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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

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

EVOFEM BIOSCIENCES, INC.
(Exact name of Registrant as specified in its Charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**20-8527075** **(I.R.S. Employer Identification No.)**
7770 Regents Rd, Suite 113-618 **San Diego, CA** **(Address of principal executive offices)**	**92122** **(Zip Code)**

Registrant's telephone number, including area code: **(858) 550-1900**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	EVFM	OTCQB

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $1.9 million as of June 30, 2023, based upon the closing sale price on the OTCQB Venture Market reported for such date. Shares of common stock held by each executive officer and director and certain holders of more than 10% of the outstanding shares of the registrant's common stock have been excluded in that such persons may be deemed to be affiliates. Shares of common stock held by other persons, including certain other holders of more than 10% of the outstanding shares of common stock, have not been excluded in that such persons are not deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock outstanding as of March 21, 2024 was 45,939,509.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K (Annual Report), contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." All statements, other than statements of historical facts, contained in this Annual Report, including statements regarding our strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management, are forward-looking statements. Words such as, but not limited to, "anticipate," "aim," "believe," "contemplate," "continue," "could," "design," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "seek," "should," "suggest," "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.

These forward-looking statements include, among other things, statements about:

- our ability to continue as a going concern;
- the consummation of the transactions contemplated by the Merger Agreement and documents related thereto;
- our ability to remediate the material weaknesses in our internal controls and procedures identified by management;
- our ability to obtain necessary approvals of any corporate action needing stockholder, FINRA, or other approvals;
- our ability to file Annual and Quarterly Reports on a timely basis;
- our ability to raise additional capital to fund our operations;
- our ability to achieve and sustain profitability;
- our estimates regarding our future performance including, without limitation, any estimates of potential future revenues;
- estimates regarding market size;
- our estimates regarding expenses, revenues, financial performance and capital requirements, including the length of time our capital resources will sustain our operations;
- our ability to maintain the listing of our shares on the OTCQB® Venture Market;
- our ability to comply with the provisions and requirements of our debt arrangements, to avoid future defaults pursuant to our debt arrangements and to pay amounts owed, including any amounts that may be accelerated, pursuant to our debt arrangements;
- estimates regarding health care providers' (HCPs) recommendations of Phexxi® (lactic acid, citric acid, and potassium bitartrate) vaginal gel (Phexxi) to patients;
- the rate and degree of market acceptance of Phexxi®;
- our ability to successfully commercialize and distribute Phexxi® and continue to develop our sales and marketing capabilities, particularly after any product rebrand;
- our estimates regarding the effectiveness of our marketing campaigns;
- our strategic plans for our business, including the commercialization of Phexxi®;
- the potential for changes to current regulatory mandates requiring health insurance plans to cover U.S. Food and Drug Administration (FDA)-cleared or -approved contraceptive products without cost sharing;
- our ability to obtain or maintain third-party payer coverage and adequate reimbursement, and our reliance on the willingness of patients to pay out-of-pocket for Phexxi® absent full or partial third-party payer reimbursement;
- our ability to protect and defend our intellectual property position and our reliance on third party licensors;
- our ability to obtain additional patent protection for our product;
- our dependence on third parties for the manufacture of Phexxi®;
- our ability to expand our organization to accommodate potential growth; and
- our ability to retain and attract key personnel.

Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual 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. 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. All forward-looking statements are qualified in their entirety by this cautionary statement. Forward-looking statements should be regarded solely as our current plans, estimates and beliefs. You should read this Annual Report and the documents that we have filed as exhibits to this Annual Report and incorporated by reference herein completely and with the understanding that our actual results may be materially different from the plans, intentions and expectations disclosed in the forward-looking statements we make. Moreover, we operate in a very competitive and rapidly changing environment and 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. The forward-looking statements contained in this Annual Report are made as of the date of this Annual 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.

This Annual Report contains estimates and other statistical data made by independent parties and by the Company relating to market size and growth and other data about its industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

Our first commercial product, Phexxi, is approved by the FDA for marketing in the United States (US). Phexxi has not yet been approved by the European Medicines Agency (EMA) or any other regulatory authority anywhere else in the world except in Nigeria, where Phexxi was approved, on October 6, 2022, as Femidence™ by the National Agency for Food and Drug Administration and Control.

Unless the context requires otherwise, references in this Annual Report to "Evofem," "Company," "we," "us" and "our" refer to Evofem Biosciences, Inc. and its subsidiaries.

This Annual Report includes our trademarks, trade names and service marks, including "Phexxi®" and "Femidence™" which are protected under applicable intellectual property laws and are the property of Evofem Biosciences, Inc. or its subsidiaries. Solely for convenience, trademarks, trade names and service marks referred to in this Annual Report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any

way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply a relationship with, or endorsement or sponsorship of us by, these other parties.

PART I

Item 1. Business.

Overview

We are a San Diego-based commercial-stage biopharmaceutical company with a strong focus on innovation in women's sexual and reproductive health. Our first commercial product, Phexxi, was approved by the FDA on May 22, 2020. Phexxi is the first and only FDA-approved, hormone-free prescription contraceptive vaginal gel. It comes in a pre-filled applicator and is applied within one hour before intercourse, empowering women with a convenient, discreet, and flexible contraception method that puts control in their hands. We commercially launched Phexxi in September 2020 in the US and since then have reported increased net product sales for each successive year. We intend to commercialize Phexxi in all other global markets through partnerships or licensing agreements.

While our pipeline includes multiple candidates that are designed to address critical unmet needs in women's health, we halted all clinical development in October 2022 to focus resources on growing sales of Phexxi for the prevention of pregnancy.

Aditxt Merger

On December 11, 2023, the Company entered into an Agreement and Plan of Merger, as amended (the Merger Agreement) with Aditxt, Inc., a Delaware corporation (Aditxt), Adicure, Inc., a Delaware corporation, and a wholly-owned Subsidiary of Aditxt (Merger Sub), pursuant to which, and on the terms and subject to the conditions thereof, Merger Sub will merge with and into the Company, with the Company surviving as a wholly owned subsidiary of Aditxt (the Merger). The Merger is expected to be closed in the second half of 2024; the accompanying consolidated financial statements in this Annual Report do not reflect the potential impact of the Merger Agreement.

On January 10, 2024, the Company, Aditxt and Merger Sub entered into the first amendment to the Merger Agreement (the First Amendment), to change the filing date for the Joint Proxy Statement (as defined in the Merger Agreement) to February 14, 2024. On January 30, 2024, the Company, Parent and Merger Sub entered into the second amendment to the Merger Agreement (the Second Amendment) to amend (i) the date of the Parent Loan (as defined in the Merger Agreement) to the Company to be February 29, 2024, (ii) to change the date by which the Company may terminate the Merger Agreement for failure to receive the Loan from Parent to be February 29, 2024, and (iii) to change the filing date for the Joint Proxy Statement (as defined in the Merger Agreement) to April 1, 2024.

On February 29, 2024, the parties entered into the third amendment to the Merger Agreement to (i) amend and restate Section 6.10 in its entirety as follows: "Parent Equity Investment. On or prior to (a) April 1, 2024, Parent shall purchase 2,000 shares of the Company's Series F-1 Preferred Stock, par value $0.0001 per share (F-1 Preferred Shares) for an aggregate purchase price of $2.0 million (the Initial Parent Equity Investment) and (b) April 30, 2024, Parent shall purchase 1,500 shares of F-1 Preferred Shares for an aggregate purchase price of $1.5 million (the Subsequent Parent Equity Investment)," (ii) the proviso in Section 6.16 was deleted in its entirety, (iii) the date to file a Joint Proxy Statement was extended to April 30, 2024, (v) a new Section 7.2(i) was added as follows "(i) *Repurchase Price*. No defaults shall have occurred and be continuing under the Loan Documents and the Outstanding Balance (as defined in the Securities Purchase Agreement) plus all accrued and unpaid interest thereon, in an amount not to exceed the Repurchase Price (as defined in the Securities Purchase Agreement) shall have been paid in full." and (iv), Section 8.1(f) is amended and restated to allow for termination of the Merger Agreement by the Company if (a) the Initial Parent Equity Investment has not been made by April 1, 2024, or (b) the Subsequent Parent Equity Investment has not been made by April 30, 2024.

The foregoing numbers of shares of Series F-1 Preferred Shares shall be equitably adjusted for any stock split, reverse stock split, stock dividend (including any dividend or other distribution of securities convertible into F-1 Preferred Shares), subdivision, reorganization, reclassification, recapitalization, combination, exchange of shares or other like change with respect to the number of shares of F-1 Preferred Shares outstanding after the date hereof and prior to the Effective Time or any change to the Stated Value thereof as set forth in that certain Certificate of Designations of Series F-1 Convertible Preferred Stock of the Company.

As consideration for the Merger, the Parent will (i) issue 610,000 shares of Parent common stock (Parent Common Stock) (ii) exchange the Company's preferred stock for Parent preferred stock (Parent Preferred Stock and together with Parent Common Stock, the Merger Shares) (iii) execute an assignment agreement by and between Baker Brothers Life Sciences, L.P. and the Parent for the certain secured and unsecured promissory notes aggregately valued at $18.0 million. In addition, Parent has agreed to issue up to an aggregate of 89,126 shares of preferred stock to the holders of the Company's currently outstanding unsecured notes, purchase rights, certain warrants, and preferred stock. The closing issuance of Merger Shares may be adjusted pursuant to procedures set forth in the Merger Agreement, in connection with the finalization of exchange ratio of the Company and Parent shares.

Each stock option of the Company that was outstanding and unexercised immediately prior to the effective time of the Merger (the Effective Time) will be cancelled as of the Effective Time without the right to receive any consideration.

The Merger Agreement is subject to certain closing conditions and contains customary representations, warranties and covenants including, (i) the Company and Parent Shareholder approval shall have been obtained in accordance with applicable Law; (ii) no governmental entity having jurisdiction over any party shall have issue any order, decree, ruling injunction or other action that is in effect restraining the Merger; (iii) the registration statement on Form S-4 shall be declared effective by the U.S. Securities and Exchange Commission (SEC); (iv) a voting agreement shall have been executed and delivered by the parties thereto; (v) all Company preferred stock shall have been converted to Company common stock except for the Unconverted Company Preferred Stock (as defined by the Agreement); (vi) the Company shall have received agreements from all of the holders of the Company's warrants, duly executed, containing waivers with respect to any fundamental transaction, change in control or other similar rights that such warrant holders may have under any such Company warrants and exchange such Company warrants as they hold for an aggregate of not more than 551 shares of Parent Preferred Stock; (vii) the Company shall have cashed out any other warrant holder who has not provided a warrant holder agreement, provided, however, that the aggregate amount of such cash out for any and all other warrant holders who have not provided a warrant holder agreement shall not exceed $0.2 million; (viii) the Company shall have obtained waivers from holders of Company convertible notes of the original principal amount thereof with respect to any fundamental transaction rights such Company convertible note holders may have under any such Company convertible notes, including any right to vote, consent or otherwise approve or veto any of the transaction contemplated by this Merger Agreement; (ix) Parent shall have received a compliance certificate from the Company certifying Company complied with all its representations and warranties in the Merger Agreement; (x) Parent shall have received a certificate certifying that no interest in the Company is a U.S. real property interest, as required under U.S. treasury regulation section 1.897-2(h) and 1.1445-3(c); (xi) Company shall have received from Parent a compliance certificate certifying that Parent has complied with all its representations and warranties in the Merger Agreement, that Parent Common Stock included in the Merger Shares have been approved for listing on the Nasdaq, and Parent shall have regained compliance with the stockholders equity requirement in Nasdaq listing rule 5550(b)(1).

The Company will prepare and file a proxy statement with the SEC and, subject to certain exceptions, the Company's Board of Directors (the Board) will recommend that the Merger Agreement be adopted by the Company's stockholders at a special meeting of the Company's stockholders (the Company Board Recommendation). However, subject to the satisfaction of certain terms and conditions, the Company and the Board, as applicable, are permitted to take certain actions which may, as more fully described in the Merger Agreement, include changing the Company Board Recommendation and entering into a definitive agreement with respect to a Company Superior Proposal (as defined in the Merger Agreement) if the Board or any committee thereof determines in good faith, after consultation with the Company's outside legal and financial advisors and after taking into account relevant legal, financial, regulatory, estimated timing of consummation and other aspects of such proposal that the Board considers in good faith and the Person or group making such proposal, would, if consummated in accordance with its terms, result in a transaction more favorable to the Company Shareholders than the Merger. The Company would be required to pay the Parent a termination fee of $4.0 million in connection with the Company accepting a Company Superior Proposal.

In connection with the Merger Agreement Aditxt, the Company and the holders (the Holders) of certain senior indebtedness of Evofem (the Notes) entered into an Assignment Agreement dated December 11, 2023 (the December Assignment Agreement), pursuant to which the Holders assigned the Notes to Aditxt in consideration for the issuance by Aditxt of (i) an aggregate principal amount of $5.0 million in secured notes of Aditxt due on January 2, 2024 (the January 2024 Secured Notes), (ii) an aggregate principal amount of $8.0 million in secured notes of Aditxt due on September 30, 2024 (the September 2024 Secured Notes), (iii) an aggregate principal amount of $5.0 million in ten-year unsecured notes (the Unsecured Notes), and (iv) payment of $0.2 million in respect of net sales of Phexxi in respect of the calendar quarter ended September 30, 2023.

On February 26, 2024, Aditxt and the Baker Purchasers entered into an Assignment Agreement (the February Assignment Agreement), pursuant to which the Company consented to the assignment of all remaining amounts due under the Notes from Aditxt back to the Holders.

Our Leadership Team

We have assembled a world-class team with industry-recognized expertise in women's sexual and reproductive health.

The team is led by Saundra Pelletier, an expert in women's health from puberty to menopause. She has served as Chief Executive Officer, President and Executive Director of Evofem Biosciences since February 2015, and as interim Chair of the Board since November 2021. She has been responsible for the company's growth and evolution, led Evofem's transition to the public market in January 2018, and led multiple equity financing rounds which have raised over $500 million.

During her more than 25 years of experience in the pharmaceutical industry, Ms. Pelletier has launched pharmaceutical brands worldwide and expanded indications of female healthcare brands in multiple countries. Her experience includes a comprehensive range of women's healthcare products, cardiovascular drugs, pain management agents, sleep therapeutics and medical devices. She has had oversight and accountability for Sales, Marketing, Operations, Medical Affairs, Regulatory Affairs, Manufacturing, Customer Service, Business Development and Strategic Partnerships.

Our Chief Financial Officer, Ivy Zhang, is a trusted leader and a seasoned finance executive who is dedicated to advancing our mission of addressing the unmet sexual and reproductive health needs of women. She joined Evofem as Chief Financial Officer on April 13, 2023 and leads our finance organization and financial activities including financial planning and analysis, accounting, external audit, tax, controllership, and treasury functions. Ms. Zhang has more than 15 years of financial and accounting experience spanning diverse industries, including pharmaceuticals and medical devices. Most recently she was Vice President Corporate Controller of HUYABIO International. From March 2018 to November 2022, she held increasingly senior leadership roles in Evofem's finance team, ultimately serving as Controller. Earlier in her career, Ms. Zhang served in finance positions for more than two and a half years at SeaSpine Holdings Corporation (a public medical and therapeutic technology and device company) and approximately seven years at Ernst & Young LLP.

On March 20, 2023 and in connection with a Reduction in Workforce, our Board of Directors agreed to (i) eliminate the Chief Commercial Officer role effective March 17, 2023; and (ii) to reduce the Chief Executive Officer's salary by 20% in February 2023 and another 20% in March 2023, resulting in a total reduction of 30% as compared to her 2022 salary, as set forth in the "Executive Compensation" section. The Company may review, change or end the salary reduction at its discretion.

On April 5, 2023, our Board of Directors appointed Saundra Pelletier as Secretary and on April 13, 2023, Ms. Pelletier resigned as Secretary and the Board of Directors appointed Ivy Zhang.

Our Strategy

Key elements of our strategy include:

- ***Successfully commercialize Phexxi.*** Currently, our primary focus is the successful commercialization of Phexxi in the US. Outside the US, we intend to commercialize Phexxi through strategic partnerships or license agreements. We believe this approach will allow us to effectively deploy our capital to maximize the inherent value of Phexxi for the benefit of all stakeholders.

- ***Leverage our U.S. sales force through business development***. We intend to opportunistically acquire, in-license additional commercial or launch-ready products to enhance our offerings and complement our core competencies in women's health. In addition to increasing revenues, addition of other commercial assets would diversify our revenue stream. We may also defray sales force costs by promoting synergistic products for other companies on a fee-for-service basis.

Contraceptive Market Overview

US Contraceptive Market

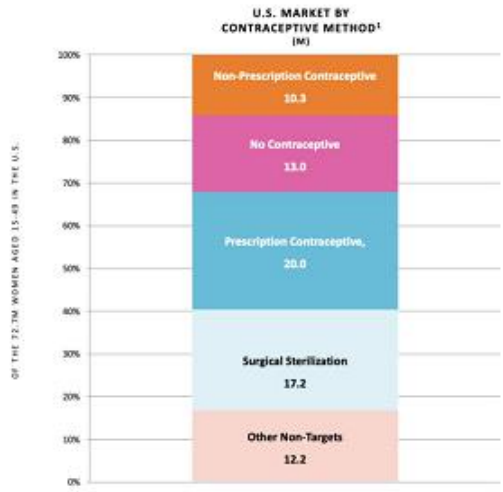
The US is the largest commercial market worldwide and presents the greatest opportunity for Phexxi and other women's health products. The total US contraceptive market was valued at $8.7 billion in 2023 and is expected to reach approximately $12 billion by 2030 with a compound annual growth rate of 4.7% (*source: Grand View Research, U.S. Contraceptive Market Size, Share & Trends Analysis Report By Product and Segment Forecasts, 2023 – 2030.*)

In the US, current contraceptive options include:

- devices designed to prevent pregnancy through physical means, such as condoms and diaphragms.
- hormone-based pharmaceutical products, including oral contraceptives (OCs), vaginal rings, transdermal patches, intramuscular injections, subcutaneous implants and intrauterine devices (IUDs). These can be associated with undesirable side effects such as weight gain, loss of libido and mood changes that may lead women to discontinue their use and seek alternative contraceptive methods. Further, a peer-reviewed analysis published in the journal *PLOS Medicine* in March 2023 found that the use of all kinds of hormonal birth control is associated with a slight increase in the risk of breast cancer.
- a hormone-free copper IUD; and
- Phexxi, a prescription vaginal pH modulator that was introduced to the market in September 2020.

The only non-hormonal option within the top five sales-generating segments in 2022 was the male condom, which is an over-the-counter (OTC) product. Besides condoms, the only currently available OTC contraceptive products in the US are nonoxynol-9 containing (N-9) spermicides. These surfactant-based products can potentially cause genital irritation and inflammation that may increase the risk of contracting human immunodeficiency virus (HIV) or other STIs from an infected partner. The FDA requires specific warnings to appear on all N-9 products that state: "this product does not protect against HIV/AIDS or other STDs and may increase the risk of getting HIV from an infected partner" as well as: "Do not use if you or your sex partner has HIV/AIDS. If you do not know if you or your sex partner is infected, choose another form of birth control method."

As shown in the chart below, in the US, of the 72.7 million women of reproductive age (15-49) in the US, 13.0 million women use no method of birth control, putting them at risk of unintended pregnancy. An additional 10.3 million women in the US rely on condoms or some other form of non-hormonal OTC birth control (e.g. rhythm, withdrawal). Another 20.0 million women in the US use prescription birth control methods; these are predominantly hormone-based with the sole exception of the copper IUD.



Source: Daniels-K-and-Abma-J.-Current-Contraceptive-Status-Among-Women-Aged-15-49_NCHS-Data-Brief-Number-388-October-2020.pdf (evofem.com)

An aggregate 23.3 million women who are currently at risk for pregnancy are not using hormone-based contraceptives as their primary form of contraception. Evofem expects that Phexxi will grow the prescription birth control market through adoption by women in these groups.

Market Opportunity: Contraception

Hundreds of millions of women worldwide seek sexual and reproductive health products that provide them with their self-defined control of their individual needs during their (on average) 30+ years of fertility. However, an estimated 257 million women who want to avoid pregnancy are not using safe, modern methods of contraception and nearly half of all pregnancies – 121 million each year - are unintended according to the United Nations 2022 State of World Population 2022 report.

According to the CDC, reducing the percentage of all unintended pregnancies has been one of the National Health Promotion Objectives since its establishment in 1980. Approximately two million unintended pregnancies occur in the US annually. 36%, or 1.97 million of the 5.51 million total pregnancies in the US, were unintended in 2019. (CDC National Center for Health Statistics (NCHS). *National Pregnancy Rate Estimates* released April 12, 2023).

Our Commercial Product: Phexxi

Phexxi vaginal gel is the only FDA-approved, hormone-free, on-demand, woman-controlled prescription contraceptive drug product available in the US. We believe Phexxi's attributes address significant gaps and underserved and unmet needs in the contraceptive market and make it an attractive contraceptive choice for women.

Phexxi key benefits:

- **Hormone-free:** Phexxi is an innovative gel that works to prevent pregnancy without the use of hormones. Because Phexxi is completely hormone-free, women are less likely to worry about the hormone-related side effects, like weight gain, mood swings, or blood clots which are associated with hormonal birth control methods.

- **Only when you need it:** With Phexxi, women no longer need to have birth control in their bodies 24/7. Phexxi is used in the moment, 0-60 minutes before each and every act of sex, so no daily commitment is required. This also makes Phexxi easily reversible, providing women with a flexible option for family planning.

- **First in class:** Phexxi is the first and only hormone-free prescription birth control gel that women control. Phexxi works to prevent pregnancy by maintaining the vaginal pH, which reduces sperm motility, and lowers the chance of sperm reaching the egg. This revolutionary mechanism of action is unique to Phexxi, meaning we know of no other products like it in the market.

- **Woman-controlled:** Phexxi puts women in control of their bodies and their pregnancy prevention. With Phexxi, there is no need to rely on a partner to bring a condom, to take a pill at the same time every day, and no need for an in-office injection or procedure to prevent pregnancy. The quick and easy pre-sex application is designed with spontaneity and convenience in mind.

Phexxi is designed to address underserved and unmet needs in the birth control market, as seen in the table below.

Prescription Contraceptive Products and Associated Benefits

Product Class	Non-Hormonal	No Systemic Side Effects	Non-invasive	Convenient
Vaginal pH Modulator (*i.e.*, Phexxi)	✔	✔	✔	✔
28 Day OCs			✔	
Extended Regimen OCs			✔	
Hormone Releasing IUDs				✔
Copper IUD	✔	✔		✔
Implant				✔
Vaginal Ring			✔	✔
Transdermal Patch			✔	

Vaginal pH Modulator Mechanism of Action

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.

Phexxi was developed to have acid-buffering (pH 3.5), lubricating and viscosity-retaining properties to provide effective acidification of the male ejaculate in the vagina. 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. The active ingredients in Phexxi produce a normal vaginal pH (3.5-4.5) even in the presence of semen, creating an inhospitable environment for sperm. The maintenance of the acidic vaginal pH reduces the availability of calcium ions which are needed to drive sperm tail movement. *In vitro* studies show immediate sperm motility reduction. Phexxi prevents pregnancy by reducing sperm motility, inhibiting sperm from reaching the ovum to form a zygote. Other properties contributing to Phexxi's mechanism of action are its capacity to maintain sufficient viscosity even upon dilution with the introduction of semen into the vagina, impede cervical mucus penetration by sperm, and form a protective layer over the vaginal and cervical epithelium.

Commercialization Strategy

Evofem's commercial operations are focused on the US, which is the largest commercial market worldwide and presents the greatest opportunity for Phexxi and other women's health products. Our strategy is to commercialize Phexxi and potentially other innovative women's health products in the US through our dedicated sales team, supported by a telehealth platform.

Outside of the US, we aim 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 Phexxi. We expect these third parties to be involved in the regulatory process in their respective markets as well as any clinical trials to support regulatory submissions, if required.

Commercialization of Phexxi in the US

The US is the largest commercial market worldwide and presents the greatest opportunity for Phexxi and other women's health products. Our sales force promotes Phexxi directly to obstetrician/gynecologists and their affiliated health professionals, who collectively write the majority of prescriptions for contraceptive products. As of March 21, 2024, our sales force consisted of 16 sales representatives, who have on average 16 years in the Pharma industry and 12 years in women's health. They are supported by three business managers as well as a self-guided virtual health care provider (HCP) learning platform. The sales team is geographically focused on territories with most favorable Phexxi coverage, targeting HCPs with an abundance of the Phexxi patient type.

Additionally, we offer women direct access to Phexxi through our telehealth partner. Using this platform, women can have a telehealth visit with an HCP to determine their eligibility for a Phexxi prescription and, if eligible, have the prescription written by the HCP, filled, and mailed directly to them by a third-party pharmacy.

Our commercial strategy for Phexxi includes targeting women of reproductive potential in the US, particularly the approximately 23 million women who are not using hormonal contraception and the approximately 20 million women who are using a prescription contraceptive, some of whom, particularly pill users, may be ready to move to an FDA-approved, non-invasive, hormone-free contraceptive. Additionally, we target certain identified target HCP segments.

Payer and Reimbursement Strategy: US

Pricing Strategy

Our pricing strategy for Phexxi was informed by extensive payer research including discussions with decision makers at major health plans and PBMs across the US who at the time controlled nearly 83 million commercial lives. Based on this gathered intelligence, we initially priced Phexxi at $267.50 per box of 12 applicators. The price for a box of 12 Phexxi applicators beginning January 1, 2024, is $348.24 which, when annualized, is comparable to all other commercially available branded contraceptives.

Phexxi is classified in the databases and pricing compendia of Medi-Span and First Databank, two major drug information databases that payers can consult for pricing and product information, as the first and only "vaginal pH modulator."

Third-party Payers

Market acceptance and sales of Phexxi depend, in part, on the extent to which reimbursement is available from third-party payers, which include government health administration authorities, managed care organizations, private health insurers and PBMs. Third-party payers decide which therapies they will pay for and establish reimbursement levels for those therapies. Decisions regarding the extent of coverage and amount of reimbursement to be provided for any product are 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 that drug.

Managed care organizations and other private insurers frequently adopt their own payment or reimbursement reductions. The continued integration between commercial health plans and PBMs has increased the negotiating power of these entities. Third-party payers increasingly employ formularies to control costs; they negotiate discounted prices in exchange for formulary inclusion. These formularies often do not include all products approved for any particular indication. We continue to work with health plans and PBMs to improve and secure additional formulary positioning for Phexxi.

In the second quarter of 2022, we successfully negotiated a contract with one of the largest PBMs in the nation, which added Phexxi to its formulary with no restrictions for most women covered by the plan. The agreement was retroactive and took effect January 1, 2022 and is representative of approximately 46 million lives. An additional 13.7 million lives are covered under our December 2020 contract award from the U.S. Department of Veterans Affairs.

We also participate in government programs including the 340B and the Medicaid Drug Rebate Program, which took effect January 1, 2021, and affords access to Phexxi for the U.S. Medicaid population. As of November 2023, Medicaid served approximately 86 million members; an estimated 14.9 million of these are women 19-44 years of age.

As of October 2023, Evofem had 73% coverage within its Commercial and Medicaid books of business, including 19.8 million lives covered at no out-of-pocket cost. Approximately 83% of commercial and Medicaid Phexxi prescriptions are being approved by payers. Furthermore, Phexxi co-pay card utilization has decreased 47% since Jan. 1, 2023, while claims have remained stable.

In 2022 and 2023, we gained 17.7 million unrestricted lives (people whose plans cover Phexxi with no PA required), a 5% increase in unrestricted coverage for Phexxi from January 2022 (47%) to November 2023 (53%).

Affordable Care Act

The Affordable Care Act (ACA) guarantees coverage of women's preventive services, including free birth control and contraceptive counseling, for all individuals and covered dependents with reproductive capacity. This includes all contraceptives approved, granted, or cleared by the FDA.

History

Under section 2713 of the Public Health Service (PHS) Act, group health plans and health insurers are required to cover preventive care and screenings under guidelines issued by the Health Resources and Services Administration (HRSA). PHS Act section 2713 took effect when added by the Affordable Care Act (ACA) in 2010.

HRSA guidelines issued in 2019 required broad coverage of contraceptive care and services for women. HRSA issued updated guidelines in late 2021, under which:

a. The full range of FDA- approved, -granted, or -cleared contraceptives, effective family planning practices, and sterilization procedures should be available as part of contraceptive care.

b. The full range of contraceptives includes those currently listed in the FDA's Birth Control Guide and any additional contraceptives approved, granted, or cleared by the FDA.

The current HRSA Women's Preventive Services Guidelines took effect on January 1, 2023, for calendar year plans.

Separately, on January 10, 2022, the U.S. Department of Health and Human Services (HHS), alongside the Departments of Labor and of the Treasury (the "Departments") issued updated guidance related to contraceptive access.

Under the Departments' FAQ Update:

a. Plans are required to cover an FDA- approved, cleared, or granted contraceptive, if a provider deems it medically necessary, at $0 cost share, whether or not it is specifically identified in the current FDA Birth Control Guide.

b. Plans may not require patients to try and fail multiple options within a method, or force trying and failing other methods, if a provider deems a product medically necessary.

The Departments also established clear communications channels for consumers with concerns about their plan's compliance with HSRA requirements.

Collectively, this new guidance specifies that most insurers and pharmacy benefit managers (PBMs) must provide coverage, with no out-of-pocket costs to women, for FDA-approved contraceptive products, like Phexxi® (lactic acid, citric acid and potassium bitartrate), prescribed by healthcare providers.

In July 2022 after the fall of Roe v. Wade and in the wake of action in many states to restrict access to emergency contraception, the Departments released further guidance regarding birth control coverage. Key points of this guidance include:

– Most private health plans and health insurance issuers must cover contraceptives at no additional cost to individuals under the Affordable Care Act no matter where they live or work.

– Violators of the preventive care coverage requirements may be subject to the $100 per person per day excise tax under section 4980D of the Internal Revenue Code or a civil monetary penalty under PHS Act section 2723.

– The Departments "will take enforcement action as warranted."

As of January 1, 2023, most insurers and pharmacy benefit managers (PBMs) must provide coverage, with no out-of-pocket costs (*e.g.* $0 copay) to the subscriber or dependent, for FDA-approved contraceptive products, like Phexxi, prescribed by healthcare providers.

As a result, to comply with these Guidelines, payers are increasingly covering Phexxi by:

- Adding Phexxi to formulary (commercial insurers) or preferred drug list (Medicaid)
- Removing the requirement for a Prior Authorization letter from the HCP (commercial insurers)
- Moving Phexxi to $0 copay (commercial insurers)

Birth Control Guide

The FDA's Birth Control Guide (the Guide) is used as an educational tool by many obstetrician/gynecologists to assist in counseling patients on their contraceptive options and to help them find the method that best suits their needs. It has not been undated since it was developed more than a decade ago and does not reflect subsequent changes to the contraceptive landscape including methods that were subsequently approved by the FDA, including the vaginal pH modulator (Phexxi). The updated HSRA Guidelines, while highly favorable to Phexxi, remove the impetus for the FDA to update the Guide.

The Guide was developed and is used as an educational tool by many obstetrician/gynecologists to assist in counseling patients on their contraceptive options and to help them find the method that best suits their needs. Methods not on the current, outdated Guide may be underrepresented in these contraceptive counseling dialogues. Evofem therefore believes the Guide should include all FDA-approved methods of birth control.

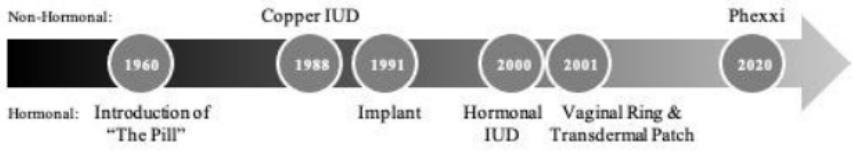
Further, even though the FDA Guide was intended as an educational tool, certain insurers have used it to block coverage of methods not included in the Guide. While this is explicitly prohibited by the current HSRA Guidelines, and there has been considerable progress since January 1, 2023, two notable plans continue to flout the law.

With the FDA not yet moving to update its Guide, in 2022 Evofem developed and introduced a new educational chart that provides high-level information about birth control methods that are currently available to women in the US, adding new categories including vaginal pH modulator.

This educational tool has been extremely well received and has had a positive impact with HCPs and patients alike.

Contraceptive Market Landscape

The modern contraception market was established in 1960 with the introduction of "the pill," the first oral contraceptive widely available to women in the US. Innovation and new product introductions in the women's reproductive and sexual health care arena have been limited when compared to other therapeutic categories. As shown in the timeline below, there was no notable innovation providing additional options in women's reproductive health until almost 30 years after the introduction of "the pill," when pharmaceutical companies introduced the non-hormonal copper IUD and synthetic hormonal products with different hormonal delivery systems, including the hormonal IUD, implants, the patch, and vaginal ring.



While several new contraceptive category entrants have been introduced in recent years, Evofem believes Phexxi is the first innovative contraceptive method introduced in the US since NuvaRing was approved by the FDA in 2001.

U.S. Market

In the US today, contraceptive options include:

- devices designed to prevent pregnancy through physical means, such as condoms and diaphragms.
- hormone-based pharmaceutical products, including oral contraceptives (OCs), vaginal rings, transdermal patches, intramuscular injections, subcutaneous implants and intrauterine devices (IUDs). These can be associated with undesirable side effects such as weight gain, loss of libido and mood changes that may lead women to discontinue their use and seek alternative contraceptive methods. Further, a peer-reviewed analysis published in the journal PLOS Medicine in March 2023 found that the use of all kinds of hormonal birth control is associated with a slight increase in the risk of breast cancer.
- a hormone-free copper IUD; and
- Phexxi, a prescription vaginal pH modulator that was introduced to the market in September 2020.

The only non-hormonal option within the top five sales-generating segments in 2022 was the male condom, which is an over-the-counter (OTC) product.

As shown in the "US Market by Contraceptive Method" chart above, of the 72.7 million women of reproductive age (15-49) in the US, 13.0 million women use no method of birth control, putting them at risk of unintended pregnancy. An additional 10.3 million women in the US rely on condoms or some other form of non-hormonal OTC birth control (e.g. rhythm, withdrawal). Another 20.0 million women in the US use prescription birth control methods, which are predominantly hormone-based with the sole exception of the copper IUD. Note: this study and its data predate the commercial availability of Phexxi.

An aggregate 23.3 million women who are currently at risk for pregnancy and are not using hormone-based contraceptives as their primary form of contraception. Evofem expects that Phexxi will grow the prescription birth control market through adoption by women in these groups.

As women's expectations change throughout their contraceptive journey, we expect Phexxi to compete for market share in at least three categories:

1. Hormonal short-acting reversible contraceptives consisting of oral contraceptive pills, patches, and rings;
2. Long-Acting Reversible Contraception, comprising IUDs, implants, and injectables; and
3. OTC methods, dominated primarily by the male condom.

1. Short-Acting, Reversible Hormonal Contraceptives (Prescription)

Oral contraceptives

Oral contraceptives (OCs), also known as the pill, are the most commonly used form of birth control in the US today. There are two main kinds of hormonal OCs: combination birth control pills, which contain both estrogen and progestin, and the progestin only pill. Use of either kind is associated with a slight increase in the risk of breast cancer. OCs typically must be taken at the same time every day to be the most effective.

Contraceptive Patch

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 health care and contraception as a promotional category. A new branded patch was launched in late 2020 under the brand name Twirla (Agile Therapeutics) and is competing against a generic entrant Xulane (Mylan).

