our stock-based awards. Post-Merger, the fair value of our common stock will be equal to the closing price of our stock.

### *Series D 2X Liquidation Preference*

Prior to completion of the Merger, we valued our Series D 2X liquidation preference in accordance with Accounting Standards Codification No. 815 —*Derivatives and Hedging*, using a PWERM, which is sensitive to changes in assumptions regarding the timing of additional financings, potential exit scenarios and revisions in our financial forecast. Changes in any one of the assumptions could have had a material impact on the fair value of the Series D 2X liquidation preference. Our management used the most reliably available information at each valuation date in determining the fair value of the Series D 2X liquidation preference. Due to the nature of the assumptions and the sensitive nature of the PWERM, management could not reliably provide sensitivity analysis around the impact of changes in assumptions utilized in the PWERM used to estimate the fair value of our Series D 2X liquidation preference.

### *Fair Value of Series D*

Prior to completion of the Merger, we valued our Series D using a PWERM, which is sensitive to changes in assumptions regarding the timing of additional financings, potential exit scenarios and revisions in our financial forecast. Changes in any one of the assumptions could have had a material impact on the estimated fair value of the Series D. Our management used the most reliably available information at each issuance of Series D to determine the fair value of the Series D. Due to the nature of the assumptions and the sensitive nature of the PWERM, management could not reliably provide

[Table of Contents](#)

sensitivity analysis around the impact of changes in assumptions utilized in the PWERM used to estimate the fair value of our Series D.

**ITEM 3. Quantitative and Qualitative Disclosures about Market Risk**

Not applicable.

**ITEM 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this quarterly report on Form 10-Q. Based on such evaluation, our principal executive officer and principal financial officer has concluded that as of such date, our disclosure controls and procedures were effective.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during our latest fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Inherent Limitations of Internal Controls**

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

From time to time we may be involved in various disputes and litigation matters that arise in the ordinary course of business. We are currently not a party to any material legal proceedings.

**Item 1A. Risk Factors**

*An investment in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should carefully consider the risks described below together with the information included in this report including our financial statements and the related notes appearing in our 2017 Audited Financial Statements incorporated by reference into this report and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations". If any of these risks occur, our business, financial condition, results of operations or cash flow could be harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. There may be additional risks we do not presently know of or we currently believe are immaterial which could also impair our business and financial position.*

**Risks Related to Our Business**

**Risks Related to Our Financial Condition and Capital Requirements**

## [Table of Contents](#)

*We have incurred significant losses since our inception and anticipate we will continue to incur significant losses for the foreseeable future.*

We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred yearly losses since inception, including net losses of \$105.3 million and \$66.7 million for the years ended December 31, 2017 and 2016, respectively, and net losses of \$69.1 million and \$5.3 million for the three months ended March 31, 2018 and 2017, respectively. As of March 31, 2018, we had an accumulated deficit of \$376.5 million. Negative cash flows from our operations are expected to continue for the foreseeable future. Our utilization of cash has been and will continue to be highly dependent on our product development programs, particularly our programs for the development of our Multi-purpose Prevention Technology (MPT) vaginal gel product candidates and our lead product candidate, Amphora. Our cash expenses will be highly dependent on the product development programs we choose to pursue, the progress of these product development programs, the results of our preclinical and clinical trials, the cost, timing and outcomes of regulatory decisions regarding potential approval for our product candidate or any future product candidates we may choose to develop, the terms and conditions of our contracts with service providers and license partners, and the rate of recruitment of patients in our clinical trials. In addition, the continuation of our clinical trials, and quite possibly our entire business, will depend on results of upcoming clinical data analyses and our financial resources at the time. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates.

We have devoted substantially all our financial resources to develop our product candidates, including conducting clinical trials and providing general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities and related-party funding. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or grants. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- continue the clinical development Amphora and our BV product candidate for the treatment of recurrent bacterial vaginosis (BV);
- continue efforts to discover new product candidates;
- undertake the manufacturing of our product candidates or increase volumes manufactured by third parties;
- advance our programs into larger, more expensive clinical trials;
- initiate additional preclinical, clinical, or other trials for our product candidates or any product candidates we may choose to develop in the future;
- seek regulatory and marketing approvals and reimbursement for our product candidates or any product candidates we may choose to develop in the future;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market for ourselves;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty or other payments under third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel; and
- experience any delays or encounter issues with the development and regulatory approval of our product candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned trials, additional major trials or supportive studies necessary to support marketing approval.

Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

*We must raise additional funds to finance our operations to remain a going concern.*

Based on our cash balance, recurring losses since inception and inadequacy of existing capital resources to fund planned operations during the remainder of 2018, we will require significant additional funding to continue operations. If we are unable to raise additional funds when needed, we may not be able to continue development of Amphora, or we will be required to delay, scale back or eliminate some or all our development programs or cease operations. In addition, we will be unable to initiate the Phase 2b/3 trial of our BV product candidate until we raise additional funds. Any additional equity or debt financing we may obtain will be dilutive to our current stockholders and debt financing, if available, may involve restrictive covenants or unfavorable terms. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to our technology or product candidates we would otherwise seek to develop or commercialize. Moreover, if we are unable to continue as a going concern, we may be forced to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

## [Table of Contents](#)

*We have never generated any revenue from product sales and may never be profitable.*

We have no products approved for commercialization and have never generated any material amount of revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of, and obtain necessary regulatory and marketing approvals to commercialize one or more of our current or future product candidates. We do not anticipate generating revenue from product sales until early 2020. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including, but not limited to:

- completing research and development of Amphora for contraception and/or one or more of our current or future product candidates;
- obtaining regulatory and marketing approvals for one or more of our current or future product candidates;
- manufacturing one or more product candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, meet regulatory requirements and our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;
- marketing, launching and commercializing one or more product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of one or more of our product candidates as treatment options;
- addressing any competing products;
- protecting, maintaining and enforcing our intellectual property rights, including patents, trade secrets and know-how;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- obtaining reimbursement or pricing for Amphora and/or one or more of our current or future product candidates that supports profitability; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates we develop is approved for commercial sale, we anticipate incurring significant costs associated with launching and commercializing any approved product candidate. We also will have to develop or acquire manufacturing capabilities or continue to contract with contract manufacturers for continued development and potential commercialization of our product candidates. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

*We are heavily reliant on our ability to access funding through capital market transactions. Due to our small public float, limited operating history and lack of revenue, it may be difficult and expensive for us to raise additional funds.*

We are heavily reliant on our ability to raise funds through the issuance of shares of our common stock or securities linked to our common stock. Our ability to raise these funds may be dependent on several factors, including the risk factors further described herein and the low trading volume and volatile trading price of our shares of common stock. The stocks of small cap companies in the biotechnology sector similar to us tend to be highly volatile. We expect the price of our common stock will be highly volatile for the next several years. Even if we expand our portfolio of products and product candidates, we may never successfully commercialize or monetize our current product candidate or any future product candidates we may seek to develop.

As a result, we may be unable to access funding through sales of our common stock or other equity-linked securities. Even if we are able to access funding, the cost of capital may be substantial. The terms of any funding we are able to obtain may not be favorable to us and may be highly dilutive to our stockholders. We may be unable to access capital due to unfavorable market conditions or other market factors outside of our control. There can be no assurance we will be able to raise additional capital when needed. The failure to obtain additional capital when needed would have a material adverse effect on our business.

*Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights.*

Our cash reserves will not sufficient for us to complete the development of Amphora for sexually transmitted infections (STIs) and our BV product candidate and we must raise significant additional capital to complete the clinical trials required for these indications. To the extent we raise additional capital through the sale of equity, convertible debt or other securities convertible into equity, the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect rights of our stockholders. Debt financing, if available at all, would likely involve agreements with covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions or declaring dividends. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We do not know if we will be able to obtain additional funding if or when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to

## [Table of Contents](#)

expand our operations or otherwise capitalize on potential business opportunities, which could materially harm our business, financial condition, and results of operations.

*Our limited operating history makes it difficult to evaluate the success of our business to date and to assess our future viability.*

To date, our activities have been largely limited to staffing, business planning, raising capital, developing our MPT vaginal gel product candidates, identifying potential products and undertaking preclinical and clinical trials of our product candidates. We have a limited operating history that makes it difficult to evaluate our business and prospects. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. As a clinical-stage company, we have not yet demonstrated our ability to obtain regulatory approvals, generate significant revenue or conduct biopharmaceutical marketing activities necessary for successful product commercialization. In addition, given our limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. Our likelihood of success must be evaluated in light of such challenges and variables associated with a clinical-stage biopharmaceutical product development company and we may not be successful in our commercialization efforts or may incur greater costs than expected, both of which would materially adversely affect our business, results of operations or financial condition.

*The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.*

On December 22, 2017, the President signed into law the “Tax Cuts and Jobs Act,” or TCJA, which significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to United States federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and put into effect the migration from a “worldwide” system of taxation to a territorial system. Our net deferred tax assets and liabilities were revalued at the newly enacted United States corporate rate, and the impact was recognized in our tax expense in the year of enactment. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform is uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

### **Risks Related to the Development of Our Product Candidates**

*Our success will depend heavily on whether we can develop our lead product candidate, Amphora, as a contraceptive. Failure to develop Amphora as a contraceptive would likely cause our business to fail.*

We currently have a single platform technology, our MPT vaginal gel, from which we intend to create multiple product candidates. However, we will rely primarily on Amphora, for use as a contraceptive for our commercial success. Amphora is currently the subject of an ongoing confirmatory Phase 3 clinical trial intended to demonstrate efficacy as a contraceptive. While we believe our MPT vaginal gel product candidate may also be useful in other indications, currently our business depends almost entirely on the successful clinical development and regulatory approval of Amphora for use as a contraceptive, which may never occur. In April 2016, we received a complete response letter from the FDA on our original submission of an NDA for Amphora for the prevention of pregnancy due to matters relating to certain data from patients in Russia. While we intend to resubmit an NDA for Amphora in this indication in 2019, the FDA may not approve Amphora for this indication and numerous factors may delay our ability to resubmit the NDA in a timely manner. We have never received regulatory approval for any product. Even if we are able to successfully complete our clinical trial for Amphora as a contraceptive, we may be unable to obtain regulatory approval for Amphora as a contraceptive, which would have a material adverse effect on our business, financial position, results of operations and prospects.

*Our inability to develop our MPT vaginal gel product candidates for additional indications could have an adverse effect on our business and our ability to successfully market Amphora as a contraceptive.*

We believe Amphora may also be useful in certain other indications and we are conducting a Phase 2b/3 clinical trial designed to assess the product candidate for the prevention of prevention of urogenital *Chlamydia trachomatis* infection (chlamydia) in women and for the prevention of urogenital *Neisseria gonorrhoeae* infection (gonorrhea) in women. In addition, we are currently designing a Phase 2b/3 trial of our BV product candidate. We do not know if we will successfully complete either of these clinical trials. Even if we do complete these clinical trials, there is no assurance we will obtain regulatory approval of Amphora product candidate for the prevention of either chlamydia or gonorrhea or of our BV product candidate. Such a failure could impede our ability to market Amphora as a contraceptive or our BV product candidate because all our product candidates are based on the same active ingredients and technology. Also, any failure to obtain regulatory approvals for additional indications will likely have a material adverse effect on our business, results of or financial condition and operations.

*Indemnity claims from lawsuits or damages against our clinical trial sites could cause us to incur substantial liabilities and to limit commercialization of Amphora, and any future product candidates we may develop.*

## [Table of Contents](#)

In connection with our clinical trials, our third-party investigators and clinical trial sites face inherent risk of liability exposure from patients enrolled in our clinical trials. We have entered into indemnification agreements with each of our clinical trial sites obligating us to defend the sites against third party claims or reimburse the sites should they incur certain costs or liability in connection with our clinical trials.

We currently carry product liability insurance with policy limits we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or is in excess of the limits of our insurance coverage.

If we or our clinical trial sites cannot successfully defend against these product liability or other health related claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for Amphora, our BV product candidate, and any future product candidates we may develop, injury to our reputation, negative media attention and the diversion of our management's time and attention from our product development and commercialization efforts to address claim related matters.

*The success of our business is also expected to depend in part upon our ability to identify, license, discover, develop or commercialize additional product candidates. Failure to identify additional product candidates would have a negative impact on our business and operations.*

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of Amphora as a contraceptive and for the preventative of certain STIs and our BV product candidate, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop or commercialize additional product candidates. We are seeking to license, or otherwise obtain, product and technology rights to a variety of products and product candidates in the field of women's health, but there can be no assurance we will be able to do so, or do so on favorable terms. Research programs to identify new product candidates require substantial technical, financial and human resources. There are risks, uncertainties and costs associated with identifying, licensing and advancing product candidates through successful clinical development. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program such that a product may become unreasonable to continue to develop;
- research and development programs are quite costly and we may be unable to obtain the financing and resources to do so;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payers.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, partner, discover, develop or commercialize additional product candidates, which would have a material adverse effect on our business, financial condition or results of operations and could potentially cause us to cease operations. Moreover, even if we were able to obtain the rights to additional product candidates, there can be no assurance these candidates will ever be advanced successfully through clinical development.

*Clinical trials are costly, time consuming and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.*

Clinical development is expensive, time consuming and involves significant risk. We cannot guarantee any clinical trials will be conducted as planned or completed on schedule, if at all. In addition, our product candidates are targeted toward pregnancy prevention and the prevention of certain infectious diseases. Therefore, it may be especially difficult to recruit patients to participate in our clinical trials when doing so will require patients to refrain from other methods of contraception and disease prevention. A failure of one or more clinical trials can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include, but are not limited to:

- inability to obtain the funding necessary to initiate or complete any clinical trial;

## [Table of Contents](#)

- inability to generate satisfactory preclinical, toxicology or other in vivo or in vitro data or to develop diagnostics capable of supporting the initiation or continuation of clinical trials;
- delays in reaching agreement on acceptable terms with clinical research organizations (CROs) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays or failure in obtaining required institutional review board approval at each clinical trial site;
- failure to obtain or delays in obtaining a permit from regulatory authorities to conduct a clinical trial;
- delays in recruiting or failure to recruit sufficient eligible patients in our clinical trials;
- failure by clinical sites, CROs or other third parties to adhere to clinical trial requirements;
- failure by clinical sites, CROs or other third parties to perform in accordance with the good clinical practices requirements of the Food and Drug Administration (the FDA) applicable laws or applicable foreign regulatory requirements;
- patients withdrawing from our clinical trials;
- adverse events or other issues of concern significant enough for an Institutional Review Board (IRB) to suspend or terminate a clinical trial or for the FDA, or comparable foreign regulatory authority, to put an Investigational New Drug Application or comparable foreign application on clinical hold;
- occurrence of adverse events associated with our product candidates that may make it more difficult to recruit subjects or cause other material delays in the clinical programs;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of our product candidates;
- negative or inconclusive results from our clinical trials that may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in other ongoing or planned indications for a product candidate; and
- delays in reaching agreement on acceptable terms with third-party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for one or more of our product candidates could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional non-clinical studies and/or clinical trials to show the results obtained from such new formulation are consistent with previous results obtained. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

*Contraception is a highly competitive healthcare niche. The success of Amphora and any other future contraceptive product candidate we may pursue will be related to our efficacy and safety outcomes during clinical trials.*

Today, there are a variety of hormonal and non-hormonal contraceptive options available to women, including: oral contraceptive pills and intrauterine devices; newer hormonal contraceptive products including implants, injectables, vaginal rings, patches, and hormonal intrauterine systems; and non-hormonal methods such as female condoms, novel diaphragms, and new methods of female sterilization. Based on our market research, we believe clinical testing of Amphora may need to demonstrate efficacy for typical use of approximately 80% to be commercially viable. Should Amphora fail to generate the safety and efficacy data expected, our business prospects would be materially damaged.

*Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our MPT vaginal gel product candidates and we may be unable to pursue and complete the clinical trials we would like to pursue and complete.*

We have limited financial and technical resources to determine the indications on which we should focus the development efforts for our product candidates and any future candidates we may choose to develop. Due to our limited available financial resources, we may be required to curtail clinical development programs and activities that might otherwise have led to more rapid progress of our product candidates, or product candidates we may in the future choose to develop, through the regulatory and development processes. We may make incorrect determinations regarding the indications and clinical trials on which to focus our available resources. The decisions to allocate our research, management and financial resources towards particular indications may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate development programs may also cause us to miss valuable opportunities.

### **Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters**

*We must obtain regulatory approval prior to marketing or commercializing our product candidates. To obtain regulatory approval, we must complete our preclinical studies and clinical trials in compliance with the regulatory approval requirements*

## [Table of Contents](#)

*of the FDA and any applicable and comparable foreign regulators. If our clinical trials fail to satisfactorily demonstrate safety and efficacy or our product candidates to the FDA and other comparable foreign regulators, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. While we have received a Qualified Infectious Disease Product (QIDP) designation for certain of our product candidates based on their current formulations, we may be required to reapply for this designation should we alter the formulations of these product candidates.*

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable foreign regulatory authorities impose similar restrictions. We may never receive such approvals, and we must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates before we may be able to obtain these approvals.

Any inability to complete preclinical and clinical development successfully could result in additional costs to us, and impair our ability to generate revenues. Moreover, if (1) we are required to conduct additional clinical trials or other nonclinical testing of our product candidates beyond the trials and testing we currently contemplate (2) we are unable to successfully complete clinical trials of our product candidates or other testing, (3) the results of these clinical trials or tests are unfavorable, uncertain or are only modestly favorable or (4) there are unacceptable safety concerns associated with our product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

We have received QIDP designation from the FDA for Amphora for the prevention of gonorrhea in women, and we have received QIDP designation for the prevention of recurrence of BV. However, we anticipate that we may revise the formulation of our BV product candidate during the course of development. As a result, we may be required to resubmit a request for QIDP designation for our BV product candidate.