Vaginal Ring

The hormonal vaginal ring was introduced to the market in 2001 by Merck & Co.; generic versions are now available. 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 of the vaginal ring is similar to hormonal oral contraception. A meta-analysis of 18 studies found that users of the vaginal ring reported more vaginal irritation and discharge than combination pill users, but less nausea, acne, irritability, depression, and emotional changes *(source: Lopez et al. Skin patch and vaginal ring versus combined oral contraceptives for contraception. Cochrane Database Syst Rev. 2013 Apr 30;2013(4):CD003552. doi: 10.1002/14651858.CD003552.pub4)*.

An annual hormonal vaginal ring was launched in the US in 2020 under the brand name Annovera (Mayne Pharma).

2. Long-Acting Reversible Contraception (Prescription)

Long-acting reversible contraception (LARC) is 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. LARC methods include the Intrauterine Device (IUD) and the Contraceptive Implant.
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. All IUDs must be inserted and removed by a physician.

Many women have opted against the IUD for 1) fear of a bad insertion experience; a peer-reviewed study published in 2015 found that "all women had a high expectation of pain prior to IUD insertion." *(source: Brima et al. A comparison of the expected and actual pain experienced by women during insertion of an intrauterine contraceptive device. Open Access J Contracept. 2015 Feb 16;6:21-26. doi: 10.2147/OAJC.S74624.)* and 2) concern over having something in them (i.e. a "foreign body effect"), which has been frequently demonstrated in medical literature. *(source: Ferguson et al. Patient Opinions About Foreign Body Contraceptives. Women's Health Rep (New Rochelle). 2020 Oct 8;1(1):451-458. doi: 10.1089/whr.2020.0048.*). Among women who opt-in to the insertion procedure, many decide to remove their IUD due to the hormonal and other side effects that they experience.

Implants

The contraception implant must be implanted under the skin and removed by a qualified HCP, requiring a medical procedure. It provides contraception by releasing hormones over a three-year period. The implant is marketed in the US as Nexplanon (Organon).

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 optimal contraceptive protection. Depo-Provera was introduced to the market in 1992.

3. ***OTC Methods (Non-prescription)***

As noted in the "US Market by Contraceptive Method" chart above, in the US, an estimated 10.3 million women rely on OTC products for their contraceptive needs.

Condoms are the dominant product offering in OTC sales, with estimated domestic sales of approximately $450 million in 2022 (Fortune Business Insights). Approximately 5.5 million women depend on condom use as their only method of birth control. The predominant brands are Trojan (Church & Dwight) and Durex (Reckitt Benckiser).

Besides condoms, the only currently available OTC contraceptive products in the US are nonoxynol-9 containing (N-9) spermicides, which are available in sponges, jelly/creams and foams, and have very limited utilization. These surfactant-based products can potentially cause genital irritation and inflammation that may increase the risk of contracting human immunodeficiency virus (HIV) or other STIs from an infected partner. The FDA requires specific warnings to appear on all N-9 products that state: "this product does not protect against HIV/AIDS or other STDs and may increase the risk of getting HIV from an infected partner" as well as: "Do not use if you or your sex partner has HIV/AIDS. If you do not know if you or your sex partner is infected, choose another form of birth control method."

4. ***Vaginal pH Modulator***

The first and only Vaginal pH Modulator - Phexxi - was launched by Evofem in 2020. Phexxi is a hormone-free, prescription contraceptive that women apply 0-60 minutes before intercourse. It is used on-demand, only when needed, and comes in a box of 12 pre-filled applicators.

Data on Phexxi is not reflected in the "US Market by Contraceptive Method" chart above, since the underlying study predates its commercial availability. New adopters of Phexxi are expected to come equally from each category discussed, as interest in Phexxi falls into three distinct segments: (1) those women who are not currently using hormone-based contraceptives; (2) those women seeking an alternative to hormonal contraception; and (3) those women who are expected to utilize Phexxi as added protection to their current form of birth control, including those who have been placed on drugs like GLP-1s and Paxlovid, which can reduce efficacy of hormonal birth control. Evofem's market research has indicated that the hormone-free, on-demand, woman-controlled aspect of Phexxi makes it an attractive option across the entire competitive set.

Ex-US Markets

According to the United Nations Department of Economic and Social Affairs, nearly 1.1 billion women worldwide desire contraception. This demand is reflected by the significant market growth projections for non-hormonal birth control; Growth Plus Reports forecasts global sales of non-hormonal contraceptives will increase from $27.7 billion in 2022 to $52.2 billion by 2031.

In markets outside of the US, 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 Phexxi in that market. We believe this approach will allow us to maximize the inherent value of Phexxi for the benefit of all stakeholders.

In October 2021, Evofem submitted the registration for its hormone-free contraceptive vaginal gel to the Mexican Regulatory Agency COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios) (COFEPRIS). It has also submitted marketing applications for Phexxi under the trademark Femidence™ in Nigeria, Ethiopia, and Ghana. These were the first of several strategic regulatory submissions planned under Evofem's 2020 Global Health Agreement with Adjuvant Capital. In October 2022, Phexxi was approved in Nigeria, where the product will be potentially marketed under the brand name Femidence™. This is the first regulatory approval for the contraceptive vaginal gel outside the U.S.

Manufacturing

We outsource the manufacturing of Phexxi to a third party. We are currently contracted with a gel manufacturer to manufacture Phexxi in accordance with all applicable current good manufacturing practices (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. As of December 31, 2023, we estimated that we had manufactured inventory on hand to support approximately six months of anticipated demand for Phexxi. Manufacturing is scheduled in 2024 to support further sales.

Our Pipeline

Evofem's pipeline includes multiple candidates that are designed to address critical unmet needs in women's health. The Company halted all clinical development in October 2022 due to financial constraints.

EVO100 for STI Prevention

EVO100 vaginal gel was in development for the prevention of urogenital chlamydia and gonorrhea in women. Chlamydia and gonorrhea are among the many bacterial and viral pathogens that require a higher pH environment to thrive. in 2018, the CDC reported that infections with these two sexually transmitted pathogens cost the U.S. healthcare system $1 billion, in aggregate direct and indirect costs. There are no FDA-approved drugs to prevent these sexually transmitted diseases (STIs), and there is a clear need for new prophylactics given the rising incidence and increasing antibiotic resistance of gonorrhea. The FDA granted Fast Track Designation to EVO100 for the prevention of both chlamydia and gonorrhea, and designated EVO100 a Qualified Infectious Disease Product (QIDP) or the prevention of urogenital chlamydia infection in women and the prevention of urogenital gonorrhea infection in women.

The Phase 2B/3 trial (*AMPREVENCE*) achieved its primary and secondary endpoints, demonstrating statistically significant reductions in chlamydia and gonorrhea infections of 50% and 78%, respectively, in women receiving EVO100 vs. placebo. Based on these highly positive clinical outcomes we initiated a Phase 3 clinical trial (*EVOGUARD*) to evaluate EVO100 for these potential indications in 2020. On October 11, 2022, we reported that *EVOGUARD* did not meet its primary efficacy endpoint.

EVO200 Vaginal Gel for Recurrent Bacterial Vaginosis

Our investigational candidate for the reduction of recurrent bacterial vaginosis (BV), EVO200 vaginal gel, uses the same proprietary vaginal pH modulator platform as Phexxi. In a Phase 1 dose-finding trial for this indication, the highest dose formulation of the study drug demonstrated reduced vaginal pH for up to seven days following a single administration. The FDA has designed EVO200 as a Qualified Infectious Disease Product (QIDP) for this indication, which provides several important potential advantages including, but not limited to, longer market exclusivity.

MPT Vaginal Gel for HIV Prevention

In December 2021, we launched a collaboration with Orion Biotechnology Canada Ltd. (Orion) to evaluate the compatibility and stability of Orion's novel CCR5 antagonist, OB-002, in Phexxi with the goal of developing a Multipurpose Prevention Technology (MPT) product candidate for indications including the prevention of HIV in women. Assuming positive preclinical results, Evofem and Orion may seek government and philanthropic funding for subsequent clinical trials of any resulting MPT vaginal gel product candidate.

Thin Film Project

In February 2020, we contracted with the University of South Australia to develop a vaginally applied thin film as a second-generation vaginal pH modulator product. The target indications of the thin film are the prevention of pregnancy, chlamydia, and gonorrhea in women. The lead thin film candidates have been selected, and stability data has been generated with positive results. Next steps are to optimize the lead candidates and select the appropriate packaging for long-term storage.

Rush License Agreement

In 2014, we entered into an amended and restated license agreement with Rush University (the Rush License Agreement) pursuant to which Rush University granted us an exclusive, worldwide license of certain patents and know-how related to our multipurpose vaginal pH modulator technology (the Rush License IP) 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 birth control. Pursuant to the Rush License Agreement, we are obligated to pay quarterly royalty payments in amounts equal to a single-digit percentage of the gross amounts we receive on a quarterly basis less certain deductions incurred in the quarter based on a sliding scale. We are also obligated to pay a minimum annual royalty amount of $0.1 million to the extent these earned royalties do not equal or exceed $0.1 million in a given year. The royalty costs for the year ended December 31, 2023 were $0.7 million.

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). 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. Rush University retained a royalty free, non-exclusive license from us for the Rush License IP for non-commercial research purposes.

The Rush License Agreement contains additional customary representations and warranties, covenants, indemnification and insurance and confidentiality provisions for agreements of its type. 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 this breach within 30 days after receiving written notice of the breach or default.

Unless terminated in accordance with its terms, 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, including any patent claiming an improvement made during the term of the Rush License Agreement in the course of research supported or developed by Rush University utilizing the technology.

Intellectual Property

We strive to protect the proprietary vaginal pH modulator gel technology both internationally and domestically. We seek and maintain patents intended to cover Phexxi and its methods of use, as well as any other inventions that are commercially important to the development of our business. We endeavor to properly file patent applications for new inventions we believe may have commercial value. 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, in part: to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; to defend and enforce our patents and other intellectual property rights; and to 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 21, 2024, we owned or had exclusive license to approximately 47 issued patents and allowed applications in the US and other countries and jurisdictions, and had approximately 16 patent applications pending in the US and other countries and jurisdictions. This includes four U.S. patents which cover Phexxi and its labeled indication that are listed in the U.S. FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book):

- U.S. Patent No. 11,337,989: Method of use patent covering contraception using Phexxi;
- U.S. Patent No. 11,439,610: Composition of matter patent covering Phexxi;
- U.S. Patent No. 10,568,855: Method of use patent covering contraception using Phexxi; and,
- U.S. Patent No. 6,706,276: Composition of matter patent covering Phexxi.

We solely own several patent application families relating to the composition and therapeutic use of our vaginal pH modulator gel, which, upon issue, would expire at the earliest in 2033. We also have the Rush License IP, which provides general protection for our vaginal pH modulator platform. Our Rush License IP could be eligible for regulatory extensions to 2026 in the US and in certain European jurisdictions, if granted by those regulatory bodies. Rush University has submitted a patent term extension (PTE) application requesting a five-year PTE for the U.S. patent and has received multiple Orders Granting Interim Extension (OGIE), which have extended the expiration of the U.S. patent to March 2025. We believe that our licensed and solely owned non-hormonal birth control gel patents and pending patent applications, 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 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 Phexxi 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, through 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 these incidents. 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, Phexxi and Femidence. All of our logos and trademarks appearing in this Annual Report are the property of Evofem Biosciences, Inc. All other third-party trademarks appearing in this Annual Report are the property of their respective holders. Our use or display of other parties' trademarks, trade dress, or products in this Annual Report is not intended to, and does not, imply a relationship with, or endorsement or sponsorship of us, by the trademark, trade dress, or product owner.

Government Regulation and Product Approval

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 US and other countries. The processes for obtaining regulatory approvals in the US and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory requirements, require the expenditure of substantial time and financial resources.

In the US, the FDA regulates drugs and other medical products under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. Failure to comply with the applicable US requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending New Drug Applications (NDAs), warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

Post-Approval Requirements in the US

Following approval of a new product or indication, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, and complying with promotion and advertising requirements, which include restrictions on promoting approved drugs for unapproved uses or patient populations (known as "off-label use"). Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA. Prescription drug promotional materials also must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the approved drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies or clinical trials.

Any limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur while the product is on the market.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for Phexxi must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities' satisfaction before it is approved and can be manufactured. Evofem relies, and expects to continue to rely, on third parties for the production of clinical and commercial quantities of Phexxi in accordance with cGMPs. These manufacturers must also comply with cGMPs that require, among other things, quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or combination products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including recall.

After approval of a drug is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information, or imposition of additional post-market surveillance or clinical trials to assess new safety risks. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on investigational or post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (PDMA), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. In 2013, the Drug Supply Chain Security Act (DSCSA) was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the US, including most biological products. The DSCSA mandates phased-in resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period. By November 27, 2024, all authorized trading

partners, including dispensers and manufacturers, will be required to incorporate serial numbers into their DSCSA processes, providing enhanced unit-level tracking.

From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations will be changed or what the impact of such changes, if any, may be.

Hatch-Waxman Act and Marketing Exclusivity

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments) to the Federal Food, Drug, and Cosmetic Act (FDCA), Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute and also enacted Section 505(b)(2) of the FDCA. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application (ANDA), to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug (RLD). Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. In contrast, 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. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. The FDA may then approve the new product for all or some of the label indications for which the RLD has been approved, or for any new indication sought by the Section 505(b)(2) applicant, as applicable.

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. The Orange Book listing for the Phexxi vaginal gel NDA includes two patents covering the product's composition of matter and its method of use in prevention of pregnancy. Except for patents covering methods of use for which the follow-on applicant is not seeking approval, the applicant is required to certify to the FDA concerning any patents listed in the Orange Book for the RLD, when an ANDA applicant submits its application to the FDA. To the extent the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, such an applicant is also required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, an ANDA or 505(b)(2) applicant for a follow-on drug product with respect to each patent must certify that: (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, unenforceable 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 ANDA or 505(b)(2) application.

A certification that the new product will not infringe the RLD's listed patents or that such patents are invalid is called a Paragraph IV certification. If the follow-on 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 RLD 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 ANDA or 505(b)(2) NDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the follow-on applicant's ANDA or 505(b)(2) NDA will not be subject to the 30-month stay.

In addition, under the Hatch-Waxman Amendments, the FDA may not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the referenced RLD has expired. These market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the US to the first applicant to gain approval of an NDA for a drug containing a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for a NDA, 505(b)(2) NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications for drugs containing the original active agent. Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. The three-year new product exclusivity for the Phexxi NDA expired on May 22, 2023. The product's intellectual property also includes four U.S. patents which cover Phexxi and its labeled indication that are listed in the U.S. FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book); these patents are expected to protect Phexxi into 2033.

Designation of and Exclusivity for Qualified Infectious Disease Products

In 2012 as part of the Food Drug Administration Safety and Innovation Act, Congress passed legislation known as the Generating Antibiotic Incentives Now Act (GAIN Act), which amended the FDCA to encourage the development of antibacterial and antifungal drug products that treat pathogens that cause serious and life-threatening infections. The law grants an additional five years of marketing exclusivity upon the approval of an NDA for a drug product previously designated by FDA as a QIDP. As a result, if applicable to a designated QIDP, upon approval the periods of five-year new chemical entity exclusivity and three-year new clinical investigation exclusivity would become ten years and eight years, respectively.

A QIDP is defined in the GAIN Act to mean "an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by: (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens;" or (2) certain "qualifying pathogens." A "qualifying pathogen" is a pathogen that has the potential to pose a serious threat to public health (e.g., resistant gram positive pathogens, multi-drug resistant gram negative bacteria, multi-drug resistant tuberculosis and *Clostridium difficile*) and that is included in a list established and maintained by FDA. A drug sponsor may request FDA to designate its product as a QIDP any time before the submission of an NDA for that indication. FDA must make a QIDP determination within 60 days of the designation request. A product designated as a QIDP may be granted priority review by FDA upon submission and can also qualify for "Fast Track" status, described further below. We have received two QIDP designations from the FDA for EVO100 for the prevention of urogenital infection in women with both chlamydia and gonorrhea and one for EVO200 for BV.

Fast Track and Priority Review Designations

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include Fast Track designation and priority review designation.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast Track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA for a Fast Track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the NDA. Fast Track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging in the clinical trial process. A product candidate designated as a QIDP is eligible for Fast Track designation under the provisions of the GAIN Act, but the NDA sponsor must specifically request Fast Track designation from the agency as with non-infectious disease product candidates. Fast Track designation may be requested concurrent with or at any time after the QIDP designation. In addition, although QIDP designation may be requested prior to submission of an Investigational New Drug Application (IND), a request for Fast Track designation may only be made concurrently with, or any time after, submission of an IND.

The FDA also may designate a product for priority review if it is a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case- by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for acting on a marketing application from ten months to six months for an original new molecular entity NDA from the date of filing. Although the FDA automatically gives priority review designation to the first application submitted for a specific drug product and indication for which a QIDP designation was granted, a subsequent application from the same sponsor for the same product and indication will receive priority review designation only if it otherwise meets the criteria for priority review.

Finally, even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, Fast Track designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

We have received two Fast Track designations from the FDA for EVO100 for the prevention of urogenital chlamydia and gonorrhea infection in women.

Patent Term Restoration in the US

Depending upon the timing, duration and specifics of FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited PTE under other provisions of the Hatch-Waxman Amendments. These PTEs permit a patent restoration term of up to five years as compensation for any patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The US Patent and Trademark Office (USPTO) in consultation with the FDA, reviews and approves the application for any PTE or restoration.

Other US Governmental Regulations and Environmental Matters

If we establish international operations, we will be subject to compliance with the US Foreign Corrupt Practices Act of 1977, as amended (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.

Importantly, US authorities that enforce the FCPA, including the Department of Justice, deem most health care professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public health care or public education systems to be "foreign officials" under the FCPA. If and when we interact with foreign health care professionals and researchers in testing and marketing our products abroad, we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection with marketing our products and services or securing required permits and approvals such as those needed to initiate clinical trials in foreign jurisdictions. The FCPA also obligates companies whose securities are listed in the US to comply with accounting provisions requiring the maintenance of books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and the development and maintenance of an adequate system of internal accounting controls for international operations.

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

In addition to regulations in the US, we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and future commercial sales and distribution of our products, if approved in those markets.

We must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of a product in those countries. Moreover, the time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

As of January 31, 2020, the United Kingdom (UK) is no longer a member state of the European Union (EU), and therefore a separate marketing authorization application (MAA) and approval will be required to market a medicinal product in the UK.

We are assessing the optimal regulatory legal basis for the Phexxi MAA in the EU and the UK. As in the US, medicinal products can be marketed in the EU only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the US, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

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. In April 2014, the new Clinical Trials Regulation, Regulation EU No 536/2014 (Clinical Trials Regulation) was adopted and it came into application on January 31, 2022. The Clinical Trials Regulation will be directly applicable in all the EU member states, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable, the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single entry point; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU member states in which an application for authorization of a clinical trial has been submitted. Part II is assessed separately by each EU member state concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU member state. However, overall related timelines will be defined by the Clinical Trials Regulation.

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 (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) 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. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use (CHMP). Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding stop-clocks.

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 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. A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause). Even if authorized to be marketed in the EU, prescription-only medicines may only be promoted to health care 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 (among 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 drug product, seizure of promotional materials, fines and possible imprisonment.

EU Regulatory Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Rest of the World Regulation

For other countries outside of the EU and the US, such as countries in Eastern Europe, Latin America, Asia, or Africa, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Other U.S. Health Care Laws and Regulations

We must comply with various U.S. federal and state laws, rules and regulations pertaining to health care fraud and abuse, including anti-kickback laws. HCPs and third-party payers play a primary role in the recommendation and prescription of drug products and medical devices. Our current and future arrangements with health care professionals, principal investigators, consultants, third-party payers and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations. Such restrictions under applicable federal and state health care 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 health care 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 federal False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from 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 health care benefit program or making any false statements relating to health care 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 its 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 HCPs, health plans, and health care 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 Statutes prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement to the federal government, including executive or administrative agencies.

Sunshine Act – the federal transparency or "sunshine" requirements of 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, teaching hospitals and certain advanced non-physician health care practitioners, as well as ownership and investment interests held by physicians and their immediate family members.

State Transparency Laws – some U.S. 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 HCPs and other HCPs 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 HCPs or marketing expenditures and pricing information; and some state and local laws 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 health care 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 and may conflict, while applying simultaneously with HIPAA, thus complicating compliance efforts.

The scope and enforcement of these laws is uncertain and subject to rapid change. Notably, in November 2020, DHHS finalized significant changes to the regulations implementing the Anti-Kickback Statute, as well as the civil monetary penalty rules regarding beneficiary inducements, with the goal of offering the health care industry more flexibility and reducing the regulatory burden associated with those fraud and abuse laws, particularly with respect to value-based arrangements among industry participants. Regulatory authorities might challenge our current or future activities under these laws, regulations, and safe harbors. 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 health care 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.

Health Care Reform and Potential Changes to Laws and Regulations

In the US and some foreign jurisdictions, there have been, and continue to be, legislative and regulatory changes both enacted and proposed related to the health care system, which could prevent or delay marketing approval of Phexxi, restrict or regulate post-approval activities, and affect our ability to profitably sell Phexxi or any other approved product we may seek to commercialize. In particular, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted. For example, in December 2016, the 21st Century Cures Act (Cures Act), was passed by Congress and signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and devices and to spur innovation, but its ultimate implementation is uncertain. In addition, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA's user fee programs and included additional drug and device provisions that build on the Cures Act. A subsequent FDA reauthorization package was finalized by Congress on September 30, 2022, and several other FDA-related changes are being proposed in Congress, including several within a "Cures 2.0" bill that is likely to have bipartisan support. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition, and results of operations.

Among policy makers and payers in the US and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access. In the US, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; and established a Center for Medicare Innovation at the U.S. Centers for Medicare and Medicaid Services (CMS) to test innovative payment and service delivery models to lower Medicare and Medicaid spending. As another example, the 2021 Consolidated Appropriations Act, signed into law on December 27, 2020, incorporated extensive health care provisions and amendments to existing laws, including a requirement that all manufacturers of drug products covered under Medicare Part B report the product's average sales price (ASP) to DHHS beginning on January 1, 2022, subject to enforcement via civil money penalties.

Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA, and as a result certain sections of the ACA have not been fully implemented or effectively repealed. However, following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA's constitutionality. Further legislative and regulatory changes under the ACA remain possible, although the new federal administration under President Biden has signaled that it plans to build on the ACA and expand the number of people who are eligible for health insurance subsidies under it. It is unknown what form any such changes or any law would take, and how or whether it may affect the pharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, such as changes allowing the federal government to directly negotiate drug prices, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the US.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030 unless additional congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), which was signed into law on March 27, 2020, and was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. The suspension was subsequently extended through March 31, 2022, with a reduction of the suspension to 1% sequester through June 30, 2022. The suspension was lifted in steps during 2022 and for 2023, the 2% sequester rate established on July 1, 2022 was in effect for the entire year.

As another example, on December 20, 2019, the Further Consolidated Appropriations Act for 2020 was signed into law (P.L. 116-94), which includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (the CREATES Act). The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic product developers will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown. Other new laws may result in additional reductions in Medicare and other health care funding, which could have an adverse effect on customers for our approved product and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the US of manufacturers' 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. DHHS has solicited feedback on various measures intended to lower drug prices and reduce the out-of-pocket costs of drugs and has implemented others under its existing authority. For example, in 2020, the FDA finalized a rulemaking to establish a system whereby state governmental entities could lawfully import and distribute prescription drugs sourced from Canada. More recently, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and health care insurance industries. Among other things, the executive order directs the FDA to work towards implementing a system for importing drugs from Canada (following on the Trump administration notice-and-comment rulemaking on Canadian drug importation that was finalized in October 2020). The Biden order also called on DHHS to release a comprehensive plan to combat high prescription drug prices, and it includes several directives regarding the Federal Trade Commission's oversight of potentially anticompetitive practices within the pharmaceutical industry. The drug pricing plan released by DHHS in September 2021 in response to the executive order makes clear that the Biden Administration supports aggressive action to address rising drug prices, including allowing DHHS to negotiate the cost of Medicare Part B and D drugs, but such significant changes will require either new legislation to be passed by Congress or time-consuming administrative actions.

Coverage, Pricing, and Reimbursement

Sales of Evofem's products approved for marketing by the FDA and foreign regulatory authorities depend, in part, on the extent to which such products will be covered by third-party payers, such as government health programs, commercial insurance and managed care organizations. In the US, no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of Evofem's FDA-approved products will be made on a payer-by-payer basis. Prescriptions generated through the Phexxi telehealth platform may be subject to additional payer requirements. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our approved products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the DHHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price (AMP), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Congress has expressed its intention to repeal or repeal and replace the ACA. If that is done, many if not all of the provisions of the ACA may no longer apply to prescription drugs.

The marketability of any products for which Evofem has or will receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the US has increased, and Evofem expects will continue to increase, the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of Phexxi to currently available therapies (so called health technology assessment) in order to obtain reimbursement or pricing approval. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of Evofem's approved drug products. Historically, products launched in the EU do not follow price structures of the US and generally prices tend to be significantly lower.

Corporate Information

Effective April 1, 2023, our corporate headquarters are located at 7770 Regents Rd, Suite 113-618, San Diego, CA 92122-1967, and our telephone number is (858) 550-1900. Our website is located at www.evofem.com. Our Annual Report, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act) will be made available free of charge on our website as soon as reasonably practicable after we electronically file these materials with, or furnish it to, the Securities and Exchange Commission (SEC) on their website located at www.sec.gov. The contents of our website are not incorporated into this Annual Report, and our reference to the URL for our website is intended to be an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of this Annual Report.

Employees

As of March 21, 2024, we had a total of 37 full-time employees and one part-time employee. We also engage consultants and contract workers on an as-needed basis. We believe that relations with our employees and consultants are good.

Item 1A. Risk Factors.

Summary of Risk Factors

The risk factors described below are a summary of the principal risk factors associated with an investment in Evofem. These are not the only risks we face. You should carefully consider the following risk factors, together with all other information included in this Annual report, including the consolidated financial statements and related notes, when deciding to invest in us. You should be aware that the occurrence of any of the events described in this Risk Factors section and elsewhere in this Annual Report could have a material adverse effect on our business, financial position, results of operations and cash flows and the trading price of our securities could decline and you could lose all or part of your investment.

Risks Related to Our Financial Condition and Capital Requirements

- We are currently over 90 days past due on a significant amount of vendor obligations. We may not be able to refinance, extend or repay our substantial indebtedness owed to our secured and unsecured lenders, which would have a material adverse effect on our financial condition and ability to continue as a going concern.
- We have incurred significant losses and negative cash flows since our inception and anticipate we will continue to incur significant losses and negative cash flow for the foreseeable future.
- We must raise significant additional funds to finance our operations and to remain a going concern. If we are unable to raise additional capital when needed or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our business initiatives.
- We have a limited number of shares of common stock available for future issuance which could adversely affect our ability to raise capital or consummate strategic transactions.

Risks Related to the Aditxt Merger

- Failure to complete the merger could negatively impact our stock price and the future business and financial results of the Company.
- We may not be able to effect the merger pursuant to the Merger Agreement and we could incur substantial costs.
- While the Merger Agreement is in effect, we are subject to certain interim covenants.
- The announcement and pendency of the merger could cause disruptions in our business, which could have an adverse effect on our business and financial results.
- Certain provisions of the Merger Agreement may discourage third parties from submitting alternative acquisition proposals.
- We may be subject to litigation relating to the Merger.

Risks Related to Potential Bankruptcy

- We are subject to risks and uncertainties associated with potential bankruptcy proceedings including a long and protracted restructuring.

Risks Related to Commercialization and sales expansion of Phexxi

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

Risks Related to Regulatory Approval of Phexxi

- We may fail to receive approval to market Phexxi outside the US.
- We have not paid our Fiscal Years 2023 or 2024 PDUFA Invoice for Phexxi to the FDA. We cannot submit any new applications or supplements subject to fees until paid but have arranged a payment plan to settle these balances.

Risks Related to Our Post-Marketing Legal and Regulatory Compliance

- Developments after a product reaches the market may adversely affect sales of the product.
- Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of Phexxi.
- The FDA and other regulatory agencies actively enforce the laws and regulations relating to the promotion of our products.

Risks Related to Our Intellectual Property

- Our rights to develop and commercialize Phexxi are subject, in part, to the terms and conditions of licenses granted to us by third parties. The patent protection and patent prosecution of Phexxi is dependent on third parties.
- If we are unable to obtain and maintain patent protection for Phexxi, 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 Phexxi may be adversely affected.
- We may not be able to protect our intellectual property and proprietary rights throughout the world.
- If we do not obtain patent term extensions (PTE) for Phexxi, our business may be materially harmed.
- The patent protection and patent prosecution for Phexxi are dependent on third parties.
- If an event of default occurs under our issued and outstanding secured notes issued pursuant to the Baker Bros. Purchase Agreement the note holders could take possession of all assets owned by us, including any directly owned intellectual property.

Risks Related to Our Reliance on Third Parties

- Our success relies on third-party suppliers and one contract manufacturer.
- We have no significant internal distribution capabilities.

Risks Related to Our Commercialization of Health Care Products

- Changes in health care 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 Phexxi.
- Health care legislative reform measures may have a negative impact on our business and results of operations.

Risks Related to Our Common and Preferred Stock

- Our management has identified material weakness in our internal controls and procedures.
- Our stock price is and may continue to be volatile.
- There may not be an active, liquid trading market for our equity securities.
- Because our Common Stock is subject to the "penny stock" rules, brokers cannot generally solicit the purchase of our Common Stock, which adversely affects its liquidity and market price.
- We may not obtain shareholder approval to approve an increase in the authorized, reverse split or other corporate action relating to the common stock when and if needed.
- Our common stock could be further diluted as the result of the issuance of additional shares of common stock, convertible securities, warrants or options.
- We are and may continue to be subject to short-selling strategies.
- Our business could be negatively affected as a result of the actions of activist stockholders.
- We may become a defendant in one or more stockholder derivative or class-action litigation(s), and any such future lawsuit(s) may adversely affect our business, financial condition, results of operations and cash flows.

Risks Related to Our Financial Condition and Capital Requirements

We are currently over 90 days past due on a significant amount of vendor obligations. We may not be able to refinance, extend or repay our substantial indebtedness owed to our secured and unsecured lenders, which would have a material adverse effect on our financial condition and ability to continue as a going concern.

As of February 29, 2024, we have approximately $17.5 million in accounts payable with approximately $15.6 million that is over 90 days past due. If we are unable to repay these amounts, as well as our existing debt obligations at maturity, and we are otherwise unable to extend the maturity dates or refinance these obligations, we would be in default. We cannot provide any assurances that we will be able to raise the necessary amount of capital to repay these obligations or that we will be able to extend the maturity dates or otherwise refinance these obligations. Upon a default, our secured lenders would have the right to exercise their rights and remedies to collect, which would include foreclosing on our assets. Accordingly, a default would have a material adverse effect on our business, and we would likely be forced to seek bankruptcy protection.

Our audited consolidated financial statements included a statement that there is a substantial doubt about our ability to continue as a going concern and a continuation of negative financial trends could result in our inability to continue as a going concern.

Our management has determined that there is substantial doubt about our ability to continue as a going concern over the next 12 months from the filing date of March 27, 2024. Our independent auditors have included a "going concern" explanatory paragraph in their report on our consolidated financial statements as of and for the year ended December 31, 2023 as filed in this Annual Report on Form 10-K. The reaction of investors to the inclusion of a going concern statement by our independent auditors, and our potential inability to continue as a going concern, could materially adversely affect the price of our common stock.

Additionally, if our operating results fail to improve we could violate additional debt covenants, our liquidity could be further adversely impacted and we may need to seek additional sources of funding. There is no assurance that we will be able to raise additional capital to fund our operations or that debt or equity financing will be available in sufficient amounts or on acceptable terms. If our operating results fail to improve, then our financial condition could render us unable to continue as a going concern.

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

We have incurred yearly losses and negative cash flows since our inception, other than the net income of $53.0 million (excluding deemed dividends) for the year ended December 31, 2023, which was primarily attributable to a non-cash gain on debt extinguishment. As of December 31, 2023, we had an accumulated deficit of $888.7 million. Negative cash flows from our operations are expected to continue for the foreseeable future. To date, we have devoted substantially all our financial resources to the development and commercialization of Phexxi for hormone-free contraception and to the development of EVO100 for the prevention of chlamydia and gonorrhea and our other product candidates, as well as providing general and administrative support for our operations. Our utilization of cash has historically been highly dependent on these development programs and the commercialization of Phexxi in the US. In October 2022, we discontinued development of EVO100 and have no plans to advance clinical development of this program or to significantly invest in other clinical programs or product candidates for the foreseeable future. We plan to allocate capital to fund our continued commercialization efforts. Our cash expenses will also continue to be dependent on the terms and conditions of our contracts with service providers and any license partners.

To date, we have financed our operations primarily through the sale of equity securities, notes, warrants, convertible notes, convertible preferred stock and through other debt arrangements. The amount of our future net losses will depend, in large part, on our ability to generate revenue from the sale of Phexxi, the rate of our future expenditures and our ability to obtain additional funding through equity or debt financings, strategic collaborations or grants which may be particularly challenging or impossible in light of market conditions. The commercialization and development of biopharmaceutical products involves a substantial degree of risk.

We expect to continue to incur significant operating expenses and to continue to incur significant losses for the foreseeable future as we:

- incur sales, marketing, and distribution costs to commercialize Phexxi;
- incur costs associated with the commercial manufacturing of Phexxi;
- implement post-approval changes and process improvements to manufacturing;
- seek regulatory and marketing approvals for Phexxi outside the US;
- seek reimbursement for Phexxi or any product(s) we may commercialize in the future
- continue our efforts to identify, assess, acquire, and/or commercialize other products;
- work to close the Merger Agreement (as defined herein);
- make milestone, royalty or other payments under third-party license agreements;
- make payments related to debt agreements;
- seek to maintain, protect, and expand our intellectual property portfolio; and
- seek to attract and retain skilled personnel.

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. Due to the recurring losses, negative cash flows from operating activities since inception, and net working capital at December 31, 2023, the report of our independent registered public accountant on our consolidated financial statements as of and for the year ended December 31, 2023 filed with this Annual Report on Form 10-K for the year ended December 31, 2023 includes explanatory language describing the existence of substantial doubt about our ability to continue as a going concern. In addition, our management has further determined that there is a substantial doubt about our ability to continue as a going concern over the next 12 months from the filing date of March 27, 2024.

Although we have generated revenue from product sales, we may never be profitable. Our operating results may differ from any guidance we may announce.

Our current business is substantially dependent on the commercial success of Phexxi. The commercial launch of Phexxi took place on September 8, 2020, and although we have generated revenue from sales of Phexxi, we may never achieve or sustain profitability. Our ability to generate revenue and achieve and sustain profitability depends on our ability, alone or with strategic collaborators, to successfully commercialize Phexxi and, to a lesser extent, any future products we may license, acquire, or otherwise commercialize. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including, but not limited to:

- the rate and degree of market acceptance for Phexxi and any other products in our commercial portfolio;
- the effectiveness of our commercialization strategy for Phexxi and any other products in our commercial portfolio, either directly or with one or more distribution partners, including the effectiveness of our sales force, the Phexxi telehealth platform, media and digital campaigns, and contracted tele-sales vendor;
- reimbursement and pricing for Phexxi and any other approved products in our commercial portfolio in amounts that support profitability;
- successfully competing against other contraceptive products;
- manufacturing Phexxi and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, as well as complying with applicable regulatory requirements and meeting our supply needs in sufficient quantities to meet market demand for Phexxi;
- obtaining regulatory approval of Phexxi (Femidence) in territories outside of the US;
- 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; and
- attracting, hiring and retaining qualified personnel.

From time to time, we may provide guidance as to our anticipated future performance and certain unit shipment information, prescription and prescriber statistics, website and search statistics and other metrics. We may fail to achieve the performance described in any such guidance, and any information or metrics we may provide may be not be indicative of future results. In addition, we provide co-pay assistance to commercially insured patients with an approved Phexxi prescription and utilize a sample program to promote demand for Phexxi. The co-pay program reduces the amount of profit we realize per unit sold, however it is a value-add program to patients that we aim to continue in 2024. Because of the expense to run the program, we will look to modify the business rules surrounding the co-pay program in the future, particularly as payers increasingly cover Phexxi at $0 co-pay to comply with HRSA guidelines; compliance is mandated beginning January 1, 2023 and enforcement action is anticipated. If we are not able to generate sufficient revenue from product sales of Phexxi, the revenue from product sales of Phexxi is not sufficiently profitable, we fail to meet our guidance, or our information or metrics is not indicative of our future results of operations, this could materially and adversely affect our business results of operations, the price of our common stock, our financial condition and our ability to raise additional capital.

We will need to raise significant additional funds to finance our operations, including the commercialization of Phexxi, and to remain a going concern. If we are unable to raise additional capital when needed or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our business initiatives or to cease our operations entirely.

We have incurred significant losses and negative cash flows since our inception. We believe our existing capital resources as of the filing of this Annual Report are sufficient to fund our planned operations into the second half of 2024. Our ability to raise additional funds will depend, in part, on our ability to successfully commercialize Phexxi in the US. If, for whatever reason, we are unsuccessful in these efforts, it may make any necessary debt, equity or alternative financing more difficult, more costly and more dilutive. Attempting to secure additional financing will divert our management from our day-to-day activities, which may adversely affect our ability to commercialize Phexxi. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Furthermore, the global credit and financial markets have experienced extreme volatility and disruptions in recent history, particularly for life science companies. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise additional funds when needed or on acceptable terms, we may be unable to continue commercializing Phexxi as a contraceptive. In addition, we may be required to delay, scale back or eliminate some or all of our business initiatives or be forced to cease operations entirely. 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 the rights of our stockholders. Future debt financings, if available at all, would likely involve agreements with additional 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 (including, but not limited to closing the Merger Agreement with Aditxt), alternative non-dilutive financing, such as royalty-based financing, or licensing arrangements with third parties, we may have to relinquish valuable rights to Phexxi or future revenue streams or grant licenses on terms that are not favorable to us.

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 consolidated financial statements. Given the amounts currently owed pursuant to the Adjuvant Notes, the Baker Notes and other debt arrangements, holders of our common stock may not receive value for their shares in the event of a liquidation.

We have certain obligations pursuant to our issued and outstanding promissory notes, convertible notes and related note purchase agreements, and our failure to comply with these obligations could have a material adverse effect on our business, intellectual property, financial condition, or results of operations.

In April 2020, we entered into a Securities Purchase and Securities Agreement (the Baker Bros. Purchase Agreement) with certain institutional investors and their designated agent pursuant to which we issued and sold secured convertible promissory notes in an aggregate principal amount of $25.0 million and warrants to purchase shares of our common stock. In November 2021, we entered into the first amendment to the Baker Bros. Purchase Agreement which extended the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2022 to June 30, 2023. On March 7, 2023, Baker Bros. Advisors, LP (the Designated Agent) provided a Notice of Event of Default and Reservation of Rights (the Notice of Default) relating to the Baker Bros. Purchase Agreement.

In March 2023, the Company received a Notice of Event of Default and Reservation of Rights (the Notice of Default) from Baker Bros claiming that the Company failed to maintain the required shares reserved amount per the Third Baker Amendment as defined in Note 4 – Debt. In addition, the Notice of Default resulted in a cross default under all outstanding debt; which became currently due and the Company did not have sufficient capital to repay such obligations during the period of default. However, the Company once again had sufficient required reserve number of shares upon the effectuation of the Reverse Stock Split in May 2023. As of June 30, 2023, the Company had not met the affirmative covenant requiring achievement of $100.0 million in cumulative net sales of Phexxi by such date as per the First Baker Amendment (as defined in Note 4 – Debt). In September 2023, the Company entered into a Fourth Baker Amendment (as defined in Note 4 – Debt), upon which the cumulative net sales covenant was removed and all defaults existing at the time of signing were cured.

The Fourth Baker Amendment amends certain provisions within the Baker Bros. Purchase Agreement including:

(i) the rescission of the Notice of Default delivered to the Company on March 7, 2023 and waiving the Events of Default named therein;

(ii) The waiver of any and all other Events of Default existing as of the Fourth Baker Amendment date;

(iii) the removal of the conversion feature into shares of Company common stock, including the removal of any requirement to reserve shares of common stock for conversion of the Baker Notes as well as any registration rights related thereto;

(iv) the clarification that for the sole purpose of enabling an ex-U.S. license agreement for such assets, any Patents, Trademarks or Copyrights acquired after the Effective Date shall be excluded from the definition of Collateral; and,

(v) the removal of the requirement for the Company to obtain $100 million in cumulative net Phexxi sales in the specified timeframe.

The current outstanding balance of the Baker Notes will continue to accrue interest at 10% per annum and, in the event of a default in the agreement or a failure to pay the Repurchase Price (as defined below) on or before September 8, 2028 (the Maturity Date), the Baker Purchasers may collect on the full principal amount then outstanding. Additionally, the Company was required to make a $1.0 million upfront payment by October 1, 2023 (which payment was made in late September 2023) as well as quarterly cash payments based upon a percentage of the Company's global net product revenue. The cash payments will be determined based upon the quarterly global net revenue of Phexxi such that if the global net revenue is less than or equal to $5.0 million, the Company will pay 3%; if the global net revenue is over $5.0 million and less than or equal to $7.0 million, the Company will continue to pay 3% on net revenue up to $5.0 million and 4% on the net revenue over $5.0 million; and if the global net revenue is over $7.0 million, the Company will pay 3% on the net revenue up to $5.0 million, 4% on the net revenue over $5.0 million up to $7.0 million, and 5% on net revenue over $7.0 million. The cash payments will be payable beginning in the fourth quarter of 2023. Regardless of the percentage paid, the quarterly cash payment amounts, along with the $1.0 million upfront payment, will be deducted from the Repurchase Price as Applicable Reductions.

The Fourth Baker Amendment also granted the Company the ability to repurchase the principal amount and accrued and unpaid interest of the Baker Notes for up to a five-year period for the one-time Repurchase Price designated below:

Date of Notes' Repurchase	**Repurchase Price**
On or prior to September 8, 2024	$14,000,000 (less Applicable Reductions)
September 9, 2024-September 8, 2025	$16,750,000 (less Applicable Reductions)
September 9, 2025-September 8, 2026	$19,500,000 (less Applicable Reductions)
September 9, 2026-September 8, 2027	$22,250,000 (less Applicable Reductions)
September 9, 2027-September 8, 2028	$25,000,000 (less Applicable Reductions)

On December 11, 2023, Baker Bros assigned to Aditxt, Inc. (Assignee) all remaining amounts due under the Securities Purchase and Security Agreement by and among Borrower, Baker and Designated Agent, dated as of April 23, 2020, as amended on November 20, 2021, March 21, 2022, September 15, 2022 and September 8, 2023 (the Agreement). Upon such assignment, the Assignee was the Company's senior secured debtholder and the Company is obligated to make all payments under the Fourth Baker Amendment to the Assignee as of December 31, 2023. As described in Note 13 – Subsequent Events, the Notes were re-assigned back to Baker on February 26, 2024 and as such, Baker Bros is the Company's senior secured debtholder as of the filing date.

In October 2020, we entered into a Securities Purchase Agreement (the Adjuvant Purchase Agreement) pursuant to which we issued and sold to certain institutional investors unsecured convertible promissory notes in an aggregate principal amount of $25.0 million. On April 4, 2022, we entered into the first amendment to the Adjuvant Purchase Agreement (the First Adjuvant Amendment). The First Adjuvant Amendment extended, effective as of the date on which we achieved the Qualified Financing Threshold upon the closing of the May 2022 Public Offering, the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2022 to June 30, 2023. The First Adjuvant Amendment also provided for an adjustment to the conversion price of the Adjuvant Notes such that the conversion price for these Notes, effective as of the reverse stock split the conversion price will now be the lesser of (i) $678.49, and (ii) 100% of the lowest price per share of common stock (or with respect to securities convertible into common stock, 100% of the applicable conversion price) sold in any equity financing until we have met the Qualified Financing Threshold.

Between December 2022 and September 2023, we entered into various securities purchase agreements (SPAs), with certain investors (the Investors) providing for the sale and issuance of senior secured convertible notes due in the aggregate gross cash receipt of $5.6 million (the Notes), warrants to purchase an aggregate 25,956,854 shares of common stock (Warrants), pre-funded warrants to purchase an aggregate 6,432,306 shares of common stock (Pre-funded Warrants), and an aggregate 70 shares of Series D Preferred Stock (the Preferred Shares) (collectively, the Senior Subordinate Notes). Each Investor paid approximately $650 for each $1,000 of principal amount of Notes, Preferred Shares and Warrants.

These debt arrangements limit our ability to incur debt, merge, or declare dividends and, in certain circumstances. The Baker Notes are secured by substantially all of our assets but all of the prior defaults have been cured. Our failure to make payments as due under any of the Notes could be an event of default under all of the Notes. Events of default under these arrangements could also include, but are not limited to, a material breach of representations, our failure to comply with our obligation to convert convertible notes, our failure to perform or observe, and in certain instances, cure, certain covenants, including, but not limited to, a covenant requiring us to maintain the listing of shares of our common stock on the OTCQB. In the event of a default and depending on the terms of each Note, a holder of the Notes may be entitled to redemption premiums, treble amounts and other remedies described in their respective agreements. Any default could materially and adversely impact our business, results of operations and financial condition, as well as increase our need to raise additional capital, cause us to cease our operations entirely and may result in the holders of our common stock not receiving any value for their investment.

We have a limited number of shares of common stock available for future issuance which could adversely affect our ability to raise capital or consummate strategic transactions.

We are currently authorized to issue 3,000,000,000 shares of common stock under our amended and restated certificate of incorporation. As of March 21, 2024 we have issued 45,939,509 shares of common stock and approximately 915 million shares of common stock were committed for issuance giving effect to the assumed exercise of all outstanding warrants, options, purchase rights and the assumed conversion of all issued and outstanding convertible notes after accounting for the security holders who have waived the requirement for shares to be reserved for conversion of their instruments, as discussed in Note 13 – Subsequent Events. The conversion prices of the Adjuvant Convertible Notes (as amended) and Senior Subordinate Notes may also be subject to adjustment depending on the price of issuances in future financings as described above. These adjustments would further increase the numbers of shares of common stock to be reserved as a result of these adjustments. Due to the limited number of authorized shares common stock available for future issuance, we may not able to raise additional equity capital or complete a merger or other business combination unless we increase the number of shares we are authorized to issue. We would need to seek stockholder approval to increase the number of our authorized shares of Common Stock, and we can provide no assurance that we would succeed in amending our amended and restated certificate of incorporation to increase the number of shares of Common Stock we are authorized to issue which could negatively impact our business, prospects and results of operations.

Use of net operating loss carryforwards may be limited and U.S. federal income tax reform could adversely affect us.

Our ability to utilize our net operating loss (NOL) carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes. Corresponding rules may apply under state tax laws. Even if there is no limitation on utilization of our NOL carryforwards as the result of an ownership change, the utilization of NOL carryforwards may be limited by other applicable laws. Pursuant to the TCJA passed in December 2017, carryforwards originating from a loss incurred in a year after 2017 are limited and may reduce taxable income in any post-2020 year by no more than 80% of the pre-NOL taxable income in such year. The Coronavirus Aid, Relief and Economic Security Act (the CARES Act) temporarily suspended this 80% taxable income limitation, allowing an NOL carryforward to fully offset taxable income in tax years beginning before January 1, 2021. Additional legislation or regulation which could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results, including a potential increase in federal corporate tax rates generally. We cannot estimate how the changes in tax law from this legislation will affect our tax liability in future years, but we have recorded a valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits from those assets. We have established a full valuation allowance for our deferred tax assets due to uncertainties as to their utilization. While we use our best judgment in attempting to quantify and reserve for our tax obligations. A challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions may cause actual results to deviate from previous estimates.

Risks Related to the Aditxt, Inc. Merger Agreement

The Merger may not be completed on the terms or timeline currently contemplated, or at all. Our stockholders will be subject to a number of material risks if the Merger is not completed.

The consummation of the Merger is subject to certain closing conditions, including:

(1) adoption of the Merger Agreement by the holders of a majority of our outstanding common stock and Series E-1 Shares (shares of which vote on an as-converted basis, and thus have greater voting power than shares of our common stock) at a meeting of our stockholders;
(2) approval of the issuance of shares of Aditxt Common Stock in the Merger by the majority of the votes cast at a meeting of Aditxt's stockholders;
(3) the effectiveness of the registration statement on Form S-4 filed to be filed with the SEC by April 30, 2024;
(4) a Voting Agreement shall have been executed and delivered to the parties;
(5) all Company Preferred Stock shall been converted to Company common stock except for Unconverted Company Preferred Stock;
(6) the Company shall have received waiver agreements from all the holders of the Company's Warrant holders other than those who are cashed out;
(7) the Company shall have obtained waivers from convertible debt holders;
(8) Aditxt will have made the requisite Initial parent Equity Investment in the Company by April 1, 2024;
(9) Aditxt will have made the Subsequent Parent Equity Investment in the Company by April 30, 2024;
(10) the absence of certain legal impediments, and;
(11) other customary closing conditions.

If the Merger is not completed for any reason, including the failure to complete the Merger by May 8, 2024 (or such later date to which such date may be extended in accordance with the terms of the Merger Agreement), the price of Aditxt Common Stock and/or the price of our common stock may decline to the extent that the market price of Aditxt Common Stock or our common stock, as applicable, reflects or previously reflected positive market assumptions that the Merger would be completed and the related benefits would be realized. In addition, the Company and Aditxt have expended and will continue to expend significant management time and resources and have incurred and will continue to incur significant expenses due to legal, advisory, printing and financial services fees related to the Merger. These expenses must be paid regardless of whether the Merger is consummated.

There is no assurance that the Merger will be consummated. If the Merger is not consummated because the Merger Agreement is terminated under certain circumstances, we may be required to pay Aditxt a termination fee of $4.0 million. If the Merger is not timely completed, we may have to materially alter our respective business plans.

We may not be able to effect the Merger pursuant to the Merger Agreement. If we are unable to do so, we will incur substantial costs associated with withdrawing from the transaction.

In connection with the Merger Agreement and its amendments, we have incurred substantial costs planning and negotiating the transaction. These costs include, but are not limited to, costs associated with employing and retaining third-party advisors who perform financial, auditing and legal services required before we were able to enter into the Merger Agreement and which services will continue to be utilized as we seek to complete the transaction. If, for whatever reason, the transactions contemplated by the Merger Agreement fail to close, we will still be responsible for these costs, which could adversely affect our liquidity and financial results.

While the Merger Agreement is in effect, we are subject to certain interim covenants.

The Merger Agreement generally requires us to operate our business in the ordinary course, subject to certain exceptions, including as required by applicable law, pending consummation of the merger, and subjects us to customary interim operating covenants that restrict us, without approval (such approval not to be unreasonably conditioned, withheld, or delayed), from taking certain specified actions until the merger is completed or the Merger Agreement is terminated in accordance with its terms. These restrictions could prevent us from pursuing certain business opportunities that may arise prior to the consummation of the merger and may affect our ability to execute our business strategies and attain financial and other goals and may impact our financial condition, results of operations and cash flows.

The announcement and pendency of the Merger could cause disruptions in our business, which could have an adverse effect on our business and financial results.

We have operated and, until the completion of the merger, will continue to operate independently. Uncertainty about the effect of the merger on employees, customers, distributors and vendors may have an adverse effect on us. These uncertainties may impair our ability to retain and motivate key personnel and could cause customers, distributors, vendors and others with whom we deal to seek to change existing business relationships which may materially and adversely affect our business. Moreover, integration efforts will also divert management attention and resources. These integration matters could have an adverse effect on the Company.

Certain provisions of the Merger Agreement may discourage third parties from submitting alternative acquisition proposals.

The terms of the Merger Agreement prohibit us from soliciting alternative acquisition proposals or cooperating with persons making alternative acquisition proposals, except in limited circumstances when our Board of Directors determines in good faith that an alternative acquisition proposal is or is reasonably likely to result in a superior proposal and that failure to cooperate with the proponent of the proposal is reasonably likely to be inconsistent with our Board of Directors' fiduciary duties. In addition, if we terminate the Merger Agreement under certain circumstances, including terminating because of a decision of ours to enter into an alternative acquisition agreement with respect to a superior proposal, we would be required to pay a termination fee of $4.0 million to Aditxt. This termination fee described above may discourage third parties from submitting alternative acquisition proposals to our stockholders and may cause our Board of Directors to be less inclined to recommend an alternative acquisition proposal.

We may be subject to litigation relating to the Merger.

We may be subject to legal claims, including stockholder claims, related to the merger. Litigation is distracting and costly and subject to inherent uncertainties, and unfavorable rulings could occur. An unfavorable ruling could include monetary damages or other adverse effects. Were an unfavorable ruling to occur, there exists the possibility of a material adverse impact on our business, financial position, and results of operations, and the merger may not be completed and our stock price could decline significantly.

Risks Related to Potential Bankruptcy

Given our current financial condition, we have considered and may continue to consider filing for bankruptcy protection. While we have not initiated bankruptcy proceedings, we caution that trading in our securities is highly speculative and poses substantial risks relating to the potential of bankruptcy proceedings should we fail to consummate the Merger (as defined in Note 1 - Business) Trading prices for our securities may bear little or no relationship to the actual recovery, if any, by holders of our securities in Bankruptcy proceedings, if any.

We are subject to risks and uncertainties associated with potential bankruptcy proceedings.

Our operations and ability to develop and execute our business plan, our financial condition, our liquidity and our continuation as a going concern, are subject to risks and uncertainties associated potential or actual bankruptcy. These risks include the following:

- our ability to prosecute, confirm and consummate a plan of reorganization with respect to the Chapter 11 proceedings;
- the high costs of bankruptcy proceedings and related fees;
- our ability to obtain sufficient financing to allow us to emerge from bankruptcy and execute our business plan post emergence;
- our ability to maintain our current relationships with or attract new suppliers, service providers, customers, employees, and other third parties;
- our ability to maintain contracts that are critical to our operations;
- our ability to execute our business plan in the current depressed commodity price environment;
- our ability to attract, motivate and retain key employees;
- the ability of third parties to seek and obtain court approval to terminate contracts and other agreements with us or make other third-party motions in the proceedings;
- the ability of third parties to seek and obtain court approval to convert Chapter 11 proceedings to Chapter 7 proceedings, if applicable; and
- the actions and decisions of our creditors and other third parties who have interests in proceedings that may be inconsistent with our plans.

Delays in filing for or moving forward with the proceedings increase the risks of our being unable to reorganize our business and emerge from bankruptcy and increase our costs associated with the bankruptcy process.

These risks and uncertainties could affect our business and operations in various ways. For example, negative events associated with either Chapter 11 or Chapter 7 proceedings could adversely affect our relationships with our suppliers, service providers, customers, employees, and other third parties, which in turn could adversely affect our operations and financial condition. Also, we need the prior approval of the Bankruptcy Court for transactions outside the ordinary course of business, which may limit our ability to respond timely to certain events, take advantage of certain opportunities or pursue our business strategies. Because of the risks and uncertainties associated with potential proceedings, we cannot accurately predict or quantify the ultimate impact that events that may occur during the proceedings will have on our business, financial condition and results of operations.

As of December 31, 2023, we have negative stockholders' equity. If we are unable to raise additional capital, or otherwise become unable to satisfy our obligations as they become due, we may become insolvent and face the risk of bankruptcy.

Since inception, we have incurred significant operating losses. As of December 31, 2023, we had a working capital deficit of $63.3 million and an accumulated deficit of $888.7 million. We have financed our operations to date primarily through the issuance of preferred stock, common stock and warrants, cash received from private placement transactions, the issuance of convertible notes and, to a lesser extent, product sales. Accordingly, if we are unable to raise additional capital, or if we otherwise become unable to satisfy our obligations as they become due, we may become insolvent and face the risk of bankruptcy and other adverse action by our existing and future creditors.

Further, we may currently, or in the future, be operating in the "zone of insolvency" as described under Delaware law, which is our jurisdiction of incorporation. Generally, a corporation's directors owe a fiduciary duty to the corporation's shareholders and not to its creditors. However, when a corporation is operating in the "zone of insolvency," some courts have concluded that the fiduciary duty of directors shifts to include creditors. Delaware courts have taken the position that directors of a corporation operating in the zone of insolvency continue to owe a fiduciary duty to the corporation's stockholders but also owe such duty to its creditors. Accordingly, our management and directors may be required to consider their duties with regard to both stockholders and creditors in their decision making processes.

Our businesses could suffer from a long and protracted restructuring.

Our future results could be dependent upon the successful confirmation and implementation of a bankruptcy plan or other alternative restructuring transaction, including a sale of all or substantially all of our assets. A long period of operations under Bankruptcy Court protection could have a material adverse effect on our business, financial condition, results of operations and liquidity. Failure to obtain confirmation of a Chapter 11 plan or approval and consummation of an alternative restructuring transaction in a timely manner may harm our ability to obtain financing to fund our operations, and there is a significant risk that the value of our securities and assets would be substantially eroded to the detriment of all stakeholders. If a Chapter 11 plan that complies with the applicable provisions of the Bankruptcy Code cannot be agreed upon, it is possible that we would have to liquidate our assets, in which case it is likely that holders of claims would receive substantially less favorable treatment than they would receive if we were to emerge as a viable, reorganized entity.

If filed, as long as bankruptcy proceedings continue, we will be required to incur substantial costs for professional fees and other expenses associated with the administration of the Chapter 11 or Chapter 7 proceedings. Chapter 11 proceedings may also require us to seek debtor-in-possession financing to fund operations. If we are unable to obtain such financing on favorable terms or at all, our chances of successfully reorganizing our business may be seriously jeopardized, the likelihood that we instead will be required to liquidate our assets may be enhanced, and, as a result, any securities in us could become further devalued or become worthless.

In the event we decide to initiate bankruptcy proceedings, there can be no assurance that we will successfully reorganize and emerge from Chapter 11 proceedings or, if we do successfully reorganize, as to when we would emerge from the Chapter 11 proceedings. Even after a Chapter 11 plan is confirmed and implemented, our operating results may be adversely affected by the possible reluctance of prospective lenders, suppliers and other counterparties to do business with a company that recently emerged from bankruptcy proceedings.

In certain instances, a Chapter 11 case may be converted to a case under Chapter 7 of the Bankruptcy Code.

We have not yet filed for bankruptcy and therefore have not yet decided upon Chapter 11 or Chapter 7. However, should we choose to pursue Chapter 11, upon a showing of cause, the Bankruptcy Court may convert our Chapter 11 case to a case under Chapter 7 of the Bankruptcy Code. In such event, a Chapter 7 trustee would be appointed or elected to liquidate our assets for distribution in accordance with the priorities established by the Bankruptcy Code. We believe that liquidation under Chapter 7 would result in significantly smaller distributions being made to our creditors because of (i) the likelihood that the assets would have to be sold or otherwise disposed of in a distressed fashion over a short period of time rather than in a controlled manner and as a going concern, (ii) additional administrative expenses involved in the appointment of a Chapter 7 trustee, and (iii) additional expenses and claims, some of which would be entitled to priority, that would be generated during the liquidation and from the rejection of leases and other executory contracts in connection with a cessation of operations.

If we choose to file under Chapter 11, we may be subject to claims that will not be discharged in the bankruptcy proceedings, which could have a material adverse effect on our financial condition and results of operations.

The Bankruptcy Code provides that the confirmation of a plan of reorganization discharges a debtor from substantially all debts arising prior to confirmation. With few exceptions, all claims that arose prior to confirmation of the plan of reorganization (i) would be subject to compromise and/or treatment under the plan of reorganization and/or (ii) would be discharged in accordance with the Bankruptcy Code and the terms of the plan of reorganization. Any claims not ultimately discharged through a plan of reorganization could be asserted against the reorganized entities and may have an adverse effect on our financial condition and results of operations on a post-reorganization basis.

Our financial results may be volatile and may not reflect historical trends.

During bankruptcy proceedings, we expect our financial results to continue to be volatile as asset impairments, asset dispositions, restructuring activities and expenses, contract terminations and rejections, and claims assessments occur, which may significantly impact our consolidated financial statements. As a result, our historical financial performance is likely not indicative of our financial performance after the date of a bankruptcy filing.

In addition, if we emerge from Chapter 11, the amounts reported in subsequent consolidated financial statements may materially change relative to historical consolidated financial statements, including as a result of revisions to our operating plans pursuant to a plan of reorganization. We also may be required to adopt fresh start accounting, in which case our assets and liabilities will be recorded at fair value as of the fresh start reporting date, which may differ materially from the recorded values of assets and liabilities on our consolidated balance sheets. Our financial results after the application of fresh start accounting also may be different from historical trends.

Risks Related to Commercialization of Phexxi and Any Other Approved Products

Our success will depend heavily on whether we can successfully commercialize our only commercially available product, Phexxi, for prevention of pregnancy. Failure to successfully commercialize Phexxi for the prevention of pregnancy would likely cause our business to fail.

Our overall success will rely heavily on the commercial success of Phexxi vaginal gel for prevention of pregnancy. Failure to successfully commercialize Phexxi for the prevention of pregnancy would likely cause our business to fail.

If we are unable to maintain effective internal sales and marketing capabilities, or enter into agreements with third parties to market and sell Phexxi, our ability to continue to successfully commercialize Phexxi and generate revenue would be adversely affected.

We may not be able to maintain the requisite sales force to market Phexxi and we may face difficulties recruiting and hiring sales representatives and otherwise obtaining marketing capabilities. In the fourth quarter of 2022 and first quarter of 2023, we completed two reductions in workforce (RIFs) which reduced the total number of sales employees, among others; this negatively impacted our ability to maintain our sales and marketing capabilities. Any failure or future delay in the timely development of our internal commercialization capabilities could adversely impact the potential for commercial success of Phexxi. We expect to continue to expend significant time and resources to train our sales consultants in marketing Phexxi. In addition, we must train our sales force to ensure that an appropriate and compliant message about Phexxi is being delivered. If we are unable to effectively train our sales force and equip them with compliant and effective materials, including medical and sales literature to help them appropriately inform and educate physicians regarding the potential benefits of Phexxi, our efforts to successfully commercialize Phexxi could be put in jeopardy, which would negatively impact our ability to generate product revenues.

Our use of social media platforms to market and promote Phexxi, a prescription product, presents risks and operational challenges.

We believe that our customer base and potential patient populations for Phexxi are active on social media, and we have engaged and intend to continue to engage through those platforms to conduct direct-to-consumer marketing. Social media practices in the pharmaceutical, biotechnology and medical device industries are evolving, which creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, our product, which could result in regulatory reporting obligations or the need for us to conduct an investigation. The use of influencers and patient ambassadors to promote Phexxi also may be subject to federal truth-in-advertising laws enforced by the Federal Trade Commission (FTC), as well as comparable state consumer protection laws, and we are responsible for training those influencers on the compliant messages they can deliver to consumers about Phexxi. Any actual or perceived non-compliance by our influencers and patient ambassadors with those requirements could lead to an investigation by the FTC or a comparable state agency or could lead to allegations of misleading advertising by private plaintiffs. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us or our product on any social networking website. If any of these events were to occur or we otherwise fail to comply with any applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business such as reputational damage.

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

The medical device, biotechnology and biopharmaceutical industries, and the women's health sector, 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 must demonstrate advantages in efficacy, convenience, tolerability, and/or safety, among other things. In addition, new products developed by others could emerge as competitors to Phexxi. These products could potentially offer an alternative form of non-hormonal contraception that is more convenient, is more effective and/or provides protection over longer periods of time as compared to Phexxi. We also compete with these organizations to recruit management, and sales and marketing personnel. Any failure to attract and retain such personnel could negatively affect our level of expertise and our ability to execute our business plan. We also face competition in connection with identifying and engaging in strategic transactions. 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 who have significantly more resources than Evofem. These companies include Merck & Co., Inc., Allergan PLC, Pfizer Inc., Bayer AG, Johnson & Johnson, CooperSurgical Inc. and Mylan Inc. Additionally, several generic manufacturers currently market and continue to introduce new generic contraceptives.

Phexxi and any other approved products we promote may not gain sufficient market acceptance among physicians, patients or the medical community, thereby limiting our potential to generate revenue, which will undermine our future growth prospects.

Even though Phexxi has been approved by the FDA for commercial sale for the prevention of pregnancy, the degree of market acceptance of any new product by physicians, patients and the medical community will depend on a number of factors, including:

- demonstrated evidence of efficacy and safety and potential advantages compared to competing products;
- perceptions by the medical community, physicians, and patients, regarding the safety and effectiveness of the product and the willingness of the target patient population to try it and of physicians to prescribe it;
- relative convenience and ease of administration compared to other products approved for the same indication;
- the regulatory label requirements for the product, including any potential restrictions on use or precautionary statements;
- sufficient third-party insurance coverage and adequate reimbursement;
- the willingness of wholesalers and pharmacies to stock the products;
- the prevalence and severity of any adverse side effects;
- the ability to sufficiently educate physicians with respect to the product's safety and efficacy; and
- availability of alternative products and the cost-effectiveness of our product relative to competing products.

If any approved product that we may license, acquire or sell, including Phexxi, does not provide a benefit over currently available options, that product is unlikely to achieve market acceptance, and we will not generate sufficient revenues to achieve profitability.

The telehealth market continues to develop, and if it encounters negative publicity over privacy issues, fails to engage sufficient numbers of providers, or if limitations on reimbursement or new state law regulatory requirements impede our ability to implement our telehealth platform, the growth of our business may be harmed.

We utilize a telehealth platform where women can directly meet with HCPs to determine their eligibility for Phexxi and potentially have prescriptions written. Our success will depend to a substantial extent on the willingness of women to use the telehealth platform. Negative publicity concerning our telehealth platform, or the telehealth industry as a whole, could limit market acceptance and utilization of the Phexxi telehealth platform. Additionally, telehealth laws are rapidly changing. There is no guarantee that telehealth will be permitted in the same way in perpetuity. Changes by state professional licensing boards to the standards of care or other requirements governing the practice of telehealth, including the imposition of new requirements for prescriptions from state and federal regulatory bodies, could impact the success of our telehealth solution. Similarly, individual and health care industry concerns or negative publicity regarding patient confidentiality and privacy in the context of telehealth could limit market acceptance and utilization of our platform. If any of these events occur, it could have a material adverse effect on our business, financial condition, or results of operations.

The success of Phexxi will depend on the availability of competitive products and women's preferences, in addition to the market's acceptance of the vaginal pH modulator.

The commercial success of Phexxi will depend upon the contraceptive market as well as market acceptance of Phexxi as a new form of contraception, a vaginal pH modulator. Risks related to market acceptance include, among other things:

- minimum acceptable contraceptive efficacy rates and the related regulatory label requirements, including any potential restrictions on use or precautionary statements;
- perceived safety differences of hormonal and/or non-hormonal contraceptive options;
- changing women's preferences;
- the effect of the Affordable Care Act (ACA) on pharmaceutical coverage, reimbursement and pricing, and the coverage of preventable services (including contraception under certain conditions); and
- new generic contraceptive options including the possibility of a future potential generic version of Phexxi.

For example, the pregnancy rate with typical use of Phexxi in the FDA-approved label is higher than that of hormonal contraceptives, and we cannot be certain that the associated risk of unintended pregnancy will not deter adoption of Phexxi as a method of pregnancy prevention. In addition, Phexxi's label contains a warning related to use by women with a history of recurrent urinary tract infections, which could limit the willingness of HCPs to prescribe or certain women to use Phexxi. These risks could reduce the market potential for Phexxi 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 Phexxi and/or any future products we promote will depend in significant measure on the label claims that the FDA or other regulatory authorities approve for those products.

The commercial success of Phexxi vaginal gel and/or future products we promote, if any, will depend in significant measure upon the prescribing information and the patient-directed labeling describing the product's features, benefits and risks.

We are required to submit all revisions to approved product labeling for Phexxi as part of a supplemental NDA to the FDA for review and approval. Failure to achieve approval from the FDA or other regulatory authorities of product labeling revisions could have a material adverse impact on our business, financial condition, results of operations and prospects.

The FDA and other regulatory agencies actively enforce laws and regulations prohibiting the promotion of off-label uses for prescription drugs and medical devices. If we are found or alleged to have improperly promoted our commercial product for off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products such as Phexxi. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. Promotional labeling for Phexxi, and for any other products that we may promote, must be submitted to FDA at the time of first use. The agency actively solicits reports from health care professionals about improper drug manufacturer promotional claims or activities. If we are found to have promoted Phexxi or other product for any off-label use, we may become subject to significant liability and potentially reputational harm. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of Phexxi or other product to ensure compliance with these legal and regulatory requirements, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we suffer negative publicity concerning the safety or efficacy of Phexxi our reputation and the commercialization of Phexxi could be harmed.

If concerns should arise about the safety or efficacy of Phexxi, such concerns could adversely affect the market's perception which could lead to a decline in investors' expectations, adverse effects on our results of operations, and a decline in the price of our common stock.

We rely, and expect to continue to rely, on market research conducted internally and on our behalf to evaluate the potential commercial acceptance of Phexxi for the prevention of pregnancy.

We have contracted with and expect to continue to perform market research and to contract with third parties to perform research on our behalf. 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 Phexxi for contraception. Moreover, our internal and external research that has informed our views with respect to our sales and marketing strategy, payer coverage, pricing and reimbursement with respect to Phexxi may prove to be incorrect. For example, we believe that women who are most likely to use Phexxi as their primary method of preventing pregnancy are those who are unwilling to use hormone-based contraceptives and are unsatisfied with other commercially available non-hormonal alternatives. If our market research has overestimated the size of this population or the willingness of these women to try Phexxi, the commercialization of Phexxi may be less successful than we or others expect.

There can be no assurance on the accuracy or completeness of certain facts, forecasts and other statistics obtained from various government publications, market data providers and other independent third-party sources, including industry expert reports, contained in this Annual Report or other statements we may make from time to time.

Certain facts, forecasts and other statistics contained herein and that we may discuss from time to time have been derived from various government publications, market data providers and other third-party sources. While we have no reason to believe that this information is false or misleading or that any fact has been omitted that would render this information false or misleading, we cannot guarantee the accuracy and completeness of this information. While we have taken reasonable care to ensure that these facts, forecasts and other statistics have been accurately reproduced from their respective sources, these facts, forecasts and other statistics have not been independently verified by us, our directors, advisers or any other parties and none of us make any representation as to the accuracy or completeness of such information. Due to possibly flawed or ineffective collection methods or discrepancies between published information and market practice and other problems, the facts, forecasts and statistics contained herein may be inaccurate or may not be comparable to information produced by other parties. Therefore, you should give consideration as to how much weight or importance you should attach to or place on these facts, forecasts or statistics and in all cases, but particularly with respect to market size, this information should not be unduly relied upon.

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

The proportion of the U.S. market that is made up of generic products has been increasing over time. This trend is occurring in the women's health segment as well, where many of the most popular oral contraceptive pills brands have experienced genericization. Assuming this trend continues, it may be more challenging to commercialize Phexxi at a price that will maximize our revenue and profits. Also, there may be additional marketing costs to commercialize Phexxi in order to overcome the trend towards generics and to gain access to reimbursement by payers. If we are unable to gain reimbursement from payers for Phexxi, or if patients are unwilling to pay any price differential between Phexxi and a generic contraceptive product, our revenues will be limited. We are currently covering the cost of Phexxi for the first month for women with commercial insurance whose health plans do not reimburse for Phexxi or whose health plans require a co-pay for Phexxi, and we are covering the cost of subsequent refills of Phexxi at a $25 co-pay for these women if their co-pay is above that amount with a cap of $650 annual benefit to each patient. However, we cannot be certain that these initiatives will be successful in overcoming general inclinations of physicians and their patients to avoid branded contraceptives and these initiatives may become prohibitively expensive. If we choose to curtail our co-pay programs, demand for Phexxi may decrease. In addition, if health care plans do not add Phexxi to their covered formularies within the timelines we expect, or continue to include it on their covered formularies, or impose a more restrictive co-pay than we expect, our costs of providing these incentive programs will increase beyond our expectations and reduce our product margins and net revenues from sales of Phexxi.