*Amphora is a drug/device combination and the process for obtaining regulatory approval for Amphora in the United States will require compliance with requirements of two divisions of the FDA. A change in the FDA's primary oversight responsibility would adversely impact our development timeline and significantly raise our costs.*

Amphora is composed of both drug and device components and is considered a combination product by the FDA. It is a method of self-applied contraception that uses a pre-filled applicator to apply a semi-solid bioadhesive gel. The key active ingredient has been shown to be an active anti-inflammatory and anti-infective that works in combination with other active ingredients to stabilize the pH levels in the vagina without altering the vaginal microbiome, which results in both the inhibition and the immobilization of sperm. Other properties contributing to the contraceptive effect of Amphora are its capacity to reduce/inhibit cervical mucus penetration, its ability to maintain sufficient viscosity even on dilution, and its bioadhesive strength.

The FDA has different divisions responsible for assessing and approving devices and drugs. The Center for Drug Evaluation and Research (CDER) has responsibility for drug products, while the Center for Devices and Radiological Health (CDRH) has oversight responsibility for medical devices. Amphora previously underwent a request for designation (RFD) process with the FDA that determined the CDER would lead the review and that the product should be submitted for marketing authorization pursuant to a New Drug Application (NDA). If the designation of the lead center were to be changed to CDRH, or if either division or the FDA Office of Combination Products were to institute additional requirements for the approval of Amphora, we could be required to complete clinical trials with more patients and over longer periods of time than is currently anticipated or comply with regulatory requirements that are not currently anticipated. This would likely require us to raise additional funds and would cause us to miss anticipated timelines. The impact of either a change in lead agency center for pre-market review or the imposition of additional requirements for approval would be significant to us and would have a material adverse effect on the prospects for the development of Amphora, our business and our financial condition.

*Serious adverse events arising post marketing or during clinical trials of our product candidates could have a material, adverse effect on our product development timeline or our ability to develop and market our MPT vaginal gel product candidates, including our lead product candidate, Amphora.*

If serious adverse events or undesirable side effects occur during the clinical investigation of our MPT vaginal gel product candidate, including Amphora, or post marketing, the following events could materially and adversely affect our business:

- IRBs may suspend or terminate our clinical trials;

## [Table of Contents](#)

- regulatory authorities may impose a clinical hold, which could result in substantial delays and adversely impact our ability to continue development of our MPT vaginal gel product candidates, including Amphora;
- regulatory authorities may require the addition of specific warnings or contraindications to product labeling or the issuance of alerts to physicians and pharmacies;
- we may be required to change the way the MPT vaginal gel product candidate and/or Amphora is administered or to revise the labeling of the MPT vaginal gel product candidates, including Amphora;
- we may be required to conduct additional clinical trials with more patients or over longer periods of time than anticipated;
- we may be required to implement risk evaluation and mitigation strategies, which could result in substantial cost increases and have a negative impact on our ability to commercialize our MPT vaginal gel product candidate, including Amphora;
- we may be required to limit the patients who can receive our MPT vaginal gel product candidates, including Amphora;
- we may be subject to promotional and marketing limitations on our MPT vaginal gel product candidates, including Amphora;
- sales of our MPT vaginal gel product candidates, including Amphora, may decrease significantly;
- regulatory authorities may require us to take an approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our MPT vaginal gel product candidates, including Amphora, or any future product candidates we may seek to develop, or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from our MPT vaginal gel product candidates, including Amphora, sales or the sales from any future product candidates.

If FDA approval is received for our MPT vaginal gel product candidates, including Amphora, or any other future product candidates we may develop, serious adverse events or side effects could require the product to be taken off the market, may require the product to be packaged with safety warnings or may otherwise limit our sales of the product.

*Even if we obtain regulatory approval for a product, we will remain subject to ongoing regulatory requirements.*

If our MPT vaginal gel product candidates are approved, we will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing clinical trials and submission of safety, efficacy and other post-approval information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring quality control and manufacturing procedures conform to current good manufacturing practices (cGMP) regulations and corresponding foreign regulatory manufacturing requirements. Accordingly, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA submission to the FDA or any other type of domestic or foreign marketing authorization application.

Any regulatory approvals we receive for any of our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm the clinical benefit for our products. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or it disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;

## [Table of Contents](#)

- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- require a product recall.

Any government investigation of alleged violations of law would require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products and the value of our business and our operating results would be adversely affected.

*Even if we receive approval from the FDA in the United States to market our MPT vaginal gel product candidates or future product candidates we may seek to develop, we may fail to receive similar approval outside the United States.*

To market a new product outside the United States, we must obtain separate marketing approvals in each jurisdiction and comply with numerous and varying regulatory requirements of other countries, including clinical trials, commercial sales, pricing manufacture distribution and safety requirements. The time required to obtain approval in other countries might differ from, and be longer than, that required to obtain FDA approval. The marketing approval process in other countries may include all the risks associated with obtaining FDA approval in the United States, as well as other risks. Further, we may be unable to obtain rights to the necessary clinical data and may be required to develop our own. In addition, in many countries outside the United States, a new product must receive pricing and reimbursement approval prior to commercialization. This can result in substantial delays in these countries. Additionally, the product labeling requirements outside the United States may be different and inconsistent with the United States labeling requirements, negatively affecting our ability to market our products in countries outside the United States.

In addition, if we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. In such an event, our ability to market to our full target market will be reduced and our ability to realize the full market potential of our product candidate will be harmed, which could have a materially adverse effect on our business, financial condition, results of operations and prospects.

*Our development and commercialization strategy for our MPT vaginal gel product candidates depend, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of approved products based on data developed by others that the FDA may rely on in reviewing our NDA.*

The Drug Price Competition and Patent Term Restoration Act added section 505(b)(2) to the Federal Food, Drug and Cosmetic Act (the FDCA). Section 505(b)(2) of the FDCA permits the filing of a NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets section 505(b)(2) of the FDCA, for the purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. The FDA may also require the applicant to perform additional clinical trials or measurements to support any deviation from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the section 505(b)(2) applicant. The FDA may require an applicant's product label to have all or some of the limitations, contraindications, warnings or precautions included in the reference product's label, including a black box warning, or may require the label to have additional limitations, contraindications, warnings or precautions.

We plan to submit an NDA for Amphora under section 505(b)(2) of the FDCA and it will rely, in part, on the FDA's previous findings of safety and efficacy from investigations for approved products and published scientific literature for which we have not received a right of reference. We have previously had to certify against patents in the Orange Book covering reference products identified in our NDA and anticipate that we will have to make such certifications upon resubmission of our Amphora NDA, which could result in patent litigation and delay of approval for our NDA. In addition, notwithstanding the approval of many products by the FDA pursuant to section 505(b)(2) of the FDCA, over the last few years some pharmaceutical companies and others have objected to the FDA's interpretation of section 505(b)(2) of the FDCA. If the FDA changes its interpretation of section 505(b)(2) of the FDCA, or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any section 505(b)(2) NDAs we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and commercialization of our product candidates.

*Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our MPT vaginal gel product candidates, including our lead product candidate, Amphora, and any future product candidates we may develop.*

## [Table of Contents](#)

We face an inherent risk of product liability exposure in conducting clinical trials and should we commercialize Amphora. We will face similar risks with any other future indications for our MPT vaginal gel product candidates or other product candidates we may develop or commercialize. If we cannot successfully defend ourselves against these product liability claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for our MPT vaginal gel product candidates, including Amphora, or, as applicable, any future product candidates we may develop, injury to our reputation, negative media attention and the diversion of our management's time and attention from our product development and commercialization efforts to address claim related matters.

We will need to maintain liability insurance coverage as we seek to conduct and continue to conduct clinical trials for our MPT vaginal gel product candidates, including Amphora. Such insurance may become increasingly expensive and difficult to procure. In the future, such insurance may not be available to us at all or may only be available at a very high cost and, if available, may not be adequate to cover all liabilities we may incur. In addition, we may need to increase our liability insurance coverage in connection with the commercialization of our MPT vaginal gel product candidates, including Amphora, or any other product candidate we may commercialize. If we are not able to obtain and maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise, our business could be harmed, possibly materially.

*If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition or results of operations.*

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations; environmental damage resulting in costly clean-up; and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of specified materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

### **Risks Related to Our Intellectual Property**

*Our rights to develop and commercialize our MPT vaginal gel product candidates, including our lead product candidate, Amphora, are subject, in part, to the terms and conditions of licenses granted to us by third parties. The patent protection and patent prosecution of our MPT vaginal gel product candidates including our lead product candidate, Amphora, is dependent on third parties.*

We are reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of Amphora. For example, and as discussed in the section entitled "Business" in Item 5 of this report, our amended and restated license agreement with Rush University (the Rush License Agreement) includes intellectual property rights to our MPT vaginal gel product candidates. This agreement requires us, as a condition to the maintenance of our license and other rights, to make milestone and royalty payments and satisfy certain performance obligations. Our obligations under this in-license agreement impose significant financial and logistical burdens upon our ability to carry out our business plan. Furthermore, if we do not meet such obligations in a timely manner, and, in the case of milestone payment requirements, if we were unable to obtain an extension of the deadlines for meeting such payment requirements, we could lose the rights to this proprietary technology, which would have a material adverse effect on our business, financial condition and results of operations.

There is no assurance the existing Rush License Agreement covering the rights related to our MPT vaginal gel product candidates, including Amphora, will not be terminated due to a material breach of the underlying agreement. This would include a failure on our part to make the milestone and royalty payments, our failure to obtain applicable approvals from governmental authorities, or the loss of rights to the underlying intellectual property by any such licensors. Under the current circumstances and as we have not paid royalties to date, the Rush License Agreement may be terminated at Rush University's option. We could make payments to Rush University in order to delay the effect of such termination until March 2019. While we believe we will be able to negotiate an extension, if needed, there is no assurance we will be able to renew or renegotiate an extension to the Rush License Agreement or that we will be able to do so on acceptable terms. The termination of this license

## [Table of Contents](#)

agreement or our inability to enforce our rights under this license agreement would materially and adversely affect our ability to commercialize our MPT vaginal gel product candidates, including Amphora.

In addition, with respect to our MPT vaginal gel product candidates, including Amphora, Rush University has the right, in certain instances, to control the defense against any infringement litigation arising from the manufacture or development (but not the sale) of our MPT vaginal gel product candidates, including Amphora. While our license agreement with Rush University requires Rush University to indemnify us for certain losses arising from these claims, this indemnification may not be sufficient to adequately compensate us for any related losses or the potential loss of our ability to manufacture and develop our MPT vaginal gel product candidates, including Amphora.

In general, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

*If we are unable to obtain and maintain patent protection for our MPT vaginal gel product candidates, including our lead product candidate, Amphora, and other proprietary technologies we may develop, or if the scope of the patent protection we have or will obtain is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to our products and technology, and our ability to successfully commercialize Amphora, our BV product candidate, and other proprietary technologies we may develop may be adversely affected.*

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to Amphora, our BV product candidate and other proprietary technologies we may develop. We seek to protect our proprietary position by in-licensing intellectual property and filing patent applications in the United States and abroad relating to Amphora, our BV product candidate and other proprietary technologies we may develop. If we or our licensors are unable to obtain or maintain patent protection with respect to Amphora, our BV product candidate and other proprietary technologies we may develop, our business, financial condition, results of operations, and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

## [Table of Contents](#)

The patent position of biotechnology and biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our owned or in-licensed pending and future patent applications may not result in patents being issued which protect Amphora, our BV product candidate and other proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents we own or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our MPT vaginal gel product candidates and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We or our licensors may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office (the USPTO) or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or interference proceedings or other similar proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned or in-licensed patent rights, allow third parties to commercialize generic versions of Amphora, our BV product candidate and other proprietary technologies we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our licensor's priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of Amphora, our BV product candidate and other proprietary technologies we may develop. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, given the amount of time required for the development, testing, and regulatory review of our MPT vaginal gel product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

*We may not be able to protect our intellectual property and proprietary rights throughout the world.*

Filing, prosecuting, and defending patents on our MPT vaginal gel product candidates and other proprietary technologies we may develop in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technology in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biopharmaceutical

## [Table of Contents](#)

products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan, and China, may have a higher standard for patentability than in the United States, including for example the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in United States and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

*Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.*

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to United States and non-United States patent agencies. The USPTO and various non-United States government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

*Changes in United States patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.*

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the America Invents Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our MPT vaginal gel product candidates, including Amphora, and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

## [Table of Contents](#)

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the United States Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

*Issued patents covering our MPT vaginal gel product candidates and other proprietary technologies we may develop could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.*

If we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering our MPT vaginal gel product candidates, including Amphora, and other proprietary technologies we may develop, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our owned or in-licensed patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our MPT vaginal gel product candidates, including Amphora, and other proprietary technologies we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on Amphora product candidate and other proprietary technologies we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

*If we do not obtain patent term extension and data exclusivity for our MPT vaginal gel product candidates, our business may be materially harmed.*

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidate we may develop, one or more of our owned or in-licensed United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (the Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent term extension (PTE) of up to five years as compensation for patent term lost during the FDA regulatory review process. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate (SPC).

An important part of our patent strategy is reliant on our ability to obtain patent term extension on the patents licensed from Rush University, which currently expire in 2021. However, we may not be granted an extension, such as PTE for the United States patent and SPC for the European patents because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time or the scope of patent protection afforded could be less than our request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

*The patent protection and patent prosecution for our MPT vaginal gel product candidates are dependent on third parties.*

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our MPT vaginal gel product candidates, there may be times when the filing and prosecution activities for patents relating to

## [Table of Contents](#)

our product candidate are controlled by our licensors or collaboration partners. If any of our current or future licensing or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidate, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize our product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

*We may be subject to claims challenging the inventorship of our patents and other intellectual property.*

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing Amphora product candidate and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensor's ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

*If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.*

In addition to seeking patents for our MPT vaginal gel product candidates, including Amphora, and other proprietary technologies we may develop, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. With respect to our MPT vaginal gel product candidates, including Amphora, we consider trade secrets and know-how to be one of our important sources of intellectual property. Trade secrets and know-how can be difficult to protect. In particular, our trade secrets and know-how in connection with our MPT vaginal gel product candidates and other proprietary technology we may develop over time may be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel with scientific positions in academic and industry.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, it may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to Amphora product candidate and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

*We may not be successful in obtaining necessary rights to any product candidate we may develop through acquisitions and in-licenses.*

## [Table of Contents](#)

We currently have rights to intellectual property, covering our MPT vaginal gel product candidates. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. To avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for our MPT vaginal gel product candidates and other proprietary technologies we may develop. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow it to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

*We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.*

Many of our employees, consultants, and advisors are currently or were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that it regards as its own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

*Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the development and commercialization of our MPT vaginal gel product candidates, including our lead product candidate, Amphora, and other proprietary technologies we may develop.*

The field of contraceptive and/or anti-STIs vaginal gel is competitive and dynamic. Due to the significant research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. There may be significant intellectual property related litigation and proceedings, in addition to the ongoing interference proceedings, relating to our owned and in-licensed, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in United States law referred to as patent reform, new procedures including inter partes review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous United States and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we intend to commercialize Amphora and our BV product candidate and in which we are developing other proprietary technologies. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidate may give rise to claims of infringement of the patent rights of others. We cannot assure you that our MPT vaginal gel product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidate, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or

## [Table of Contents](#)

treatment that cover our product candidate. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our MPT vaginal gel product candidates, including Amphora, and other proprietary technologies we may develop, could be found to be infringed by our product candidate. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidate may infringe.

Third parties may currently have patents or obtain patents in the future, and claim that use of our technology or the manufacture, use or sale of our MPT vaginal gel product candidates infringes upon these patents. In the event a third party claims we infringed their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our technology or product candidate. In this case, the holders of such patents may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidate or technology or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing products or technology. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technology, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidate or technology, which could harm our business significantly. Further, we cannot predict whether any required license would be available at all or whether we would be available on commercially reasonable terms. In the event we could not obtain a license, we may be unable to further develop our product candidate and commercialize our product and product candidate, if approved, which could harm our business significantly. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter licenses on acceptable terms.

Engaging in litigation defending us against third parties alleging infringement of patent and other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

*We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming, and unsuccessful.*

Competitors may infringe our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. In addition, our patents or the patents of our licensing partners also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide a patent owned or in-licensed by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other

## [Table of Contents](#)

resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

*If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.*

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, including those for Amphora, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to those rejections, it may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

*Intellectual property rights do not necessarily address all potential threats.*

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidate or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technology without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

### **Risks Related to Our Reliance on Third Parties**

*Our success relies on third-party suppliers and manufacturers. Any failure by such third parties, including failure to successfully perform and comply with regulatory requirements, could negatively impact our business and our ability to develop and market Amphora and potential future product candidates, and our business could be substantially harmed.*

We have a small number of employees and no internal manufacturing capability. Our management does not expect to manufacture any products and expects to rely on third parties to make our products, and as such we will be subject to inherent uncertainties related to product safety, availability and security. To date, our contract manufacturer has only produced our product candidates for clinical testing. They have also not previously manufactured prescription drug products and will likely need to successfully pass a pre-approval inspection by FDA during review of any NDA resubmission for Amphora. Furthermore, we have only a single source of supply for some of the key raw materials and components of our MPT vaginal gel product candidates, and while we believe we would be able to obtain supplies through alternative sources if needed, alternate sources of supply may not be readily available.