Even though we have received approval from the FDA in the US to market Phexxi for the prevention of pregnancy, and, as Femidence, by the National Agency for Food and Drug Administration and Control of Nigeria, we may fail to receive similar approval in other territories outside the US.

To market a new product outside the US, 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 US, as well as other risks. In addition, in many countries outside the US, 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 US are different and may be inconsistent with the US labeling requirements, negatively affecting our ability to market our products in countries outside the US.

In addition, if we are unable 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 Phexxi will be harmed, which could have a materially adverse effect on our business, financial condition, results of operations and prospects.

We have not paid our Fiscal Year 2023 and 2024 PDUFA Invoices to the FDA and cannot submit any application or supplements subject to fees to the FDA, and the amount payable continues to accrue interest and penalties.

We have not paid our Fiscal Year 2023 and 2024 PDUFA invoices for Phexxi to the FDA totaling approximately $0.9 million, including interest and penalties. As a result, any drug application or supplement subject to fees we submit will be considered incomplete and will not be accepted for consideration for filing until all fees, interest and penalties are paid. In March 2024, we have arranged a payment plan with the Department of Health & Human Services starting on May 1, 2024.

Risks Related to Our Post-Marketing Legal and Regulatory Compliance

Even though we have obtained FDA approval for Phexxi for prevention of pregnancy, we remain subject to ongoing regulatory requirements.

Even though Phexxi vaginal gel has been approved by the FDA for the prevention of pregnancy, we are and 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 US and requirements of comparable foreign regulatory authorities.

In addition, 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 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 MAA.

Any regulatory approvals we have received and may in future receive for Phexxi may be subject to limitations on the approved indicated uses for which it may be marketed, and usual and customary surveillance to monitor its safety and efficacy. 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 commercialization, or increased costs to assure compliance.

If a regulatory agency discovers previously unknown problems with Phexxi or a future product we may commercialize, 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 on us, including requiring withdrawal of the product from the market. If we are unable to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

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

Developments after a product reaches the market may adversely affect sales of the product.

Even though Phexxi has been approved in the US for the prevention of pregnancy, certain developments could decrease market demand for it, including the following:

- the re-review of a product that is already marketed;
- new scientific information and evolution of scientific theories;
- the recall or loss of marketing approval of a product that is already marketed;
- changing government standards or public expectations regarding safety, efficacy or labeling changes; and
- greater examination of advertising and promotion.

In the past, clinical trials and post-marketing surveillance of certain marketed drugs have raised concerns that have led to recalls, withdrawals or addition of restrictive labeling of marketed products. If previously unknown side effects are discovered with one of the active ingredients in, or if there is an increase in negative publicity regarding known side effects related to Phexxi or any other FDA-approved or -cleared product we may commercialize, this could significantly reduce demand for the product or require us to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of Phexxi for the prevention of pregnancy. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.

We face an inherent risk of product liability exposure in commercializing Phexxi for the prevention of pregnancy and other products we may commercialize. If serious adverse events or undesirable side effects occur, the following events could occur which would materially and adversely affect our business:

- regulatory authorities may require the addition of specific warnings or contraindications to product labeling or the issuance of alerts to physicians, pharmacies and the general public;
- we may be required to change the way Phexxi is administered or to revise the labeling of Phexxi;
- we may be subject to promotional and marketing limitations on Phexxi;
- sales of Phexxi may decrease significantly;
- regulatory authorities may require us to take Phexxi off the market;
- 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 (REMS), which could result in substantial cost increases and have a negative impact on our ability to commercialize Phexxi;
- we may be required to limit the patients who can receive Phexxi;
- 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 Phexxi, or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from Phexxi. Serious adverse events or side effects could require Phexxi to be taken off the market, may require it to be packaged with safety warnings, or may otherwise limit our sales.

Further, 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 Phexxi, injury to our reputation, negative media attention and the diversion of our management's time and attention from our commercialization efforts to address claim related matters.

We will need to maintain liability insurance coverage as we continue to commercialize Phexxi. This insurance may become increasingly expensive and difficult to procure. In the future, this 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, while we have increased our liability insurance coverage in connection with the commercialization of Phexxi, we cannot be certain our coverage limits will be sufficient to cover liability claims we may face. We will also need to increase liability coverage if we promote any other product. 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 third-party manufacturer's and suppliers' activities may involve the controlled storage, use, and disposal of hazardous materials. We and our manufacturer and suppliers, and our potential future manufacturers and suppliers, are and will be 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 may be stored at our and our current and potential future manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization 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 current third-party manufacturers for handling and disposing of 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.

The FDA and other regulatory agencies actively enforce the laws and regulations relating to the promotion of our product.

If we are found to have improperly promoted uses of our product in the US, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drug and device products. In particular, a product may not be promoted in a manner that results in the company making false or misleading claims. If the FDA determines that our or our partners' public disclosures, promotional materials or training constitutes promotion of false or misleading claims, it could request modifications to disclosure policies, training or promotional materials or subject us or our partners to regulatory or enforcement actions, including the issuance of an untitled letter, a Warning Letter, injunction, seizure, civil fine or criminal penalties and a requirement for corrective advertising, including Dear Doctor letters. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our or our partners' promotional or training materials to constitute promotion of false or misleading claims which could result in significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, increased losses and diminished profits and the curtailment or restructuring of operations, any of which could adversely affect our or our partners' ability to operate and, thus, adversely impact our business and our financial results. The FDA or other enforcement authorities could also request that we enter into a consent decree or a corporate integrity agreement or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product in the US, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Risks Related to Our Intellectual Property

Our rights to develop and commercialize Phexxi are subject, in part, to the terms and conditions of licenses granted to us by third parties. The patent protection and patent prosecution of Phexxi 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 commercialization of Phexxi. For example, the Rush License Agreement includes intellectual property rights to Phexxi. This agreement currently 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 through March 2025. As of December 31, 2023, we have accrued all such obligations pursuant to the Rush License Agreement, we have obtained a waiver of any potential claim of breach based on any provisions requiring us to timely exploit the licensed patent or make minimum royalty payments.

In addition, with respect to Phexxi, 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 Phexxi. While the Rush License Agreement 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 Phexxi. 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 Phexxi, 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-license. 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.

We may be required to stop using the Phexxi name and trademark prior to July 18, 2024.

On December 14, 2020, a trademark dispute captioned TherapeuticsMD, Inc. v Evofem Biosciences, Inc., filed in the United States District Court for the Southern District of Florida against the Company, alleging trademark infringement of certain trademarks owned by TherapeuticsMD under federal and state law. On July 18, 2022, the Company settled the lawsuit with TherapeuticsMD, pursuant to which the Company agreed to rebrand its product by July 2024 to coincide with its specific strategic marketing objectives. In January 2023, TherapeuticsMD sold the relevant asset. As a result, the Company believes that rebranding of Phexxi may not be required. If the Company were required to rebrand and/or relaunch Phexxi, it could have an adverse commercial impact. A rebrand of Phexxi could result in a loss of brand recognition and could require us to devote resources to developing, securing, trademarking, advertising and marketing a new brand. Further, failure to rebrand, if required, could result in paying damages or being subject to a court order or injunction prohibiting us from selling Phexxi.

If we are unable to obtain and maintain patent protection for Phexxi for the prevention of pregnancy, and its underlying vaginal pH modulator technology, 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 product and technology, and our ability to successfully commercialize Phexxi may be adversely affected.

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

Changes in either the patent laws or their interpretation in the US 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. Our pending and issued patent claims for Phexxi are not broad, and it is possible that a competitor may seek to make modifications to their product in an effort to design around our patent claims and avoid infringement. Furthermore, if any such competitor or third party is able to demonstrate bioequivalence without infringing our patents, then such a competitor or third party would then be able to introduce a competitive generic product onto the market once any available regulatory exclusivity has expired. The FDA has broad discretion in determining whether a potential competitive product demonstrates bioequivalence; we are not able to predict the extent to which a competitor or third party might be able to demonstrate bioequivalence without infringing our patents.

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 be unsuccessful in our efforts 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 US 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.

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 Phexxi 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 Phexxi 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 US and abroad. We or our licensors may be subject to a third-party pre-issuance submission of prior art to 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 Phexxi 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 Phexxi. 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.

The patent rights licensed to us under the Rush University License are expected to expire in March 2025. If we are unable to obtain extensions of the patent rights, these patent rights will no longer protect Phexxi, and we will be relying solely on our directly owned patent formulas and patent application families for patent protection for Phexxi. 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 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 Phexxi (Femidence) 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 US. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the US, or from selling or importing products made using our inventions in and into the US 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 US. 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 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 US, 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 US 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 we initiate, 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 US 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 U.S. and non-U.S. patent agencies. The USPTO and various non-US 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 U.S. 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 US 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 US, the first to invent the claimed invention was entitled to the patent, while outside the US, 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 US 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 do 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 US 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 Phexxi 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 U.S. 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. 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 U.S. 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 U.S. 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 Phexxi could be found invalid or unenforceable if challenged in court or before administrative bodies in the US or abroad.

If we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering Phexxi, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the US, 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 US 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 Phexxi. 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 Phexxi. 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 a Patent Term Extension (PTE) for our Phexxi, our business may be materially harmed.

One or more of our owned or in-licensed U.S. patents covers Phexxi for the prevention of pregnancy, and our patents may be eligible for limited PTE under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a PTE of up to 5 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). Further, if the FDA determines that the Phexxi does not represent the first permitted commercial marketing or use of the product, or the active ingredients, we may fail to satisfy applicable requirements which could materially harm us and our operations.

In 2020, Rush University submitted a PTE application for the U.S. patent which we licensed from them, requesting a five-year PTE to 2026. Two Orders Granting Interim Extension (OGIEs) were received from the USPTO, extending the expiration of this patent to 2023. An additional request for interim patent term extension was granted, extending the exclusivity through March 2025. However, we may not be granted a full five-year PTE for this patent or any similar extension outside the US, such as SPC for the European patents, because of, for example, our inability to exercise due diligence during the testing phase or regulatory review process, our inability to apply within applicable deadlines, our inability to apply prior to expiration of relevant patents, or if we are otherwise unable to satisfy applicable requirements. Moreover, the applicable time or the scope of patent protection afforded could be less than our or Rush University's request. If we or Rush University are unable to obtain PTE, 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 product is dependent on third parties, including Rush University.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product, there may be times, such as with respect to our agreement with Rush University, when the filing and prosecution activities for patents relating to our is 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 Phexxi, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize Phexxi for the prevention of pregnancy 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.

If an event of default continues and remains uncured under our issued and outstanding secured convertible notes issued pursuant to the Baker Notes, the note holders could take possession of all assets owned by us, including any directly owned intellectual property.

On March 7, 2023, Baker Bros. Advisors, LP (the Designated Agent) provided a Notice of Event of Default and Reservation of Rights (the Notice of Default) relating to the Securities Purchase and Security Agreement dated April 23, 2020, and subsequently amended (SPA), by and among Evofem, Designated Agent, the Guarantors and Baker Purchasers. The Notice of Default claimed that the Company failed to maintain the "Required Reserve Amount" as required by Section 2.7 of the Third Amendment to the Securities Purchase Agreement and Section 8.1(e) of the SPA. The Designated Agent claims such failure constitutes an immediate Event of Default pursuant to Section 9.1(e) of the SPA. The Designated Agent, at the direction of the Baker Purchasers, accelerated repayment of the outstanding balance payable and elected its remedies pursuant to Section 5.07(b) of the Securities Purchase Agreement. As a result, approximately $92.7 million, representing two times the sum of the outstanding balance and all accrued and unpaid interest thereon and all other amounts due under the SPA and other documents, was due and payable within three business days of receipt of the Notice of Default. The Company and Baker entered into the Fourth Amendment, which, as described in more detail in Note 4 - Debt, waived the Notice of Default and removed the Company's need to reserve enough equity to cover the value of the note and allowed the company to repurchase the note at a discounted price. On December 11, 2023, Baker Bros assigned to Aditxt, Inc. (Assignee) all remaining amounts due under the Securities Purchase and Security Agreement. As described in Note 13 – Subsequent events, the notes were transferred back to Baker Bros on February 26, 2024. Given our current inability to pay any amounts due under the Purchase Agreement or under the convertible notes, the designated agent of these note holders has the right to take possession of all of our assets and/or pursue any available legal remedies against us.

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 Phexxi. 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. 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 and maintaining patents for Phexxi, 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 Phexxi, 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 Phexxi 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 US 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 Phexxi. 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 Phexxi. 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 be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have no knowledge of any claims against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. To date, none of our employees have been subject to such claim.

We may be at risk that our former employees may wrongfully use or disclose our trade secrets.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants, and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee, former employee, consultant, former consultant or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

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, induced intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the commercialization of our product.

The contraceptive market is competitive and dynamic. Due to the significant research and development activities that are taking place by several companies in this field, including us and our competitors, 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 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, inducing infringement, 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 U.S. 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 U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we intend to commercialize Phexxi. We cannot assure you that Phexxi will not infringe 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 commercializing our product, might assert are infringed by Phexxi, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to Phexxi, could be found to be infringed by our product. 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 may infringe.

Third parties may currently have patents or obtain patents in the future and may claim that use of our technology 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. In this case, the holders of such patents may be able to block our ability to commercialize Phexxi 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 Phexxi 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, 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 commercialize our product, 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 forced to cease some aspect of our business operations such as the commercialization of Phexxi, 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.

In the ordinary course of business, we have been and again 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 or other third parties may infringe our patents or the patents of our licensing partners. We have and may again be required to defend against claims of infringement or otherwise engage in legal action to protect our intellectual property. Any commercial success we may achieve with Phexxi for the prevention of pregnancy may incentivize third parties to challenge or infringe our intellectual property. 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 these claims is 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. These 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 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.

Some intellectual property that we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Intellectual property rights we have licensed or may in the future license are generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current product pursuant to the Bayh-Dole Act of 1980 (Bayh-Dole Act) and implementing regulations. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation and may change in the future. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the US. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the US or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

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 have, in the ordinary course of our business, been challenged and may again be challenged by third parties. These trademarks and trade names may also be infringed, circumvented or may not be registered with the USPTO or determined to be infringing on other marks. During trademark registration proceedings, 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, we 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 in the US 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. 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, we may be subject to 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 or that allege we have infringed on their trademarks and 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 or to defend ourselves in suits related to our 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 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 one contract manufacturer. Any failure by these third parties, including their inability to successfully perform and comply with regulatory requirements, could negatively impact our business and our ability to develop and market our product, 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 solely on third parties to manufacture our products, including our FDA-approved commercial product Phexxi, and as such we will be subject to inherent uncertainties related to product safety, availability and security. We currently have only one contract manufacturer for drug product, DPT Laboratories, Ltd. (DPT), with whom we entered into a supply and manufacturing agreement in November 2019 (the Manufacturing Agreement). Pursuant to the Manufacturing Agreement, subject only to a supply failure, we are obligated to purchase all of our requirements with respect to Phexxi from DPT. We expect to rely on DPT to increase the manufacturing of Phexxi in amounts needed to support commercialization. If DPT does not perform as agreed or is unable to increase manufacturing of Phexxi as needed to support commercialization, including as a result of being adversely affected by COVID-19, or terminates our agreement, we will be required to replace them as our manufacturer, and we may be unable to do so on a timely basis, on similar terms or at all. Furthermore, we have only a single source of supply for some of the key raw materials and components of Phexxi, 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 and alternate sources of supply may also be affected by COVID-19.

Moreover, we do not control the manufacturing processes for the production of Phexxi, 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 Phexxi; 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 demand for Phexxi, we could experience delays in research, planned clinical trials and/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, including our commercialization timeline, which would materially adversely affect our business, financial conditions, results of operations and prospects.

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

- we may be unable to identify other 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;
- DPT and potential future third-party 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 inspections 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; and,
- our third-party manufacturers could breach or terminate their agreements with us.

Each of these risks could impact the continued availability of Phexxi 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 Phexxi 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, timely availability of raw materials, lot consistency, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product 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 will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource 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 distribute Phexxi would be harmed. There is no assurance that our manufacturers will be successful in establishing a larger-scale commercial manufacturing process for Phexxi that achieves our objectives for manufacturing capacity and cost of goods. There is no assurance that our manufacturers will be able to manufacture or continue to manufacture Phexxi to specifications acceptable to the FDA or other regulatory authorities, or to produce it in sufficient quantities to meet future demand. Any delay or failure in the production of Phexxi would impair our ability to commercialize and obtain revenue therefrom. These circumstances would materially harm our business, results of operations, financial conditions and prospects.

We have no significant internal distribution capabilities. We intend to engage third-party distributors for distribution of products outside the US, if approved, and have engaged additional third-party wholesale distributors for the distribution of Phexxi in the US. 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.

If we are unable to engage additional wholesale distributors and/or maintain our relationship with our wholesale distributors within the US for Phexxi, our domestic commercialization activities may be disrupted. If we are able to identify and enter into a strategic relationship with one or more third party collaborators for the development of Phexxi outside of the US, we intend to work with that third party or third parties to obtain marketing approval for Phexxi in each relevant jurisdiction and to enter into distribution agreements with such third party or parties for distribution of Phexxi in each relevant jurisdiction outside the US. We cannot guarantee that we will be able to enter into any such additional wholesale distribution agreements on commercially reasonable terms, or at all, or that we will be able to identify any third party collaborators for the development and commercialization of Phexxi outside the US or that we will be able to enter into any such distribution agreement with any such third party for the distribution of Phexxi outside the US. For our current distribution agreements and for any future distribution agreements we may enter into, we would 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 U.S. 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 Foreign Corrupt Practices Act (FCPA) and the Drug Supply Chain Security Act (DSCSA) in the US. 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 Phexxi, 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. If we grant any such third-party distributor the right to manufacture any applicable product, we would also be subject to the risk factors set forth above with respect to third-party manufacturing of our product as well as the requirement to have any such additional manufacturer pre-approved by FDA or other relevant regulatory authorities. Further, third-party distributors may not perform as agreed or may terminate their agreements with us. Any significant problem or disruption that our distributors experience, including any disruption resulting from the COVID-19 pandemic, 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. Due to the global nature of the COVID-19 pandemic, we may be unable to find any alternative distributor. Any failure or delay in distributing products would likely have a negative impact on our business and operations.

We rely on third parties for the delivery of telehealth services through the Phexxi telehealth platform. Failure of these third parties to provide services of a suitable quality, in accordance with applicable regulations and within acceptable time frames may cause the delay or failure of our telehealth strategy.

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, quality assurance, clinical monitoring, and regulatory expertise. 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 rely on the efforts of these organizations and individuals and could suffer significant delays in our 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 or data integrity, which in turn could lead to delays in clinical development and obtaining regulatory approval. Third parties may not pass FDA or other regulatory audits. In addition, the cost of such services could significantly increase over time.

The Phexxi telehealth platform is designed to provide physicians with on-demand educational support, and to remove certain barriers to women's access to Phexxi by removing the need for an in-office visit. With the Phexxi telehealth platform, women can directly meet with an HCP to determine their eligibility for a Phexxi prescription and potentially have it written by the HCP, filled, and mailed directly to them by a third-party pharmacy. These telehealth platform services are not core to our business of developing and commercializing innovative products to address unmet needs in women's sexual and reproductive health. These services are also subject to complex federal and state laws and regulations and professional practice standards, and we do not have the resources to provide these telehealth services internally. Any pharmacy that fills Phexxi prescriptions will be fully independent from us. We do not control or own or possess any ownership stake in any pharmacy that we expect may fill prescriptions for Phexxi or in any telehealth service provider. All prescriptions will be routed through our independent third-party telehealth service providers. If our telehealth service providers fail to perform or fail to perform in compliance with applicable laws, regulations and standards of care, our business, financial condition, commercial launch of Phexxi and results of operation would be adversely affected.

If we are unable to enter into or maintain strategic relationships or collaborations with respect to Phexxi for the prevention of pregnancy, or if we are unable to realize the potential benefits from such collaborations, our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.

We do not presently expect to commercialize Phexxi, assuming international marketing approval is obtained, outside of the US unless we enter into a strategic relationship or collaboration with a third party. We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming arrangements to negotiate and document.

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 any clinical trials that may be required by relevant foreign regulatory authorities, 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.

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 commercialization activities at our own expense. If we elect to fund commercialization activities on our own, we would need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we enter into a collaboration agreement regarding a product, 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 either for convenience, if permitted, or 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. In addition, actions taken by a collaborator within its licensed territory, many of which we may not be able to control, could negatively impact our commercialization of the product in the US.

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 or will enter into manufacturing, distribution, wholesale, 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 Our Commercialization of Health Care Products

Phexxi and any other approved product we commercialize may face follow-on competition sooner than anticipated.

Although Phexxi vaginal gel is FDA-approved for commercialization in the US, it and any other product we may commercialize may face competition from generic products earlier or more aggressively than anticipated, depending upon how well such approved products perform in the US prescription drug market. In addition to creating the 505(b)(2) NDA pathway, the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to an Abbreviated New Drug Application (ANDA). An ANDA relies on the preclinical and clinical testing conducted for a previously approved reference listed drug (RLD) and must demonstrate to the FDA that the generic drug product is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is "bioequivalent" to the RLD. The FDA is prohibited by statute from approving an ANDA when certain marketing or data exclusivity protections apply to the RLD. If any such competitor or third party is able to demonstrate bioequivalence without infringing our patents, then this competitor or third party may then be able to introduce a competing generic product onto the market.

Phexxi is indicated for the prevention of pregnancy and was granted three (3) years of data exclusivity that expired on May 22, 2023, and it has been designated as an RLD by the FDA. We cannot predict the future Phexxi market, whether someone will attempt to force the FDA to take other actions, or how quickly others may seek to come to market with competing products now that the three-year data exclusivity period has ended.

If the FDA approves generic versions of our products, it could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments in those products.

Changes in health care 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 Phexxi. Our management expects our success will be dependent on the willingness or ability of patients to pay out-of-pocket for Phexxi 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 remain available for Phexxi vaginal gel for the prevention of pregnancy, or if reimbursement is available, that the amount of any such reimbursement would not change. We provide a financial assistance program for Phexxi patients to offset any co-pay or patient out of pocket costs, but we do not know if this program will be successful in increasing market acceptance or that such program will not prove to be prohibitively costly. Demand for Phexxi may decrease if we elect to discontinue our co-pay programs. The ACA and subsequent regulations enacted by the U.S. Department of Health and Human Services (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. In January 2022, the DHHS, Department of Labor, and Treasury Department jointly issued guidance on implementation of this ACA mandate, among other things. The recently issued federal guidance makes clear that all FDA-approved or cleared contraceptive products that are determined by an individual's medical provider to be medically appropriate for such individual must be covered without-cost sharing, regardless of whether the product is specifically identified in the FDA's Birth Control Guide.

However, certain members of Congress and other stakeholders may attempt 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; for example, the Trump administration in 2017 altered the mandate to allow certain employers and insurers to opt-out of birth control coverage for religious or moral reasons, which was partially upheld by the Supreme Court in July 2020. The DHHS, Department of Labor, and Treasury Department are expected to initiate rulemaking in 2022 that would amend existing regulations to account for recent litigation. We cannot predict the timing or impact of any future rulemaking 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 Phexxi, at all. We expect that health care reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that may be charged for Phexxi or any other product we commercialize. Even with coverage for any approved product, the resulting reimbursement payment rates might not be adequate or may require a co-pay that patients find unacceptably high. Patients are unlikely to use any products we may market unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of those products. 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 Phexxi in the event that their third-party payer either does not cover and reimburse Phexxi or requires payment of a portion of Phexxi by the patient, thus increasing the patient's overall cost to use Phexxi. This could reduce market demand for Phexxi or any future product we commercialize, which would have a material adverse effect on our business, financial conditions, and prospects.

We may also experience pressure from payers as well as state and federal government authorities concerning certain promotional approaches that we may implement, such as our co-pay programs. Certain state and federal enforcement authorities and members of Congress have initiated inquiries about co-pay programs. Some state legislatures have been considering proposals that would restrict or ban co-pay coupons. For example, legislation was recently signed into law in California that would limit the use of co-pay coupons in cases where a lower cost generic drug is available and if individual ingredients in combination therapies are available over the counter at a lower cost. It is possible that similar legislation could be proposed and enacted in additional states. If we are unsuccessful with or discontinue our co-pay programs, or we are unable to secure adequate coverage from third-party payers, we may experience financial pressure which would have a material adverse effect on our business and make it difficult to commercialize successfully.

Despite FDA-approval for Phexxi and even if we are successful in obtaining additional products to commercialize in the US, revenues may be adversely affected if Phexxi or any other product does not obtain coverage and adequate reimbursement from third-party payers in the US.

Market acceptance and sales of Phexxi vaginal gel or any other product we may commercialize 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 US 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 that we commercialize 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, including Phexxi. The U.S. 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. Coverage decisions can depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. We may incur significant costs to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our future products, in addition to the costs required to obtain the necessary FDA marketing approvals. Third-party payer coverage may not be available to patients for Phexxi or any future product we may seek to commercialize. If third-party payers do not provide coverage and adequate reimbursement for Phexxi or other products we may commercialize, if approved, HCPs may not prescribe them or patients may ask their HCPs 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 Phexxi 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 health care laws, including, without limitation, the U.S. Federal Anti-Kickback Statute, the U.S. Federal False Claims Act and the FCPA.

HCPs 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 health care professionals, principal investigators, consultants, third-party payers, customers and other organizations may expose us to broadly applicable fraud and abuse and other health care laws and regulations in the US. 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 others:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal health care program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws, including the False Claims Act, which can be enforced by private individuals through civil whistleblower or *qui tams* actions, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent;

- the Health Insurance Portability and Accountability Act (HIPAA) which, among other things, created new federal criminal statutes that prohibit executing a scheme to defraud any health care benefit program and making false statements relating to health care matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and its implementing regulations, which imposes certain requirements on certain covered HCPs, health plans, and health care clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information;

- the Physician Payments Sunshine Act, enacted as part of the ACA, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments and other transfers of value to physicians, as defined by such law, teaching hospitals, and certain advanced non-physician health care practitioners and ownership and investment interests held by physicians and their immediate family members; and,

- foreign and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to HCPs and other potential referral sources; state laws that require product manufacturers to report information related to payments and other transfers of value to physicians and other HCPs or marketing expenditures; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and which may conflict, thus complicating compliance efforts.

The scope and enforcement of these laws and regulations is uncertain and subject to rapid change. Notably, in November 2020, DHHS finalized significant changes to the regulations implementing the Anti-Kickback Statute, as well as the civil monetary penalty rules regarding beneficiary inducements, with the goal of offering the health care industry more flexibility and reducing the regulatory burden associated with those fraud and abuse laws, particularly with respect to value-based arrangements among industry participants. 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. These risks may be increased where there are evolving interpretations of applicable regulatory requirements, such as those applicable to manufacturer co-pay programs. Pharmaceutical manufacturer co-pay programs, including pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations, are the subject of ongoing litigation, enforcement actions and settlements (involving other manufacturers and to which we are not a party) and evolving interpretations of applicable regulatory requirements and certain state laws, and any change in the regulatory or enforcement environment regarding such programs could impact our ability to offer such programs. 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 and debarment from participation in Medicare, Medicaid and other federal health care 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.

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

In the US and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the health care system that could restrict or regulate post-approval activities and affect our ability to profitably sell any product.

Among policy makers and payers in the US and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access. In the US, the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, Congress passed the ACA, which substantially changed the way health care is financed by both the government and private insurers, and significantly impacts the US pharmaceutical industry. As another example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive health care provisions and amendments to existing laws, including a requirement that all manufacturers of drug products covered under Medicare Part B report the product's Average Sales Price (ASP) to DHHS beginning on January 1, 2022, subject to enforcement via civil money penalties.

There remain judicial and Congressional challenges to certain aspects of the ACA, and as a result certain sections of the ACA have not been fully implemented or effectively repealed. However, following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA's constitutionality. Further legislative and regulatory changes under the ACA remain possible, although the new federal administration under President Biden has signaled that it plans to build on the ACA and expand the number of people who are eligible for health insurance subsidies under it. It is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, such as changes allowing the federal government to directly negotiate drug prices, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the U.S.

Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In addition, CMS published a final rule that would give states greater flexibility, effective January 1, 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. If there are not adequate reimbursement levels, our business and results of operations could be adversely affected.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030 unless additional Congressional action is taken. However, the Medicare sequester reductions under the Budget Control Act of 2011 will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic, pursuant to provisions of the CARES Act which also extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. The suspension was subsequently extended through March 31, 2022, with a reduction of the suspension to 1% sequester through June 30, 2022.

In addition, in 2013, the Drug Supply Chain Security Act (DSCSA) enacted imposed obligations on manufacturers of pharmaceutical products related to product tracking and tracing. On December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the CREATES Act. The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. The CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown. Other legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are unsure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or whether such changes will have any impact on our business.

Additionally, there has been heightened governmental scrutiny in the US 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. For example, state legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical 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. In December 2020, the U.S. Supreme Court unanimously held that federal law does not preempt the states' ability to regulate PBMs or other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area.

At the federal level, DHHS has solicited feedback on various measures intended to lower drug prices and reduce the out of pocket costs of drugs and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. In addition, in 2020, the FDA finalized a rulemaking to establish a system whereby state governmental entities could lawfully import and distribute prescription drugs sourced from Canada. The Biden Administration, which assumed control of the Executive Branch on January 20, 2021, has also indicated that lowering prescription drug prices is a priority. For example, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and health care insurance industries. Among other things, the executive order directs the FDA to work towards implementing a system for importing drugs from Canada (following on the Trump administration notice-and-comment rulemaking on Canadian drug importation finalized in October 2020). The Biden order also called on DHHS to release a comprehensive plan to combat high prescription drug prices, and it includes several directives regarding the Federal Trade Commission's oversight of potentially anticompetitive practices within the pharmaceutical industry. The drug pricing plan released by DHHS in September 2021 in response to the executive order makes clear that the Biden Administration supports aggressive action to address rising drug prices, including allowing DHHS to negotiate the cost of Medicare Part B and D drugs, but such significant changes will require either new legislation to be passed by Congress or time-consuming administrative actions. The implementation of cost containment measures or other health care reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Current and future health care legislation could have a significant impact on our business. There is uncertainty with respect to the impact these changes, if any, may have, and any changes likely will take time to unfold. Any additional federal or state health care reform measures could limit the amounts that third-party payers will pay for health care products and services, and, in turn, could significantly reduce the projected value of certain development projects and reduce our profitability.

We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We and our third-party service providers are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the US, we and our third-party service providers may be subject to state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure and transmission of personal information. These laws overlap and often conflict and each of these laws are subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our third-party service providers. In particular, our Phexxi telehealth platform and our online, digital and media marketing strategies are required to comply with these laws and regulations. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain information that is protected by HIPAA (protected health information) from a covered entity or business associate in a manner that is not authorized or permitted by HIPAA or for aiding and abetting a violation of HIPAA.

The regulatory environment surrounding information security, data collection, and privacy is increasingly demanding. We are subject to numerous U.S. federal and state laws and regulations governing the protection of health, personal information, and financial information of our customers, clinical subjects, clinical investigators, employees, and vendors/business contacts. For example, California has implemented the California Confidentiality of Medical Information Act that imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information, and California has recently adopted the CCPA, which went into effect in January of 2020. The CCPA mirrors a number of the key provisions of the EU General Data Protection Regulation (GDPR) described below. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Additionally, a new privacy law, the California Privacy Rights Act (CPRA), was a ballot measure approved by California voters in the election on November 3, 2020, and certain provisions are effective as of January 1, 2022 with full effectiveness as of January 1, 2023. The CPRA modifies and expands the CCPA significantly, and among other things, creates the California Privacy Protection Agency with full administrative power, authority and jurisdiction to implement and enforce CCPA. CPRA transferred rulemaking authority from the California attorney General to the California Privacy Protection Agency effective July 1, 2021 with final CPRA regulations due by July 1, 2022. CPRA enforcement began July 1, 2023. The CCPA creates the potential for further uncertainty, additional costs and expenses in our efforts to comply with California privacy requirements and additional potential for harm and liability for failure to comply. Virginia and Colorado enacted similar data protection laws in 2021, and other U.S. states have proposals under consideration, increasing the regulatory compliance risk.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations.

On May 25, 2018, the GDPR went into effect, implementing a broad data protection framework that expanded the scope of EU data protection law, including to non-EU entities that process, or control the processing of, personal data relating to individuals located in the EU, including clinical trial data. The GDPR sets out a number of requirements that must be complied with when handling the personal data of EU based data subjects, including: providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be "forgotten" and rights to data portability, as well as enhanced current rights (e.g. access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; and a new mandatory data breach regime. In particular, medical or health data, genetic data and biometric data where the latter is used to uniquely identify an individual are all classified as "special category" data under the GDPR and afford greater protection and require additional compliance obligations. Further, EU member states have a broad right to impose additional conditions—including restrictions—on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). As the EU states continue to reframe their national legislation to harmonize with the GDPR, we will need to monitor compliance with all relevant EU member states' laws and regulations, including where permitted derogation from the GDPR are introduced.

We will also be subject to evolving EU laws on data export if we transfer data outside the EU to ourselves or third parties. The GDPR only permits exports of data outside the EU where there is a suitable data transfer solution in place to safeguard personal data (e.g. the EU Commission approved Standard Contractual Clauses). On July 16, 2020, the Court of Justice of the EU (CJEU) issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C-311/18) (Schrems II). This decision calls into question certain data transfer mechanisms as between the EU member states and the US. The CJEU is the highest court in Europe and the Schrems II decision heightens the burden on data importers to assess U.S. national security laws on their business future actions of EU data protection authorities are difficult to predict at the early date. Consequently, there is some risk of any data transfers from the EU being halted. If we have to rely on third parties to carry out services for us, including processing personal data on our behalf, we are required under GDPR to enter into contractual arrangements to help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could cause customers to lose trust in us, which would have an adverse impact on our reputation and business. Any contractual arrangements requiring the processing of personal data from the EU to us in the US will require greater scrutiny and assessments as required under Schrems II and may have an adverse impact on cross-border transfers of personal data or increase costs of compliance. The GDPR provides an enforcement authority to impose large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. We will be subject to GDPR when we have a EU presence or "establishment" (e.g. EU based subsidiary or operations), when conducting clinical trials with EU based data subjects, whether the trials are conducted directly by us or through a vendor or partner, or offering approved products or services to EU based data subjects, regardless of whether involving a EU based subsidiary or operations.

Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, we may find that we are violating the laws or regulations of another jurisdiction. Despite our efforts, we may not have fully complied in the past and may not in the future. If we become liable under laws or regulations applicable to us, we may be required to pay significant fines and penalties, our reputation may be harmed, and we may be forced to change the way we operate. That could require us to incur significant expenses, which could significantly affect our business.

Our business may be adversely affected by unfavorable macroeconomic conditions, including the COVID-19 pandemic, geopolitical conflicts, and other factors.

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), trade disputes between nations 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.

In addition, U.S. and global financial markets have experienced disruption due to various macroeconomic and geopolitical events. These include, but are not limited to, rising inflation, rising interest rates, the risk of a recession and other ongoing global conflicts. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. At the time of the closure we held assets in an account with SVB, however we were able to retrieve such funds and move them to other institutions, and as of the date of this Annual Report, we have minimal funds in an SVB account. On March 12, 2023, the FDIC announced that SVB was closed and that the FDIC was appointed as receiver. On March 13, 2023, the FDIC announced that all of SVB's deposits and substantially all of its assets had been transferred to a newly created, full-service FDIC-operated bridge bank, Silicon Valley Bridge Bank, N.A. (SVBB). SVBB assumed all loans that were previously held by SVB. On March 27, 2023, First-Citizens Bank & Trust Company assumed all of SVBB's customer deposits and certain other liabilities and acquired substantially all of SVB's loans and certain other assets from the FDIC. While we have had full access to the assets and were able to successfully protect them since March 13, 2023, we may be impacted by other disruptions to the U.S. banking system caused by the recent developments involving SVB, including potential delays in our ability to transfer funds and potential delays in making payments to vendors while new banking relationships are established. We cannot predict at this time to what extent our or our collaborators, employees, suppliers, contract manufacturers and/or vendors could be negatively impacted by these and other macroeconomic and geopolitical events.

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. 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. Failure by any of them to remain in business could affect our ability to manufacture Phexxi.

Some physician offices appear to have been negatively impacted by restrictions on elective procedures and office visits during the pandemic. To the extent physician offices are again closed or visits are again reduced, patients could be less likely to be prescribed Phexxi. Even with our ongoing telehealth efforts through channels such as the Phexxi telehealth platform, we may not be able to effectively commercialize Phexxi for the prevention of pregnancy as a result of our reduced sales force, any reduction in physician office visits, or other circumstances related to a public health emergency. Any such emergency may adversely affect us and our business in manner we may be unable to reliably predict or quantify.

Also, as a result of the ongoing geopolitical tensions and conflict between Russia and Ukraine, and the invasion by Russia of Ukraine, the governments of the US, European Union, Japan and other jurisdictions have announced the imposition of sanctions on certain industry sectors and parties in Russia and the regions of Donetsk and Luhansk, as well as enhanced export controls on certain products and industries throughout 2023 and the situation continues to evolve with additional sanctions possible. Further, the Israel-Hamas wars, and any escalations thereof, may result in adverse impacts on the global economy which may in turn negatively impact our business. These and any additional sanctions and export controls, as well as any counter responses by the governments of the countries in conflict or at war, or other jurisdictions, could adversely affect, directly or indirectly, the global supply chain, with negative implications on the availability and prices of raw materials, energy prices, and our customers, as well as the global financial markets and financial services industry.

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 are unable to attract and retain management and other key personnel, we may be unable to successfully commercialize Phexxi or otherwise implement our business plan.

As of March 21, 2024, we had a total of 37 full-time employees and one part-time employee. In addition, we use third-party consultants to assist with finance, including regulatory filings, sales, marketing and market access research and programs, as well as general and administrative activities. As our development and commercialization plans and strategies continue to 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, or that our staffing levels may turn out to be too robust for our actual business activity.

Our ability to compete in the highly competitive pharmaceutical industry 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, 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, we 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.

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 legal requirements or 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 health care 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 health care 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, cybersecurity 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, human error, and telecommunication and electrical failure. Cybersecurity risks continue to increase for our industry, including for our third-party vendors, who may hold some of our data, and the proliferation of new technologies and the increased sophistication and activities of the actors behind such attacks present risks for compromised or lost data, which could result in substantial costs and harm to our reputation. 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 commercialization or product development programs. For example, the loss of clinical study data from future clinical trials could result in liability, 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. In addition, our commercialization of Phexxi is partially reliant on the use of the Phexxi telehealth platform and our other digital or media marketing strategies. We are in turn reliant on third parties and limited internal resources to ensure the Phexxi telehealth platform and these other digital and marketing resources function appropriately. Our commercialization of Phexxi may be adversely affected to the extent the Phexxi telehealth platform and our other online marketing resources do not work properly or are disrupted. 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 commercialization or development of our products may be delayed. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches and these costs could be significant.

The US federal and various state and foreign governments have adopted or proposed requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals, and federal and state consumer protection laws are being applied to enforce regulations related to the collection, use, and dissemination of data. Some of these federal, state and foreign government requirements include obligations of companies to notify individuals and others of security breaches involving health information or particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Even though we may have contractual protections with such vendors, contractors, or other organizations, notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers.

The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated or remote areas of the world. For example, there may be an increased risk of cybersecurity attacks by state actors due to the current conflict between either Russia and Ukraine or between Israel and Hamas. Additionally, Russian ransomware gangs have threatened to increase hacking activity against critical infrastructure of any nation or organization that retaliates against Moscow for its invasion of Ukraine. Any such increase in such attacks on our third-party provider or other systems could adversely affect our network systems or other operations. We may not be able to address these techniques proactively or implement adequate preventative measures. There can be no assurance that we will promptly detect any such disruption or security breach, if at all. If our computer systems are compromised, we could be subject to fines, damages, reputational harm, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business, in addition to possibly requiring substantial expenditures of resources to remedy. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. In addition, a cybersecurity breach could adversely affect our reputation and could result in other negative consequences, including disruption of our internal operations, increased cyber security protection costs, lost revenues or litigation. Despite precautionary measures to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business.

Any such security breach may compromise information stored on our networks and may result in significant data losses or theft of our intellectual property or proprietary business information, it may also subject us to significant fines, penalties or liabilities for any noncompliance with certain privacy and security laws. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches. A cybersecurity breach could adversely affect our reputation and could result in other negative consequences, including disruption of our internal operations, increased cybersecurity protection costs, lost revenue or litigation.

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. Now that we are no longer an emerging growth company, we expect these expenses will further increase. 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 the OTC Markets have 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.

While we remain a smaller reporting company and have revenues of less than $100 million per year, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If and when we are required to achieve compliance with regulatory auditor attestation report requirements 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. As described herein, we have identified 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 consolidated financial statements.

Loss of 39 employees during the 2022 RIF, 11 employees during the March 2023 RIF and the inability to attract and retain qualified key management personnel would impair our ability to implement our business plan.

Our success largely depends on the continued service of key management, advisors and other specialized personnel, including Saundra Pelletier our Chief Executive Officer, who is employed at-will and for whom we do not have “key man” insurance coverage. On March 3, 2023 Justin J. File, our Chief Financial Officer tendered his resignation effective April 3, 2023. On March 6, 2023, our Board of Directors appointed Albert Altro as Interim Chief Financial Officer and on April 13, 2023, our Board of Directors appointed Ivy Zhang as Chief Financial Officer and Secretary.

As a result of the RIF in the fourth quarter of 2022, we reduced our workforce by 39 employees. As a result of the RIF in the first quarter of 2023, we further reduced our workforce by 11 employees. The loss of one or more members of our management team or other key employees or advisors could delay our commercialization efforts and could also have a material and adverse effect on our business, financial condition, results of operations and prospects. Our future success will depend in large part on our continued ability to attract and retain other highly qualified management personnel, as well as personnel with expertise in women’s health care, drug development, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations (many of whom have substantially greater financial resources than us), and we might not be able to attract or retain these key employees on conditions that are economically acceptable. Our inability to attract and retain these key employees could prevent us from achieving our objectives and implementing our business strategy, which could have a material adverse effect on our business and prospects.

In connection with the departure of key personnel, we may be subject to certain separation payments, legal actions or other claims.

We are and may continue to be responsible for the payment of all earned and unpaid wages, vacation, bonuses and other forms of compensation due to certain employees. Our failure to pay such may result in claims being filed against us and us being subject to further penalties for any violations. The failure to successfully remediate any such disputes or pay any amounts payable could negatively impact our business, financial conditions, results of operations and prospects.

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 FCPA, the U.S. domestic bribery statute contained in 18 US Code (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 US, 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.

We or the third parties upon whom we depend may be adversely affected by earthquakes, medical epidemics or pandemics, or other natural disasters. These natural disasters may be exacerbated by the effects of climate change.

Our principal offices are located in our facilities in San Diego, California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents that results in us being unable to fully utilize our facilities, effects the ability of our employees working remotely to communicate with us and our systems, or that affects the operations of our third party manufacturers, distributors, service providers or consultants may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. These natural events may become worse over time due to the ongoing effects of climate change. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Common Stock

Our shares of common stock have been delisted from the Nasdaq Capital Market which have and could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock.

Our common stock was listed on the Nasdaq Capital Market, but as a result of our failure to maintain a minimum $1.00 per share bid price requirement for continued inclusion on the Nasdaq Capital Market pursuant to the Bid Price Requirement, on October 27, 2022, we were delisted. Since July 12, 2021, the closing bid price for our common stock has been below $1.00 per share. On August 23, 2021, we received a deficiency letter from the Staff of Nasdaq notifying us, that, for the preceding 30 consecutive trading days, the closing bid price for shares of our common stock was below the minimum $1.00 per share requirement and that we had failed to comply with the Bid Price Requirement. In accordance with Nasdaq rules, we were provided until the Compliance Date to regain compliance with the Bid Price Requirement. We did not evidence compliance with the Bid Price Requirement by the Compliance Date and, as a result, the Staff of Nasdaq notified us on February 22, 2022 that shares of our common stock were subject to delisting unless we timely requested a hearing before the Nasdaq Hearings Panel. On October 27, 2022, the Nasdaq Stock Market, LLC filed the Notification of Removal From Listing and Registration Under 12(b) of the Securities Exchange Act of 1934 with the SEC.

Delisting from the Nasdaq Capital Market has made trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. Other possible consequences could include: a default under our Notes, an adverse effecting on our ability to obtain equity financing at acceptable terms or at all, a negative effect on the common stock trading volume, price, and an increase in the stock volatility, and a possible loss of confidence by shareholders, employees, and business partners. As noted above, in the event of a default under our Notes, holders of our common stock may not receive the value of their investment.

Our stock price is and may continue to be volatile.

Our Common Stock is currently quoted for public trading on the OTCQB under the symbol "EVFM". The market price for our common stock is volatile and may fluctuate significantly in response to a number of factors, many of which we cannot control, such as potential irregularity in financial results from quarter to quarter, political developments related to women's reproductive rights and contraception, the content and tone of media coverage and commentary, or changes in securities analysts' recommendations, any of which could cause the price of our common stock to fluctuate substantially. Each of these factors, among others, could harm your investment in our securities and could result in your being unable to resell any of our securities that you purchase at a price equal to or above the price you paid.

In addition, 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 delisting of our common stock from Nasdaq;
- failure to file all future required filings in a timely fashion;
- the failure to consummate the transactions in the Merger Agreement;
- the loss of key personnel;
- the results of our efforts to commercialize Phexxi or any other products, particularly in the event of a rebrand;
- the results of our efforts to acquire or in-license products;
- 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 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;
- 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, wars, terrorism and political unrest, outbreak of disease (e.g., the COVID-19 pandemic), boycotts and other business restrictions;
- regulatory or legal developments in the US 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 and related debt and equity issuances;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock;
- stockholder activism;
- any stockholder derivative actions; and
- other factors described in this "Risk Factors" section.

Upon being listed on the OTCQB Marketplace on October 10, 2022 the closing sales price started at $21.25, was $0.064 as of December 31, 2023, and was $0.0158 as of March 21, 2024. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. 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.

There may not be an active, liquid trading market for our equity securities.

Our common stock trades exclusively on the OTCQB Marketplace. Trading volumes on the OTCQB Marketplace can fluctuate significantly, which could make it difficult for investors to execute transactions in our securities and could cause declines or volatility in the prices of our equity securities.

Because our Common Stock is subject to the "penny stock" rules, brokers cannot generally solicit the purchase of our Common Stock, which adversely affects its liquidity and market price.

The SEC has adopted regulations which generally define "penny stock" to be an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. The market price of our Common Stock on the OTCQB Marketplace is presently less than $5.00 per share and therefore we are considered a "penny stock" company according to SEC rules. Further, we do not expect our stock price to rise above $5.00 in the foreseeable future. The "penny stock" designation requires any broker-dealer selling our securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules limit the ability of broker-dealers to solicit purchases of our Common Stock and therefore reduce the liquidity of the public market for our shares.

Moreover, as a result of apparent regulatory pressure from the SEC and the Financial Industry Regulatory Authority (FINRA), a growing number of broker-dealers decline to permit investors to purchase and sell or otherwise make it difficult to sell shares of penny stocks. The "penny stock" designation may have a depressive effect upon our Common Stock price.

Because we do not have sufficient authorized capital on a fully diluted basis, the excess outstanding capital exposes us to liability, and we will need to increase our authorized capital, effectuate a reverse split or obtain effective waivers from derivative securityholders.

As of December 31, 2023, and March 21, 2024, our authorized capital consists of 3,000,000,000 shares of common stock and 5,000,000 shares of Preferred Stock. As of December 31, 2023, of the authorized common stock, 20,007,799 shares were issued and outstanding and 1,424,078,365 shares were reserved for issuance under potential conversions of convertible notes, purchase rights, preferred shares, warrants and all other derivatives. As of March 21, 2024, of the authorized common stock, 45,939,509 shares were issued and outstanding and approximately 915 million shares were reserved for issuance under potential conversions of convertible notes, purchase rights, preferred shares, warrants and all other derivatives, exclusive of instruments for which the reservation requirement was waived by the respective holders. As such, our fully diluted capital structure is more than the amount of common stock we are authorized to issue. Therefore, until we either increase our authorized common stock, effectuate a reverse split, or another manner of reducing the number of instruments convertible to common stock, we are exposed to the risk of liability arising from the excess fully diluted capitalization. In addition to the dilutive effect any exercises of the derivative securities would have, in the event we are unable to obtain the requisite approvals or the current waivers are rescinded, or we are delayed in those efforts, the Company and your investment in us would be at risk.

Our common stock could be further diluted as the result of the issuance of additional shares of common stock, convertible securities, warrants or options.

In the past, we have issued common stock, convertible securities (such as convertible notes) and warrants in order to raise capital. We have also issued common stock as compensation for services and incentive compensation for our employees, directors and certain vendors. We have shares of common stock reserved for issuance upon the exercise of certain of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional common stock, convertible securities, options and warrants could affect the rights of our stockholders, could reduce the market price of our common stock or could result in adjustments to exercise prices of outstanding warrants (resulting in these securities becoming exercisable for, as the case may be, a greater number of shares of our common stock), or could obligate us to issue additional shares of common stock to certain of our stockholders.

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. Future issuances of our securities may cause additional reduction in the percentage interests of our current stockholders in the voting power, liquidation value, our book and market value, and in any future earnings. As of March 21, 2024, there were approximately 3,747 shares of our common stock subject to outstanding options which have been registered on registration statements on Form S-8. Furthermore, as of March 21, 2024, there were an aggregate of approximately and approximately 915 million shares were reserved for issuance under potential conversions of convertible notes, purchase rights, preferred shares, warrants and all other derivatives, exclusive of instruments for which the reservation requirement was waived by the respective holders. We have granted (or are required to grant) certain of our security holders registration rights pursuant to our agreements with these holders, including agreements requiring us to register for resale the shares of our common stock issued upon the conversion or exercise of our convertible notes and related warrants.

The issuance or resale of our common stock issued to our security holders upon conversion of convertible notes or upon exercise of our warrants or options could cause the market price of our common stock to decline. In addition, the increase in the number of issued shares of our common stock issuable upon conversion of our convertible notes or upon exercise of our warrants may have an incidental anti-takeover effect in that these additional shares could be used to dilute the stock ownership of parties seeking to obtain control of us. The resulting increased number of issued shares could discourage the possibility of, or render more difficult, certain mergers, tender offers, proxy contests or other change of control or ownership transactions.

We are and may continue to be subject to short-selling strategies.

Short sellers of our stock may be manipulative and may attempt to drive down the market price of shares of our Common Stock. Short selling is the practice of selling securities that the seller does not own but rather has, borrowed from a third party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is therefore in the short seller's best interests for the price of the stock to decline, many short sellers (sometime known as "disclosed shorts") publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects to create negative market momentum and generate profits for themselves after selling a stock short. Although traditionally these disclosed shorts were limited in their ability to access mainstream business media or to otherwise create negative market rumors, the rise of the Internet and technological advancements regarding document creation, videotaping and publication by weblog (blogging) have allowed many disclosed shorts to publicly attack a company's credibility, strategy and veracity by means of so-called "research reports" that mimic the type of investment analysis performed by large Wall Street firms and independent research analysts. These short attacks have, in the past, led to selling of shares in the market, on occasion in large scale and broad base. Issuers who have limited trading volumes and are susceptible to higher volatility levels than large-cap stocks, can be particularly vulnerable to such short seller attacks. These short seller publications are not regulated by any governmental, self-regulatory organization or other official authority in the US, are not subject to certification requirements imposed by the SEC and, accordingly, the opinions they express may be based on distortions or omissions of actual facts or, in some cases, fabrications of facts. In light of the limited risks involved in publishing such information, and the enormous profit that can be made from running a successful short attack, unless the short sellers become subject to significant penalties, it is more likely than not that disclosed short sellers will continue to issue such reports.

Significant short selling of a company's stock creates an incentive for market participants to reduce the value of that company's common stock. Short selling may lead to the placement of sell orders by short sellers without commensurate buy orders because the shares borrowed by short sellers do not have to be returned by any fixed period of time. If a significant market for short selling our common stock develops, the market price of our common stock could be significantly depressed.

Continued failure to remediate current material weaknesses and establish and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

As a publicly traded company, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. As discussed below, we have identified internal control weaknesses, and need to undertake various actions, such as implementing new internal controls, new systems and procedures and hiring additional accounting or internal audit staff, which could increase our operating expenses. In addition, we may identify additional deficiencies in our internal control over financial reporting as part of that process.

In addition, if we are unable to resolve internal control deficiencies in a timely manner, investors could lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected.

We identified material weaknesses in our internal control over financial reporting as of December 31, 2023 and 2022 and these or other material weaknesses could continue to materially impair our ability to report accurate financial information in a timely manner.

As of December 31, 2023 (the period covered by this Annual Report), the Company's management, with the participation of its principal executive officer and principal financial officer, has evaluated the effectiveness of its disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on such evaluation, the principal executive officer and principal financial officer have concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2023 due to the identified material weaknesses in internal control over financial reporting as discussed below.

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Management, under the supervision and with the participation of the principal executive officer and principal financial officer, conducted an assessment of the effectiveness of internal control over financial reporting as of December 31, 2023, based on the framework and criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO framework). Based on this assessment, management concluded that, as of December 31, 2023, its internal control over financial reporting was not effective due to the existence of material weaknesses described below.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of the annual or interim financial statements would not be prevented or detected on a timely basis.

Management identified material weaknesses in the Company's internal control over financial reporting primarily related to limited finance and accounting staffing levels that are not commensurate with the Company's complexity and its financial accounting and reporting requirements. The Company continued to undergo organizational changes in 2023, including the resignation of the principal financial officer and the decision to operate with a very lean finance and accounting department. Despite performing some remediation activities in 2023, bringing new staff up to speed with key processes, including some very complicated financial instruments and transactions, caused the Company to lack the resources to fully monitor and operate internal controls of financial reporting.

Based on the above, the Company did not fully implement components of the COSO framework, including elements of the control environment, risk assessment, control activities, information and communication, and monitoring activities components.

Management continues to evaluate the material weaknesses discussed above and is implementing its remediation plan. However, assurance as to when the remediation efforts will be complete cannot be provided and the material weaknesses cannot be considered remedied until the applicable controls have operated for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Management cannot assure readers that the measures that have been taken to date, and are continuing to be implemented, will be sufficient to remediate the material weaknesses identified or to avoid potential future material weaknesses.

We are a "smaller reporting company", and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a "smaller reporting company" under SEC regulations. For so long as we remain a 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 smaller reporting companies. These exemptions include:

- for so long as we remain a smaller reporting company with annual revenues of less than $100 million per year and a public float value as of our most recently completed second fiscal quarter of less than $700 million, not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; and
- reduced disclosure obligations regarding executive compensation.

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 price may be more volatile.

We do not anticipate paying any cash dividends on our common 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. As noted above, we are also restricted from paying cash dividends pursuant to our debt arrangements. Except as may be required to redeem our issued and outstanding promissory notes or shares of Series E-1 Shares, 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;
- 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 indemnities, 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 cease publishing 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 cease regularly publishing 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.

Our business could be negatively affected as a result of the actions of activist stockholders.

It is possible that one or more of our stockholders may publicly voice opposition to our financing strategy, the Merger Agreement, and/or certain aspects of our corporate governance and strategy, or undertake a proxy contest to reconstitute our board. Proxy contests have been waged against many companies in the biopharmaceutical industry over the last several years. If faced with a proxy contest or other type of stockholder activism, we may not be able to respond successfully to the contest or other type of activism which would be disruptive to our business. Even if we are successful, our reputation and/or business could be adversely affected by a proxy contest or other form of stockholder activism because:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees;
- perceived uncertainties as to our company and future strategic direction may result in the loss of potential financing, acquisitions, collaboration, in-licensing or other business opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

Any or all of these activities could cause our stock price to decline or experience periods of volatility, and could be particularly problematic as our company seeks to transition to a commercial enterprise in a challenging environment.

We may become a defendant in one or more stockholder derivative or class-action litigations, and any such future lawsuit may adversely affect our business, financial condition, results of operations and cash flows.

We and certain of our officers and directors may become defendants in one or more future stockholder derivative actions or other class-action lawsuits. These lawsuits would divert our management's attention and resources from our ordinary business operations, and we would likely incur significant expenses associated with their defense (including, without limitation, substantial attorneys' fees and other fees of professional advisors and potential obligations to indemnify current and former officers and directors who are or may become parties to such actions). If these lawsuits do arise, we may be required to pay material damages, consent to injunctions on future conduct and/or suffer other penalties, remedies or sanctions. In addition, any such future stockholder lawsuits could adversely impact our reputation and/or to launch and commercialize Phexxi, thereby harming our ability to generate revenue. Accordingly, the ultimate resolution of these matters could have a material adverse effect on our business, financial condition, results of operation and cash flow and, consequently, could negatively impact the trading price of our common stock.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We recognize the importance cybersecurity has to the success of our business. We also recognize the need to continually assess cybersecurity risk and evolve our response in the face of a rapidly and ever-changing environment. Accordingly, we aim to protect our business operations, including customer records and information, against known and evolving cybersecurity threats.

Risk Management and Strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards. Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with the Director, Information Technology who reports to our Head of Human Resources and the Chief Executive Officer, to manage the risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our safeguards and train our employees on these safeguards, in collaboration with Information Technology and management. Personnel at all levels and departments are made aware of our cybersecurity policies through trainings.

We engage consultants, or other third parties in connection with our risk assessment processes if required. These service providers assist us in designing and implementing our cybersecurity policies and procedures. We require each third-party service provider to certify that it has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our company.

We have not encountered cybersecurity challenges that have materially impaired our operations or financial standing. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, "Risk Factors," in this annual report on Form 10-K.

Governance

One of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its cybersecurity risk oversight function directly as a whole, as well as through the audit committee.

Our management team is primarily responsible for assessing and managing our material risks from cybersecurity threats with assistance from third-party service providers as needed.

Our management team oversees our cybersecurity policies and processes, including those described in the "Risk Management and Strategy" above. The cybersecurity risk management program includes tools and activities to prevent, detect, and analyze current and emerging cybersecurity threats, and plans and strategies to address threats and incidents.

Our management team will also provide periodic briefings to the audit committee regarding our Company's cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like. Our audit committee will then provide updates to the Board on such reports.

Item 2. Properties.

Effective April 1, 2023, our corporate headquarters are now virtual and are located at 7770 Regents Rd, Suite 113-618, San Diego, California. We maintain this address for mail service.

We believe that our existing facilities are adequate for our current needs.

Item 3. Legal Proceedings.

From time to time, we may be involved in various actual and threatened legal proceedings, claims, investigations and government inquiries arising in the ordinary course of our business, including intellectual property, securities, stockholder derivative claims, employment, governance, workplace culture, contractual rights, false or misleading advertising, or other legal claims relating to our products and operations. Any proceedings, claims or inquiries involving us, whether successful or not, may be time consuming, result in costly litigation, unfavorable outcomes, increased costs of business, may require us to change our business practices or products, require significant amount of management's time, may harm our reputation or otherwise harm our business and future financial results.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on the Nasdaq Global Market on November 20, 2014 under the ticker symbol "NEOT" and corporate name Neothetics, Inc. (Neothetics). Prior to November 20, 2014, there was no public market for our common stock. On January 17, 2018, we completed a merger (the Merger) with privately-held Evofem Biosciences Operations, Inc. (Private Evofem) where Private Evofem survived as our wholly owned subsidiary. In connection with the Merger, we changed our name from "Neothetics, Inc." to "Evofem Biosciences, Inc." and changed the ticker symbol for our common stock to "EVFM." Shares of our common stock began trading on the Nasdaq Capital Market (Nasdaq) under the ticker symbol EVFM on January 18, 2018.

On August 11, 2022, our stock was suspended from trading on the Nasdaq due to noncompliance with its minimum bid price requirement. On October 26, 2022, our common stock was formally delisted from Nasdaq. The delisting of our shares from Nasdaq makes our common stock less liquid and makes it more difficult for us to raise funds when and as needed to fund operations. Our common stock began trading on the OTCQB® Venture Market (the OTCQB) of the OTC Markets Group, Inc., a centralized electronic quotation service for over-the-counter securities, effective October 3, 2022 under the symbol "EVFM."

Holders of Common Stock

As of March 21, 2024, there were 45,939,509 shares of our common stock outstanding and 14 holders of record of our common stock. This number was derived from our stockholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Recent Sales of Unregistered Securities

Except as previously disclosed in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, we had no sales of unregistered equity securities during the year ended December 31, 2023.

Dividend Policy

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

Our series E-1 Shares does earn shares dividends payable in shares of common stock, at a rate of 10% per annum. On the 18-month anniversary of the initial issuance date for the Series E-1 convertible preferred stock, the dividend rate shall further increase by 30 percent on the first calendar day of each calendar quarter thereafter until no shares of Series E-1 Shares remain outstanding.

Equity Compensation Plan Information

Information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report.

Issuer Repurchases of Equity Securities

For the quarter ended December 31, 2023, we did not repurchase any equity securities.

Item 6. [RESERVED]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis is set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a San Diego-based commercial-stage biopharmaceutical company with a strong focus on innovation in women's health. Our first commercial product, Phexxi, was approved by the FDA on May 22, 2020. Phexxi is the first and only FDA-approved, hormone-free prescription contraceptive vaginal gel. It comes in a pre-filled applicator and is applied within one hour before intercourse, empowering women with a convenient, discreet, and flexible contraception method that puts control in their hands. We commercially launched Phexxi in September 2020 in the US and since then have reported increased net product sales for each successive year. We intend to commercialize Phexxi in all other global markets through partnerships or licensing agreements.

We halted all remaining clinical development of investigational product candidates in October 2022 to focus resources on growing sales of Phexxi for the prevention of pregnancy.

Recent Developments

Effective January 1, 2024, the Washington State Health Care Authority (HCA) removed the Prior Authorization for Phexxi, facilitating Phexxi access for nearly 1.8 million covered Washingtonians on the state HCA's Managed Medicaid and Fee for Service Medicaid plans. Phexxi continues to be included on the Washington State HCA Preferred Drug List.

On February 26, 2024, Aditxt and the Holders (defined below) entered into an Assignment Agreement (the February Assignment Agreement), pursuant to which the Company consented to the assignment of all remaining amounts due under the Notes from Aditxt back to the Holders.

Aditxt Merger

On December 11, 2023, the Company entered into an Agreement and Plan of Merger, as amended (the Merger Agreement) with Aditxt, Inc., a Delaware corporation (Aditxt), Adicure, Inc., a Delaware corporation, and a wholly-owned Subsidiary of Aditxt (Merger Sub), pursuant to which, and on the terms and subject to the conditions thereof, Merger Sub will merge with and into the Company, with the Company surviving as a wholly owned subsidiary of Aditxt (the Merger). The Merger is expected to be closed in the second half of 2024; the accompanying consolidated financial statements in this Annual Report do not reflect the potential impact of the Merger Agreement.

On January 10, 2024, the Company, Aditxt and Merger Sub entered into the first amendment to the Merger Agreement (the First Amendment), to change the filing date for the Joint Proxy Statement (as defined in the Merger Agreement) to February 14, 2024. On January 30, 2024, the Company, Parent and Merger Sub entered into the second amendment to the Merger Agreement (the Second Amendment) to amend (i) the date of the Parent Loan (as defined in the Merger Agreement) to the Company to be February 29, 2024, (ii) to change the date by which the Company may terminate the Merger Agreement for failure to receive the Loan from Parent to be February 29, 2024, and (iii) to change the filing date for the Joint Proxy Statement (as defined in the Merger Agreement) to April 1, 2024. On February 29, 2024, the parties entered into the third amendment to the Merger Agreement to (i) Amend and restate Section 6.10 in its entirety as follows: "Parent Equity Investment. On or prior to (a) April 1, 2024, Parent shall purchase 2,000 shares of the Company's Series F-1 Preferred Shares, par value $0.0001 per share for an aggregate purchase price of $2.0 million (the Initial Parent Equity Investment) and (b) April 30, 2024, Parent shall purchase 1,500 shares of F-1 Preferred Shares for an aggregate purchase price of $1.5 million (the Subsequent Parent Equity Investment). (ii) the proviso in Section 6.16 was deleted in its entirety, (iii) the date to file a Joint Proxy Statement was extended to April 30, 2024, (iv) a new Section 7.2(i) was added as follows "(i) *Repurchase Price*. No defaults shall have occurred and be continuing under the Loan Documents and the Outstanding Balance (as defined in the Securities Purchase Agreement) plus all accrued and unpaid interest thereon, in an amount not to exceed the Repurchase Price (as defined in the Securities Purchase Agreement) shall have been paid in full." and (v), Section 8.1(f) is amended and restated to allow for termination of the Merger Agreement by the Company is either (a) the Initial Parent Equity Investment has not been made by April 1, 2024, or (b) the Subsequent Parent Equity Investment has not been made by April 30, 2024.

The foregoing numbers of shares of F-1 Preferred Shares shall be equitably adjusted for any stock split, reverse stock split, stock dividend (including any dividend or other distribution of securities convertible into F-1 Preferred Shares), subdivision, reorganization, reclassification, recapitalization, combination, exchange of shares or other like change with respect to the number of shares of F-1 Preferred Shares outstanding after the date hereof and prior to the Effective Time or any change to the Stated Value thereof as set forth in that certain Certificate of Designations of Series F-1 Convertible Preferred Stock of the Company.

As consideration for the Merger, the Parent will (i) issue 610,000 shares of Parent common stock (Parent Common Stock) (ii) exchange the Company's preferred stock for Parent preferred stock (Parent Preferred Stock and together with Parent Common Stock, the Merger Shares) (iii) execute an assignment agreement by and between Baker Brothers Life Sciences, L.P. and the Parent for the certain secured and unsecured promissory notes aggregately valued at $18.0 million. In addition, Parent has agreed to issue up to an aggregate of 89,126 shares of preferred stock to the holders of the Company's currently outstanding unsecured notes, purchase rights, certain warrants, and preferred stock. The closing issuance of Merger Shares may be adjusted pursuant to procedures set forth in the Merger Agreement, in connection with the finalization of exchange ratio of the Company and Parent shares.

Each stock option of the Company that was outstanding and unexercised immediately prior to the effective time of the Merger (the Effective Time) will be cancelled as of the Effective Time without the right to receive any consideration.

The Merger Agreement is subject to certain closing conditions and contains customary representations, warranties and covenants including, (i) the Company and Parent Shareholder approval shall have been obtained in accordance with applicable Law; (ii) no governmental entity having jurisdiction over any party shall have issue any order, decree, ruling injunction or other action that is in effect restraining the Merger; (iii) the registration statement on Form S-4 shall be declared effective by the U.S. Securities and Exchange Commission (SEC); (iv) a voting agreement shall have been executed and delivered by the parties thereto; (v) all Company preferred stock shall have been converted to Company common stock except for the Unconverted Company Preferred Stock (as defined by the Agreement); (vi) the Company shall have received agreements from all of the holders of the Company's warrants, duly executed, containing waivers with respect to any fundamental transaction, change in control or other similar rights that such warrant holders may have under any such Company warrants and exchange such Company warrants as they hold for an aggregate of not more than 551 shares of Parent Preferred Stock; (vii) the Company shall have cashed out any other warrant holder who has not provided a warrant holder agreement, provided, however, that the aggregate amount of such cash out for any and all other warrant holders who have not provided a warrant holder agreement shall not exceed $0.2 million; (viii) the Company shall have obtained waivers from holders of Company convertible notes of the original principal amount thereof with respect to any fundamental transaction rights such Company convertible note holders may have under any such Company convertible notes, including any right to vote, consent or otherwise approve or veto any of the transaction contemplated by this Merger Agreement; (ix) Parent shall have received a compliance certificate from the Company certifying Company complied with all its representations and warranties in the Merger Agreement; (x) Parent shall have received a certificate certifying that no interest in the Company is a U.S. real property interest, as required under U.S. treasury regulation section 1.897-2(h) and 1.1445-3©; (xi) Company shall have received from Parent a compliance certificate certifying that Parent has complied with all its representations and warranties in the Merger Agreement, that Parent Common Stock included in the Merger Shares have been approved for listing on the Nasdaq, and Parent shall have regained compliance with the stockholders equity requirement in Nasdaq listing rule 5550(b)(1).

The Company will prepare and file a proxy statement with the SEC and, subject to certain exceptions, the Company's Board of Directors (the Board) will recommend that the Merger Agreement be adopted by the Company's stockholders at a special meeting of the Company's stockholders (the "Company Board Recommendation"). However, subject to the satisfaction of certain terms and conditions, the Company and the Board, as applicable, are permitted to take certain actions which may, as more fully described in the Merger Agreement, include changing the Company Board Recommendation and entering into a definitive agreement with respect to a Company Superior Proposal (as defined in the Merger Agreement) if the Board or any committee thereof determines in good faith, after consultation with the Company's outside legal and financial advisors and after taking into account relevant legal, financial, regulatory, estimated timing of consummation and other aspects of such proposal that the Board considers in good faith and the Person or group making such proposal, would, if consummated in accordance with its terms, result in a transaction more favorable to the Company Shareholders than the Merger. The Company would be required to pay the Parent a termination fee of $4.0 million in connection with the Company accepting a Company Superior Proposal.

In connection with the Merger Agreement Aditxt, the Company and the holders (the Holders) of certain senior indebtedness of Evofem (the Notes) entered into an Assignment Agreement dated December 11, 2023 (the December Assignment Agreement), pursuant to which the Holders assigned the Notes to Aditxt in consideration for the issuance by Aditxt of (i) an aggregate principal amount of $5.0 million in secured notes of Aditxt due on January 2, 2024 (the January 2024 Secured Notes), (ii) an aggregate principal amount of $8.0 million in secured notes of Aditxt due on September 30, 2024 (the September 2024 Secured Notes), (iii) an aggregate principal amount of $5.0 million in ten-year unsecured notes (the Unsecured Notes), and (iv) payment of $0.2 million in respect of net sales of Phexxi in respect of the calendar quarter ended September 30, 2023.

On February 26, 2024, Aditxt and the Holders entered into an Assignment Agreement (the February Assignment Agreement), pursuant to which the Company consented to the assignment of all remaining amounts due under the Notes from Aditxt back to the Holders.