Moreover, we do not expect to control the manufacturing processes for the production of Amphora, our other product candidates or any of our other future products or product candidates, which must be made in accordance with relevant regulations including, among other things, quality control, quality assurance, compliance with cGMP and the maintenance of records and documentation. In the future, it is possible that our suppliers or manufacturers may fail to comply with FDA regulations, the requirements of other regulatory bodies or our own requirements, any of which would result in suspension or prevention of commercialization and/or manufacturing of our products or product candidates, including Amphora and our BV product candidate; suspension of ongoing research; disqualification of data or other enforcement actions such as product recall, injunctions, civil penalties or criminal prosecutions against us. Furthermore, we may be unable to replace any supplier or manufacturer with an alternate supplier or manufacturer on a commercially reasonable or timely basis, or at all.

If we were to experience an unexpected loss of supply of, or if any supplier or manufacturer were unable to meet our demand for our product candidates, we could experience delays in research, planned clinical trials or commercialization. We might be unable to find alternative suppliers or manufacturers with FDA approval, of acceptable quality, and that are able to supply products/ingredients in the appropriate volumes and at an acceptable cost. The long transition periods necessary to switch manufacturers and suppliers would significantly delay our timelines, which would materially adversely affect our business, financial conditions, results of operations and prospects.

In addition, our reliance on third-party manufacturers exposes us to the following additional risks:

- we may be unable to identify manufacturers on acceptable terms or at all;
- our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures appropriately;
- our future third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMPs and other government regulations and corresponding foreign standards, and we do not have control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates; and
- our third-party manufacturers could breach or terminate their agreements with us.

Each of these risks could delay our clinical trials, the approval, if any of our product candidates by the FDA or the commercialization of our product candidates or could result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our product candidates prior to delivery to patients. If these tests are not appropriately conducted and test data are not reliable, patients could be put at risk of serious harm, which could result in product liability suits.

The manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period to investigate and remedy the contamination. We cannot be assured that any stability or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource

## [Table of Contents](#)

constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

*We have no internal distribution capabilities and intend to engage third-party distributors for distribution of products outside the United States. Our inability to identify, or enter into an agreement with, any such third-party distributor, would likely have a material adverse effect on our business and operations.*

Although we currently plan to market and sell our lead product candidate, Amphora, directly in the United States, we do intend to enter into distribution agreements with one or more distributors of Amphora outside the United States. We currently have not entered into any such distribution agreement with any such distributor, and we cannot guarantee that we will be able to enter into any such distribution agreement on commercially reasonable terms, or at all. If we were to outsource product distribution, including the distribution of Amphora or any future product candidates or product, this outsourcing would also be subject to uncertainties related to such distribution services, including the quality of such distribution services. For example, distributors may not have the capacity to supply sufficient product if demand increases rapidly. Further, we would be dependent on the distributors to ensure that the distribution process accords with applicable foreign and United States regulations, which include, among other things, compliance with current good documentation practices, the maintenance of certain records, and compliance with other regulations, including, without limitation, the United States Foreign Corrupt Practices Act (the FCPA). Failure to comply with these requirements could result in significant remedial action, including enforcement action requiring distributors to implement physical changes or improvements to their facilities, suspension of distribution or recall product. Additionally, any failure by us to forecast demand for finished product, including Amphora, and failure by us to ensure our distributors have appropriate capacity to distribute such quantities of finished product, could result in an interruption in the supply of certain products and a decline in sales of that product. Further, third-party distributors may not perform as agreed or may terminate their agreements with us. Any significant problem that our distributors experience could delay or interrupt our sale of products in the applicable jurisdiction until the applicable distributor cures the problem or until we identify and negotiate an acceptable agreement with an alternative distributor, if one is available. Any failure or delay in distributing products would likely have a negative impact on our business and operations.

*We rely and intend to rely on third parties for the execution of our development programs for our MPT vaginal gel product candidates and our potential future product candidates. Failure of these third parties to provide services of a suitable quality and within acceptable time frames may cause the delay or failure of our development programs.*

We employ a business model that relies on the outsourcing of certain functions, tests and services to CROs, medical institutions and other specialist providers, including, without limitation, the conduct, management and monitoring of our ongoing and planned clinical trials. As a result, we rely on these third parties for, among other things, quality assurance, clinical monitoring, clinical data management and regulatory expertise. For Amphora, we have engaged a single CRO to run substantially all aspects of our confirmatory Phase 3 clinical trial of Amphora for the prevention of pregnancy (AMP002). We also intend to engage a CRO for all future clinical trial requirements needed to file for regulatory approvals. There is no assurance that such organizations or individuals will be able to provide the functions, tests or services as agreed upon, or to the requisite quality. We will rely on the efforts of these organizations and individuals and could suffer significant delays in the development of our product or processes should they fail to perform as expected.

There is also no assurance that these third parties will not make errors in, or simply fail to be effective in, the design, management or retention of our data or data systems. Any failures by such third parties could lead to a loss of data, which in turn could lead to delays in clinical development and obtaining regulatory approval. Third parties may not pass FDA or other regulatory audits, which could delay or prohibit regulatory approval. In addition, the cost of such services could significantly increase over time. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, regulatory approval of our current or any future product candidates may be delayed, prevented or cost significantly more than expected, all which would have a material adverse effect on our business, financial conditions, results of operations and prospects.

*If we fail to enter into or maintain strategic relationships or collaborations with respect to future product candidates, or if we are unable to realize the potential benefits from such collaborations, our business, financial condition, commercialization prospects and results of operation may be materially adversely affected.*

If we are successful in identifying and in-licensing the rights to additional product candidates, our expected strategy with respect to the development of any such future product candidates is to supplement internal efforts with third-party collaborations. We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming arrangements to negotiate and document.

## [Table of Contents](#)

Our success in entering into a definitive agreement for any collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design and outcomes of the clinical trials, the collaborator's history of regulatory compliance, the likelihood of approval by regulatory authorities, the potential market for the product, the costs and complexities of manufacturing and delivering such products to customers, the potential of competing products, the strength of the intellectual property and industry and market conditions generally. The collaborator may also consider alternative products or technologies for similar indications that may be available to collaborate on with one of our competitors and whether such collaboration could be more attractive than the one with us for our products or product candidates.

Any potential collaboration agreement into which we might enter may call for licensing or cross-licensing of potentially blocking patents, know-how or other intellectual property. Due to the potential overlap of data, know-how and intellectual property rights, there can be no assurance that one of our collaborators will not dispute our right to use, license or distribute such data, know-how or other intellectual property rights, and this may potentially lead to disputes, liability or termination of the collaboration.

We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators and may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If that were to occur, we may have to curtail the development of a particular product, reduce or delay our development program, delay commercialization, reduce the scope of sales or marketing activities, or increase expenditures and undertake development or commercialization activities at our own expense. If we elect to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms or at all. Absent sufficient funds, we may not be able to commercialize a product candidate. If we enter into a collaboration agreement regarding a product or product candidate, we could be subject to, among other things, the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

- we may not be able to control the amount and timing of resources that the collaborator devotes to the product development program;
- we may experience financial difficulties and thus not commit sufficient financial resources to the product development program;
- we may be required to relinquish important rights to the collaborator such as marketing, distribution and intellectual property rights;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors;
- a collaborator could terminate the agreement (for convenience if permitted) for our breach; or
- business combinations or significant changes in a collaborator's business strategy may adversely affect our willingness to complete our obligations under any arrangement.

As a result, a collaboration may not result in the successful development or commercialization of our product candidates.

*We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we must perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.*

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, including the Rush License Agreement, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to collaboration agreements, we may have to indemnify our collaborators from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right owned by a third party. With respect to consultants, we indemnify them from claims arising from performance of their services in accordance with legal and contractual requirements.

If our obligations under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

### **Risks Related to Commercialization of Our Product Candidates**

*If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.*

## [Table of Contents](#)

Although some of our employees may have marketed, commercialized and sold other pharmaceutical products, including contraceptives, in the past while employed at other companies, we have no experience selling and marketing our product candidates, and we currently have no marketing or sales organization. To successfully commercialize any products that may result from our development programs, we will need to find one or more collaborators to commercialize our products or invest in and develop these capabilities, either on our own or with others, which would be expensive, difficult and time consuming. Any failure or delay in the timely development of our internal commercialization capabilities could adversely impact the potential for success of our products.

If commercialization collaborators do not commit sufficient resources to commercialize our future products and we are unable to develop the necessary marketing and sales capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations, particularly in the markets our product candidates are intended to address. Without appropriate capabilities, whether directly or through third-party collaborators, we may be unable to compete successfully against these more established companies.

*We face competition from other medical device, biotechnology and biopharmaceutical companies and our operating results will suffer if we fail to compete effectively.*

The medical device, biotechnology and biopharmaceutical industries are intensely competitive. Significant competition among various contraceptive products already exists. Existing products have name recognition, are marketed by companies with established commercial infrastructures and are marketed with greater financial, technical and personnel resources than we have. To compete and gain market share, any new product will need to demonstrate advantages in efficacy, convenience, tolerability or safety. In addition, new products developed by others could emerge as competitors to Amphora, if it is approved for our lead indication, the prevention of pregnancy. Such products could offer an alternative form of non-hormonal contraceptive that provides protection over longer periods of time. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Our potential competitors include large, well-established pharmaceutical companies and specialty pharmaceutical companies. These companies include Merck & Co., Inc., Allergan PLC, Pfizer Inc., Bayer AG, Johnson & Johnson, Cooper and Mylan Inc. Additionally, several generic manufacturers currently market and continue to introduce new generic contraceptives. There are other contraceptive product candidates in development that, if approved, would potentially compete with Amphora, including hormonal patches and hormonal vaginal rings.

*Amphora, our BV product candidate and any future product candidates, may not gain acceptance among physicians, patients or the medical community, thereby limiting our potential to generate revenue, which will undermine our future growth prospects.*

Even if Amphora, our BV product candidate or any future product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any new product by physicians, health care professionals and third-party payers will depend on a number of factors, including:

- demonstrated evidence of efficacy and safety;
- sufficient third-party insurance coverage and adequate reimbursement;
- effectiveness of our or our collaborators' sales and marketing strategy;
- the willingness of consumers, without third-party insurance coverage and adequate reimbursement, to pay for the product;
- the willingness of pharmacy chains to stock the products;
- the prevalence and severity of any adverse side effects; and
- availability of alternative products.

If Amphora, our BV product candidate or other product candidate that we may license, develop or sell do not provide a benefit over currently available options, that product candidate is unlikely to achieve market acceptance and we will not generate sufficient revenues to achieve profitability.

*The success of Amphora or any future contraceptive product candidate we may seek to develop will depend on the availability of contraceptive alternatives and women's preferences, in addition to the market's acceptance of our new form of contraception.*

The commercial success of Amphora or any other future contraceptive product candidate we may seek to develop will depend upon the contraceptive market as well as market acceptance of our new form of contraception. Risks related to market acceptance include, among other things:

- minimum acceptable contraceptive efficacy rates;
- perceived safety differences of hormonal and/or non-hormonal contraceptive options;
- changes in healthcare laws and regulations, including implementation of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the ACA) and its effect on

## [Table of Contents](#)

pharmaceutical coverage, reimbursement and pricing, and the coverage of preventable services (including contraception under certain conditions) and future new executive orders, legislation or agency rulemaking;

- competition from new lower dose hormonal contraceptives with more favorable side effect profiles; and
- new generic contraceptive options including the possibility of a future potential generic version of Amphora as a contraceptive (if it is approved for marketing by the FDA).

The occurrence of one or more of these risks could reduce the market potential for Amphora or any future contraceptive product we may seek to develop, and place pressure on our business, financial condition, results of operations and prospects.

*The commercial success of our current product candidates and any future product candidates will depend in significant measure on the label claims that the FDA or other regulatory authorities approve for the product.*

The commercial success of Amphora, our BV product candidate and any of our future product candidates will depend in significant measure upon our ability to obtain approval from the FDA or other regulatory authorities of labeling describing a product candidate's expected features or benefits. Failure to achieve approval from the FDA or other regulatory authorities of product labeling containing certain types of information on features or benefits will prevent or substantially limit our advertising and promotion of such features in order to differentiate Amphora, our BV product candidate or any future product candidates from those products already existing in the market. This failure would have a material adverse impact on our business, financial condition, results of operations and prospects.

*Our proposed proprietary name of Amphora has not yet been approved by the FDA, and any brand recognition or goodwill that we have accumulated may be lost if, at the time of NDA approval, we are forced to select a different proprietary name.*

We have used the proprietary name Amphora to describe our investigational product since December 28, 2010. This proprietary name will not be approved, if at all, until the time of NDA approval. FDA may not approve the name Amphora if it is likely to be confused with previously approved drug product proprietary names. If Amphora is not approved as the proprietary name, we will need to nominate alternative proprietary names. Any such rebranding could result in loss of brand recognition or goodwill and could require us to devote resources to identifying alternative proprietary names.

*If we suffer negative publicity concerning the safety or efficacy of our products in development, our reputation could be harmed and we may be forced to cease development of such products.*

If concerns should arise about the actual or anticipated clinical outcomes regarding the safety of any of our product candidates, such concerns could adversely affect the market's perception of these candidates. Such concerns could lead to a decline in investors' expectations and a decline in the price of our common stock.

*We rely, and expect to continue to rely, on market research conducted on our behalf to evaluate the potential commercial acceptance of Amphora, our BV product candidate, and other future product candidates.*

We have contracted with and expect to continue to contract with third parties to perform market research on our behalf. Based on the results of our market research to date, we believe that Amphora, if approved, would be an attractive alternative to hormonal birth control to certain women. However, these research findings may not be indicative or predictive of actual or overall market acceptance and any future market research may not be indicative of the acceptance for another product candidate or future product candidates we may develop.

*The proportion of the contraceptive market that is made up of generic products continues to increase, making introduction of a branded contraceptive difficult and expensive.*

The proportion of the United States market that is made up of generic products has been increasing over time. This trend is consistent in the women's health segment, as well, where many of the most popular oral contraceptive pills (OCP), brands have experienced genericization. Currently, only two branded OCPs remain and both have a relatively low market share. Assuming this trend continues, it may be more challenging to introduce Amphora, if approved, or any future approved contraceptive product candidate we may develop, as a branded contraceptive, at a price that will maximize our revenue and profits. Also, there may be additional marketing costs to introduce Amphora in order to overcome the trend towards generics and to gain access to reimbursement by payers. If we are unable to introduce Amphora or any future approved product candidate at a price that is commensurate with that of current branded products, or we are unable to gain reimbursement from payers for Amphora, or if patients are unwilling to pay any price differential between Amphora and a generic contraceptive product, our revenues will be limited.

*Changes in healthcare laws and regulations may eliminate current requirements for health insurance plans to cover and reimburse FDA-cleared or FDA-approved contraceptive products without cost sharing, which could reduce demand for products such as Amphora. Even if Amphora is approved for commercialization, our management expects our success will be*

[Table of Contents](#)

*dependent on the willingness or ability of patients to pay out-of-pocket should they not be able to obtain third-party reimbursement or should such reimbursement be limited.*

We cannot be certain that third-party reimbursement will be available for Amphora if it is approved for the prevention of pregnancy, or if reimbursement is available, the amount of any such reimbursement. The ACA and subsequent regulations enacted by the United States Department of Health and Human Services (the DHHS) require, under certain conditions, health plans to provide coverage for women's preventive care, including all forms of FDA-cleared or FDA-approved contraception, without imposing any cost sharing on the plan beneficiary. These regulations ensure that women who wish to use an approved form of contraception may request it from their doctors and their health insurance plan must cover all costs associated with such products, under certain conditions. However, the Trump administration and Congress are attempting to repeal or repeal and replace the ACA and corresponding regulations, as more fully described below, which could eliminate the requirement for health plans to cover women's preventive care without cost sharing. Even if the ACA is not repealed, the DHHS regulations to specifically enforce the preventive health coverage mandate could be repealed or modified under the Trump Administration, which in 2017 altered the mandate to allow certain employers and insurers to opt-out of birth control coverage for religious or moral reasons. We cannot predict the timing or impact of any future rule making or changes in the law. Any repeal or elimination of the preventive care coverage rules would mean that women seeking to use prescribed forms of contraceptives may have to pay some portion of the cost for such products out-of-pocket, which could deter some women from using prescription contraceptive products, such as Amphora, at all. As a result, we expect that our success, to some degree, will be dependent on the willingness of patients to pay out-of-pocket for Amphora in the event that their third-party payer either does not cover and reimburse Amphora or requires payment of a portion of Amphora by the patient, thus increasing the patient's overall cost to use Amphora. This could reduce market demand for Amphora or any future product candidates we may seek to develop, if and when they receive FDA approval, which would have a material adverse effect on our business, financial conditions, and prospects

*In the event we are successful in obtaining regulatory approval to market our current or future product candidates in the United States, revenues may be adversely affected if the product fails to obtain coverage and adequate reimbursement from third-party payers in the United States.*

Market acceptance and sales of any product candidates that we commercialize, if approved by the FDA or foreign regulatory authorities, will depend in part on the extent to which reimbursement for these products will be available from third-party payers, including government health administration authorities, managed care organizations and private health insurers. Third-party payers decide which therapies they will pay for and establish reimbursement levels. Third-party payers in the United States often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payer-by-payer basis. One payer's determination to provide coverage for a drug does not assure that other payers will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payer's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved.