On February 29, 2024, the Company entered into the third amendment to the Merger Agreement to (i) Amend and restate Section 6.10 in its entirety as follows: "Parent Equity Investment. On or prior to (a) April 1, 2024, Parent shall purchase 2,000 shares of the Company's Series F-1 Preferred Shares, par value $0.0001 per share for an aggregate purchase price of $2.0 million (the Initial Parent Equity Investment) and (b) April 30, 2024, Parent shall purchase 1,500 shares of F-1 Preferred Shares for an aggregate purchase price of $1.5 million (the Subsequent Parent Equity Investment). (ii) the proviso in Section 6.16 was deleted in its entirety, (iii) the date to file a Joint Proxy Statement was extended to April 30, 2024, (iv) a new Section 7.2(i) was added as follows "(i) *Repurchase Price*. No defaults shall have occurred and be continuing under the Loan Documents and the Outstanding Balance (as defined in the Securities Purchase Agreement) plus all accrued and unpaid interest thereon, in an amount not to exceed the Repurchase Price (as defined in the Securities Purchase Agreement) shall have been paid in full." and (v), Section 8.1(f) is amended and restated to allow for termination of the Merger Agreement by the Company if (a) the Initial Parent Equity Investment has not been made by April 1, 2024, or (b) the Subsequent Parent Equity Investment has not been made by April 30, 2024.

Phexxi as a Contraceptive; Commercial Strategies

In September 2020, we commercially launched Phexxi. Our sales force promotes Phexxi directly to obstetrician/gynecologists and their affiliated health professionals, who collectively write the majority of prescriptions for contraceptive products. Our sales force comprises approximately 16 regional sales representatives, three business managers and a VP of sales, supported by a self-guided virtual health care provider (HCP) learning platform. Additionally, we offer women direct access to Phexxi via a telehealth platform. Using the platform, women can directly meet with an HCP to determine their eligibility for a Phexxi prescription and, if eligible, have the prescription written by the HCP, filled, and mailed directly to them by a third-party pharmacy.

Our comprehensive commercial strategy for Phexxi includes marketing and product awareness campaigns targeting women of reproductive potential in the U.S., including the approximately 23.3 million women who are not using hormonal contraception and the approximately 20.0 million women who are using a prescription contraceptive, some of whom, particularly pill users, may be ready to move to an FDA-approved, non-invasive hormone-free contraceptive, as well as certain identified target HCP segments. In addition to marketing and product awareness campaigns, our commercial strategy includes payer outreach and execution of our consumer digital and media strategy.

July 2022 research into the demographics of women who were using Phexxi revealed that 81% of women had previously not been on any method of prescription contraception while 19% switched over from either an oral contraceptive, hormone patch/ring, or long-acting reversible contraception.

We continue working to increase the number of lives covered and to gain a preferred formulary position for Phexxi. We gained 17.7 million unrestricted lives (people whose plans cover Phexxi with no PA required) in the past two years, a 5% increase in unrestricted coverage for Phexxi from January 2022 (47%) to November 2023 (53%).

Payer wins in 2023 included:

- New York Medicaid, the largest of all Commercial and Medicaid payers in New York, which transitioned to a single Preferred Drug List effective April 1, 2023, that includes no Prior Authorization requirement for Phexxi.
- Mississippi Medicaid
- Indiana State Medicaid
- Multiple Blue Cross Blue Shield plans, and
- The largest commercial payer in Michigan.

In the second quarter of 2022, we successfully negotiated a contract with one of the largest PBMs in the nation, which added Phexxi to its formulary with no restrictions for most women covered by the plan. The agreement was retroactive and took effect January 1, 2022 and is representative of approximately 46 million lives. An additional 13.7 million lives are covered under our December 2020 contract award from the U.S. Department of Veterans Affairs.

We also participate in government programs, including the 340B and the Medicaid Drug Rebate Program. As a result of our participation in the Medicaid National Drug Rebate Program, the U.S. Medicaid population gained access to Phexxi on January 1, 2021. As of August 2023, Medicaid provides health coverage to approximately 90 million members; an estimated 15.6 million of these are women 19-44 years of age.

Evofem had 73% coverage within its Commercial and Medicaid books of business as of October 2023, including 19.8 million lives covered at no out-of-pocket cost. Approximately 83% of commercial and Medicaid Phexxi prescriptions are being approved by payers.

Furthermore, Phexxi co-pay card utilization has decreased 47% since January 1, 2023, while claims have remained stable. This directly reflects improvements in Phexxi coverage throughout the year.

Phexxi is classified in the databases and pricing compendia of Medi-Span and First Databank, two major drug information databases that payers can consult for pricing and product information, as the first and only "Vaginal pH Modulator."

As of January 1, 2023, most insurers and pharmacy benefit managers (PBMs) must provide coverage, with no out-of-pocket costs (*e.g.* $0 copay) to the subscriber or dependent, for FDA-approved contraceptive products, like Phexxi, prescribed by healthcare providers.

As a result, to comply with these Guidelines, payers are increasingly covering Phexxi by:

- Adding Phexxi to formulary (commercial insurers) or preferred drug list (Medicaid)
- Removing the requirement for a Prior Authorization letter from the HCP (commercial insurers)
- Moving Phexxi to $0 copay (commercial insurers)

In 2022, Evofem developed and introduced a new educational chart for patients and HCPs that details high-level information about birth control methods currently available to women in the U.S., including the vaginal pH modulator. This new educational tool has been extremely well received and has had a positive impact with HCPs and patients alike.

Financial Operations Overview

Net Product Sales

Our revenue recognition is based on unit shipments from our third-party logistics warehouse to our customers, which consist of wholesale distributors, retail pharmacies, telehealth companies, and a mail-order specialty pharmacy. We have recognized net product sales in the US since the commercial launch of Phexxi in September 2020. The year ended December 31, 2023 was our third full year of product sales.

For the year ended December 31, 2023, there was an approximate 8% increase in net product sales as a result of more favorable payer coverage despite a 12% decrease in unit shipments to customers compared to the year ended December 31, 2022. Gross revenues, as discussed in Note 3 - Revenue, were adjusted for variable consideration, including our patient support programs.

Cost of Goods Sold

Inventory costs include all purchased materials, direct labor and manufacturing overhead. In addition, we are obligated to pay quarterly royalty payments pursuant to our license agreement with Rush University, in amounts equal to a single-digit percentage of the gross amounts we receive on a quarterly basis, less certain deductions incurred in the quarter based on a sliding scale. We are also obligated to pay a minimum annual royalty amount of $0.1 million to the extent these earned royalties do not equal or exceed $0.1 million in a given year. Such royalty costs were $0.7 million and $1.1 million for the years ended December 31, 2023 and 2022, respectively, and were included in the costs of goods sold in the consolidated financial statements.

Operating Expenses

Research and Development Expenses

Our research and development expenses primarily consist of costs associated with the continuous improvements related to Phexxi. These expenses include:

- continuous improvements of manufacturing and analytical efficiency;
- on-going product characterization and process optimization;
- alternative raw material evaluation to secure an uninterrupted supply chain and reduce cost of goods sold;
- employee-related expenses, including salaries, benefits, travel and noncash 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.

In 2022, research and development expenses also included costs associated with the clinical development of EVO100 for the prevention of chlamydia and gonorrhea, including:

- external development expenses incurred under arrangements with third parties, such as fees paid to clinical research organizations (CROs) relating to our 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;
- costs to acquire, develop and manufacture clinical trial materials, including fees paid to contract manufacturers;
- costs related to compliance with drug development regulatory requirements;

We discontinued all clinical development programs in October 2022 and do not intend to re-start these initiatives; instead, we are focusing resources on commercial activities.

We expense internal and third-party research and development expenses as incurred. The following table summarizes research and development expenses by product candidate (in thousands):

	Years Ended December 31,	
	2023	**2022**
Allocated third-party development expenses:		
EVO100 for prevention of chlamydia/gonorrhea - Phase 3 (*EVOGUARD*)	$ (92)	$ 17,374
Total allocated third-party development expenses	(92)	17,374
Unallocated internal research and development expenses:		
Noncash stock-based compensation expenses	117	553
Payroll related expenses	1,330	3,820
Outside services costs	481	1,240
Other	1,103	2,045
Total unallocated internal research and development expenses	3,031	7,658
Total research and development expenses	$ 2,939	$ 25,032

As anticipated, research and development expenses decreased significantly in 2023 compared to 2022 primarily due to the completion of *EVOGUARD* in the fourth quarter of 2022 and discontinuation of all clinical development as discussed above. We do not anticipate investing in clinical development for the foreseeable future.

Selling and Marketing Expenses

Our selling and marketing expenses consist primarily of Phexxi commercialization costs, the Phexxi telehealth platform, training, salaries, benefits, travel, noncash stock-based compensation expense and other related costs for our employees and consultants.

In connection with our overall cost reduction strategy, our selling and marketing expenses decreased significantly in the year ended December 31, 2023 compared to the prior year. Key drivers were the downsizing of the sales and marketing team in the fourth quarter of 2022 and first quarter of 2023; reductions in media and marketing activities for Phexxi, including direct to consumer (DTC) and HCP advertising; and termination of the sample program.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries, benefits, travel, business development expenses, investor and public relations expenses, noncash stock-based compensation, and other related costs for our employees and consultants performing executive, administrative, finance, legal and human resource functions. Other general and administrative expenses include facility-related costs not otherwise included in research and development or selling and marketing, and professional fees for accounting, auditing, tax and legal fees, and other costs associated with obtaining and maintaining our patent portfolio.

Our general and administrative expenses decreased in 2023 compared to 2022 primarily due to reduced headcount as well as a decreased use of professional and other outside services.

Other Income (Expense)

Other income (expense) consists primarily of interest expense and the change in fair value of financial instruments issued in various capital raise transactions. The change in fair value of financial instruments was recognized as a result of mark-to-market adjustments for those financial instruments. Additionally, other income (expense) also includes a gain or loss on debt modification or extinguishment and gain or loss on issuance of financial instruments in each of the presented periods.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles (GAAP) in the US. The preparation of consolidated financial statements requires us to make use of estimates, assumptions and judgments that affect the reported amounts of assets, expenses, and liabilities, as well as the disclosure of contingent liabilities on the date of the consolidated financial statements. 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 estimate used in the preparation of our consolidated financial statements, which, in turn, could materially change our results from those reported. Management evaluates its use of estimates, assumptions, and judgments on an ongoing basis. However, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may 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 - Summary of Significant Accounting Policies.

Revenue Recognition and Trade Accounts Receivable

The Company recognizes revenue from the sale of Phexxi in accordance with ASC 606, *Revenue from Contracts with Customers* (ASC 606). The provisions of ASC 606 require the following steps to determine revenue recognition: (1) Identify the contract(s) with a customer; (2) Identify the performance obligations in the contract; (3) Determine the transaction price; (4) Allocate the transaction price to the performance obligations in the contract; (5) Recognize revenue when (or as) the entity satisfies a performance obligation.

In accordance with ASC 606, the Company recognizes revenue when its performance obligation is satisfied by transferring control of the product to a customer. In accordance with the Company's contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is sold to and received by a customer. The Company's customers consist of wholesale distributors, retail pharmacies, and a mail-order specialty pharmacy. Payment terms vary by customer, but typically range from 31 to 66 days and include prompt pay discounts. Trade accounts receivable due to the Company from contracts with its customers are stated separately in the consolidated balance sheets, net of various allowances as described in the Trade Accounts Receivable policy in Note 2 - Summary of Significant Accounting Policies.

The amount of revenue recognized is equal to the amount of consideration which is expected to be received from the sale of product to its customers. Revenue is only recognized when it is probable that a significant reversal will not occur in future periods. To determine the amount of revenue to recognize, the Company assesses both the likelihood and magnitude of any such potential reversal of revenue.

Phexxi is sold to customers at the wholesale acquisition cost. However, the Company records product revenue net of estimates for applicable variable consideration.

Revenue recognition is subject to uncertainty due to the variable consideration estimates that are required to be made by management. These estimates include chargebacks, rebates and patient support programs. Management must estimate and accrue for these amounts primarily by estimating the portion of product in the distribution supply channel at the reporting date that will be sold through to an entity or end user that will result in a variable consideration expense, which is recorded as a reduction of revenue. To accomplish this, management relies on historical sales data showing the amount of various end-user consumer types, inventory reports from the wholesale distributors and mail-order specialty pharmacy, and other relevant data reports. The recorded variable consideration is directly sensitive to the estimated inputs made by management that are used in the calculation. The total reserves for variable consideration was $3.5 million and $2.7 million, as of December 31, 2023 and 2022, respectively.

Clinical Trial Accruals

As part of the process of preparing its consolidated financial statements, the Company is required to estimate expenses resulting from obligations under contracts with vendors, CROs and consultants and under clinical site agreements relating to conducting 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.

The Company's objective is to reflect the appropriate clinical trial expenses in its consolidated financial statements by recording those expenses in the period in which services are performed and efforts are expended. The Company accounts 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. The Company determines 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, the Company adjusts the clinical expense recognition if actual results differ from estimates. Estimates of accrued expenses as of each balance sheet date are made based on the facts and circumstances known at that time. Clinical trial accruals are partially dependent upon accurate reporting by CROs and other third-party vendors. Although the Company does not expect estimates to differ materially from actual amounts, its 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 years ended December 31, 2023 and 2022 there were no material adjustments to our prior period estimates of accrued expenses for clinical trials.

Fair Value of the Baker Notes

The owner of the Baker Notes became Aditxt under the Assignment Agreement (as described in Note 4 - Debt) in December 2023, and then reverted back to the Baker Purchasers on February 26, 2024 as disclosed in Note 13 – Subsequent Events.

We elected the fair value option under ASC 825, Financial Instruments, for the Baker Notes issued pursuant to that certain Baker Bros. Purchase Agreement with the Baker Purchasers, and Baker Bros. Advisors LP, as designated agent, dated April 23, 2020, as they are qualified financial instruments and are, in whole, classified as liabilities. Under the fair value option, we recognized the hybrid debt instrument at fair value inclusive of embedded features. Through June 30, 2022, the fair value of the Baker Notes issued, and the change in fair value of the Baker Notes at the reporting date, were determined using a Monte Carlo simulation-based model. The Monte Carlo simulation was used to take into account several embedded features and factors, including the future value of our common stock, a potential change of control event, the probability of meeting certain debt covenants, the maturity term of the Baker Notes, the probability of an event of voluntary conversion of the Baker Notes, the probability of the failure to meet the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2023, and the probability of exercise of the put right and the probability of exercise of the call right.

The fair value of the Baker Notes was subject to uncertainty due to the assumptions that were used in the Monte Carlo simulation-based model. These factors included but were not limited to the future value of the Company's common stock, the probability and timing of a potential change of control event, the probability of meeting certain debt covenants, the probability of an event of voluntary conversion of the Baker Notes, exercise of the put right, and exercise of the Company's call right. The fair value of the Baker Notes was sensitive to these estimated inputs made by management that are used in the calculation.

From the third quarter of 2022 through the second quarter of 2023, the fair value of the Baker Notes issued as described in Note 4 - Debt, and subsequent changes in fair value recorded at each reporting date, was determined by estimating the fair value of the Market Value of Invested Capital ("MVIC") of the Company. This was estimated using forms of the cost and market approaches. In the Cost approach, an adjusted net asset value method was used to determine the net recoverable value of the Company, including an estimate of the fair of the Company's intellectual property. The estimated fair value of the Company's intellectual property was valued using a relief from royalty method which required management to make significant estimates and assumptions related to forecasts of future revenue, and the selection of the royalty and discount rates. The guideline public company method served as another valuation indicator. In this form of the Market approach, comparable market revenue multiples were elected and applied to the Company's forward revenue forecast to ultimately derive a MVIC indication. If the resulting fair value from these approaches was not estimated as greater than the contractual payout, then the fair value of the Baker Notes became only the Company MVIC available for distribution to this first lien note holder.

Starting in the third quarter of 2023, the fair value of the Baker Notes was determined using a Monte Carlo simulation-based model. The Monte Carlo simulation was used to take into account several embedded features and factors, including the exercise of the repurchase right, the Company's future revenues, meeting certain debt covenants, the maturity term of the note and dissolution. For the dissolution scenario, the cost approach, an adjusted net asset value method was used to determine the net recoverable value of the Company, including an estimate of the fair value of the Company's intellectual property. The estimated fair value of the Company's intellectual property was valued using a relief from royalty method which required management to make significant estimates and assumptions related to forecasts of future revenue, and the selection of the royalty (5.0%) and discount (15.0%) rates.

The fair value of the Baker Notes was $13.5 million and $39.3 million as of December 31, 2023 and 2022, respectively.

Fair Value of Stock Options, Purchase Rights, and Warrants

Upon issuance of financial instruments, they are initially measured at fair value and reviewed for the appropriate classification (liability or equity). Financial instruments determined to require liability accounting are subsequently re-measured with changes in fair value being recognized as a component of other income (expense), net in the consolidated statements of operations. Financial instruments are valued using an option pricing model (OPM), such as Black-Scholes, based on the applicable assumptions, which include the exercise price of the warrants, option, or purchase right, time to expiration, expected volatility of our peer group, risk-free interest rate, and expected dividends. The Company re-evaluates the classification of its financial instruments at each balance sheet to determine the proper balance sheet classification for them. The assumptions used in the OPM are considered level 3 assumptions and include, but are not limited to, the market value of invested capital, the Company's cumulative equity value as a proxy for the exercise price, the expected term the instruments will be held prior to exercise and a risk-free interest rate, and probability of change of control events.

Inventories

Inventories, consisting of purchased materials, direct labor and manufacturing overheads, are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. At each balance sheet date, the Company evaluates ending inventories for excess quantities, obsolescence, or shelf-life expiration. The evaluation includes an analysis of current and future strategic plans, anticipated future sales, the price projections of future demand, and the remaining shelf life of goods on hand. To the extent that the Company determines there is excess or obsolete inventory or quantities with a shelf life too near its expiration to reasonably be expected to be sold prior to their expiration, the Company adjusts the carrying value to estimated net realizable value in accordance with the first-in, first-out inventory costing method.

Results of Operations

Year Ended December 31, 2023 Compared to Year Ended December 31, 2022 (in thousands):

Net Product Sales

	Twelve Months Ended December 31,		2023 vs. 2022	
	2023	2022	$ Change	% Change
Product sales, net	$ 18,218	$ 16,837	$ 1,381	8%

The increase in net product sales was primarily due to more favorable payer coverage in 2023, partially offset by lower Phexxi ex-factory unit sales due to the absence of marketing and DTC promotion and the 73% sales force reduction, and $1.6 million in product returns recorded in the current period. This was product manufactured to meet anticipated demand based on pre-launch, pre-COVID sales forecasting. At the time of manufacture, the product shelf life was 30 months. We succeeded in extending the product shelf life to 48 months in June 2022, but product sold prior to that date could not be relabeled. COVID hindered our ability to access HCP's, fully execute on our commercial strategy and meet forecasted sales levels, resulting in product returns.

Cost of Goods Sold

	Twelve Months Ended December 31,		2023 vs. 2022	
	2023	2022	$ Change	% Change
Cost of goods sold	$ 6,512	$ 4,415	$ 2,097	47%

The increase in cost of goods sold was primarily due to an increase in inventory reserve for excess and obsolete product which might not be sold before its expiration recorded in the current period. Additionally, several lots were re-packaged to reflect the extended shelf life approved by the FDA in June 2022, which added costs to each re-worked unit.

Research and Development Expenses

	Twelve Months Ended December 31,		2023 vs. 2022	
	2023	2022	$ Change	% Change
Research and development	$ 2,939	$ 25,032	$ (22,093)	(88)%

The decrease in research and development expenses was primarily due to a $16.2 million decrease in clinical trial costs associated with the completion of the *EVOGUARD* trial, which was completed in the fourth quarter of 2022; a $2.9 million decrease in personnel costs due to reduced headcount and lower noncash stock-based compensation; and a $2.7 million decrease in outside services and facilities costs.

Selling and Marketing Expenses

	Twelve Months Ended December 31,		2023 vs. 2022	
	2023	2022	$ Change	% Change
Selling and marketing	$ 11,664	$ 43,951	$ (32,287)	(73)%

The decrease in selling and marketing expenses was primarily due to a $18.9 million reduction in outside services, facilities and media and marketing costs; a $12.1 million decrease in payroll and related expenses due to lower headcount following the November 2022 and March 2023 reductions in force, including elimination of the Chief Commercial Officer role; and a $1.3 million reduction in travel and other expenses.

General and Administrative Expenses

	Twelve Months Ended December 31,		2023 vs. 2022	
	2023	2022	$ Change	% Change
General and administrative	$ 14,950	$ 27,563	$ (12,613)	(46)%

The decrease in general and administrative expenses primarily reflects a $6.1 million decrease in legal, corporate, and financing-related expenses as well as a $3.3 million decrease in personnel costs due to reduced headcount. Reductions of $2.7 million in facilities and outside services, $0.3 million in travel and other and $0.2 million related to business development expense also contributed.

Total Other Income, Net

	Twelve Months Ended December 31,		2023 vs. 2022	
	2023	2022	$ Change	% Change
Total other income, net	$ 70,843	$ 7,470	$ 63,373	848%

Total other income, net, for the year ended December 31, 2023 primarily included a $75.3 million gain related to the Baker Fourth Amendment, which was treated as a debt extinguishment and $4.9 million in gain on the change in the fair value of financial instruments as a result of mark-to-market adjustments. The gains were partially offset by $6.8 million in loss on the issuance of financial instruments and $2.3 million of interest expense related to the Adjuvant Note.

Total other expense, net, for the year ended December 31, 2022, primarily due to gains of $92.2 million from the change in fair value of the liability classified warrants issued in 2022 and $2.5 million from the partial extinguishment of the Adjuvant Notes, as described in Note 4 - Debt. These gains were partially offset by losses of: $73.0 million recorded upon issuance of financial instruments, primarily from the June 2022 Baker Warrants; $10.3 million from the change in the fair value of the May Notes as a result of mark-to-market adjustments; $2.0 million from the change in fair value of the Baker Notes as a result of mark-to-market adjustments unrelated to changes in credit risk; and $2.2 million in interest expense related to the Adjuvant Notes.

Liquidity and Capital Resources

Overview

As of December 31, 2023, we had a working capital deficit of $63.3 million and an accumulated deficit of $888.7 million. We have financed our operations to date primarily through the issuance of preferred stock, common stock and warrants, cash received from private placement transactions, the issuance of convertible notes and, to a lesser extent, product sales. As of December 31, 2023, we had approximately $0.6 million in cash and cash equivalents comprised entirely of restricted cash available for use as prescribed in the Adjuvant Notes (as defined in Note 4 - Debt). Our cash and cash equivalents include amounts held in checking accounts. Management believes that the Company's cash and cash equivalents as of December 31, 2023 are insufficient to fund operations for at least the next 12 months from the date on which this Annual Report on Form 10-K is filed with the SEC.

We have incurred losses and negative cash flows from operating activities since inception. During the year ended December 31, 2023, we received gross proceeds before issuance costs, of approximately $5.6 million, in aggregate, from the sale and issuance of senior subordinated convertible notes and warrants, and $0.3 million from the exercise of common warrants.

In 2023, we focused on further improving and increasing Phexxi access and delivered our third consecutive year of Phexxi net sales growth. We have restructured many of our trade payables with extended terms and implemented measures to better align our cost structure with projected revenues.

In 2024, we will continue to focus on top-line growth and while maintaining a lean operating structure. We will continue to explore opportunities for organic growth, entry into new markets, and expansion of our product offering beyond Phexxi.

As mentioned above, all defaults existing in prior quarters have been resolved as of the filing date.

As of December 31, 2023, the Company's significant commitments include the Baker Notes, as described in Note 4 - Debt and fleet leases, as described in Note 7 - Commitments and Contingencies. The purpose of these commitments is to further the commercialization of Phexxi. Management's plans to meet the Company's cash flow needs in the next 12 months include generating revenue from the sale of Phexxi and additional products, further restructuring of its current payables, and obtaining additional funding through means such as the issuance of its capital stock, non-dilutive financings, or through collaborations or partnerships with other companies, including license agreements for Phexxi in the US or foreign markets, or other potential business combinations (including the Merger, as defined in Note 1 - Business).

If the Company is not able to obtain the required funding through a significant increase in revenue, equity or debt financings, license agreements for Phexxi in the US or foreign markets, or other means, or is unable to obtain funding on terms favorable to the Company, there will be a material adverse effect on commercialization and development operations and the Company's ability to execute its 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 further reductions in spending, including spending in connection with its commercialization activities, extend payment terms with suppliers, liquidate assets where possible at a potentially lower amount than as recorded in the consolidated financial statements, suspend or curtail planned operations, or cease operations entirely. Any of these could materially and adversely affect the Company's liquidity, financial condition and business prospects, and the Company would not be able to continue as a going concern. The Company has concluded that these circumstances and the uncertainties associated with the Company's ability to obtain additional equity or debt financing on terms that are favorable to the Company, or at all, and otherwise succeed in its future operations raise substantial doubt about the Company's ability to continue as a going concern.

If we are unable to continue as a going concern, we may have to liquidate our assets and, in doing so, we may receive less than the value at which those assets are carried on our consolidated financial statements. Any of these developments would materially and adversely affect the price of our stock and the value of an investment in our stock. As a result, our consolidated financial statements include explanatory disclosures expressing substantial doubt about our ability to continue as a going concern.

The opinion of our independent registered public accounting firm on our audited consolidated financial statements as of and for the years ended December 31, 2023 and 2022 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. Future reports on our consolidated financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. Our audited consolidated financial statements as of and for the years ended December 31, 2023 and 2022 included in this Annual Report 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.

2023 Debt and Equity Financings

As described in Note 4 - Debt, we received gross proceeds of approximately $5.6 million, before issuance costs, from the issuance of notes and warrants in seven registered direct offerings in the year ended December 31, 2023.

As described in Note 8 - Stockholders' Deficit, we received approximately $0.3 million in the year ended December 31, 2023 from the exercise of common warrants.

2022 Debt and Equity Financings

As described in Note 4 - Debt, we received net proceeds of $10.0 million, before issuance costs, from the sale of notes and warrants in two registered direct offerings in the first quarter of 2022. These notes were then exchanged for the May 2022 Notes during the May 2022 Exchange transaction, as defined in Note 4 - Debt, which were subsequently exchanged for Purchase Rights during the debt restructuring in September 2022 with a total outstanding balance of $21.8 million immediately prior to the restructuring.

As described in Note 8 - Stockholders' Deficit, we received net proceeds of $18.1 million upon the sale and issuance of common stock and warrants from an underwritten public offering in May 2022, net proceeds of $7.4 million from the sale and issuance of common stock pursuant to the Stock Purchase Agreement, and $25.2 million from the exercise of common warrants.

As described in Note 4 - Debt, we received gross proceeds of $2.3 million, before issuance costs, from the sale of notes, warrants and non-convertible Series D preferred stock in the December 2022.

Summary Statements of Cash Flows

The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2023 and 2022 (in thousands):

	Twelve Months Ended		2023 vs. 2022	
	2023	2022	$ Change	% Change
Net cash and restricted cash used in operating activities	$ (8,968)	$ (70,410)	$ 61,442	(87)%
Net cash and restricted cash used in investing activities	(4)	(341)	337	(99)%
Net cash and restricted provided by financing activities	4,776	61,939	(57,163)	(92)%
Net change in cash and restricted cash	$ (4,196)	$ (8,812)	$ 4,616	(52)%

Cash Flows from Operating Activities. During the years ended December 31, 2023 and 2022, the primary use of cash, cash equivalents and restricted cash was to fund commercialization of Phexxi, to support selling and marketing and general and administrative operations, and, in 2022, to fund the Phase 3 *EVOGUARD* clinical trial.

Cash Flows from Investing Activities. During the years ended December 31, 2023 and 2022, the change in net cash, cash equivalents and restricted cash used in investing activities was due entirely to the purchase of property and equipment.

Cash Flows from Financing Activities. During the year ended December 31, 2023, the primary source of cash, cash equivalents and restricted cash was the issuance of senior subordinated convertible notes and warrants for proceeds of approximately $5.9 million, in aggregate, before debt issuance costs. Proceeds were offset, in part, by the $1.0 million upfront payment and $0.2 million quarterly cash payment required under the Baker Fourth Amendment.

During the year ended December 31, 2022, the primary source of cash, cash equivalents and restricted cash was the issuance of 181,320 shares of common stock, warrants to purchase 568,000 shares of common stock and pre-funded warrants to purchase 102,680 shares of common stock for net proceeds of $24.9 million; the issuance of 282,518 shares of our common stock for net proceeds of $25.2 million from the exercise of common warrants; and the issuance of 15,714 shares of common stock for net proceeds of $7.4 million and net proceeds of $11.5 million from the issuance of term notes and warrants, net of original issue discount when applicable.

Operating and Capital Expenditure Requirements

Our specific future operating and capital expense requirements are difficult to forecast. However, we can anticipate the general types of expenses and areas in which they might occur. In 2024, while we expect to maintain a lean operating structure at approximately the same level as 2023, should resources become available we may increase marketing spend to drive further sales growth.

Contractual Obligations and Commitments

Operating Leases

On December 31, 2023, operating lease ROU assets and lease liabilities were $0.1 million each, and were $4.4 million and $5.4 million, respectively, on December 31, 2022. See Note 7 - Commitments and Contingencies for more detailed discussions on leases and financial statements information under ASC 842, *Leases.*

Other Contractual Commitments

As described in Note 7 - Commitments and Contingencies, in November 2019, the Company entered into a supply and manufacturing agreement with a third-party to manufacture Phexxi, with potential to manufacture other product candidates, in accordance with all applicable current good manufacturing practice regulations. There were no purchases or purchase orders under the supply and manufacturing agreement for the year ended December 31, 2023, and as such no commitment exists at such date and $1.0 million was purchased under the agreement for the year ended December 31, 2022.

Intellectual Property Rights

As described in Note 7 - Commitments and Contingencies, royalty costs owed to Rush University pursuant to the Rush License Agreement were $0.7 million and $1.1 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, approximately $1.1 million and $0.6 million were included in accrued expenses in the consolidated balance sheets and will be paid via the agreed upon payment plan.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company" as defined in Rule 12(b) of the Exchange Act, we are not required to provide the information required by this item.

Item 8. Financial Statements and Supplementary Data.

The consolidated financial statements and the report of our independent registered public accounting firm required pursuant to this item are included in this Annual Report on Form 10-K beginning on page F-1.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

The Audit Committee of the Board of the Company conducted a competitive process to select a firm to serve as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2023. The Audit Committee invited several firms to participate in this process. Thereafter, the Audit Committee recommended, and the Board approved, the dismissal of Deloitte & Touche LLP (Deloitte) as the Company's independent registered public accounting firm on July 11, 2023.

The reports of Deloitte on the Company's consolidated financial statements for the years ended December 31, 2022 and 2021 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles, except that the reports included an explanatory paragraph relating to substantial doubt about the Company's ability to continue as a going concern.

During the Company's fiscal years ended December 31, 2022 and 2021 and through the subsequent interim period through July 11, 2023, the Company did not have any disagreements within the meaning of Item 304(a)(1)(iv) of Regulation S-K under the Securities Exchange Act of 1934, as amended (Regulation S-K) and related instructions thereto, with Deloitte on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures, which disagreement, if not resolved to Deloitte's satisfaction, would have caused Deloitte to make reference to the subject matter of the disagreement in their reports on the Company's consolidated financial statements.

There were no reportable events within the meaning of Item 304(a)(1)(v) of Regulation S-K, and related instructions thereto, during the fiscal years ended December 31, 2022 and 2021, and through the subsequent interim period through July 11, 2023, except that, as previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 (the 2022 10-K) and Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023, the Company reported material weaknesses in its internal control over financial reporting during such period. As disclosed in the 2022 10-K, in connection with the Company's evaluation of the effectiveness of its internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934), the Company concluded that its internal control over financial reporting was not effective as of December 31, 2022. The material weaknesses primarily related to limited finance and accounting staffing levels that are not commensurate with the Company's complexity and its financial accounting and reporting requirements. The Audit Committee discussed the material weaknesses in the Company's internal control over financial reporting with Deloitte and authorized Deloitte to respond fully to the inquiries of BPM LLP concerning such material weaknesses.

On July 11, 2023, the Company appointed BPM LLP (BPM) as the Company's new independent registered public accounting firm effective as of July 11, 2023 upon recommendation of the Audit Committee and approval of the Board. The Audit Committee's selection of BPM was approved by the Company's stockholders at the Company's 2023 Annual Meeting held on September 14, 2023.

During the fiscal year ended December 31, 2022 and the interim period from January 1, 2023 through July 11, 2023, neither the Company, nor anyone acting on its behalf, consulted with BPM regarding (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that may be rendered on the Company's consolidated financial statements, and BPM did not provide either a written report or oral advice to the Company that was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue, or (ii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a reportable event (as described in Item 304(a)(1)(v) of Regulation S-K).

Item 9A. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2023 (the period covered by this Annual Report), the Company's management, with the participation of its principal executive officer and principal financial officer, has evaluated the effectiveness of its disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on such evaluation, the principal executive officer and principal financial officer have concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2023 due to the identified material weaknesses in internal control over financial reporting as discussed below.

Notwithstanding the conclusion by the principal executive officer and principal financial officer that the disclosure controls and procedures as of December 31, 2023 were not effective and the material weaknesses identified in internal controls over financial reporting described below, management believes that the consolidated financial statements and related financial information included in this Annual Report on Form 10-K fairly present in all material respects the Company's financial condition, results of operations and cash flows as of the dates presented, and for the periods ended on such dates, in conformity with accounting principles generally accepted in the US of America (US GAAP).

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Management, under the supervision and with the participation of the principal executive officer and principal financial officer, conducted an assessment of the effectiveness of internal control over financial reporting as of December 31, 2023, based on the framework and criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO framework). Based on this assessment, management concluded that, as of December 31, 2023, its internal control over financial reporting was not effective due to the existence of material weaknesses described below.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of the annual or interim financial statements would not be prevented or detected on a timely basis.

Management identified material weaknesses in the Company's internal control over financial reporting primarily related to limited finance and accounting staffing levels that are not commensurate with the Company's complexity and its financial accounting and reporting requirements. The Company continued to undergo organizational changes in 2023, including the resignation of the principal financial officer and the decision to operate with a very lean finance and accounting department. Despite performing some remediation activities in 2023, bringing new staff up to speed with key processes, including some very complicated financial instruments and transactions, caused the Company to lack the resources to fully monitor and operate internal controls of financial reporting.

Based on the above, the Company did not fully implement components of the COSO framework, including elements of the control environment, risk assessment, control activities, information and communication, and monitoring activities components.

Remediation Activities:

Management continues to evaluate the material weaknesses discussed above and is implementing its remediation plan. However, assurance as to when the remediation efforts will be complete cannot be provided and the material weaknesses cannot be considered remedied until the applicable controls have operated for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Management cannot assure readers that the measures that have been taken to date, and are continuing to be implemented, will be sufficient to remediate the material weaknesses identified or to avoid potential future material weaknesses.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting because that requirement under Section 404 of the Sarbanes-Oxley Act of 2002 was permanently removed for smaller reporting company filers pursuant to the provisions of Section 989G(a) set forth in the Dodd-Frank Wall Street Reform and Consumer Protection Act enacted into federal law in July 2010.

Changes in Internal Control over Financial Reporting

Except for the remediation activities described in the preceding paragraphs, there were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Internal Controls

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, 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 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 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.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The Board of Directors

Our Board currently consists of eight seats with three vacancies (two for Class II and one for Class III). Vacancies on the Board may be filled by potential candidates nominated by the Nominating and Corporate Governance Committee of the Board, who may seek out potential candidates that meet the criteria for selection as a Board nominee and have the specific qualities or skills being sought, and one or more of such candidates may be appointed as directors as appropriate and in accordance with the Company's organizational documents. The vacancies, if filled, will be filled until the end of the class term. Our Board is divided into three classes as set forth below, each serving staggered three-year terms until their respective successors are duly elected and qualified:

- Our Class I directors are Kim Kamdar, Ph.D., Colin Rutherford, and Lisa Rarick, M.D. and their terms expire at the Annual Meeting of Stockholders in 2024;
- Our Class II director is Tony O'Brien and his term expires at the Annual Meeting of Stockholders in 2025; and
- Our Class III director is Saundra Pelletier and her term expires at the Annual Meeting of Stockholders in 2026.

There are no familial relationships among our current directors and executive officers.

The following table lists the names, ages as of March 21, 2024, and positions of the individuals who serve as our directors:

	Name and Principal Occupation	Age	Director Since	Board Committees	Other Current Public Directorships
	Class I Directors				
	**Colin Rutherford | Independent** Current member of the board of Spanish based Biopharma Hifas da Terra SA	65	2015	A*	Mitchells & Butlers Plc Renaissance Services SAOG Brookgate Limited
	**Kim Kamdar, Ph.D. | Independent** Managing Partner, Domain Associates, LLC	56	2011	A, C, N*	Seraphina Therapeutics, Inc. Truvian Sciences
	**Lisa Rarick, M.D. | Independent** Board-certified Obstetrician/ Gynecologist and Regulatory Affairs Expert	64	2020	N	
	Class II Director				
	**Tony O'Brien | Independent** Former Director General of Ireland's Health Service Executive	61	2018	A, C*	Global Leadership and Governance Solutions Limited
	Class III Director				
	**Saundra Pelletier | Interim Chair of the Board of Directors** President and Chief Executive Officer, Evofem Biosciences, Inc.	54	2013		TRACON Pharmaceuticals, Inc.

A Audit Committee

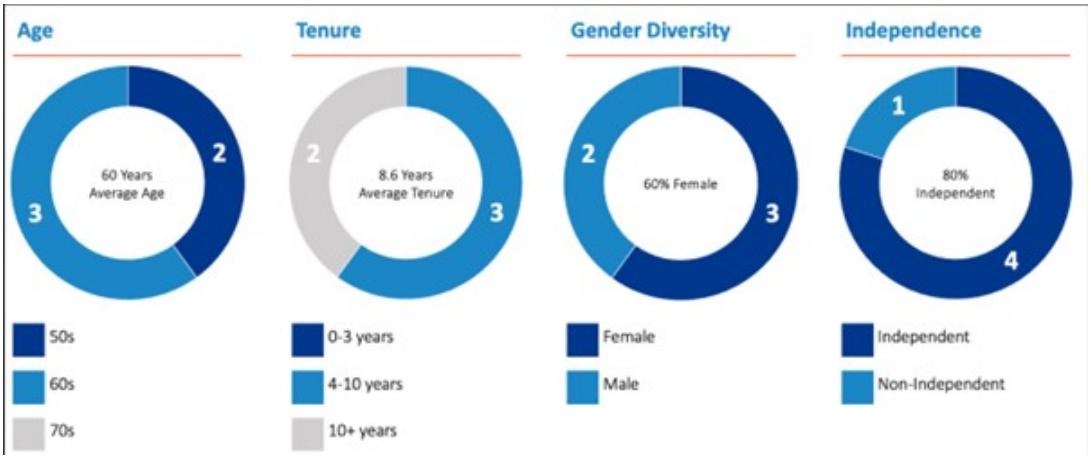
C Compensation Committee

N Nominating and Corporate Governance Committee

* Committee Chair

Board Demographics

The charts below represent certain demographics of the current composition of our directors and director nominees.



We discuss in the Non-employee Directors section below the qualifications, attributes and skills that led our Board to conclude that each of our directors should serve as a director.

Executive Officers

The following table sets forth certain information regarding our executive officers and their respective ages as of March 21, 2024. All executive officers are at-will employees.

Saundra Pelletier

Chief Executive Officer, Evofem Biosciences, Inc.

Age: 54

Background

- Since joining the Company in 2015, Ms. Pelletier has been responsible for Evofem's rapid growth and evolution, including the Company's transition to the public market in January 2018 and multiple equity financing rounds that have raised in excess of $500 million.
- Under her leadership, the Company launched its first commercial product in September 2020. Phexxi is the first and only hormone-free, on-demand, prescription vaginal gel approved in the US for the prevention of pregnancy.
- Ms. Pelletier brings more than two decades of broad executive leadership experience to Evofem, including a strong track record driving multiple billion-dollar product launches, expanding commercial capabilities in ex-U.S. markets and advocating for women's health. Throughout her career, she has had oversight and accountability for Sales, Marketing, Operations, Medical Affairs, Regulatory Affairs, Manufacturing, Customer Service, Business Development, and Strategic Partnerships.
- Ms. Pelletier was previously the founding CEO of Woman Care Global (WCG), an international nonprofit organization focused on creating sustainable supply chains that delivered products to women in more than 100 developing countries. Under her leadership, WCG secured approximately $68M in committed funding from major foundations and USAID.
- Earlier in her career, Ms. Pelletier served as Corporate Vice President and Global Franchise Leader for G.D. Searle, where she managed a $250 million business unit focused on women's healthcare. She later moved to Women First Healthcare, where she served as Vice President of Pharmaceuticals and raised $40 million in capital.
- She is a Director of TRACON Pharmaceuticals, Inc., a clinical stage biopharmaceutical company focused on novel targeted therapeutics for cancer, where she serves as the chair of the Governance/Nomination Committee and is a member of the Audit Committee.
- Ms. Pelletier is a published author, skilled moderator, and coveted keynote speaker. She has appeared at TEDx San Diego, Harvard School of Public Health, Davos World Economic Forum, the Clinton Global Initiative, MAKERS Conference, Women Deliver, University of Virginia's Darden School of Business, University of Oregon's Lundquist School of Business and University of California, San Diego. She was named as a New Champion for Reproductive Health by the United Nations Foundation, awarded the Athena San Diego's Pinnacle Award for Life Sciences, named 2019 Businesswoman of the Year by the San Diego Business Journal, and named to Inc. Magazine's 2020 Female Founders 100 List.

Ivy Zhang

Chief Financial Officer

Age: 46

Background

- Ivy Zhang is a trusted leader who is dedicated to advancing Evofem Biosciences' mission of addressing the unmet sexual and reproductive health needs of women. She has more than 15 years of financial and accounting experience spanning diverse industries, including pharmaceuticals and medical devices, and leads the Company's finance organization and financial activities including financial planning and analysis, accounting, external audit, tax, controllership, and treasury functions.
- Ms. Zhang re-joined Evofem as Chief Financial Officer and Secretary in April 2023 from HUYABIO International, where she served as Vice President Controller.
- Previously Ms. Zhang held increasingly senior finance roles at Evofem from March 2018 until November 2022. She served as Director of SEC Reporting and SOX Compliance until her promotion to Controller in April 2020.
- Earlier in her career, she served in finance positions for approximately seven years at Ernst & Young LLP, and for more than two and a half years at SeaSpine Holdings Corporation (a public medical and therapeutic technology and device company).
- Ms. Zhang holds a Master's in Assurance from Virginia Tech and a Master's in Economics from the University of Victoria, Canada. She is a certified public accountant (CPA) in the state of California.

Non-Employee Directors

Tony O'Brien, 61

Independent

Director Since: January 2018

Committees:

- Audit
- Compensation (Chair)

KEY EXPERIENCE AND QUALIFICATIONS

We believe Mr. O'Brien's extensive experience as an executive and member of the boards of directors for health care and life sciences companies qualifies him to be a member of our Board.

CAREER HIGHLIGHTS

- Director General of Ireland's Health Service Executive (HSE), an organization responsible for the provision of health and personal social services for the residents of Ireland (2012 to 2018)
- Chief Operating Officer of the Department of Health's Special Delivery Unit and a member of the Department's Management Board (2011 to 2014)
- Director of Clinical Strategy and Programs in the HSE (2011 to 2012)
- Chief Executive Officer of the National Treatment Purchase Fund (2011 to 2013)
- Chief Advisor to the HSE on the implementation of the National Cancer Control Strategy (2006 to 2010)
- Project Director for the National Plan for Radiation Oncology (2005 to 2008)
- Chairman of the National Cancer Registry Board (2009 to 2012)
- Founding Chief Executive Officer of the National Cancer Screening Service (2007 to 2011)
- Director of BreastCheck, CervicalCheck (2002 to 2010)
- Associate and Interim Director of the National Cancer Control Programme (2007 to 2011)
- Chief Executive of the Irish Family Planning Association (1991 to 2002)
- Chief Executive of the UK Family Planning Association (1995 to 1996)
- Chartered Director of the Institute of Directors in Ireland
- Adjunct Assistant Professor in Health Strategy and Management at Trinity College Dublin

OTHER PROFESSIONAL EXPERIENCE AND COMMUNITY INVOLVEMENT

- Director and owner of Global Leadership and Governance Solutions Limited, a private limited company organized in the Republic of Ireland

EDUCATION

- M.Sc. in Management Practice from Trinity College, University of Dublin

Colin Rutherford, 65

Independent

Director Since: November 2015 (Private Evofem); January 2018 (Evofem Biosciences)

Committees:

- Audit (Chair)

KEY EXPERIENCE AND QUALIFICATIONS

We believe that Mr. Rutherford is qualified to serve as a member of our Board because of his prior experience as a member of Private Evofem's board of directors and his many years of finance and operations leadership experience in the health care and life sciences industries.

CAREER HIGHLIGHTS

- Former Chairman and CEO of LSE quoted European finance specialist Euro-Sales Plc (with 18 offices across Europe), sold to Royal Bank of Scotland Plc (2000 to 2002)
- Former Chairman of SGI Funds, a Guernsey-, Cayman- and Hong Kong-based diversified fund management group (2004 to 2009)
- Former Chairman and CEO of the LSE quoted UK fund management group, MAM Funds Plc (2008 to 2011)
- Former Member of the board and Audit Committee Chairman of Mitchells & Butlers Plc, the LSE's largest quoted hospitality group (2013 to 2021)
- Former Member of the board and Audit Committee Chairman of the MSE quoted Oil & Gas shipping logistics business, Renaissance Services SAOG, based in Muscat and Dubai (2007 to 2019)
- Former Chairman of European Health Care Group before its acquisition by two U.S.-based hedge funds (2012 to 2014)
- Current Member of the Board of Meallmore Health Care Group (2014 to Present)
- Current Member of the Board of Spanish based Biopharma Hifas da Terra SA, a leader in the field of mycotherapy-related oncology products (2018 to Present)
- Current Chairman of Brookgate Limited, a UK property development business backed by Goldman Sachs and

Sixth Street (2010 to Present)
Former visiting Professor at Edinburgh University's Business School

EDUCATION

- A member of the Scottish Institute of Chartered Accountants, he graduated in Accountancy and Finance from Heriot Watt University in 1980 and qualified with Deloitte (formerly Touche Ross) in 1984.
- Harvard Business School Alumni, having attended over a 10-year period and subsequently Chairing the HBS/YPO Presidents leadership seminar for 5 years.

Lisa Rarick, M.D., F.A.C.O.G., 64

Independent

Director Since: February 2020

Committees:

- Nominating and Corporate Governance

KEY EXPERIENCE AND QUALIFICATIONS

We believe that Dr. Rarick is qualified to serve as a member of our Board because of her extensive experience in health care/women's health matters as well as her vast prior experience with regulatory matters and the life sciences industry.

CAREER HIGHLIGHTS

- Board-certified obstetrician/gynecologist and regulatory affairs expert with 35 years' experience in women's health and 15 years' experience leading several offices within the U.S. Food and Drug Administration (FDA)
- Began her career at the FDA as a Medical Officer, responsible for the management of products indicated for a variety of reproductive health conditions, including oral, transdermal and vaginal contraceptives (1988)
- Director for the Division of Reproductive and Urologic Products (DRUP) at the FDA (1996)
- Held several management roles in the Center for Drug Evaluation and Research (CDER), including Deputy Director of the Office of Drug Evaluation 2 and Associate Director in the Office of the Center Director
- Focused on HIV prevention, pregnancy prevention, pre- and post-pregnancy care and menopausal therapy in her final year at the FDA in the Office of Women's Health
- Reproductive health and regulatory affairs consultant, helping numerous companies navigate the development of their products from early-stage development through FDA approval
- Member of the Scientific Advisory Committee for the National Institute of Child Health and Human Development (since 2004)
- Member of the board of directors for Alliance Partners 360 from (2017 to 2019)
- Family Planning clinical care provider (2020 to present)

EDUCATION

- B.S. and M.D. from the Loma Linda University School of Medicine
- Completed residency training in Obstetrics and Gynecology at Georgetown University

Kim Kamdar, Ph.D., 56

Independent

Director Since: April 2011 (Private Evofem); January 2018 (Evofem Biosciences)

Committees:

- Audit
- Compensation Committee
- Nominating and Corporate Governance (Chair)

KEY EXPERIENCE AND QUALIFICATIONS

We believe Dr. Kamdar is qualified to serve on our Board based on her extensive experience working and serving on the boards of directors of life sciences companies and her experience working in the venture capital industry.

CAREER HIGHLIGHTS

- Managing Partner of Domain Associates, LLC, a life sciences venture capital firm (since 2005)
- Chair of the board of directors of Seraphina Therapeutics, Inc. and Truvian Sciences
- Member of the board of directors of several private companies including Alume, Epic Sciences, Epitel and Pleno Inc.
- Member of the board of directors of several public companies including NASDAQ: SERA and NASDAQ: OMIC
- Past investments include Ariosa (acquired by Roche), Corthera (acquired by Novartis), BiPar Sciences (acquired by Sanofi-Aventis) and Omniome (acquired by NASDAQ: PACB)
- Kauffman Fellow with MPM Capital (MPM) (2003 through 2004)
- Research director at Novartis, where she built and led a research team that focused on the biology, genetics and genomics of model organisms (1995 to 2003)
- Author of ten papers as well as the inventor of seven patents
- Advisory board member of Dr. Eric Topol's NIH supported Clinical and Translational Science Award for Scripps Medicine

EDUCATION

- B.A. from Northwestern University
- Ph.D. in Biochemistry and Genetics from Emory University

Audit Committee and Financial Expert

Audit Committee

Chair:	Members:	Meetings in 2023: 4
Colin Rutherford	Kim Kamdar, Ph.D. Tony O'Brien	

Our Audit Committee's role and responsibilities are set forth in the Audit Committee's written charter.

Principal Responsibilities:

- Reviews annual consolidated financial statements;
- Considers matters relating to accounting policy and internal controls;
- Reviews the scope of annual audits;
- Assists the Board in its oversight of Evofem's consolidated financial statements, including internal control over financial reporting;
- Reviews and discusses with senior management the guidelines and policies by which Evofem assesses and manages risk;
- Assists the Board in its oversight of the qualifications, independence, and performance of Evofem's independent registered public accounting firm, including responsibility for the appointment, compensation, retention, and oversight of the work of the firm;
- Assists the Board in its oversight of the performance of Evofem's internal audit function, including responsibility for the appointment, replacement, reassignment, or dismissal of, and being involved in the performance reviews of, Evofem's internal auditor; and
- Assists the Board in its oversight of Evofem's compliance with legal and regulatory requirements, including reviewing periodically with management any significant legal, compliance, and regulatory matters that have arisen or that may have a material impact on Evofem's business, consolidated financial statements, or compliance policies, Evofem's relations with regulators and governmental agencies, and any material reports or inquiries from regulators and government agencies.

All members of the Audit Committee satisfy the current independence standards promulgated by the SEC, OTCQB and Nasdaq, as such standards apply specifically to members of audit committees. The Board has determined that Mr. Rutherford is an "audit committee financial expert," as the SEC has defined that term in Item 407 of Regulation S-K. Please also see the report of the Audit Committee set forth elsewhere in this proxy statement.

A copy of the Audit Committee's written charter is publicly available on our website at www.evofem.com.

Code of Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees, which is available on our website at www.evofem.com and will be made available to stockholders without charge, upon request, in writing to our Corporate Secretary, Evofem Biosciences, Inc., 7770 Regents Road, Suite 113-618, San Diego, California 92122-1967. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, disclosure regarding any amendments to, or waivers from, provisions of our Code of Business Conduct and Ethics that apply specifically to our directors, principal executive officer and principal financial officer will be included in a Current Report on Form 8-K within four business days following the date of the amendment or waiver, unless website posting or the issuance of a press release of such amendments or waivers is then permitted by the rules of the OTCQB.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities.

To our knowledge, based solely upon a review of Forms 3, 4, and 5 filed with the SEC during the fiscal year ended December 31, 2023, we believe that our directors, executive officers, and greater than 10% beneficial owners have complied with all applicable filing requirements during the fiscal year ended December 31, 2023, with the exception of a Form 3 filing by Ivy Zhang on April 26, 2023, with respect to her initial ownership upon her appointment as CFO which was late due to a delay in acquiring the relevant SEC filing codes.

Item 11. Executive Compensation.

Summary Compensation Table

The following table summarizes information concerning the compensation awarded to, earned by, or paid for services rendered in all capacities by our named executive officers during the years ended December 31, 2023 and 2022:

Name and Principal Position	Year Ended December 31,	Salary	Retention Paid	Unpaid Compensation(1)	Restricted Stock Awards (2)	Option Awards (2)	All other Compensation(3)	Total
Saundra Pelletier	2023	$ 560,338(4)	$ 450,000(5)	$ 493,747	$ -	$ -	$ 16,370(6)	$ 1,520,455
Chief Executive Officer	2022	$ 812,083	$ -	$ 203,021	$ -	$ 293,850(7)	$ 15,716(8)	$ 1,324,670
Ivy Zhang	2023	$ 293,570	$ -	$ 94,439	$ -	$ -	$ 50,840(9)	$ 438,849
Chief Financial Officer and Secretary	2022	$ -(10)	$ -(10)	$ -(10)	$ -(10)	$ -(10)	$ -(10)	$ -
Justin J. File	2023	$ 177,905(11)	$ -	$ -	$ -	$ -(11)	$ 175,483(12)	$ 353,388
Chief Financial Officer	2022	$ 589,240	$ -	$ -(11)	$ -	$ 176,310(13)	$ 1,903	$ 767,453
Katherine Atkinson	2023	$ 97,211(14)	$ -	$ -	$ -	$ -	$ 38,253	$ 135,464
Chief Commercial Officer	2022	$ 450,000	$ -	$ -	$ -	$ 39,180(15)	$ 3,558	$ 492,738
Alexander A. Fitzpatrick	2023	$ -	$ -	$ -	$ -	$ -	$ -	$ -
General Counsel	2022	$ 409,865(16)	$ -	$ -	$ -	$ 117,540(17)	$ 10,233(18)	$ 537,638

(1) Consists of estimated compensation amounts that have been accrued, but not yet paid, in respect of the named executive officer's performance and the Company's performance during each respective fiscal year.

(2) There have not been any equity awards granted to officers since February 2022. Additionally, all current outstanding options are underwater. Amounts listed in this column represent the aggregate fair value on the date of vesting of the Company's equity awards granted to the named executive officers determined in accordance with Financial Accounting Standards Board (FASB) ASC Topic 718, Compensation-Stock Compensation (FASB ASC Topic 718). See Note 9 – Stock-Based Compensation included herein for details as to the assumptions used to determine the fair value of these awards.

(3) All Other Compensation primarily includes premiums paid for group term life insurance, except for Ms. Pelletier, Ms. Zhang, Mr. File, and Mr. Fitzpatrick, as discussed in notes (6) and (8), (9), (12), and (18), respectively, below.

(4) Ms. Pelletier's annual base salary was reduced by 20% in February 2023 and another 20% in March 2023, resulting in a total reduction of 30% as compared to her 2022 salary. The Company may review, change or end the salary reduction at its discretion.

(5) A retention bonus, in amounts approved by the board per each applicable position, was paid to all remaining members of the executive team after the March 2023 RIF, in order to retain experienced staff to salvage the Company and prevent bankruptcy.

(6) In 2023, All Other Compensation for Ms. Pelletier includes (i) a $1,932 premium paid for group term life insurance and (ii) $14,438 in fringe benefits paid on behalf of Ms. Pelletier.

(7) On February 18, 2022, the Company granted Ms. Pelletier 400 stock options which vest in a series of forty-eight (48) successive equal monthly installments upon completion of each additional month of service for the Company measured from the vesting commencement date of February 18, 2022.

(8) In 2022, All Other Compensation for Ms. Pelletier includes (i) a $1,903 premium paid for group term life insurance and (ii) $13,812 in fringe benefits paid on behalf of Ms. Pelletier.

(9) In 2023, All Other Compensation for Ms. Zhang includes a hiring bonus of $50,000.

(10) Ms. Zhang was appointed Chief Financial Officer and Secretary on April 13, 2023.

(11) Mr. File resigned from his position as Chief Financial Officer effective April 3, 2023, as of which date the Compensation Committee had yet to determine and approve any cash incentive bonus for fiscal year 2022.

(12) In 2023, All Other Compensation for Mr. File includes an agreed upon payment in conjunction with the end of his employment in addition to the group term life insurance premiums.

(13) On February 18, 2022, the Company granted Mr. File 240 stock options, which vest in a series of forty-eight (48) successive equal monthly installments upon completion of each additional month of service for the Company measured from the vesting commencement date of February 18, 2022.

(14) Ms. Atkinson was the Chief Commercial Officer until that position was eliminated as part of the March 2023 RIF.

(15) On February 18, 2022, the Company granted Ms. Atkinson 53 stock options, which vest in a series of forty-eight (48) successive equal monthly installments upon completion of each additional month of service for the Company measured from the vesting commencement date of February 18, 2022.

(16) Consists of (i) $386,399 paid to Mr. Fitzpatrick pursuant to Mr. Fitzpatrick's employment agreement with the Company and (ii) $23,466 paid to Mr. Fitzpatrick for vacation payout.

(17) On February 18, 2022, the Company granted Mr. Fitzpatrick 160 shares of common stock issued as RSAs, which are subject to vesting upon the verification by our Compensation Committee of the achievement of certain to the Company's achievement of certain performance milestones in 2022. On December 31, 2022, these RSAs were cancelled due to forfeiture under their vesting provisions.

(18) In 2022 All Other Compensation for Mr. Fitzpatrick includes (i) a $2,806 premium paid for group term life insurance and (ii) $7,427 in fringe benefits paid on behalf of Mr. Fitzpatrick.

Employment, Severance and Separation Agreements

Current Executive Officers

Our current principal executive officer (Ms. Pelletier) was appointed to her office in January 2018 in connection with the Merger (as defined in the "Related Person Transactions" section below). The amounts reported for her in the Summary Compensation Table above include compensation paid to or earned by her pursuant to offer letters for her services provided as our principal executive officer pursuant to her offer letter and subsequent employment agreement described below.

Our current Chief Financial Officer (Ms. Zhang) was appointed to her office in April 2023.

Current Employment Agreements and Severance Obligations

On November 8, 2023, we entered into amended employment agreements with Ms. Pelletier and Ms. Zhang. If Ms. Pelletier is terminated other than for cause or Ms. Pelletier resigns for good reason, then pursuant to her amended employment agreement, the Company will pay and provide to Ms. Pelletier: (i) all accrued obligations as of the date of termination, (ii) any accrued but unpaid bonus for the prior fiscal year, (iii) a pro-rated bonus for the year in which the termination occurs as of her termination date, (iv) an amount equal to twenty-four months of her then-current base salary in a lump sum and (v) eighteen months of continuing health benefits coverage, each subject to the conditions outlined in the agreement. In addition, fifty percent (50%) of any unvested and outstanding equity interests Ms. Pelletier may have shall immediately vest and become exercisable, in each case subject to the conditions outlined in her equity agreements. If Ms. Pelletier's employment is terminated without cause or if Ms. Pelletier resigns for good reason, in each case within three months prior to or twelve months following a change of control, then the Company will pay and provide to Ms. Pelletier: (i) all accrued obligations as of the date of termination, (ii) an amount equal to thirty-six months of her then-current base salary in a lump sum, (iii) any accrued but unpaid bonus for the prior fiscal year, (iv) her target annual bonus for the year in which the termination occurs at the rate in effect immediately prior to such termination multiplied by a factor of 2.0 and (v) twenty-four months of continuing health benefits coverage, each subject to the conditions outlined in the agreement. In addition, any unvested and outstanding equity interests Ms. Pelletier may have shall fully vest and become exercisable, in each case subject to the conditions outlined in her equity agreements.

If Ms. Zhang is terminated other than for cause or resigns for good reason, then the Company will pay and provide to Ms. Zhang: (i) all accrued obligations as of the date of termination, (ii) any accrued but unpaid bonus for the prior fiscal year, (iii) a pro-rated bonus for the year in which the termination occurs as of her termination date, (iv) an amount equal to twelve months of her then current base salary in a lump sum and (v) twelve months of continuing health benefits coverage, each subject to the conditions outlined in her agreement. In addition, fifty percent (50%) of any unvested and outstanding equity interests Ms. Zhang may have shall immediately vest and become exercisable, in each case subject to the conditions outlined in her equity agreements. If Ms. Zhang's employment is terminated without cause or if she resigns for good reason, in each case within three months prior to or twelve months following a change of control, then the Company will pay and provide to Ms. Zhang: (i) all accrued obligations as of the date of termination, (ii) an amount equal to eighteen months of her then-current base salary in a lump sum, (iii) any accrued but unpaid bonus for the prior fiscal year, (iv) her target annual bonus for the year in which the termination occurs at the rate in effect immediately prior to such termination multiplied by a factor of 1.5 and (v) eighteen months of continuing health benefits coverage, each subject to the conditions outlined in the agreement. In addition, any unvested and outstanding equity interests Ms. Zhang may have shall fully vest and become exercisable subject to the conditions outlined in her equity agreements.

Severance Tax Matters

All payments made and benefits available to each executive officer in connection with his or her employment agreement will or were intended to comply with Section 409A of the Internal Revenue Code of 1986, as amended, (the Code) in accordance with the terms of his or her employment agreement. In the event the benefit provided to an employee (i) constitutes "parachute payments" within the meaning of Section 280G of the Code, and (ii) would otherwise be subject to the excise tax imposed by Section 4999 of the Code, then such "Payments" will be reduced. The reduced amount will be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the excise tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount results in the executive officer's receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code. If a reduction in payments or benefits constituting "parachute payments" is necessary to limit or avoid a certain employee's excise tax, the reduction shall occur at the election of such employee (provided, however, that such election shall be subject to our approval if made on or after the effective date of the event that triggers the Payment) and may reduce cash payments, cancel accelerated vesting of stock award, and/or reduce employee benefits in any order or combination that maximizes the amount of such reduced amount. In the event that acceleration of vesting of stock award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of such executive officer's stock awards unless the executive officer elects a different order for cancellation.

Compensation Overview

We are a "smaller reporting company" as such term is defined in Rule 405 of the Securities Act of 1933, as amended (the Securities Act), and Item 10 of Regulation S-K. Accordingly, and in accordance with relevant SEC rules and guidance, we have elected, with respect to the disclosures required by Item 402 (Executive Compensation) of Regulation S-K, to comply with the disclosure requirements applicable to smaller reporting companies. We are providing this "Compensation Overview" section in order to aid our stockholders' understanding of our compensation programs and policies for our executive officers as well as the Compensation Committee's role in the design and administration of these programs and policies in making specific compensation decisions for our executive officers, including our "named executive officers."

Compensation Program Administration and Process

Roles and Compensation-Setting Process

Our executive compensation program is administered by the Compensation Committee, with guidance and input from each of our Chief Executive Officer and our compensation consultant, Anderson Pay Advisors LLC (Anderson).

Historically, the Compensation Committee has made most of the significant adjustments to annual compensation for the next fiscal year, determined bonus and equity awards and established new performance objectives for the next fiscal year at one or more meetings held during the fourth quarter of the year. However, the Compensation Committee also considers matters related to individual compensation, such as compensation for new executive hires, adjustments to the compensation of existing executives, as well as high-level strategic issues, such as the efficacy of the Company's compensation strategy, potential modifications to that strategy and new trends, plans or approaches to compensation, at various meetings throughout the year.

Generally, the Compensation Committee's process comprises two related elements: (i) the determination of specific compensation packages for our executive officers, and (ii) the establishment of performance objectives for the next year. For executives other than the Chief Executive Officer, the Compensation Committee solicits and considers evaluations and recommendations submitted by the Chief Executive Officer for the Compensation Committee's review and approval. In the case of the Chief Executive Officer, the evaluation of her performance is conducted by the Compensation Committee in consultation with the Board, and the Compensation Committee recommends to the Board for approval any adjustments to her compensation as well as equity awards to be granted. Also, in each case, the Compensation Committee obtains and considers input from Anderson, including benchmarking data discussed below. Ms. Pelletier plays no role in determining her own salary, annual cash performance bonus or equity compensation.

Our Compensation Committee has the sole authority and responsibility to review and determine, or recommend to the full Board for determination, the compensation package of our Chief Executive Officer (Saundra Pelletier) and each of our other named executive officers (currently Ivy Zhang). Our Compensation Committee is composed entirely of independent directors who have never served as officers of the Company and operates under a written charter adopted and reviewed annually by our Board.

Role of Independent Compensation Consultant; Benchmarking

The Compensation Committee has the authority to directly retain the services of independent consultants and other experts to assist in fulfilling its responsibilities. The Compensation Committee has engaged Anderson to review our executive compensation programs and to assess our executive officers' base salaries, target and actual total cash bonuses, long-term incentives and total compensation from a competitive standpoint. Anderson also assists the Compensation Committee in benchmarking our director compensation program and practices against those of our peers. For such services, we paid Anderson an immaterial amount in each 2023 and 2022. Anderson performs services solely on behalf of the Compensation Committee and has no relationship with the Company or management relating to compensation or other human resources related services except as it may relate to performing such services. The Compensation Committee has assessed the independence of Anderson pursuant to SEC rules and the corporate governance rules of Nasdaq and concluded that no conflict of interest exists that would prevent Anderson from independently advising the Compensation Committee. Anderson also assisted the Compensation Committee in defining the appropriate group of peer companies for analysis of our executive compensation and practices and in benchmarking our executive compensation program against the peer group.

Roles of Management in Determining Executive Compensation

The Compensation Committee periodically meets with our Chief Executive Officer and/or other executive officers to obtain recommendations with respect to compensation programs for executives and other employees. Our Chief Executive Officer makes recommendations to the Compensation Committee on the base salaries, target cash bonuses and performance measures, and equity compensation for our executives and other key employees. The Compensation Committee considers, but is not bound to accept, management's recommendations with respect to executive compensation. Our Chief Executive Officer and certain other executives attend most of the Compensation Committee's meetings, but the Compensation Committee also holds private sessions outside the presence of members of management and non-independent directors. The Compensation Committee discusses our Chief Executive Officer's compensation package with her but makes decisions with respect to her compensation without her present. The Compensation Committee has delegated to management the authority to make certain decisions regarding compensation for employees other than executive officers. The Compensation Committee has not delegated any of its authority with respect to the compensation of the named executive officers.

Stockholder Engagement and Use of Stockholder Feedback

The Compensation Committee informally engages with the Company's stockholders to gain feedback on our stockholders' concerns and internal guidelines regarding executive compensation. The Compensation Committee then seeks to align those interests with the Company's compensation policies.

Use of Compensation Peer Group Data

Each year since 2018, the Compensation Committee has engaged Anderson to provide compensation market data and recommendations to be used to establish compensation levels and plans for our executive officers for the following year.

For the 2022 and 2023 performance cycles, the Compensation Committee again engaged Anderson to conduct a competitive review of executive compensation as compared to our peer group. This review and analysis revealed that annual cash salary and cash bonuses fell short of the target goal of the 75th percentile of our peer group. Nevertheless, for 2022, after consideration of stock performance and based in part on direct feedback from our stockholders, the Compensation Committee determined to lower the target pay positioning for both cash and equity from the market 75th percentile to the market 50th percentile for on-target performance. The equity grants in 2022, from a value perspective, are an example of the shift. The value of those grants and overall total direct compensation delivered to the executive team fell well below prior levels and we anticipate falling below the median as well. There were no equity grants in 2023.

For 2023, our target goal for annual cash salary of our named executive officers was $1.0 million, a significant reduction from the prior year. The annual potential cash bonus for our named executive officers was $0.6 million. This reflects an aggregate 30% reduction in the annual base salary for our Chief Executive Officer, a 55% reduction in total compensation for the Chief Financial Officer position, the decision not to fill the position of General Counsel, and elimination of the Chief Commercial Officer role.

For 2024, our target goal for annual gross cash salary and potential cash bonus of our named executive officers is $1.8 million, a $0.2 million difference from the prior year.

Our Peer Group

In 2023, the Compensation Committee also worked with Anderson to review our peer group. Each year, the Compensation Committee reviews and approves our selected peer group. The committee considers several factors in development and refinement of the peer group. Key factors include:

- Industry (SIC): Pharmaceutical preparation (2834)
- Stage of business: Early-stage commercialization
- Market capitalization: Target range of under $500M
- Revenue: Target range less than $100M
- Headcount: Target range less than 250 employees
- Geography: National

The Compensation Committee will continue to welcome constructive feedback from stockholders, stockholder advisory groups and other interested parties in consideration of our processes and, in particular, our benchmark peers.

During 2023, our peer group consisted of the following 24 companies:

AcelRx Pharmaceuticals	Eiger BioPharmaceuticals Inc.	Omeros	scPharmaceuticals
Agile Therapeutics	Kala Pharmaceuticals	Otonomy	SCYNEXIS
Chimerix	La Jolla Pharmaceuticals	Paratek Pharmaceuticals	Sensen Bio
Concert Pharmaceuticals	Lexicon Pharmaceuticals	Puma Biotechnology, Inc.	Spectrum Pharmaceuticals
Cyma Bay Therapeutics	MEI Pharma	Reco Pharma	TherapeuticsMD
Eagle Pharmaceuticals	ObsEva	Rigel Pharmaceuticals	Trevena

We believe that our selected peer group provides useful information to help us establish competitive compensation practices and levels of compensation that allow us to attract, retain and motivate a talented executive team and, at the same time, aligns the interests of our executives with those of our stockholders. The executive employment market in our industry in the US is very competitive because there are many high-growth life sciences companies in our region, many of which are larger and more established than we are. We believe our executive compensation must be competitive within such peer groups, yet fully aligned with our current stage of development and our responsibilities to stockholders.

Compensation Objectives and Philosophy

The objective of our executive compensation program is to attract, retain and motivate talented executives who are critical for our continued growth and success and to align the interests of these executives with those of our stockholders so that we can build long-term stockholder value. To achieve this objective, besides annual base salaries, our executive compensation program utilizes a combination of annual incentives through structured cash bonuses based on pre-defined goals as well as long-term incentives through equity-based compensation. In establishing overall executive compensation levels, our Compensation Committee considers a number of criteria, including (i) the applicable executive's scope of responsibilities, (ii) the strategic importance of the applicable executive's role, (iii) the Company's stage of development, (iv) relevant peer group data, (v) attainment of individual and overall company performance objectives, (vi) recruitment and/or retention concerns, and (vii) the results of the advisory vote of the stockholders on the "say-on-pay" proposal at the prior years' annual meeting of the stockholders. Our Compensation Committee believes that substantial portions of executive compensation should be linked to the overall performance of our Company, and that the contribution of individuals over the course of the relevant period to the goal of building a profitable business and stockholder value should also be considered in the determination of each executive's compensation.

Elements of Compensation

Our executive compensation program consists of the following forms of compensation:

- Base Salary
- Annual Performance Cash Bonus
- Long-term Equity Incentives
- Employee Benefit Program

Base Salary

Annual base salaries compensate our executive officers for fulfilling the requirements of their respective positions and provide them with a level of cash income predictability and stability with respect to a portion of their total compensation. We believe that the level of an executive officer's base salary should reflect the executive's performance, experience and breadth of responsibilities, our understanding of salaries for similar positions within our industry and peer group and any other factors relevant to that particular job.

Base salaries are typically negotiated at the outset of an executive's employment. Salary levels are considered annually as part of our performance review process, but also in cases including promotion or other changes in the job responsibilities of an executive officer. For named executive officers, initial base salaries generally are established in connection with negotiation of an offer of employment and an employment agreement. Increases in base salary have several elements. In addition to promotion and increased responsibilities, merit and Company-wide general increases are also taken into consideration. Salaries of our named executive officers for fiscal year 2023 and certain prior years are also reported in the Summary Compensation Table included under the heading "Summary Compensation Table" in this Annual Report.