Third-party payers are increasingly challenging the prices charged for pharmaceutical and medical device products. The United States government and other third-party payers are increasingly limiting both coverage and the level of reimbursement for new drugs and medical devices, in addition to questioning their safety and efficacy. We may incur significant costs to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Third-party payer coverage may not be available to patients for Amphora or any future product we may seek to commercialize. If third-party payers do not provide coverage and adequate reimbursement for Amphora, our BV product candidate or our other product candidates, if approved, healthcare providers may not prescribe them or patients may ask their healthcare providers to prescribe competing products with more favorable reimbursement.

Managed care organizations and other private insurers frequently adopt their own payment or reimbursement reductions. Consolidation among managed care organizations has increased the negotiating power of these entities. Third-party payers increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for Amphora, our BV product candidate or any future product we may seek to commercialize, or obtaining such pricing or placement at unfavorable pricing levels, could materially adversely affect our business, financial conditions, results of operations and prospects.

*The pharmaceutical and medical device industries are highly regulated and subject to various fraud and abuse, data privacy, transparency, and other healthcare laws, including, without limitation, the United States Federal Anti-Kickback Statute, the United States Federal False Claims Act and the FCPA.*

Healthcare providers and third-party payers play a primary role in the recommendation and prescription of drug products and medical devices that are granted marketing approval. Our current and future arrangements with healthcare professionals,

## [Table of Contents](#)

principal investigators, consultants, third-party payers, customers and other organizations may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include, among other things:

- the Federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate the statute in order to have committed a violation. In addition, the government may assert that a claim that includes items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the civil and criminal false claims laws, including the False Claims Act, which can be enforced by private citizens through civil whistleblower and qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created additional federal criminal laws that prohibit, among other things, individuals or entities from executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. As in the case of the Federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate the statute in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization, on entities subject to the law, such as certain healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information;
- the federal transparency or “sunshine” requirements of the ACA requires certain manufacturers of drugs, devices, biologics and medical supplies to report to the DHHS information related to payments and other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- the federal Stark Law which prohibits, subject to certain exceptions, physician referrals of Medicare or Medicaid patients to an entity providing certain “designated health services” if the physician or an immediate family member of the physician has any financial relationships, including compensation arrangements or ownership interests, with that entity;
- the FDCA, which governs all aspects of the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products, medical devices, and combination products;
- the FCPA, which prohibits corrupt payments, gifts or transfers of value to non-United States officials; and
- analogous state and foreign laws and regulations such as State Anti-Kickback and False Claims Laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to healthcare providers and other healthcare providers or marketing expenditures; state laws that require pharmaceutical companies to implement compliance programs and to track and report gifts, compensation and other remuneration provided to physicians, in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that govern the privacy and security of health and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of these laws is uncertain and subject to rapid change. Regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. In addition, efforts to ensure that our business arrangements with third parties will comply with these laws will involve substantial costs. Any investigation of us or the third parties with whom we contract, regardless of the outcome, would be costly and time consuming. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and

## [Table of Contents](#)

administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, debarment under the FDCA, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

*Healthcare legislative reform measures may have a negative impact on our business and results of operations.*

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things: (i) mandates that preventative services which have strong scientific evidence of health benefits, including in some cases contraception, must be fully covered certain private third-party payers when they are delivered by an in-network provider; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (iv) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; (v) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price; (vi) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vii) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70%, commencing January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (ix) established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (the BBA), among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". We continue to evaluate the potential impact of the ACA and its possible repeal or replacement on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result

in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

*Our business may be adversely affected by unfavorable macroeconomic conditions.*

Various macroeconomic factors could adversely affect our business, our results of operations and our financial condition, including changes in inflation, interest rates and foreign currency exchange rates and overall economic conditions and uncertainties, including those resulting from political instability (including workforce uncertainty) and the current and future conditions in the global financial markets. For example, if inflation or other factors were to significantly increase our business costs, we may be unable to pass through price increases to patients. The cost of importing similar products from foreign markets may affect our sales in any domestic market.

Interest rates and the ability to access credit markets could also adversely affect the ability of patients, payers and distributors to purchase, pay for and effectively distribute our product if, and when approved. Similarly, these macroeconomic factors could affect the ability of our current or potential future third-party manufacturers, sole source or single source suppliers, licensors or licensees to remain in business, or otherwise manufacture or supply our product candidate. Failure by any of them to remain in business could affect our ability to manufacture Amphora or any of our future product candidates.

#### **Risks Related to Our Business Operations**

*As we mature and expand our sales and marketing infrastructure, we will need to expand the size of our organization. If we experience difficulties in managing this growth or fail to attract and retain management and other key personnel, we may be unable to successfully commercialize our products, develop any product candidates or otherwise implement our business plan.*

As of April 30, 2018, we had a total of 25 full-time employees and used third-party consultants to assist with research and development activities, including regulatory filings and clinical trial operations and support, sales and marketing research and programs, as well as general and administrative activities. As our development and commercialization plans and strategies develop, we expect that we will expand the size of our employee base for managerial, operational, sales, marketing, financial, regulatory affairs and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, management may have to divert a disproportionate amount of its attention away from day-to-day activities and devote a substantial amount of time to managing these growth activities, which would lead to disruptions in our operations. We cannot provide assurance that we will be able to retain adequate staffing levels to run our operations and/or to accomplish all the objectives that we otherwise would seek to accomplish.

Our ability to compete in the highly competitive pharmaceutical and medical device industries depends upon our ability to attract and retain highly qualified managerial and key personnel. We are highly dependent on our senior management, and the loss of the services of any members of our senior management team could impede, delay or prevent the development and commercialization of our product candidates, hurt our ability to raise additional funds and negatively impact our ability to implement our business plan. If we lose the services of any of these individuals, it might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain "key man" insurance policies on the lives of these individuals.

## [Table of Contents](#)

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, medical device, biopharmaceutical and other businesses, particularly in the San Diego area where we are headquartered. As a result, we may be required to expend significant financial resources in our employee recruitment and retention efforts, including the grant of significant equity incentive awards which would be dilutive to stockholders. Many of the other companies within the contraceptive industry with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives or if we are not able to effectively manage any future growth, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

*Our current or future employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards.*

We may become exposed to the risk of employees, independent contractors, principal investigators, consultants, suppliers, commercial partners or vendors engaging in fraud or other misconduct. Misconduct by employees, independent contractors, principal investigators, consultants, suppliers, commercial partners and vendors could include intentional conduct such as failures: (i) to comply with FDA or other regulators' regulations, (ii) to provide accurate information to such regulators or (iii) to comply with manufacturing standards established by us and/or required by law. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws, regulations and industry guidance intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by current or future employees, independent contractors, principal investigators, consultants, suppliers, commercial partners and vendors could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory or civil sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees, independent contractors, principal investigators, consultants, suppliers, commercial partners and vendors, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending or asserting our rights, those actions could have a significant adverse impact on our business and we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

*We may be vulnerable to disruption, damage and financial obligations as a result of information technology system failures, security breaches, loss of data or other disruptions that could compromise our proprietary information or other sensitive information.*

Despite the implementation of security measures and internal policies and controls, any of the internal computer systems belonging to us or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, malicious attack, and telecommunication and electrical failure. Any system failure, accident, security breach or data breach that causes interruptions in our own or in third-party service vendors' operations could result in a material disruption of our product development programs. For example, the loss of clinical study data from future clinical trials could result in delays in our or our partners' regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. Further, our information technology and other internal infrastructure systems, including firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure, which could disrupt our operations. To the extent any disruption or security breach results in a loss or damage to our data or applications, sensitive information or inappropriate disclosure of confidential or proprietary information, we may incur resulting liability and reputation damage, our product development programs and competitive position may be adversely affected and the further development of our products may be delayed. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches.

*We expect to continue to incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to compliance initiatives and corporate governance practices.*

As a public company, we incur and expect to continue to incur additional significant legal, accounting and other expenses in relation to our status as a public reporting company. We expect that these expenses will further increase after we are no longer an emerging growth company. We may need to hire additional accounting, finance and other personnel in connection with our continuing efforts to comply with the requirements of being a public company, and our management and other personnel will need to continue to devote a substantial amount of time towards maintaining compliance with these requirements. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and Nasdaq have

## [Table of Contents](#)

imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), we will be required to furnish a report by our management on our internal controls over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. If we identify one or more material weaknesses, this could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

*We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.*

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

### **Risks Related to Our Common Stock**

*We expect the price of our common stock may be volatile and may fluctuate substantially.*

The stock market in general and the market for biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to companies operating performance. The market price for our common stock may be influenced by many factors, including:

- the results of our efforts to discover, develop, acquire or in-license product candidates or products, if any;
- failure or discontinuation of any of our research programs;
- actual or anticipated results from, and any delays in, any future clinical trials, as well as results of regulatory reviews relating to the approval of any product candidates we may choose to develop;
- the level of expenses related to any product candidates that we may choose to develop or clinical development programs we may choose to pursue;
- commencement or termination of any collaboration or licensing arrangement;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technology;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- new products, product candidates or new uses for existing products introduced or announced by our competitors, and the timing of these introductions or announcements;

## [Table of Contents](#)

- results of clinical trials of product candidates of our competitors;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of healthcare payment systems;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock; and
- other factors described in this “Risk Factors” section.

In the past, following periods of volatility in companies’ stock prices, securities class-action litigation has often been instituted against such companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management’s attention and resources, which could materially and adversely affect our business and financial condition.

*Two of our stockholders own a significant percentage of our issued and outstanding common stock and will be able to exercise significant influence over matters submitted to stockholders for approval.*

As of April 30, 2018, funds affiliated with or discretionarily managed by Invesco Ltd. and funds affiliated with or discretionarily managed by Woodford Investment Management hold approximately 39.6% and 42.0%, respectively, of our outstanding common stock. We have entered into voting agreements with certain funds managed by Woodford Investment Management providing that the shares held by such holders in excess of 19.5% of our issued and outstanding common stock shall be voted in the same proportion as the shares voted by all other stockholders. Notwithstanding the voting agreements, if the funds managed by Woodford Investment Management and Invesco Ltd. were to choose to act together, they would be able to exert a significant degree of influence over matters submitted to our stockholders for approval, as well as our management and affairs. This concentration of voting power could delay or prevent an acquisition on terms that other stockholders may desire. For example, these entities, if they choose to act together, would be able to have significant influence on the election of directors, approval of any increase in the number of shares reserved under equity incentive plans, approval of new equity incentive plans, and approval of any merger, consolidation or sale of all or substantially all our assets. For more information see the section entitled “*Description of Capital Stock — Voting Agreements*” beginning on page 120 of this prospectus.

In addition, and per the terms of our amended and restated certificate of incorporation, we are not subject to or governed by Section 203 of the Delaware General Corporation Law (the DGCL), which prohibits a publicly-held Delaware corporation from engaging in a “business combination” with an “interested stockholder,” and we are able to enter into transactions with our principal stockholders. A concentration of ownership may have the effect of delaying, preventing or deterring a change of control of a company, could deprive its stockholders of an opportunity to receive a premium for their common stock as part of a sale of a company and may materially adversely affect the market price of its common stock.

*A significant portion of our total outstanding shares of common stock may be sold into the public market at any point, which could cause the market price of our common stock to drop significantly, even if our business is doing well.*

Sales of a substantial number of shares of our common stock in the public market could occur. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Outstanding shares of our common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act of 1933, as amended (the Securities Act) or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates.

As of April 30, 2018, there were 3,485,526 shares of our common stock subject to outstanding options. Of the total outstanding options, 191,173 shares have been registered on registration statements on Form S-8. Shares registered on a Form S-8 can be freely sold in the public market upon exercise, except to the extent they will be held by our affiliates, in which case such shares will become eligible for sale in the public market as permitted by Rule 144 under the Securities Act. Furthermore, as of April 30, 2018, there were 2,011,875 shares subject to outstanding warrants to purchase our common stock. 11,875 of these shares will become eligible for sale in the public market, to the extent such warrants are exercised, as permitted by Rule 144 under the Securities Act. Moreover, holders of 15,026,968 shares of our common stock and the holders of outstanding warrants to purchase up to 2,000,000 shares of our common stock have rights, subject to conditions, to require us to file registration statements covering the resale of these shares and the shares underlying these warrants or to include these shares and shares underlying these warrants in registration statements that we may file. In connection with these obligations, we filed a Registration Statement on Form S-3 (No. 333-223731) which became effective on April 3, 2018. At our annual meeting on May 8, 2018, our stockholders approved an amendment and restatement of our 2014 Equity Incentive Plan (the Amended and Restated 2014 Plan), which includes, among other things, an increase in the number of shares authorized for the issuance of

## [Table of Contents](#)

awards thereunder to an aggregate of 5,300,000 shares. We expect to file or amend a registration statement on Form S-8 with respect to this increase.

*We are an emerging growth company, and a “smaller reporting company”, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.*

We are an emerging growth company, under the JOBS Act and a “smaller reporting company” under SEC regulations. For so long as we remain an emerging growth company or smaller reporting company, we will be permitted to and intend to rely on exemptions from certain disclosure requirements applicable to other public companies that are not emerging growth companies or smaller reporting companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. Emerging growth companies may take advantage of an extended transition period for complying with new or revised accounting standards, allowing emerging growth companies to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We will continue to be an emerging growth company until the earliest to occur of (i) the last day of the fiscal year during which we had total annual gross revenues of at least \$1,070,000,000 (as indexed for inflation), (ii) December 31, 2019, (iii) the date on which we have, during the previous three-year period, issued more than \$1 billion in non-convertible debt or (iv) the date on which we are deemed to be a “large accelerated filer,” as defined under the Exchange Act. In addition, we will continue to be a smaller reporting company until we have more than \$75 million in public float (based on our common equity) measured as of the last business day of our most recently completed second fiscal quarter or, in the event we have no public float (based on our common equity), annual revenues of more than \$50 million during the most recently completed fiscal year for which audited financial statements are available.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

*We do not anticipate paying any cash dividends on our capital stock in the foreseeable future; capital appreciation, if any, will be your sole source of gain as a holder of our common stock.*

We have never declared or paid cash dividends on shares of our common stock. We currently plan to retain all our future earnings, if any, and any cash received through future financings to finance the growth and development of our business. Accordingly, capital appreciation, if any, of our common stock will be the sole source of gain for our common stockholders for the foreseeable future.

*Provisions in our amended and restated certificate of incorporation, our bylaws or Delaware law might discourage, delay or prevent a change in control of the Company or changes in our management and, therefore, depress the trading price of our common stock.*

Provisions in our amended and restated certificate of incorporation, our bylaws or Delaware law may discourage, delay or prevent a merger, acquisition or other change in control stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions might frustrate or prevent any attempts by our stockholders to replace or remove the current management by making it more difficult for our stockholders to replace members of our board of directors. These provisions include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- prohibiting our stockholders from calling a special meeting of stockholders or acting by written consent other than unanimous written consent;

## [Table of Contents](#)

- permitting our board of directors to issue additional shares of our preferred stock, with such rights, preferences and privileges as they may designate, including the right to approve an acquisition or other changes in control;
- establishing an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- providing that our directors may be removed only for cause;
- providing that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- requiring the approval of our board of directors or the holders of a supermajority of our outstanding shares of capital stock to amend our bylaws and certain provisions of our certificate of incorporation.

*Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.*

Our amended and restated certificate of incorporation and amended and restated bylaws provides that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

*If securities analysts do not publish research or reports about our business, or if they publish negative evaluations of our common stock, the price of our common stock could decline.*

The trading market for our common stock relies in part on the research and reports industry or financial analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. In addition, if one or more of these analysts cease coverage or fail to regularly publish reports on our business, we could lose visibility in the financial markets, which in turn could cause our common stock price or trading volume to decline.

## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

On January 17, 2018, immediately following completion of the Merger, we issued, in a private placement transaction (the Private Placement), an aggregate of 1,614,289 shares of our common stock to certain accredited investors pursuant to the terms of the Securities Purchase Agreement, dated October 17, 2017 (the Securities Purchase Agreement) by and among us, Private Evofem and the investors listed therein for gross proceeds of \$20.0 million. Upon consummation of the Private Placement, we terminated our existing Fourth Amended and Restated Investors' Rights Agreement, dated September 22, 2014 (the Prior Rights Agreement) by and between us and the investors listed therein, and entered into a new Registration Rights Agreement with the investors listed therein and an investor previously party to the Prior Rights Agreement. The shares of common stock sold in the Private Placement were sold in reliance on the exemption from registration afforded by Section 4(a)(2) of the Securities Act. Each of the investors represented that it was an accredited investor, as such term is defined in Rule 501(a) of Regulation D under the Securities Act, and that it was acquiring the shares for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof. We intend to use the proceeds from the Private Placement for general corporate purposes and to fund our working capital needs.

### Item 3. Defaults Upon Senior Securities

None.

### Item 4. Mine Safety Disclosures

Not applicable.

### Item 5. Other Information

#### Business

##### Overview

We are a clinical-stage biopharmaceutical company committed to developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. We leverage our proprietary Multi-purpose Prevention Technology (MPT) vaginal gel to develop product candidates for multiple indications, including contraception, sexually transmitted infections (STIs) and recurrent bacterial vaginosis (BV).

Our MPT vaginal gel technology is an acid-buffering vaginal gel with bioadhesive properties, designed to maintain an optimal vaginal pH of 3.5 to 4.5. This vaginal pH range is inhospitable to spermatozoa (sperm) as well as certain viral and bacterial pathogens associated with STIs, and it is integral to the survival of healthy bacteria in the vagina.

We are developing our lead product candidate, Amphora (L-lactic acid, citric acid, and potassium bitartrate), for three potential indications: contraception, the prevention of urogenital *Chlamydia trachomatis* infection (chlamydia) in women and the prevention of urogenital *Neisseria gonorrhoeae* infection (gonorrhea) in women.

In 2014, we completed a randomized, Phase 3 non-inferiority trial for Amphora as a contraceptive in 3,389 women. Amphora was shown to be non-inferior to control, when the complete data set was analyzed in accordance with the pre-specified statistical analysis plan, with a six-month cumulative pregnancy rate of 10.5% with typical use and 4.1% with perfect use. It was also well-tolerated with less than 2% of patients experiencing possible treatment-related adverse events (AEs) and no treatment-related serious adverse events (SAEs).

We are conducting a confirmatory, open-label, single-arm Phase 3 trial for Amphora as a contraceptive in 1,400 women in the United States. We expect to report top-line results from this trial in the first quarter of 2019 and, if positive, to resubmit the New Drug Application (NDA) to the United States Food and Drug Administration (the FDA) shortly thereafter. Subject to acceptance and timely approval of the NDA by the FDA, we plan to commercialize Amphora in early 2020.

We believe Amphora is highly differentiated from other forms of contraceptives currently available or in development. Amphora is hormone-free and, based on our clinical data collected to date, does not exhibit known side effects of traditional hormonal-based contraceptives, such as weight gain, headaches, sore breasts, irregular periods, mood changes, decreased sexual desire and nausea. Amphora is self-administered and we intend to seek regulatory approval for product labeling stating Amphora can be used on-demand, immediately before or up to one hour before intercourse. In addition, we anticipate Amphora may provide additional benefits beyond its primary use as a contraceptive, including its lubricant effect for enhanced sexual satisfaction.

We are also conducting a Phase 2b/3 clinical trial of Amphora for the prevention of certain STIs. The primary endpoint of this trial is prevention of chlamydia in women; the secondary endpoint is prevention of gonorrhea in women. We envision our STI program as developing label expansion opportunities to further differentiate Amphora from other contraceptive products in the market.

Preclinical studies conducted by Rush University Medical Center (Rush University) suggest Amphora may suppress many of the pathogens responsible for sexually transmitted and commonly occurring bacterial infections while leaving the beneficial bacteria unaffected. Amphora has been granted Qualified Infectious Disease Product (QIDP) designation by the FDA for the prevention of gonorrhea in women, and has been granted QIDP designation by the FDA for the prevention of the recurrence of BV. QIDP designation provides several key potential advantages, including qualification for the FDA Fast Track program and longer market exclusivity, among others. We also received Fast Track designation from the FDA for the development of Amphora for the prevention of chlamydia.

We are also advancing a vaginal gel product candidate for the treatment of recurrent BV, and intend to conduct a Phase 2b/3 clinical trial to evaluate efficacy of this product candidate in this indication. In a recently completed Phase 1 dose-finding

trial for this product candidate, the highest dose formulation of our BV product candidate (5-gram) reduced vaginal pH for up to seven days following a single administration.

We have assembled a very strong management team with significant operational experience in the biopharmaceutical market. Specifically, our senior executives have built a successful track record of developing and commercializing women's health products including Mirena, Plan B One-Step, Yasmin, YAZ, NuvaRing, Paragard and Seasonique, among others.

### Our Strategy

We are committed to providing women with direct control and management of their sexual and reproductive health. Key elements of our strategy include:

- **Gain regulatory approval of and subsequently commercialize Amphora.** Our initial focus is the development and successful commercialization of Amphora as a hormone-free, woman-controlled contraceptive. We intend to build an internal sales force to commercialize Amphora in the United States, if approved. Outside the United States, we intend to evaluate collaborations for commercialization. We believe this approach will allow us to effectively deploy our capital to maximize the inherent value of Amphora for the benefit of all stakeholders.
- **Leverage our MPT vaginal gel technology to develop and commercialize novel, first-in-class products for women.** We intend to expand on our potential contraceptive indication by being the first company to market a contraceptive product with additional indications for the prevention of chlamydia and gonorrhea. In addition, we are developing a product candidate for the reduction of recurrent BV, which, if approved, would be the only FDA-approved product for this indication.
- **Expand our intellectual property position by pursuing opportunities to extend the exclusivity of our highly differentiated and proprietary product candidates.** We intend to aggressively pursue additional and new patent applications to broaden our intellectual property portfolio. We will continue seeking domestic and international patent protection and endeavor to promptly file patent applications for new commercially valuable inventions.
- **Build our product portfolio through business development.** We intend to opportunistically acquire additional products or product candidates to enhance our offerings and complement our core competencies in women's health. We will focus on business development in the near to intermediate term to identify compelling acquisition and licensing candidates.
- **Establish a world-class organization committed to the discovery, development and commercialization of products addressing unmet needs in women's sexual and reproductive health.** We have assembled a world-class team with industry-recognized expertise in the development and commercialization of products in women's health. We intend to continue to build on our leadership position and grow a culture dedicated to the development and commercialization of medicines addressing the unmet needs of women.

### Contraceptive Market Overview

In 2016, the global revenue for contraceptive products was \$21.2 billion and projected to grow at 6.8% per annum to \$35.8 billion by 2024, making contraception a substantial and growing subset of the overall healthcare market. This growth is expected to continue to be driven by the United States and Europe, where favorable government policies aimed at preventing unwanted pregnancies are in place.

Current contraceptive options include devices designed to prevent pregnancy through physical means such as condoms, diaphragms and intrauterine devices (IUDs) and hormone-based pharmaceutical products, including oral contraceptives, vaginal rings, intramuscular injections, subcutaneous implants and transdermal patches.

Existing contraceptive options can have significant side effects or other limitations. Long-acting options such as IUDs, injections and implants require medical procedures and are not quickly or easily reversible. Hormonal approaches can be associated with undesirable side effects such as weight gain, loss of libido and mood changes, which may lead women to seek alternative contraceptive technologies or decide not to use any form of contraceptive options currently available. Besides condoms, the only currently available over-the-counter (OTC) products are spermicides, including Conceptrol. These products are based on surfactants, which can cause genital irritation and inflammation that may increase the risk of contracting human immunodeficiency virus (HIV) or other STIs from an infected partner. As such, spermicides were pulled from most of the European market and are rarely used in the United States. In contrast to most existing contraceptive methods, Amphora is hormone-free; its mechanism of action is to maintain the vaginal pH at the normal healthy level, even in the presence of semen. It can be easily self-administered when needed, and has lubricating properties for enhanced sexual satisfaction. Unlike other vaginal gel contraceptives currently on the market, Amphora is manufactured with ingredients that are generally recognized as safe, and is free of surfactants such as nonoxynol-9. We believe these combined attributes may make Amphora a more desirable option than currently marketed products.

The unmet needs in the contraception market and the shift away from traditional methods of contraception such as oral contraceptives make the entry of a non-hormonal contraceptive option like Amphora timely and desirable. Currently, the only non-hormonal prescription contraceptive methods approved in the United States market are a copper IUD and a diaphragm. A

[Table of Contents](#)

copper IUD requires an invasive, sometimes painful, medical procedure for insertion and may cause heavy menstrual bleeding. In addition, it could remain in the user’s body for up to 10 years. A diaphragm can be difficult to insert and must be used with contraceptive gel.

We believe the growing concern associated with the increasing prevalence of sexually transmitted diseases along with the recognized need for MPTs and the growing demand for new innovative contraception options will drive further growth in the global contraceptive market.

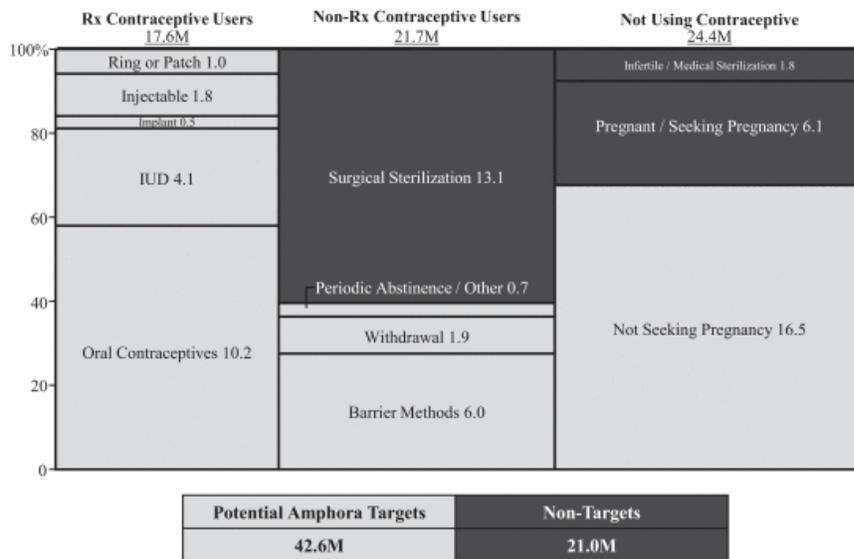
*United States Contraceptive Market*

The total United States prescription contraceptive market was valued at \$5.5 billion in 2016 and is expected to grow at a compound annual growth rate of 5.4% from 2013 to 2024 reaching approximately \$8.4 billion in 2024. The United States represented the largest segment of the global prescription contraceptives market in 2016 at 29.4% and is currently dominated by hormonal methods including birth control pills and other reversible methods such as hormone-releasing IUDs and injectables. Approximately four out of every five women with sexual experience in the United States have used the pill at least one time, which has remained stable since 1995.

As shown in the chart below, more than 15 million women in the United States use a form of hormone-based prescription contraception, an additional 9 million women in the United States rely on condoms or some other form of non-homonal contraception (e.g., copper IUD, diaphragm, rhythm, withdrawal), and another 16 million use no method of contraception, putting them at risk of pregnancy.

**Market Map: Contraceptive Methods, US Females 15 – 44 (2016)**

Total = 63.6M



*European Union Contraceptive Market*

The European Union (EU) contraceptive market was valued at approximately \$5 billion in 2016, representing 23.5% of the global market, and is expected to grow at an average compound annual growth rate of 5.4% from 2013 to 2024, reaching approximately \$7.6 billion in 2024. Approximately 30% of women in the EU use no contraception and 16.7% use condoms. Among newer products, only IUDs have a double-digit market share in the EU.

*Market Opportunity*

Innovation and new product introduction in women’s reproductive healthcare and contraception have been limited when compared to other therapeutic categories. There have been no innovative contraceptives introduced in the United States since NuvaRing was approved in 2001. There are currently no FDA-approved contraceptive products that are indicated for the prevention of chlamydia or gonorrhea, nor for the reduction of the recurrence of BV.

[Table of Contents](#)

According to the Centers for Disease Control and Prevention (CDC), reducing the percentage of all unintended pregnancies has been one of the National Health Promotion Objectives since their establishment in 1980. Despite efforts to reduce their incidence, over two million unintended pregnancies occur in the United States annually. Following decades of minimal change or increase, the percentage of unintended pregnancies in the United States decreased slightly in the period from 2008 to 2011. Despite this decrease, 45% of pregnancies in the United States are still unintended. Nearly all women with sexual experience in the United States have used some form of contraception in their lives. However, many women may not use contraception consistently or correctly, which may result in an unintended pregnancy. According to research conducted by the CDC, approximately 40% of women surveyed after giving birth to a child resulting from an unintended pregnancy who were not using contraception noted one of the following three reasons for nonuse: did not expect to have sex, worried about side effects of birth control, or male partner did not want to use birth control.

Hundreds of millions of women worldwide seek contraceptive products during their, on average, 30 plus years of fertility. As such, women utilizing contraception consider the most appropriate methods for their purposes and intended use. According to the United Nations, in 2017, model-based estimates indicate approximately 75% of women of reproductive age (18 to 49), worldwide, required some form of family planning. According to the Guttmacher Institute, there are 60 million women of reproductive age in the United States. There are approximately 69 million women of reproductive age located in the United Kingdom, Germany, France, Italy and Spain (the EU5). Additional attractive markets for global expansion include Brazil, India, the Russian Federation and China, in which there are an aggregate of 688 million women of reproductive age.

**Our Product Candidates**

*Amphora as a Contraceptive*

We believe Amphora, our lead product candidate, addresses significant gaps in the contraceptive market. If approved by the FDA, Amphora will be the only hormone-free, woman-controlled contraceptive drug product available by prescription in the United States not requiring in-office placement by a healthcare provider (HCP).

We believe Amphora has significant attributes that will make it an attractive contraceptive choice for women:

<b>Key Attributes</b>	<b>Potential Benefits</b>
Hormone-free	Amphora is hormone-free and designed to avoid known side effects of hormone-based contraceptives, including weight gain, headaches, sore breasts, irregular periods, mood changes, decreased sexual desire, acne and nausea. These side effects have been shown to discourage women from continuing to use hormonal contraception on a long-term basis, leading them to seek alternative methods or decide to use nothing at all.
On-Demand/Woman-controlled	Amphora is designed to be used as needed – no need for consistent daily, weekly, or monthly routine – immediately before or up to one hour before intercourse at a woman’s discretion.
Ease of Use	The pre-filled Amphora applicator is designed for convenience and to be stored at room temperature for ease of handling and use.
Bioadhesive Properties	Amphora has bioadhesive and viscosity-retaining properties to form a long-lasting layer of gel over the vaginal and cervical surfaces, which may reduce leakage from the vagina.
No Weight Restrictions	Amphora is designed to be used by women of any body mass index with no weight restrictions, unlike many traditional hormonal contraceptive options.
No Surgical Procedures	No physician insertion or removal required. The use of Amphora is private and discrete, requiring no need for recurring doctor appointments, or clinical or surgical procedures.
Personal Lubricant Properties	Amphora has benefits for use as a personal vaginal lubricant, beyond the primary contraceptive function. We believe Amphora’s personal lubricant properties can reduce friction and ease penetration, enhancing sexual satisfaction.
Cost Effective	We anticipate mandated coverage in the United States under the Affordable Care Act (the ACA). Amphora is only used when needed, thereby eliminating cost for daily use methods.

[Table of Contents](#)

The CDC’s recommendations for use of combined hormonal contraception, as shown below, define numerous conditions that create unacceptable health risks if hormonal contraception is used. The number of women impacted by these conditions is significant. We believe Amphora, if approved by the FDA, will provide women an attractive solution to avoid hormones and certain other negative side effects from current prescription contraceptives.

**Category 4 (a condition that represents an unacceptable health risk if the contraceptive method is used)**

- Postpartum <21 days
- Deep venous thrombosis (current or history with higher risk of recurrence)
- Pulmonary embolism (current or history with higher risk of recurrence)
- Cardiovascular disease or multiple cardiovascular risk factors (preexisting)
- Uncontrolled hypertension
- Major surgery with prolonged immobilization
- Known thrombogenic mutations
- Migraine headaches with aura or without aura in women >= 35
- Viral Hepatitis (acute or flare)
- Cirrhosis (decompensated)
- Age > 35 years and smoke 15 cigarettes or more per day
- Valvular heart disease (complicated)
- Impaired cardiac function (moderate or severe)
- Systemic lupus erythematosus with positive or unknown antiphospholipid antibodies
- Ischemic heart disease (current or history)
- Stroke (history)
- Diabetes (complicated)
- Breast cancer (current)
- Certain liver tumors
- Solid organ transplantation (complicated)

If approved by the FDA, Amphora is potentially disruptive to the existing contraceptive landscape and is designed to address underserved and unmet needs in the women’s healthcare market, as seen in the table below. We expect to benefit from a favorable shift away from the daily use of oral forms of hormonal contraception to more innovative technologies that underpin the large and growing global contraceptive market.

Product Class	Non-Hormonal	No Systemic Side Effects	Non-invasive	Convenient
<b>Amphora*</b>	✓	✓	✓	✓
<b>28 Day Oral Contraceptives</b>			✓	
<b>Extended Regimen Oral Contraceptives</b>			✓	
<b>Hormone Releasing IUDs</b>				✓
<b>Copper IUD</b>	✓			✓
<b>Implant</b>				✓
<b>Vaginal Ring</b>			✓	✓
<b>Transdermal Patch</b>			✓	

\* Investigational product

We conducted market research with 152 HCPs and 100 obstetrician/gynecologists (OB/GYNs) in two separate studies. On a scale of 1-10, approximately 40% of HCPs rated their likelihood to prescribe a contraceptive-only version of Amphora as an 8, 9 or 10. With the added ability to prevent an STI, over 50% of OB/GYNs rated their likelihood to prescribe Amphora as an 8, 9 or 10 on a 10-point scale.

Similar to our HCP and OB/GYN research, we conducted two separate studies with women of reproductive age and HCPs in the United States to evaluate potential interest in Amphora. The market research provided insight on the reasons why Amphora is appealing, which included the attributes of being non-hormonal and woman-controlled. In one of our market research studies, 71% of the women expressed concerns about hormonal exposure and 58% were not currently satisfied with their contraceptive choice. Our research confirmed there are multiple consumer segments of interest including women seeking prevention of pregnancy and STIs, or older, monogamous women seeking an alternative to hormones and condoms. Overall,

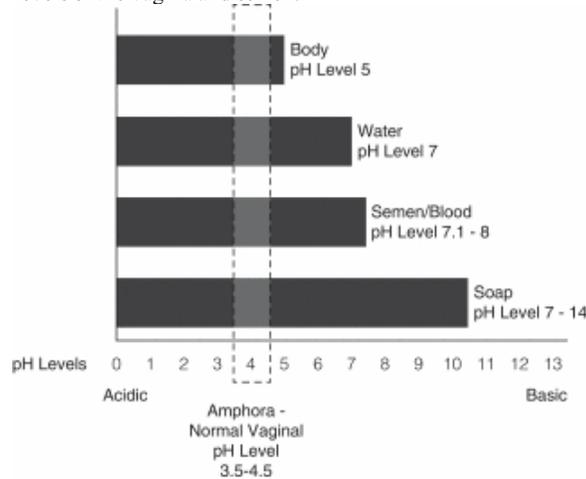
[Table of Contents](#)

approximately 40% of women in two different samples of 287 and 206 consumers rated their likelihood to use Amphora as an 8, 9, or 10 on a 10-point scale.

*Mechanism of Action in Contraception*

A normal vaginal pH of 3.5 to 4.5 is important for maintaining good vaginal health. At this optimal pH level, the vagina contains a balance of necessary healthy bacteria. Additionally, a vaginal pH in this range is inhospitable to sperm as well as certain viral and bacterial pathogens. Amphora was developed to have acid-buffering (pH 3.5), bioadhesive, and viscosity-retaining properties to provide effective acidification of the male ejaculate in the vagina and to form a long-lasting layer of gel over the vaginal and cervical surfaces. Typically, the introduction of semen (pH = 7.2-8.0) into the vagina causes a rise in pH above 6.0 due to the alkalinity of the ejaculate, which neutralizes the normally acidic vaginal environment, and allows for the survival of sperm. Amphora acts as a vaginal contraceptive by maintaining a normal vaginal pH (pH = 3.5-4.5) even in the presence of semen, inhibiting sperm from reaching the ovum to form a zygote. This buffering capacity is due to Amphora’s active pharmaceutical ingredients. Other properties contributing to the contraceptive effect of Amphora are its capacity to reduce/inhibit cervical mucus penetration, to maintain sufficient viscosity even upon dilution with the introduction of semen into the vagina and its bioadhesive strength. After proper use of Amphora, postcoital testing shows Amphora remains protective for up to 10 hours, based on a lack of progressively motile sperm.

The diagram below shows the respective pH levels of the vagina and semen.



*Amphora Clinical Trials*

*AMP001 Phase 3 Clinical Trial*

A key stage in the development of Amphora was the completion of a large-scale Phase 3 clinical trial comparing the contraceptive effectiveness, safety and acceptability of Amphora to Conceptrol, a surfactant-based spermicidal gel containing 4% nonoxynol-9, which is currently available over-the-counter for use as a vaginal contraceptive. The primary endpoint of the trial was the six-month cumulative pregnancy rate. Secondary endpoints included local and systemic signs and symptoms reported by participants or observed upon medical examination, such as itching, burning, irritation, inflammation or lesions to the cervical or vaginal epithelia and vaginal infections.

AMP001 enrolled 3,389 women at 62 research centers in the United States and Russia. This open-label, randomized, non-inferiority trial evaluated the repeated use of Amphora compared to Conceptrol over seven menstrual cycles. After completing the first seven cycles, some of the women randomized to Amphora continued for up to a total of 13 cycles (n=341). In a subset of women (75 in each treatment arm) the lower genital tract (cervix, vagina, and vulva) was observed and photographed by colposcopy. The subset was blinded to avoid possible observer bias. A second subset was also examined microbiologically to document any changes in the vaginal flora, particularly the onset of any infection by *Escherichia coli* or yeast.

The trial was fully enrolled in July 2013 and completed during the first half of 2014. In the primary efficacy analysis, the six-month cumulative pregnancy rate for typical use (defined as trial subjects who had at least one episode of coitus without using the product correctly during the study and without any backup or emergency contraception), was approximately 10.5% for Amphora, as compared to 10.0% for Conceptrol. For those subjects with perfect use (defined as trial subjects who used the product correctly at every episode of coitus within a given cycle), the cumulative pregnancy rate was approximately 4.1% for

[Table of Contents](#)

Amphora, as compared to 4.2% for Conceptrol. In summary, Amphora met its primary endpoint of non-inferiority to Conceptrol when the combined United States and Russian data were analyzed in accordance with the pre-specified statistical analysis plan.

Less than 2% of patients using Amphora experienced an AE that was “definitely” related to treatment. There were no SAEs deemed “definitely” or “probably” related to Amphora. Of the 30 subjects who experienced at least one SAE, 11 were treated with Amphora (0.8%) and 19 were treated with Conceptrol (1.3%). The AE reporting for the 13-cycle extension did not identify additional SAEs; therefore, no subject treated with Amphora experienced an SAE with an additional six cycles of exposure to Amphora. Significantly more subjects were highly satisfied Amphora as compared to Conceptrol and significantly more Amphora users would use the product again if it were available ( $p < 0.05$  for both comparisons).

**Adverse events in greater than 5% of Amphora treated subjects in the AMP001 Phase 3 Clinical Trial in the seven-cycle study in all subjects:**

	<b>Amphora</b>	<b>Conceptrol</b>	<b>All Subjects</b>
	(N=1458)	(N=1477)	(N=2935)
<b>Preferred term</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>
Total number (%) of subjects with at least one AE	793 (54.4)	857 (58.0)	1650 (56.2)
Urinary tract infection	140 (9.6)	193 (13.1)	333 (11.3)
Vaginitis bacterial	160 (11.0)	170 (11.5)	330 (11.2)
Vulvovaginal mycotic infection	156 (10.7)	168 (11.4)	324 (11.0)
Headache	96 (6.6)	80 (5.4)	176 (6.0)
Vulvovaginal pruritus (vaginal infection)	55 (3.8)	76 (5.1)	131 (4.5)
Nasopharyngitis (common cold)	76 (5.2)	48 (3.2)	124 (4.2)

*Summary of Initial NDA Submission (Contraceptive Indication)*

On July 2, 2015, pursuant to section 505(b)(2) of the Federal Food, Drug and Cosmetic Act we submitted an NDA for Amphora to the FDA for the proposed indication of prevention of pregnancy. The submission included, among other things, data from the initial Phase 3 clinical trial (AMP001) as well as other safety and efficacy information.

A Complete Response Letter (CRL) was issued by the FDA on April 28, 2016. A CRL is issued if the agency determines an application cannot be approved in its present form and will describe all the specific deficiencies identified by the agency. A CRL will also recommend actions the applicant might take to place the application or abbreviated application in condition for approval.

The primary approvability issue was the difference in results between the United States and Russian cohorts. Although the study met its primary endpoint when the combined United States and Russian data were analyzed per the statistical plan, the FDA deemed the data from Russian subjects (approximately 20% of the study population) not generalizable to the United States population. Additionally, the FDA excluded analysis data from certain cycles, specifically data from: cycle 0 (the time from enrollment until the subject’s first menstrual cycle); cycles <21 days or >42 days in duration; cycles past 196 days (the aggregate length of seven cycles of 28 days in duration); and cycles in which there was no intercourse.

A Type A meeting was held on October 31, 2016, with the FDA, during which the FDA indicated a confirmatory efficacy trial focused on participants in North America would be required. After further consultation with the FDA, the FDA confirmed a single-arm trial (non-comparative) would be sufficient to address the CRL clinical deficiency. All feedback received from the FDA was incorporated into a protocol for a single-arm trial which was submitted to the FDA on June 30, 2017 (AMP002).

*AMP002 Confirmatory Phase 3 Trial (AMPOWER)*

We are conducting a confirmatory, single-arm, Phase 3 trial entitled “A Single-Arm, Phase III, Open Label, Multicenter, Study in Women Aged 18-35 Years of the Contraceptive Efficacy and Safety of Amphora Contraceptive Vaginal Gel.” We refer to this trial as AMPOWER or AMP002. This study enrolled 1,400 women aged 18 to 35 at 112 sites in the United States. The first subject enrolled in this trial on July 28, 2017, and enrollment was completed in February 2018. We expect to report top-line data from AMP002 in the first quarter of 2019 and, if positive, to resubmit the NDA for Amphora for contraception to the FDA in the second quarter of 2019. Per the FDA Performance Goals under PDUFA VI, the FDA review timeline for this type of Class 2 resubmitted NDA is six months.

The primary endpoint of this trial is a seven-cycle cumulative pregnancy rate as assessed by the Kaplan-Meier statistical method. To meet this endpoint, Amphora must demonstrate a typical use failure rate of less than 16.5%, with an upper limit of the 95% confidence interval of 21%, meaning no more than 21% of trial subjects may become pregnant with typical use of Amphora during the study.

## [Table of Contents](#)

In addition to the primary efficacy outcome and secondary safety outcomes, this trial also includes an exploratory endpoint of sexual satisfaction as assessed by the Female Sexual Function Index, which could be further explored in future trials and potentially utilized in our labeling and marketing materials for Amphora. We believe this is the first contraceptive registration trial to include sexual satisfaction as an outcome.

### *Scientific Advice Process in the EU*

We previously conducted a regulatory gap analysis with Pharmalex GmbH to determine how the EU regulatory bodies were likely to view its marketing authorization application (MAA) upon submission to the EU. Scientific advice was previously sought in April 2016 from the Medical Products Agency of Sweden and the Agency of Medicine and Sanitary Products of Spain, but an MAA was not pursued due to a lack of resources to support a filing at that time. We have reinitiated the scientific advice process and seek marketing authorization for Amphora in the EU through a decentralized procedure.

### *Amphora for STI Prevention*

In the United States, the CDC reported there were 1.6 million new cases of chlamydia and approximately 468,000 new cases of gonorrhea in 2016. We believe this represents a significant commercial opportunity for Amphora.

Preclinical tests conducted in the early developmental stages by Rush University and later by us, suggest Amphora has the potential to suppress many of the pathogens responsible for sexually transmitted and commonly occurring bacterial infections while not affecting lactobacilli, a normal and beneficial bacterium found in a healthy vagina.

Researchers at Rush University conducted preclinical studies to assess the ability of Amphora to prevent transmission of chlamydia in mice. Data from these studies showed Amphora was highly effective at preventing upper and lower genital tract infection when compared to various vaginally-administered controls containing nonoxynol-9. The following table summarizes the results from the mouse study showing the protective effect of Amphora compared to several other vaginal gels or no treatment in the upper and lower genital tract.

<b>Treatment</b>	<b>Lower Genital Tract Protected/inoculated<sup>1</sup></b>	<b>Upper Genital Tract Protected/Inoculated</b>
No Treatment	2/29 (7%)	4/29 (14%)
Gynol II	6/16 (38%) <sup>2</sup>	6/16 (38%)
K-Y Plus	0/16 (0%)	1/16 (6%)
Advantage-S	3/16 (19%)	3/16 (19%)
Conceptrol	0/16 (0%)	0/16 (0%)
Amphora	13/16 (81%) <sup>3</sup>	8/8 (100%) <sup>4</sup>

1 Animals defined as infected if *C. trachomatis* was isolated by culture from samples collected on day 3 or 6 post challenge

2  $p < 0.05$  vs. No Treatment

3  $p < 0.001$  vs. No Treatment

4  $p < 0.01$  vs. No Treatment

In another study, Amphora (at the time called ACIDFORM) was tested for its ability to prevent transmission of gonorrhea in the genital tract compared to other vaginal microbicides in mice. Amphora displayed significant protection against transmission of gonorrhea, with only 1 of 17 Amphora-treated mice having positive gonorrhea culture results, compared with 13 of 15 untreated control mice. The following table represents recovery rates from gonorrhea in mice receiving pretreatment or no treatment before intravaginal challenge with gonorrhea strain FA1090:

Test Agent	Number of mice culture positive for gonorrhea/ total number of mice	
	Test Agent	No. Treatment
PRO2000 (0.5%)	0/17	11/12 (91.7%)
CAP gel	0/7	13/15 (86.7%)
Cellulose sulfate	2/11	8/10 (80%)
BufferGel	10/23	14/14 (100%)
CarraGuard	3/20	13/17 (76.5%)
T-PSS (5%)	0/17	11/12 (91.7%)
Carbopol 1382	10/23	14/14 (100%)
Methylcellulose	16/20	13/17 (76.5%)
Amphora	1/17	13/15 (86.7%)

Of all agents tested, Amphora was the most highly active against gonorrhea *in vitro*. The following table represents *in vitro* activity of test articles and control agents against seven strains of gonorrhea:

Test Agent	Number of gonorrhea strains inhibited/ total number of strains tested					
	Dilution of formulated agent					
	10%	5%	2.5%	1.25%	0.625%	
PRO2000	6/7	4/7	2/7	0/7	0/7	0/7
CAP gel	6/7	0/7	0/7	0/7	0/7	0/7
Cellulose sulfate	1/7	1/7	1/7	0/7	0/7	0/7
BufferGel	7/7	3/7	0/7	0/7	0/7	0/7
CarraGuard	0/7	0/7	0/7	0/7	0/7	0/7
T-PSS <sup>1</sup> (5%)	6/7	5/7	3/7	2/7	1/7	1/7
Carbopol 1382	0/7	0/7	0/7	0/7	0/7	0/7
Methylcellulose	0/7	0/7	0/7	0/7	0/7	0/7
Amphora	7/7	7/7	7/7	6/7	6/7	6/7

1 T-PSS = polysodium 4-styrene sulfonate

Building on the microbicide potential of Amphora demonstrated in preclinical trials, we are currently conducting a double-blinded, placebo-controlled pivotal Phase 2b/3 trial to evaluate the efficacy of Amphora for the prevention of sexual transmission of two common STIs, chlamydia (primary endpoint) and gonorrhea (secondary endpoint). This trial is designed to enroll 844 women 18 to 45 years of age at approximately 50 sites in the United States. Should this trial meet its primary endpoint, the FDA has indicated it may be considered as one of two pivotal trials required for approval of Amphora for the prevention of chlamydia in women, for which it has been granted Fast Track designation by the FDA. The FDA’s Fast Track program is intended to expedite or facilitate the process of reviewing new drugs and provides eligibility for priority review, if relevant criteria are met.

As previously noted, Amphora has been granted QIDP designation by the FDA for the prevention of gonorrhea in women.

*BV Product Candidate*

BV affects an estimated 21 million women, or 29.2% of women of reproductive age in the United States, and is considered to be the most common reproductive tract infection for women. Data suggests BV recurs in up to 58% of women within the first 12 months of treatment. There are currently no FDA-approved products indicated for the reduction of recurrent BV.

Preclinical tests have shown our investigational product kills many of the microbes responsible for BV while not affecting lactobacilli, a normal and beneficial bacterium found in a healthy vagina. The inhibitory mechanism comprises our BV product candidate’s buffered acidity and the presence of active pharmaceutical ingredients in the MPT vaginal gel.

We filed an Investigational New Drug Application (IND) with the FDA in March 2016 to study the ability of our BV product candidate to reduce recurrent BV. Following submission of the IND, we conducted a Phase 1 trial (EVO-002) to evaluate the ability of a single vaginal administration of our BV product candidate at three different doses to reduce vaginal pH.

## [Table of Contents](#)

The trial was completed in late 2016 and revealed the highest dose evaluated (5-gram) reduced vaginal pH for up to seven days following a single administration compared to placebo gel or no gel. We are currently designing a Phase 2b/3 trial to examine the ability of a 5-gram dose of our BV product candidate to reduce recurrent BV over a 16-week intervention period versus placebo gel. We expect this phase 2b/3 trial to enroll approximately 230 women at up to 36 sites in the United States.

As previously noted, Amphora has been granted QIDP designation by the FDA for the prevention of the recurrence of BV.

### **Commercialization Strategy**

We plan to implement a global strategy to commercialize Amphora, if approved. In the United States, our plan is to build our own integrated sales and marketing infrastructure. Outside of the United States, we expect to leverage global pharmaceutical companies or other qualified potential partners to license commercialization rights or enter collaborations for the commercialization and distribution of Amphora.

While awaiting the decision from the FDA as to the approval of Amphora, our planned pre-commercialization activities will include:

- the selection of commercial suppliers, which includes agency of record for the Amphora brand, hiring of sales and sales support personnel to support our anticipated commercialization of Amphora, initiation of payer programs including the addition of medical science liaisons and national/key account managers, and the selection of third-party logistic provider(s); and
- the optimization of manufacturing capabilities to include the installation of new equipment into manufacturers' facilities, planning and preparing for all requisite inspections, planning for process validation and registration batch quantities, and establishing secondary (back-up) manufacturing capability.

#### *United States*

We estimate the United States market is the largest commercial opportunity for our product candidates. If Amphora is approved for commercialization by the FDA, we intend to establish a commercial sales force to market Amphora directly to obstetricians and OB/GYNs who write the majority of prescriptions for contraceptive products.

The top 10% of prescribers (98% of which are OB/GYNs) account for 46% of the annual contraception prescriptions in the United States. The American Congress of Obstetricians and Gynecologists (ACOG) reports there are approximately 36,000 fellows currently practicing in the United States. We intend to target the top 30% by deploying a sales force of approximately 85 sales representatives. Our direct sales force will be complemented by print and digital advertising, social media campaigns, access programs, educational campaigns, and non-personal promotion campaigns targeting both consumers and healthcare providers.

Successful prescription drug market launches require comprehensive and integrated pre-launch activities. During the pre-commercialization phase for Amphora, we intend to assemble an experienced team of key account managers and medical science liaisons expected to focus on ensuring key payer accounts, pharmacy benefit managers, key opinion leaders and medical associations who are educated about the need to offer a wider set of options to women seeking non-hormonal, woman-controlled contraceptive methods. We expect these educational activities will be supported by presentation of clinical data at key national congresses (such as the annual meetings of ACOG and the Society of Family Planning), clinical publications, and additional market development activities. Our pre- and post-commercialization activities are expected to include multi-channel marketing campaigns to raise brand awareness, including direct-to-consumer and health care professional campaigns. These key initiatives will be supported by awareness campaigns in social media, online and print advertisements, paid and earned social media support, and public relations efforts. We expect these campaigns to encourage patients to consult their healthcare providers and ensure payer and healthcare provider strategies are implemented.

#### *Ex-United States Markets*

In markets outside of the United States, if a product candidate is approved for marketing in an individual market, we intend to establish regional and/or global partnerships by either sublicensing the commercialization rights or entering into distribution agreements with one or more third parties for the commercialization of the applicable product candidate in that market.

### **Payer and Reimbursement Strategy**

#### *United States*

We have conducted market research with 45 different healthcare plans covering approximately 80% of covered lives within the United States to better understand viable access and pricing strategies for Amphora. Overall, a majority of respondents were positive about the introduction of a new contraceptive method. These respondents cited the many unintended pregnancies, high costs associated with unwanted pregnancies, and the underlying limitations in the contraceptive category (i.e.

## [Table of Contents](#)

the lack of non-hormonal options) as reasons a new contraceptive option is desirable. We aim to have approximately 60% of all commercial healthcare plans offering full access and complete coverage of Amphora for all the reproductive aged women's lives they are managing by the end of the first year of commercialization of Amphora. This coverage is expected to build to approximately 85% to 90% at peak sales.

### *Pricing Strategy*

Overall, healthcare plans appear receptive to the idea of pricing Amphora like that of branded oral contraceptives. Healthcare plans interviewed during market research expected Amphora to be priced between \$100 and \$200 for a monthly supply of a 12-applicator box (comparable to branded contraceptives), believing Amphora would ultimately offset other costs the payer may incur (i.e. unwanted pregnancies).

### *Third-party Payers*

Market acceptance and sales of Amphora and our other product candidates, if approved, will depend in part on the extent to which reimbursement for these products will be available from third-party payers, including government health administration authorities, managed care organizations and private health insurers. Third-party payers decide which therapies they will pay for and establish reimbursement levels. Third-party payers in the United States often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates we develop will be made on a payer-by-payer basis. One payer's determination to provide coverage for a drug does not assure other payers will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payer's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved.

Third-party payers are increasingly challenging the prices charged for pharmaceutical and medical device products. The United States government and other third-party payers are increasingly limiting both coverage and the level of reimbursement for new drugs and medical devices, in addition to questioning their safety and efficacy. We may incur significant costs to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Third-party payer coverage may not be available to patients for Amphora or any future product we may seek to commercialize. If third-party payers do not provide coverage and adequate reimbursement for Amphora or our other product candidates, healthcare providers may not prescribe them or patients may ask their healthcare providers to prescribe competing products with more favorable reimbursement.

Managed care organizations and other private insurers frequently adopt their own payment or reimbursement reductions. Consolidation among managed care organizations has increased the negotiating power of these entities. Third-party payers increasingly employ formularies, which might not include all the approved products for a particular indication, to control costs by negotiating discounted prices in exchange for formulary inclusion. We intend to target those healthcare plans managing the largest number of covered lives to achieve optimal access for our product portfolio.

### *Europe*

Our market research found that EU consumers were interested in the unique benefits of Amphora product profiles, especially since Amphora is non-hormonal. Contraceptive products are not reimbursed in all the EU member countries. For example, in Italy there is no coverage for contraceptives, in France and Spain, only oral contraceptives are generally covered, and in Germany, individual reimbursement policies apply.

### *Pricing and reimbursement*

In the EU, pricing and reimbursement strategies vary widely from country to country. Some countries mandate that drug products may be marketed only after a reimbursement price has been agreed, while others may require the completion of additional studies that compare the cost-effectiveness of a product candidate to currently available therapies. For example, the EU provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of offering a drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become intense, creating increasingly high barriers for entry of new products. In addition, in some countries, cross-border imports from lower-priced markets exert competitive pressure that may reduce pricing within a country. Therefore, the development of new drug launch strategies has become very challenging to meet both patient need/demand while ensuring products are commercially viable in those markets.

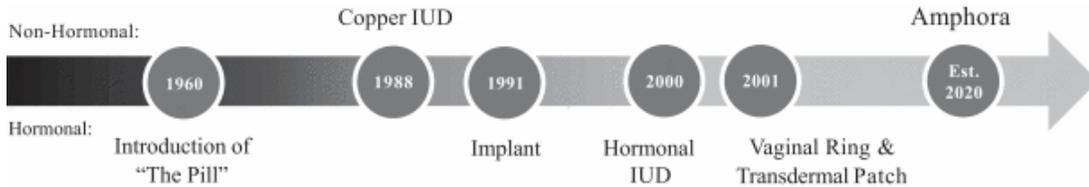
## **Amphora Manufacturing**

[Table of Contents](#)

We plan to outsource the manufacturing of Amphora (and our other potential product candidates) to third parties. Currently, we have contracted with a third party to manufacture our clinical supplies of Amphora. This third party has agreed to manufacture Amphora and potential other product candidates in accordance with all applicable cGMP regulations, as well as in compliance with all applicable laws and other relevant regulatory agency requirements for manufacture of pharmaceutical drug products and combination drug-device products.

**Competition**

As shown below, the contraception market was established in 1960 with the introduction of “the pill,” the first oral contraceptive widely available to women in the United States. This high-dose hormonal option remained the primary form of available contraception on the market until 1988 when the copper IUD was introduced, offering the first non-hormonal option for birth control. As shown in the time line below, there was no notable innovation providing additional options in women’s reproductive health until 30 years after the introduction of “the pill,” when pharmaceutical companies introduced synthetic hormonal products with different hormonal delivery systems, including the hormonal IUD, implants, the patch, and vaginal ring.



If approved, Amphora would compete for market share in at least four categories: 1) oral contraception, 2) Long-Acting Reversible Contraception (LARC) comprising IUDs, implants, and injectables, 3) non-oral hormonal contraceptives, comprising weekly or monthly options including the patch and vaginal ring, and 4) OTC methods, dominated primarily by the condom.

**Oral Contraceptives (the “pill”)**

The pill is the most commonly used form of birth control in the United States today. Birth control pills are marketed under a variety of brand names, and currently, there are only two promoted branded pills — Lo Lostrin® FE (Allergan) and Natazia® (Bayer). There are two main kinds of oral contraceptives — combination birth control pills, which contain estrogen and progestin, and the “mini pill,” which contains only progestin. Oral contraceptives typically must be taken on a regular or daily basis to be effective.

**LARC**

*Implants*

The contraception implant (principally marketed in the United States as Nexplanon® by a subsidiary of Merck & Co.), which must be implanted under the skin and removed by a qualified healthcare provider, requiring a medical procedure, provides contraception by releasing hormones over a three-year period. The implant has realized an increase in market share over the past five years, outpacing the overall contraceptive category year-over-year, with annual sales in the United States of approximately \$449 million.

*IUDs*

The copper IUD was introduced to the market in 1988 and provides protection by disrupting sperm motility and damaging sperm so that they are prevented from joining with an ovum. Today, the copper IUD is principally marketed by Cooper Surgical, Inc. as Paragard. The hormonal IUD is principally offered under the brand names, Kyleena®, Skyla® and Mirena, a family of products from Bayer Pharmaceuticals. IUDs have annual sales in North America of approximately \$1.3 billion. All IUDs must be inserted or removed by a physician.

The LARCs are not dependent on user adherence, which appeals to those who benefit from a passive form of birth control with no daily requirement to take a pill. However, many women have decided to remove their LARC due to the hormonal side effects they experience.

**Non-oral, Hormonal Contraceptives**

*Contraceptive Patch*

## [Table of Contents](#)

The weekly contraceptive patch was introduced in 2000 by Johnson & Johnson's Janssen division; however, deaths resulting from venous thromboembolism due to hormonal exposure had a significant negative impact on the patch and led to label changes restricting utilization. Following the loss of exclusivity, Johnson & Johnson's Janssen division exited women's healthcare and contraception as a promotional category.

### *Vaginal Ring*

The hormonal vaginal ring by Merck & Co. was introduced to the market in 2001 and had annual sales in 2016 in the United States of approximately \$576 million. The ring is used for three weeks and then removed for a week during menses and a new hormonal vaginal ring is inserted. The efficacy for the vaginal ring is similar to hormonal oral contraception. Users of the vaginal ring report the same incidence of hormonal related side effects as those using oral hormonal contraception.

### *Injectables*

The primary injectable hormonal contraceptive on the market is Depo-Provera® offered by Pfizer Inc. Each injection provides protection for up to 12 to 14 weeks, but patients must receive injections once every 12 weeks to get full contraceptive protection. Depo-Provera was introduced to the market in 1992 and has annual sales in the United States of approximately \$211 million.

### *Non-prescription OTC*

Condoms are the dominate product offering in OTC sales. They are manufactured primarily by Trojan® (Church & Dwight) and Durex® (Reckitt Benckiser) brands, with approximately six million women who depend on condom use as their only method of birth control. The market size in the United States for condoms in 2017 was over \$1.3 billion. In addition, spermicides are also available in sponges, jelly/creams, and foams and have very limited utilization.

The adoption of Amphora, if approved, is expected to come equally from each category discussed, as interest in Amphora falls into two distinct segments: (1) those women seeking an alternative to hormonal contraception; and (2) those women who are expected to utilize Amphora as added protection to their current form of birth control. Our market research has indicated that the hormone-free, woman-controlled aspect of Amphora makes it an attractive option across the entire competitive set.

## **Rush License Agreement**

As discussed above, we entered the Rush License Agreement, pursuant to which Rush University granted us an exclusive, worldwide license of certain patents and know-how (the Rush Licensed IP) related to our MPT vaginal gel technology authorizing us to make, distribute and commercialize products and processes for any and all therapeutic, prophylactic and/or diagnostic uses, including, without limitation, use for female vaginal health and/or contraception.

As further described in the Rush License Agreement, we are under an obligation to make tiered royalty payments in the mid-single digits to Rush University based on net sales of products and/or processes that are claimed in the patents or the know-how licensed to us under the Rush License Agreement. To the extent one of our products is not claimed in a licensed patent but does utilize the licensed know-how, the applicable royalty rate to such product and/or processes would be reduced.

In addition, if during the three years after one of our products or processes has received regulatory approval and is introduced to the market, if the amounts paid to Rush University as royalties or sublicensing fees do not total a minimum royalty amount, then we must pay a minimum annual royalty to Rush University. If we have to pay a royalty or other payment to a third party in order for us to avoid infringement of third-party rights, we may offset up to 50% owed to such third party by up to 50% of the amounts owed to Rush University under the Rush License. The above-described royalty payments expire upon termination of the Rush License Agreement in accordance with its terms.

We also have the right to sub-license our rights to affiliates (without the prior approval of Rush University) and to third parties (with the prior written approval of Rush University, not to be unreasonably delayed or conditioned). To the extent Rush University approves of a third-party sub-license, in lieu of any royalty payment obligation under the Rush License Agreement, we would then be under an obligation to pay Rush University a sub-license fee equal to a percentage of any sublicensing revenue received from any third-party sub-licensee.

Pursuant to the Rush License Agreement, Rush University, its affiliates and/or its sublicensees have the right in the form of a royalty free, non-exclusive license from us under the applicable patents and know-how to use the technology embodied by such patents and know-how for non-commercial research purposes.

The Rush License Agreement provides that we must use our best efforts to bring one or more products or processes based on the licensed patents to market, and to continue diligent marketing efforts for one or more such products or processes during the term of the agreement. Additionally, within one month of the end of each fiscal quarter until the date of first commercial sale of a product, we must provide Rush University with a written development report summarizing our product development activities since the prior such report, as well as any necessary adjustments to the plan of development.

## [Table of Contents](#)

The Rush License Agreement contains additional customary representations and warranties, insurance and confidentiality provisions and is governed by the laws of the State of Illinois, except that questions affecting the licensed patents will be determined in accordance with the national law of the country in which the applicable patent was granted. We have the first right, but not the obligation, to pursue potential infringers of the licensed patents technology and know-how and the prior written approval of Rush University is required to settle any related claim.

We have agreed to defend, indemnify and hold harmless Rush University, its employees and certain other related parties from and against any and all liabilities, damages, settlements, penalties, fines, costs or expenses arising out of any claim, complaint, suit, proceeding or cause of action brought against the relevant indemnity by a third party alleging damage arising from or occurring as a result of the activities performed by or under the authority of us, our affiliates or sub-licensees in connection with the exercise of our licenses and rights under the Rush License Agreement, except to the extent caused by Rush University's negligence or willful misconduct.

Unless terminated in accordance with its terms, the term of the Rush License Agreement continues until the expiration, revocation or invalidation of the last of the patents or the abandonment of the last patent application included within the licensed patents and technology, which includes any patent claiming an improvement made within the term of the Rush License Agreement in the course of research supported or developed by Rush University utilizing the technology.

The Rush License Agreement may be terminated upon mutual written consent of both parties or by a non-breaching party if the other party commits a breach or default of any covenant in the agreement and fails to cure such breach within thirty (30) days after receiving written notice of such breach or default.

If we are in default of our obligations under the Rush License Agreement and such default has not been cured within thirty (30) days, Rush University has the option to: (a) terminate the Rush License Agreement; or (b) convert the exclusive license to a non-exclusive license (subject to the rights of any pre-approved sub-licensee under any pre-approved sub-license). Termination of the Rush License Agreement or conversion to a non-exclusive license shall give Rush University the right to terminate all sub-licenses granted by us that were not approved by Rush University. If Rush University declines to terminate any such sub-license agreement (or such sub-license agreement was approved by Rush University) then: (a) in the case of termination of the Rush License Agreement, the sub-license agreement shall become a direct agreement between Rush University and the relevant sub-licensee; and (b) in the case of conversion of the Rush License Agreement license to a non-exclusive license, such license shall continue in full force and effect in accordance with its terms.

In addition, Rush University may terminate the agreement: (i) upon thirty (30) days' notice in the event that the aggregate royalties paid under such agreement in any calendar year following March 27, 2017 do not equal a minimum of at least \$50,000, except that we may pay to Rush University the difference between the royalties actually paid and \$50,000 to prevent Rush University from so terminating the Rush License Agreement, and under such circumstances the Rush License Agreement will continue for an additional two (2) years beyond March 27, 2017, or until March 27, 2019; and (ii) in a given country as regards our rights in such country, upon sixty (60) days' notice if, prior to March 27, 2022, we have not, in such country, engaged in certain specified activities in such country in an effort to exploit the products and processes covered by the licensed patents and technology in such country. To date, we have not paid any royalties pursuant to the Rush License Agreement. However, to the extent an extension of the Rush License Agreement is required, we believe we would be able to obtain such an extension on commercially reasonable terms.

### **Intellectual Property**

We believe we have a strong and growing intellectual property portfolio. We strive to protect the proprietary technology we believe is important to our business, including seeking and maintaining patents intended to cover our product candidates, and their methods of use, as well as any other inventions that are commercially important to the development of our business. We seek to obtain domestic and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions. We also may rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, and other intellectual property rights, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We will also rely on continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of March 2018, we own or have exclusively licensed approximately 27 issued patents and allowed applications in the United States and other countries and jurisdictions, and have approximately 33 applications pending in the United States and other countries and jurisdictions.

We have an exclusive worldwide license to a portfolio of licensed patents held by Rush University, which provide general protection for Amphora, which expire in 2021 and could be eligible for extensions to at least 2024 in the United States and to

2026 in certain European jurisdictions, if granted by those regulatory bodies. Further, we solely own several patent families relating to the composition and therapeutic use of Amphora, which, upon grant, would expire at the earliest in 2033. We believe that our licensed and solely owned non-hormonal contraceptive gel patent filings, combined with our substantial know-how in this field, will continue to provide opportunities for us to establish a significant barrier to competitor entry into the market.

In addition, we commissioned an expert opinion in 2015 whose view was that bioequivalence for Amphora would be difficult to show, thus making it potentially more difficult to develop a generic version of Amphora.

In addition to patents, we rely, and expect to rely, on trade secrets and know-how to develop and maintain our competitive positions. For example, certain aspects of the composition, manufacturing, and use of Amphora are protected by unpatented trade secrets and know-how. Although trade secrets and know-how can be difficult to protect we seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors, collaborators, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets and know-how may otherwise become known or may be independently discovered by competitors. To the extent our consultants, contractors or collaborators use intellectual property owned by third parties in their work for us, disputes may arise as to the rights in related or resulting intellectual property, including trade secret, know-how and inventions.

### **Trademark Basics and Strategy**

We own or have rights to various trademarks, copyrights and trade names used in our business, including Evofem and Amphora. Our logos and trademarks are the property of Evofem Biosciences, Inc. All other brand names or trademarks appearing in this report are the property of their respective holders. Our use or display of other parties' trademarks, trade dress, or products in this report is not intended to, and does not, imply a relationship with, or endorsement or sponsorship of us, by the trademark or trade dress owners.

### **Healthcare Laws and Regulations**

Healthcare providers and third-party payers play a primary role in the recommendation and prescription of drug products and medical devices that are granted marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include but are not limited to the following:

***Anti-Kickback Statute*** — the Federal Anti-Kickback Statute, among other things, prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federally funded healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate the statute in order to have committed a violation. In addition, the government may assert that a claim that includes items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

***Civil and Criminal False Claims Laws*** — the federal civil and criminal false claims laws, including the False Claims Act, which can be enforced by private citizens through civil whistleblower and qui tam actions, prohibit, among other things, individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

***Health Insurance Portability and Accountability Act of 1996*** — the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other things, individuals or entities from executing a scheme to defraud any healthcare benefit program or making any false statements relating to healthcare matters; as in the case of the Federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate the statute in order to have committed a violation; additionally, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization, on entities subject to the law, such as certain healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information;

***False Statements Statute*** — the federal False Statements Statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

## [Table of Contents](#)

**Stark Law** — the federal ban on physician self-referrals prohibits, subject to certain exceptions, physician referrals of Medicare or Medicaid patients to an entity providing certain “designated health services” if the physician or an immediate family member of the physician has any financial relationships, including compensation arrangements or ownership interests, with that entity.

**Sunshine Act** — the federal transparency or “sunshine” requirements of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the ACA) requires certain manufacturers of drugs, devices, biologics and medical supplies to annually report to the Department of Health and Human Services (the DHHS) information related to payments and other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

**Federal Food, Drug, and Cosmetic Act** — The Federal Food Drug and Cosmetic Act (the FDCA) and the regulations promulgated pursuant to the FDCA by the FDA govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products as well as so-called combination products, such as those consisting of a drug and a delivery device. Failure to comply with applicable FDA pre-market, post-market, or other compliance requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA’s refusal to approve pending applications, a clinical hold, warning letters, recall or seizure of products, partial or total suspension of production, withdrawal of the product from the market, injunctions, fines, civil penalties or criminal prosecution.

**State Transparency Laws** — Some United States state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to healthcare providers and other healthcare providers or marketing expenditures; some state laws require pharmaceutical companies to implement compliance programs and to track and report gifts, compensation and other remuneration provided to physicians, in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information; and some state and local laws that require the registration of pharmaceutical sales representatives.

**State and Foreign Regulatory Concerns** — There are analogous State and foreign laws and regulations, such as State Anti-Kickback and False Claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers. State and foreign laws also govern the privacy and security of health and personal information. These laws differ from each other in significant ways while applying simultaneously with HIPAA, thus complicating compliance efforts.

The scope and enforcement of these laws is uncertain and subject to rapid change. Regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. In addition, efforts to ensure that our business arrangements with third parties will comply with these laws will involve substantial costs. Any investigation of us or the third parties with whom we contract, regardless of the outcome, would be costly and time consuming. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, debarment under the FDCA, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

### **Healthcare Reform**

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things: (i) mandates that preventative services which have strong scientific evidence of health benefits, including in some cases contraception, must be fully covered certain private third-party payers when they are delivered by an in-network provider; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and

## [Table of Contents](#)

extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (iv) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; (v) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price (AMP); (vi) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vii) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70%, commencing January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (ix) established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (the BBA), among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". We continue to evaluate the potential impact of the ACA and its possible repeal or replacement on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

## **Government Regulation and Product Approval**

### *United States*

## [Table of Contents](#)

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our products are subject to extensive regulation by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. Failure to comply with the applicable United States requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDA warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution. Medical products containing a combination of new drugs, biological products or medical devices are regulated as “combination products” in the United States. A combination product generally is defined as a product comprising of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. To facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. Amphora is subject to review by the FDA, and it is anticipated that Amphora will be regulated as a drug/device combination product with a drug mode of action that requires the submission and approval of a NDA prior to marketing.

### *FDA Drug Approval Process*

Amphora and our other product candidates may not be marketed in the United States until the product has received FDA approval. The steps to be completed before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies, and formulation studies, all performed in accordance with the FDA’s Good Laboratory Practice regulations;
- submission to the FDA of an IND for human clinical testing;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication to the FDA’s satisfaction;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP regulations;
- Satisfactory completion of FDA bioresearch monitoring inspections of selected investigational sites at which the drug product was subject to clinical trials to assess compliance with GCP regulations; and
- FDA review and approval of the NDA.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials in the United States may begin and is required to be updated annually. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Our first IND submitted in 2011 relates to Amphora for the prevention of pregnancy (AMP001). Our second IND relates to our BV product candidate (EVO-002). We have also been allowed to conduct a clinical trial relating to prevention of chlamydia and gonorrhea (AMPREVENCE) under this second IND, and the first subject was enrolled in this trial in December 2017.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Clinical trials necessary for product approval are typically conducted in three sequential phases, but the phases may overlap. The trial protocol and informed consent information for trial subjects in clinical trials must also be approved by an Institutional Review Board (IRB) for each institution where the trials will be conducted, and each IRB must monitor the trial until completion; an IRB may halt a trial under its jurisdiction for safety reasons. Trial subjects must sign an informed consent form before participating in a clinical trial. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical trials, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. An NDA must be accompanied by payment of a significant user fee to the FDA, and program user fees are payable annually after a drug’s approval. Section 505(b)(1) and Section 505(b)(2) of the FDCA are the provisions governing the type of NDAs that may be submitted under the FDCA. Section 505(b)(1) is the traditional pathway for new chemical entities when no other new drug containing the same active pharmaceutical ingredient or active moiety, which is the molecule or ion responsible for the action of the drug substance, has been approved by the FDA. As an alternate pathway to FDA approval for new or improved formulations of previously approved products, a company may file a Section 505(b)(2) NDA. Section 505(b)(2) permits the

## [Table of Contents](#)

submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. During the sixty days after submission, the FDA reviews any NDA submitted to ensure that it is sufficiently complete for substantive review before the FDA accepts the NDA for filing. The FDA may request additional information rather than accept the NDA for filing. Even if the NDA is filed by the FDA, companies cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee, but it typically follows such recommendations.

The FDA may require that certain contraindications, warnings or precautions be included in the product labeling, or may condition the approval of an NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials and Risk Evaluation and Mitigation Strategies and surveillance programs to monitor the safety of approved products that have been commercialized.

### *Post-Approval Requirements*

Oftentimes, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical trials. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to (i) report certain adverse reactions to the FDA, (ii) comply with certain requirements concerning advertising and promotional labeling for their products, and (iii) continue to have quality control and manufacturing procedures conform to cGMP regulations after approval. Certain changes to the product, its manufacturing, or its labeling also require the NDA holder to submit a supplemental NDA to the Agency and, in many cases, to receive prior approval from FDA before implementing the proposed changes. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities. This latter effort includes assessment of ongoing compliance with cGMP regulations. In addition, discovery of problems with a product after approval may result in restrictions on a product, including withdrawal of the product from the market.

### *Hatch-Waxman Act*

As part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendment, Section 505(b)(2) of the FDCA was enacted. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. The FDA may also require companies to perform additional trials or measurements to support the change from the approved product. The FDA may then approve the new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent the Section 505(b)(2) applicant is relying on trials conducted for an already approved product, which is referred to as the Listed Drug, the applicant is required to certify to the FDA concerning any listed patents in the FDA's Orange Book publication that relate to the Listed Drug. Specifically, the applicant must certify for all listed patents one of the following certifications: (i) the required patent information has not been filed by the original applicant; (ii) the listed patent already has expired; (iii) the listed patent has not expired, but will expire on a specified date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product.

If a Paragraph I or II certification is filed, the FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed, the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the 505(b)(2) application. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the Listed Drug has expired.

A certification that the new product will not infringe the Listed Drug's listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders for the Listed Drug once the applicant's NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA by imposing a 30-month automatic statutory injunction, which may be shortened by the court in a pending patent case if either party fails to reasonably cooperate in expediting the case. The 30-month stay terminates if a court issues a final order determining that the patent is invalid,

## [Table of Contents](#)

unenforceable or not infringed. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

The Hatch-Waxman Amendments provide five years of data exclusivity for new chemical entities which prevents the FDA from accepting Abbreviated New Drug Applications and 505(b)(2) applications containing the protected active ingredient. The Hatch-Waxman Amendments also provide three years of exclusivity for applications containing the results of new clinical investigations (other than bioavailability studies) essential to the FDA's approval of new uses of approved products such as new indications, delivery mechanisms, dosage forms, strengths, or conditions of use.

### *Other Governmental Regulations and Environmental Matters*

The FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA.

In addition, under the Pediatric Research Equity Act (the PREA), an NDA or supplement to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA has indicated that Amphora is covered by the PREA, but the FDA may, on its own initiative or at the request of an applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. We have requested a partial waiver of the PREA in our NDA.

If we establish international operations, we will be subject to compliance with the FCPA, which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate to obtain or retain business or to otherwise influence a person working in an official capacity. We also may be implicated under the FCPA for activities by our partners, collaborators, contract research organizations, vendors or other agents.

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances used in connection with our research work are or may be applicable to our activities. Certain agreements involving exclusive license rights, if any, or acquisitions, if any, may be subject to national or supranational antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation, which might result from future legislation or administrative action, cannot accurately be predicted.

### *Review and Approval of Drug Products in the European Union*

We are currently assessing how Amphora is going to be regulated in the EU and expect that Amphora is going to be regulated as a drug. Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the EU has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of an EU member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial applications must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a drug in the EU, an applicant must submit an MAA, either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states, Iceland, Lichtenstein and Norway. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of certain diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

The decentralized procedure is available to applicants who wish to market a product in specific EU member states where such product has not received marketing approval in any EU member states before. The decentralized procedure provides for an applicant to apply to one-member state to assess the application (the reference member state) and specifically list other member states in which it wishes to obtain approval (concerned member states). Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labelling and package leaflet, to the reference member state and each concerned member state. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application which

## [Table of Contents](#)

is then reviewed and approved commented on by the concerned member states. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

In the EU, only products for which marketing authorizations have been granted may be promoted. Even if authorized, prescription-only medicines may only be promoted to healthcare professionals, not the general public. All promotion should be in accordance with the particulars listed in the summary of product characteristics. Promotional materials must also comply with various laws, and codes of conduct developed by pharmaceutical industry bodies in the EU which govern (amongst other things) the training of sales staff, promotional claims and their justification, comparative advertising, misleading advertising, endorsements, and (where permitted) advertising to the general public. Failure to comply with these requirements could lead to the imposition of penalties by the competent authorities of the EU member states. The penalties could include warnings, orders to discontinue the promotion of the medical device, seizure of promotional materials, fines and possible imprisonment.

### Facilities

Our corporate headquarters are located in San Diego, California, where we lease approximately 16,000 square feet of office space. We have two five-year renewal options, but the sub-lessor is not expected to renew its lease. In addition, we entered into an operating lease through March 2020, under which we sub-lease approximately 11,107 square feet of office space that is currently under a month-to-month leasing arrangement. We expect this lease to terminate in the second half of 2018. We believe that our existing facilities are adequate for our current needs.

### Employees

As of April 30, 2018, we had a total of 25 full-time employees and engage consultants and contract workers on an as-needed basis. We believe the relations with our employees and consultants are good.

### Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index.

#### EXHIBIT INDEX

Exhibit No.	Exhibit Title	Filed with this Form 10-Q	Incorporated by Reference		
			Form	File No.	Date Filed
2.1*	<a href="#">Agreement and Plan of Merger and Reorganization, dated as of October 17, 2017, by and among the Registrant, Evofem Biosciences Operations, Inc. and Nobelli Merger Sub, Inc.</a>		8-K	001-36754-171139916	10/17/2017
3.1	<a href="#">Amended and Restated Certificate of Incorporation.</a>		10-K	001-36754	2/26/2018
3.2	<a href="#">Amended and Restated Bylaws of the Registrant.</a>		8-K	001-36754-18546687	1/17/2018
4.1	<a href="#">Form of Stock Certificate.</a>		10-K	001-36754	2/26/2018
4.2	<a href="#">Letter Terminating Registrant's Fourth Amended and Restated Investors' Rights Agreement, dated as of January 17, 2018, by and between the Registrant and the investors listed therein.</a>		10-K	001-36754	2/26/2018
4.3	<a href="#">Form of Amended and Restated Warrant to Purchase Common Stock of the Registrant.</a>		S-4	333-221592	11/15/2017
4.4	<a href="#">Form of Voting Agreement.</a>		S-4	333-221592	11/15/2017
10.1Δ	<a href="#">Separation and Release Agreement, dated as of January 17, 2018, by and between the Registrant and Susan Knudson.</a>		8-K	001-36754-18546687	1/17/2018
10.2Δ	<a href="#">Separation and Release Agreement, dated as of January 29, 2018, by and between the Registrant and Maria Feldman.</a>		10-K	001-36754	2/26/2018
10.3Δ	<a href="#">Amended and Restated 2014 Equity Incentive Plan.</a>		8-K	001-36754-18815508	5/8/2018
10.4Δ	<a href="#">Amended and Restated Non-Employee Director Compensation Policy.</a>		10-K	001-36754	2/26/2018

[Table of Contents](#)

10.5Δ	<a href="#">Consulting Agreement, dated as of April 1, 2017, by and between Evofem Biosciences Operations, Inc. and Thomas Lynch.</a>	S-4	333-221592	11/15/2017
10.6Δ	<a href="#">Severance Agreement, dated as of November 16, 2015, by and between Evofem Biosciences Operations, Inc. and Justin J. File.</a>	S-4	333-221592	11/15/2017
10.7Δ	<a href="#">Severance Agreement, dated as of April 27, 2015, by and between Evofem Biosciences Operations, Inc. and Sandra Pelletier.</a>	S-4	333-221592	11/15/2017
10.8Δ	<a href="#">Offer Letter, dated as of April 15, 2015, by and between Evofem Biosciences Operations, Inc. and Kelly Culwell, M.D.</a>	S-4	333-221592	11/15/2017
10.9Δ	<a href="#">Offer Letter, dated as of October 16, 2014, by and between Evofem Biosciences Operations, Inc. and Sandra Pelletier.</a>	S-4	333-221592	11/15/2017
10.10Δ	<a href="#">Offer Letter, dated as of March 8, 2015, as amended, by and between Evofem Biosciences Operations, Inc. and Justin J. File.</a>	S-4	333-221592	11/15/2017
10.11Δ	<a href="#">Amended Offer Letter, dated as of November 16, 2015, by and between Evofem Biosciences Operations, Inc. and Justin J. File.</a>	S-4	333-221592	11/15/2017
10.12Δ	<a href="#">Evofem Biosciences Operations, Inc. Amended and Restated 2012 Equity Incentive Plan.</a>	S-4	333-221592	11/15/2017
10.13Δ	<a href="#">Form of Notice of Option Grant and Option Agreement under the Evofem Biosciences Operations, Inc. 2012 Equity Incentive Plan.</a>	S-4	333-221592	11/15/2017
10.14Δ	<a href="#">Form of Grant of Restricted Stock Award under the Evofem Biosciences Operations, Inc. 2012 Equity Incentive Plan.</a>	S-4	333-221592	11/15/2017
10.15Σ	<a href="#">Amended and Restated License Agreement, by and between Rush University Medical Center and Evofem, Inc. dated as of March 27, 2014.</a>	S-4	333-221592	11/15/2017
10.16	<a href="#">Consent to Sub-Sublease, dated as of January 30, 2015, by and among Evofem, Inc., Kilroy Realty, L.P., Relational Investors LLC and WomanCare Global Trading, Inc.</a>	S-4	333-221592	11/15/2017
10.17	<a href="#">Sublease Guaranty, dated as of January 30, 2015, by and between Evofem Biosciences Operations, Inc. and Relational Investors LLC.</a>	S-4	333-221592	11/15/2017
10.18	<a href="#">Office Sublease, dated as of January 30, 2015, by and between Evofem, Inc. and Relational Investors LLC.</a>	S-4	333-221592	11/15/2017
10.19	<a href="#">First Amendment to Sublease, dated as of February 22, 2017, by and between Evofem, Inc. and WomanCare Global Trading Inc.</a>	S-4	333-221592	11/15/2017
10.20	<a href="#">Sublease, dated as of January 30, 2015, by and between Evofem, Inc. and WomanCare Global Trading, Inc.</a>	S-4	333-221592	11/15/2017
10.21	<a href="#">Form of Registration Rights Agreement.</a>	8-K	001-36754-171139916	10/17/2017
16.1	<a href="#">Letter from Ernst &amp; Young LLP dated as of January 25, 2018.</a>	8-K	001-36754-18546687	1/25/2018
*31.1	<a href="#">Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxly Act of 2002</a>	X		
*31.2	<a href="#">Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxly Act of 2002</a>	X		
**32.1	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>	X		
*†101.INS	XBRL Instance Document	X		
*†101.SCH	XBRL Taxonomy Extension Schema Document	X		
*†101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X		

[Table of Contents](#)

*†101.DEF	XBRL Definition Linkbase Document	X
*†101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	X
*†101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X

\* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

\*Δ Management Compensation Plan or arrangement.

\*Σ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

These certifications are being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation by reference language in such filing.

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† The financial information of Evofem Biosciences, Inc. Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 filed on May 11, 2018 formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) Parenthetical Data to the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Operations, (iv) the Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit, (v) the Condensed Consolidated Statements of Cash Flows, and (vi) Notes to Unaudited Condensed Consolidated Financial Statements, is furnished electronically 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 hereunto duly authorized.

**EVOFEM BIOSCIENCES, INC.**

Date: May 11, 2018

By: /s/ Justin J. File

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Justin J. File

Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Sandra Pelletier, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Evofem Biosciences, Inc.;
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
-



**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Justin J. File, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Evofem Biosciences, Inc.;
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
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- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2018

By:

/s/ Justin J. File

Justin J. File

Chief Financial Officer

*(principal financial officer and principal  
accounting officer)*