The following table shows the base salary for each of our current named executive officers for 2022 and 2023 (in whole dollars):

Name	2022($)	2023 ($)	Change from Prior Year
Saundra Pelletier	812,083	568,458(1)	(30)%
Ivy Zhang	—(2)	$ 410,000	n/a

(1) Ms. Pelletier's annual base salary was reduced by 20% in February 2023 and another 20% in March 2023, resulting in a total reduction of 30% as compared to her 2022 salary cited in the above table. The Company may review, change or end the salary reduction at its discretion.
(2) Ms. Zhang was appointed Chief Financial Officer and Secretary on April 13, 2023.

Annual Performance Cash Bonuses

Each year, the Compensation Committee recommends, and the Board approves and establishes, the target cash incentive opportunity for each executive officer assuming full achievement of certain performance objectives that are also reviewed and approved by the Board. The following table shows the potential cash bonus incentive for each of our current named executive officers for fiscal 2023 and 2022 (each expressed as a percentage of annual base salary) and in actual dollar awarded:

Name and Principal Position	Year Ended December 31	Cash Incentive % of Annual Salary (Eligible)	Cash Incentive % of Annual Salary (Estimated)	Cash Incentive Bonus (Estimated)	% Change
Saundra Pelletier, Chief Executive Officer	2023	100%	76%	$ 455,173	124%
	2022	100%	25%	$ 203,021	
Ivy Zhang, Chief Financial Officer and Secretary (1)	2023	50%	23%	$ 94,439	N/A
	2022	N/A	N/A	N/A	

(1) Ms. Zhang was appointed Chief Financial Officer and Secretary on April 13, 2023.

On a periodic basis, the Compensation Committee reviews the level of the Company's achievement against the applicable performance objectives. In reviewing the Company's level of achievement against the applicable performance objectives for fiscal 2023, Management expects that the incentive bonus payment will be less than the possible target incentive bonus percentages as set forth in the table above.

As illustrated in the above table, the 2023 compensation program, consistent with prior years, was designed to reward achievement of the performance objectives that build stockholder value. When certain performance objectives are not achieved, the incentive bonus payouts will be reduced. In 2022, less than half of these weighted performance objectives were achieved, resulting in an expected partial payout of the potential cash incentive bonus, only when and if approved by the Board. At the time of the 2022 Proxy/Say on Pay vote, the results of the 2022 program were not yet complete so stockholders could not yet see the alignment of executive compensation with Company performance. We have likewise designed our 2024 cash incentive bonus program to reward achievement of key drivers of stockholder value.

The performance objectives established by the Compensation Committee for 2023 related to achieving certain level of net revenue, achieving a certain level of Earnings Before Interest, Taxes, Depreciation, and Amortization (EBITDA), approval of a reverse stock split, and executing an accretive transaction that improves both the pro-forma and cash runway for Evofem, such as adding additional products to the portfolio, merger, or entering into a license and/or distribution agreement with a third party for sale of Phexxi outside the US.

For 2024, the Compensation Committee has approved the following performance objectives as those which must be achieved in order for the named executive officers to fully realize their potential annual cash bonus amounts:

- Achieve a targeted net sales figure in 2024;
- Close a strategic transaction (i.e. enter into a license or partnership for Phexxi or add a product for co-promotion); and
- Secure a targeted amount of capital.

Following the determination of corporate achievement of the performance objectives, the Compensation Committee will also consider the performance of each named executive officer in arriving at the individual awards, if any, to be made, provided that no award will exceed the target percentage of annual base salary for annual bonus. The Compensation Committee believes this flexibility is an important tool to aid in the retention of key talent, reward significant achievement by individual executives, motivate executives and recognize management decision-making focused on generating long-term value for stockholders over short-term achievement of the corporate objectives. The potential total cash bonus amounts for fiscal 2023 and 2022 for our named executive officers are reported in the Summary Compensation Table included under the heading "Summary Compensation Table" in this Annual Report.

Discretionary Bonuses

From time to time, we have utilized discretionary retention or other bonus awards as a compensation tool to reward extraordinary performance by executives in a given year and to retain key executives. In addition, we believe that signing bonuses are consistent with our overall executive compensation philosophy to achieve our recruiting objectives, so we may award certain signing bonuses to new executives in the future.

Long-term Equity Incentive Awards

We have historically granted stock options and restricted stock to our employees within a competitive range of the market to complement cash salaries and cash incentives, incentivize new hires to achieve our corporate and strategic goals, and align executive compensation with the long-term interests of our stockholders and stock value. We historically provided stock option grants to our named executive officers upon their initial hiring, as negotiated in their employment agreements or offer letters. We have not granted any stock options or restricted stock to any employees in 2023. The Compensation Committee has the discretion to grant stock option awards and restricted stock awards to promote high performance and achievement of our corporate objectives by our executives at any time of the year. The Compensation Committee does not currently have a policy for the automatic awarding of equity awards to the named executive officers or our other employees, nor do we have any formal plan that requires us to award equity or equity-based compensation to any executive on a year-to-year basis. The timing of our typical equity awards is determined in advance. In general, we do not anticipate option grants on dates other than the scheduled meetings of the Compensation Committee. The grant date is established when the Compensation Committee approves the grant and all key terms have been determined.

In granting these awards, the Compensation Committee may establish any conditions or restrictions it deems appropriate in accordance with the Amended and Restated 2014 Plan or the 2018 Inducement Equity Incentive Plan, as the case may be. Our Chief Executive Officer typically provides recommendations to the Compensation Committee for equity grants to the executive officers, taking into account each executive's performance, achievements, and other criteria deemed relevant. The Compensation Committee reviews the proposed grants but reserves the right to reject or modify such recommendations. In addition, our Chief Executive Officer has limited discretionary authority to grant stock options under the Amended and Restated 2014 Plan to our non-executive employees, subject to certain volume limitations.

We size equity grants based on market data that expresses the awards as a percent of common shares outstanding. This sizing approach is helpful to ensure that the dilutive effects of the grants are reasonable. The exercise price of the stock options will equal the closing price of our common stock published by OTCQB on the date of the grant and the term of the options will be 10 years from the date of the grant. The Compensation Committee has taken a two-tiered approach to vesting in order to align executive compensation with long-term stockholder value. The first consists of longer term, time-based vesting for certain awards, and the second relies on performance-based vesting for certain awards that are tied to critical, more immediate goals fundamental to the Company's mission to achieve commercial success.

Executive Compensation Matters

The following table shows the outstanding equity awards held by our named executive officers as of December 31, 2023.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Grant Date	Option Expiration Date
Saundra Pelletier	20(1)	-	$ 86,925.00	9/28/2016	9/28/2026
	439	-	$ 13,668.75	3/12/2018	3/12/2028
	166	-	$ 3,937.50	7/31/2018	7/31/2028
	151	-	$ 6,468.75	11/28/2018	11/28/2028
	159	-	$ 9,131.25	2/5/2020	2/5/2030
	264	107	$ 6,093.75	2/3/2021	2/3/2031
	183	216	$ 917.50	2/18/2022	2/18/2032
Ivy Zhang	-	-	-	-	-

(1) The share numbers and exercise prices reflected are those of options issued to the executive upon completion of the Merger in January 2018. These options were issued upon completion of the Merger in exchange for options to purchase an aggregate of 874 shares of Private Evofem common stock at an exercise price of $2,231.25 per share awarded to the executive by Private Evofem in 2016.

Employee Benefit and Equity Incentive Plans

Stock Compensation Plans

Summary of the Amended and Restated 2014 Plan

The Company initially adopted the 2007 Stock Plan (the 2007 Plan) in March 2007, under which 113 shares of common stock were reserved for issuance to employees, non-employee directors, and consultants of the Company. The Company ceased granting any additional awards under our 2007 Plan, and presently grants equity awards under the Amended and Restated 2014 Plan as described below.

On September 15, 2014, our Board adopted, and our stockholders approved, the 2014 Equity Incentive Plan. The 2014 Equity Incentive Plan, as amended and restated, provides incentives that will assist us to attract, retain, and motivate employees, including officers, consultants, and directors. We may provide these incentives through the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, and units and other cash-based or share-based awards. In addition, the Amended and Restated 2014 Plan contains a mechanism through which we may adopt a deferred compensation arrangement in the future.

A total of 88 shares of our common stock was initially authorized and reserved for issuance under the Amended and Restated 2014 Plan. As of March 21, 2024, a total of 5,789 shares of our common stock were reserved and available for issuance under the Amended and Restated 2014 Plan. Per the terms of the Amended and Restated 2014 Plan, this reserve will automatically increase on each January 1 through 2024, by an amount equal to the smaller of:

- 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31; or
- an amount determined by our Board.

Appropriate adjustments will be made in the number of authorized shares and other numerical limits in the Amended and Restated 2014 Plan and in outstanding awards to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in our capital structure. Shares subject to awards which expire or are cancelled or forfeited will again become available for issuance under the Amended and Restated 2014 Plan.

The Amended and Restated 2014 Plan is administered by the Compensation Committee of our Board. Pursuant to the provisions of the Amended and Restated 2014 Plan, the Compensation Committee determines, in its discretion, the persons to whom and the times at which awards are granted, the sizes of such awards and all of their terms and conditions. The Compensation Committee has the authority to construe and interpret the terms of the Amended and Restated 2014 Plan and awards granted under it. The Amended and Restated 2014 Plan provides, subject to certain limitations, for indemnification by us of any director, officer, or employee against all reasonable expenses, including attorneys' fees, incurred in connection with any legal action arising from such person's action or failure to act in administering the Amended and Restated 2014 Plan.

In the event of a change in control as described in the Amended and Restated 2014 Plan, the acquiring or successor entity may assume or continue all or any awards outstanding under the Amended and Restated 2014 Plan or substitute substantially equivalent awards. The Compensation Committee may provide for the acceleration of vesting of any or all outstanding awards upon such terms and to such extent as it determines, except that the vesting of all awards held by members of the Board who are not employees will automatically be accelerated in full upon a change in control. Any award held by a participant whose service has not terminated prior to a change in control that is not assumed, continued, or substituted for in connection with a change in control or are not exercised or settled prior to the change in control will terminate effective as of the time of the change in control. Notwithstanding the foregoing, except as otherwise provided in an award agreement governing any award, in the discretion of the Compensation Committee, any award that is not assumed, continued, or substituted for in connection with a change in control shall, subject to the provisions of applicable law, become fully vested and exercisable and/or settleable as of a date prior to, but conditioned upon, the consummation of the change in control. The Amended and Restated 2014 Plan also authorizes the Compensation Committee, in its discretion and without the consent of any participant, to cancel each or any outstanding award denominated in shares upon a change in control in exchange for a payment to the participant with respect to each vested share subject to the cancelled award (and each unvested share, if so determined by the Compensation Committee) of an amount equal to the excess of the fair market value of the consideration to be paid per share of common stock in the change in control transaction over the exercise price per share, if any, under the award. The vesting schedules of all outstanding options of the Company, excluding any shares issuable pursuant to the assumed equity incentive plan of Private Evofem, were fully accelerated in connection with the Merger and termination of employment or service arrangement with the Company.

The Amended and Restated 2014 Plan will continue in effect until it is terminated, provided, however, that all awards will be granted, if at all, within ten years of its effective date. The Compensation Committee may amend, suspend or terminate the Amended and Restated 2014 Plan at any time, provided that without stockholder approval, the Amended and Restated 2014 Plan cannot be amended by the Compensation Committee without stockholder approval, except as described above, to increase the number of shares authorized, change the class of persons eligible to receive incentive stock options, or effect any other change that would require stockholder approval under any applicable law or listing rule.

Summary of the 2018 Inducement Equity Incentive Plan

On July 24, 2018, upon the recommendation of our Compensation Committee, the Board approved our 2018 Inducement Equity Incentive Plan and reserved 133 shares of our common stock to be used exclusively for grants of awards to individuals that were not previously employees or directors of the company, as an inducement to the individual's entry into employment with the company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. On February 25, 2020, the Board approved an increase to the number of shares of our common stock reserved and available for issuance under the 2018 Inducement Equity Incentive Plan to 666 shares. The 2018 Inducement Equity Incentive Plan was adopted without stockholder approval pursuant to Rule 5635(c)(4). The 2018 Inducement Equity Incentive Plan provides for the grant of equity-based awards, including options, restricted and unrestricted stock awards, and other stock- based awards, and its terms are substantially similar to the Amended and Restated 2014 Plan, but with such other terms and conditions intended to comply with the Nasdaq inducement award exception. As of March 21, 2024, there were 51 shares of options outstanding and 609 shares available for grant under the 2018 Inducement Equity Incentive Plan.

Summary of the 2019 Employee Stock Purchase Plan

On May 7, 2019, the Board approved the 2019 ESPP, which was approved by stockholders at the 2019 annual meeting held on June 5, 2019 and which authorizes the issuance of up to 266 shares of common stock pursuant to purchase rights granted to employees. This authorized number of shares may be increased annually on the first day of each of the Company's fiscal years beginning in 2020 and ending on the first day of 2029, in an amount equal to the lesser of (i) 533 shares, (ii) two percent (2%) of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, or (iii) such lesser number of shares as is determined by the Board. The 2019 ESPP enables eligible full-time and part-time employees to purchase shares of the Company's common stock through payroll deductions of between 1% and 15% of eligible compensation during an offering period. A new offering period begins approximately every June 15 and December 15. At the last business day of each offering period, the accumulated contributions made during the offering period will be used to purchase shares. The purchase price is 85% of the lesser of the fair market value of the common stock on the first or the last business day of an offering period. The maximum number of shares of common stock that may be purchased by any participant during an offering period will be equal to $25,000 divided by the fair market value of the common stock on the first business day of an offering period.

In October 2022, the Board terminated the offering period ending December 15, 2022, refunded all employee contributions, and suspended future offering periods. Additionally, the authorized number of shares available for issuance under the 2019 ESPP was not increased on January 1, 2023. The Board may in future reinstitute the ESPP if and when our common stock resumes trading on a national stock exchange.

As of March 21, 2024, there were 937 shares of common stock purchased and 509 shares of our common stock reserved and available for issuance under the 2019 ESPP.

Private Evofem Equity Incentive Plan

The Private Evofem Equity Incentive Plan was assumed by the Company in connection with the Merger and shares of Private Evofem common stock issuable pursuant to options previously granted under the Private Evofem Equity Incentive Plan became options to purchase our common stock upon completion of the Merger. No new awards may be granted under the Private Evofem Equity Incentive Plan. As of December 31, 2023, a total of 66 shares of our common stock were reserved for issuance upon the exercise of outstanding options under the Private Evofem Equity Incentive Plan.

The Compensation Committee has resolved that, absent unusual circumstances, stock options be granted to new hires with a vesting term of four years, with 25% vesting at the first anniversary of the date of grant and the remaining amount vesting in 36 equal monthly installments thereafter. For existing employees, the Compensation Committee has resolved that, absent unusual circumstances, time-based vesting stock options be granted with a vesting term of four years, vesting in 48 equal monthly installments. For restricted stock generally, vesting is based on achievement of critical performance goals. Further, the Compensation Committee selects these performance goals with a view to aligning executives' performance with long-term stockholder value.

As mentioned above, for 2023, no performance based restricted stock grants have been considered.

Equity awards generally do not accelerate upon a change of control; however, under each of the Amended and Restated 2014 Plan and the 2018 Inducement Equity Incentive Plan, our Board has discretion to accelerate vesting upon a change of control. The Compensation Committee also has sole discretion with respect to the tax treatment for equity awards and may decide to (1) facilitate the sale of a sufficient number of the granted shares to cover taxes, (2) require that shares having a value equal to the tax burden be withheld by the Company with the Company paying the tax in cash to the relevant taxing authority, or (3) require employees to be responsible for their own taxes. The value of any shares used to cover taxes will be calculated based on the closing stock price of the shares on the date of vesting of the shares and will be paid in proportion to the vesting schedule of the shares.

Equity Incentive Compensation

Historically, we have generally granted stock options to our employees, including our named executive officers, in connection with their initial employment with us. We also have historically granted stock options on an annual basis as part of annual performance reviews of our employees. From time to time, we have also granted, restricted stock awards to our executive management team, including our named executive officers, and certain non-executive employees, which typically vest in accordance with the Company's achievement of certain performance goals in the year.

We believe that the performance-based vesting of restricted stock grants illustrates the alignment between overall executive compensation and building long-term stockholder value. However, in 2022, when performance goals were not achieved, and our stock price suffered as a result, all of the 2022 restricted stock grants to our executive officers were forfeited.

On February 18, 2022, the Company granted Ms. Pelletier options to purchase 400 shares of our common stock with an exercise price of $734.625 per share, which vest in a series of forty-eight (48) successive equal monthly installments upon completion of each additional month of service for the Company measured from the vesting commencement date of February 18, 2022. Additionally, on February 18, 2022, the Company granted Ms. Pelletier 400 shares of common stock issued as restricted stock awards, which are subject to vesting upon the verification by our Compensation Committee of the achievement of certain to the Company's achievement of certain performance milestones in 2022. On December 31, 2022, these restricted stock awards were cancelled due to forfeiture under these vesting provisions. No options were granted in 2023.

Our Chief Executive Officer's Compensation

As set forth above, one of the key drivers in the Compensation Committee's determination of the compensation of our Chief Executive Officer is company performance.

The following table shows the total compensation (including estimated amounts accrued but not yet paid) of our Chief Executive Officer for each of 2022 and 2023, in each case, excluding the value of options (all of which are out-of-the money as of the date hereof).

	Years Ended December 31,		2023 vs. 2022	
	2023	2022	$ Change	% Change
Compensation Item				
Salary	$ 560,338	$ 812,083	$ (251,745)	(31)%
Retention Paid	450,000	-	450,000	100%
Accrued Compensation (unpaid)	493,747	203,021	290,726	143%
Restricted Stock Awards	-	-(1)	-	N/A
All other Compensation	16,370	15,716	654	4%
Total	$ 1,520,455	$ 1,030,820	$ 489,635	47%

(1) On February 18, 2022, the Company granted Ms. Pelletier 400 shares of common stock issued as Restricted Stock Awards (RSAs), which are subject to vesting upon the verification by our Compensation Committee of the achievement of certain to the Company's achievement of certain performance milestones in 2022. On December 31, 2022, these RSAs were cancelled due to forfeiture under these vesting provisions.

Perquisites, Health, Welfare and Retirement Plans

We also provide group life insurance, health, vision and dental care insurance to all employees, including the executive officers. These benefits do not discriminate in scope, terms or operation in favor of the named executive officers. All such benefits terminate at the time each individual is no longer employed with the Company or as otherwise provided in the applicable employment agreement. All of our named executive officers are eligible to participate in all of our employee benefit plans, in each case on the same basis as other employees. We maintain a 401(k) defined contribution plan, which is our primary retirement benefit for employees, including executives. The Company makes a safe-harbor contribution of 3% of each employee's gross earnings, including executives, subject to Internal Revenue Service limitations. Although permitted under the plan, we have not matched employee contributions to the 401(k) plan. We do not provide our executive officers with any type of defined benefit retirement benefit or the opportunity to defer compensation pursuant to a non-qualified deferred compensation plan. We generally do not offer our named executive officers any material compensation in the form of perquisites, but any perquisites provided to our named executive officers and described in the footnote to the Summary Compensation Table included in the Summary Compensation Table included under the heading "Summary Compensation Table" in this Annual Report are offered to encourage the long-term retention of our executives.

Director Compensation

The following table sets forth the compensation (cash and equity) received by our non-employee directors during the year ended December 31, 2023.

Name	Fees Earned or Paid in Cash	Option Awards	Totals
Kim Kamdar, Ph.D.	$ 77,620	$ -	$ 77,620
Tony O'Brien	$ 75,000	$ -	$ 75,000
Lisa Rarick, M.D.	$ 55,000	$ -	$ 55,000
Colin Rutherford	$ 70,000	$ -	$ 70,000
Gillian Greer, Ph.D.[(1)]	$ 17,366	$ -	$ 17,366
Jenny Yip[(2)]	$ -	$ -	$ -

(1) Dr. Greer resigned from the Board effective April 24, 2023.
(2) Ms. Yip elected to forego any compensation as director. She resigned from the Board effective February 10, 2023.

The following table shows the outstanding equity awards held by our non-employee directors as of December 31, 2023.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Grant Date	Option Expiration Date
Kim Kamdar, Ph.D.	47	-	$ 2,343.75	05/12/2021	05/12/2031
	48	-	$ 308.75	05/04/2022	05/04/2032
	6	-	$ 13,106.25	05/08/2018	05/08/2028
	13	-	$ 70,762.50	01/17/2018	01/17/2028
	26	-	$ 11,343.75	06/05/2019	06/05/2029
	26	-	$ 9,487.50	05/12/2020	05/12/2030
Tony O'Brien	47	-	$ 2,343.75	05/12/2021	05/12/2031
	48	-	$ 308.75	05/04/2022	05/04/2032
	13	-	$ 13,668.75	05/08/2018	05/08/2028
	6	-	$ 4,331.25	01/17/2018	01/17/2028
	26	-	$ 11,343.75	06/05/2019	06/05/2029
	26	-	$ 9,487.50	05/12/2020	05/12/2030
Lisa Rarick, M.D.	47	-	$ 2,343.75	05/12/2021	05/12/2031
	48	-	$ 308.75	05/04/2022	05/04/2032
	40	-	$ 10,968.75	02/25/2020	02/25/2030
	26	-	$ 9,487.50	05/12/2020	05/12/2030
Colin Rutherford	47	-	$ 2,343.75	05/12/2021	05/12/2031
	48	-	$ 308.75	05/04/2022	05/04/2032
	21	-	$ 13,668.75	03/12/2018	03/12/2028
	6	-	$ 13,106.25	05/08/2018	05/08/2028
	2	-	$ 3,937.50	07/31/2018	07/31/2028
	26	-	$ 11,343.75	06/05/2019	06/05/2029
	26	-	$ 9,487.50	05/12/2020	05/12/2030

Our Non-Employee Director Compensation Policy

In February 2022, our Compensation Committee amended the Non-Employee Director Compensation Policy, as described below, which took effect April 1, 2022.

- Each non-employee director will receive an annual cash retainer in the amount of $40,000 per year.
- The Chairperson of the Board will receive an additional annual cash retainer in the amount of $30,000 per year.
- The Chairperson of the Audit Committee will receive additional annual cash compensation in the amount of $20,000 per year for such chairperson's service on the Audit Committee. Each non-chairperson member of the Audit Committee will receive additional annual cash compensation in the amount of $10,000 per year for such member's service on the Audit Committee.
- The Chairperson of the Compensation Committee will receive additional annual cash compensation in the amount of $15,000 per year for such chairperson's service on the Compensation Committee. Each non-chairperson member of the Compensation Committee will receive additional annual cash compensation in the amount of $7,500 per year for such member's service on the Compensation Committee.
- The Chairperson of the Nominating and Corporate Governance Committee will receive additional annual cash compensation in the amount of $10,000 per year for such chairperson's service on the Nominating and Corporate Governance Committee. Each non-chairperson member of the Nominating and Corporate Governance Committee will receive additional annual cash compensation in the amount of $5,000 per year for such member's service on the Nominating and Corporate Governance Committee.
- Each non-employee director will receive a stock option grant with an initial grant equal to 48 shares of the Company's common stock upon a director's initial appointment or election to the Board, vesting quarterly over a three-year period and an annual stock option grant equal 48 shares of the Company's common stock on the date of each annual stockholder's meeting thereafter, fully vesting in one year from the date of grant.

The February 2022 amendment of the Non-Employee Director Compensation Policy, effective as of April 1, 2022, reduced the annual cash retainer for each non-employee director from $50,000 per year to $40,000 per year, the annual cash retainer for the chairperson of the Board from $40,000 to $30,000, and the annual cash compensation for the chairperson of the Nominating and Corporate Governance Committee from $11,250 per year to $10,000 per year.

Pay vs. Performance

The following table sets forth information concerning the compensation of our Named Executive Officers and our financial performance for the years ended December 31, 2023 and 2022:

Year	Summary Compensation Table Total for PEO[1]	Compensation Actually Paid to PEO[2]	Average Summary Compensation Table Total for Non-PEO NEOs[3]	Average Compensation Actually Paid to Non-PEO NEOs[2]	Value of Initial Fixed $100 Investment Based on Total Shareholder Return	Net Income (Loss) (in thousands)
	(a)	(b)	(c)	(d)	(e)	(f)	(g)
2023[4]	$ 1,520,455	$ 1,525,001	$ 309,234	$ 311,857	$ 0.80[5]	$ 52,979
2022	$ 1,324,670	$ 952,400	$ 599,276	$ 477,131	$ 0.18[6]	$ (76,698)

(1) PEO: Principal Executive Officer. For both 2023 and 2022, Saundra Pelletier was our PEO.
(2) See table below for amounts deducted or added to calculate executive compensation actually paid, inclusive of an accrual for the estimated bonus not yet paid.
(3) NEO: Named Executive Officer.
(4) The Non-PEO NEOs for 2023 includes Katherine Atkinson and Jay File as they were each employed for a short time in the year.
(5) The closing price of shares of our common stock on December 31, 2023 was $0.064.
(6) The closing price of shares of our common stock on December 31, 2022 was $8.00.

Year	PEO	Non-PEO NEOs
2023	Saundra Pelletier	Ivy Zhang, Jay File[4], Katherine Atkinson[4]
2022	Saundra Pelletier	Jay File, Alexander Fitzpatrick and Katherine Atkinson

The amounts reported in the "Compensation Actually Paid to PEO" and "Average Compensation Actually Paid to Non-PEO NEOs" columns do not reflect the actual compensation paid to or realized by our CEO or our non-CEO NEOs during each applicable year. The calculation of compensation actually paid for purposes of this table includes point-in-time fair values of stock awards and these values will fluctuate based on our stock price, various accounting valuation assumptions and projected performance related to our performance awards. See the Summary Compensation Table for certain other compensation of our CEO and our non-CEO NEOs for each applicable fiscal year.

Compensation actually paid to our NEOs represents the "Total" compensation reported in the Summary Compensation Table for the applicable fiscal year, as adjusted as follows:

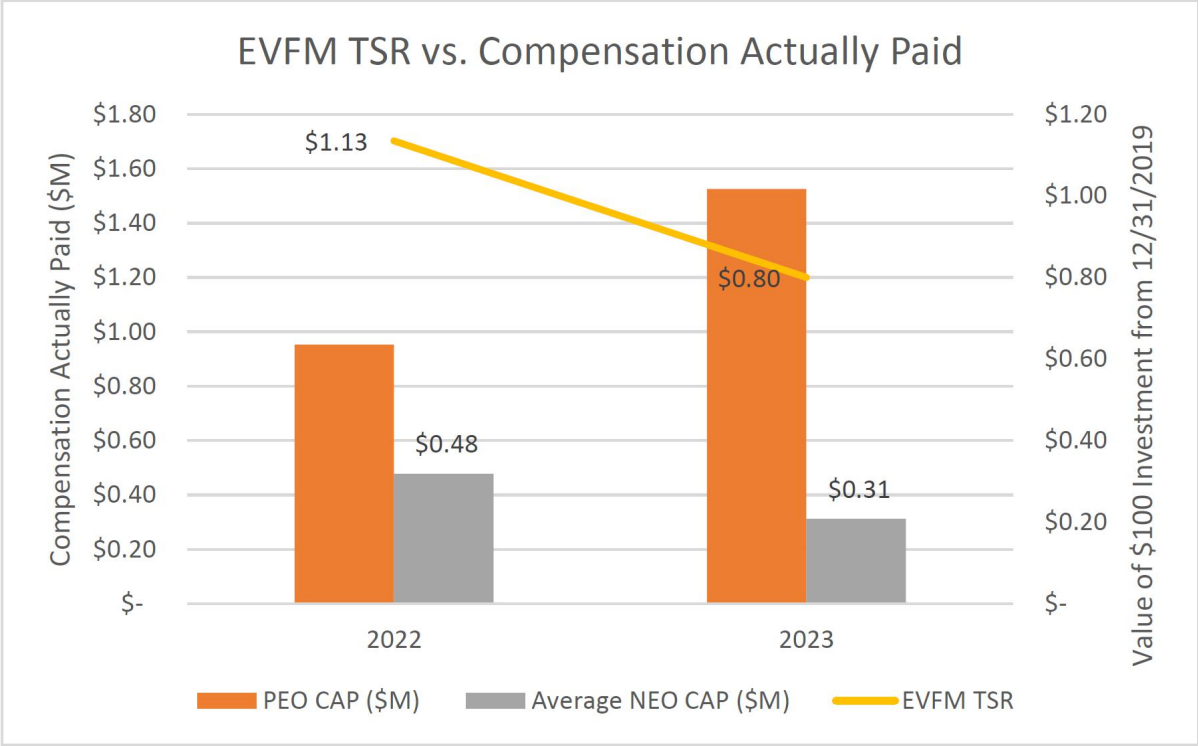
	2023		2022	
Adjustments	**PEO**	**Average Non-PEO NEOs**	**PEO**	**Average Non-PEO NEOs**
Deduction for Amounts Reported under the "Stock Awards" and "Option Awards" Columns in the Summary Compensation Table for applicable FY	$ -	$ -	$ (293,850)	$ (111,010)
Increase based on ASC 718 Fair Value of Awards Granted during Applicable FY that Remain Unvested as of Applicable FY End, Determined as of Applicable FY End	-	-	594	145
Increase based on ASC 718 Fair Value of Awards Granted during Applicable FY that Vested during Applicable FY, determined as of Vesting Date	(406)	-	9,279	3,505
Increase/deduction for Awards Granted during Prior FY that were Outstanding and Unvested as of Applicable FY End, determined based on change in ASC 718 Fair Value from Prior FY End to Applicable FY End	-	-	(69,337)	(9,764)
Increase/deduction for Awards Granted during Prior FY that Vested During Applicable FY, determined based on change in ASC 718 Fair Value from Prior FY End to Vesting Date	4,546	2,623	(18,956)	(5,021)
Total Adjustments	$ 4,140	$ 2,623	$ (372,270)	$ (122,145)

Fair value or change in fair value, as applicable, of equity awards in the "Compensation Actually Paid" columns was determined by reference to a Black Scholes value as of the applicable year-end or vesting date(s), determined based on the same methodology as used to determine grant date fair value but using the closing stock price on the applicable revaluation date as the current market price and with an expected life set equal to the remaining life of the award in the case of underwater stock options and, in the case of in the money options, an expected life equal to the original ratio of expected life relative to the ten year contractual life multiplied times the remaining life as of the applicable revaluation date, and in all cases based on volatility and risk free rates determined as of the revaluation date based on the expected life period and based on an expected dividend rate of 0%. For additional information on the assumptions used to calculate the valuation of the awards, see the Notes to the Consolidated Financial Statements in this Annual Report and for prior fiscal years.

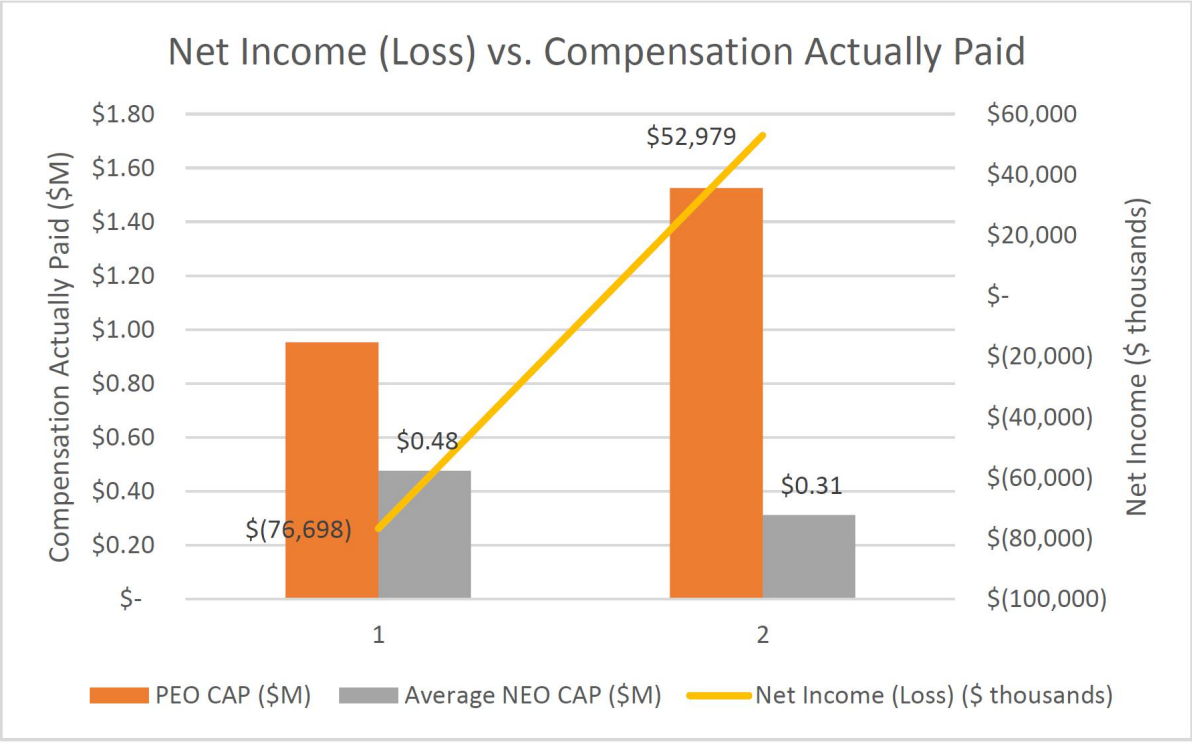
Relationship Between Financial Performance Measures

The graph below compares the compensation actually paid to our PEO and the average of the compensation actually paid to our remaining NEOs, with (i) our cumulative Total Shareholder Return (TSR), and (ii) our net income (loss) for the fiscal years ended December 31, 2023 and 2022. TSR amounts reported in the Pay Versus Performance table above and the graph below assume an initial fixed investment of $100 on December 31, 2021, and that all dividends, if any, were reinvested.

EVFM TSR vs. Compensation Actually Paid



Net Income (Loss) vs. Compensation Actually Paid



Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth certain information concerning the ownership of our common stock as of March 15, 2024, by (i) those persons who are known to us to be the beneficial owner(s) of more than five percent of our common stock, (ii) each of our directors and named executive officers and (iii) all of our directors and named executive officers as a group.

As of March 15, 2024, 45,939,509 shares of common stock, 1,913 shares of Series E-1 Shares and 22,280 shares of Series F-1 Shares were issued and outstanding.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. In the cases of holders who are not directors, director nominees, and named executive officers, Schedules 13G or 13D filed with the SEC (and, consequently, ownership reflected here) often reflect holdings as of a date prior to March 15, 2024. Under such rules, beneficial ownership generally includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after March 15, 2024, through the exercise of stock options, warrants or other rights. Unless otherwise indicated in the footnotes to this table, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Unless otherwise noted, the address of the persons in the table below is that of the Company.

Name of Beneficial Owner	Shares Beneficially Owned	Percent of Shares Beneficially Owned
Directors and Named Executive Officers		
Kim Kamdar, Ph.D.[1]	170	*
Tony O'Brien[2]	173	*
Lisa Rarick, M.D.[3]	167	*
Colin Rutherford[4]	180	*
Saundra Pelletier[5]	2,954	*
Ivy Zhang	-	*
Directors and executive officers as a group (6 Persons)[6]	3,644	*
Holders of Greater than 5% of the class (Series E-1 Convertible Preferred Shares)		
Keystone Capital Partners, LLC [7]	585	31%
Mercer Street Global Opportunity Fund, LLC [8]	531	28%
Seven Knots, LLC [9]	159	8%
Walleye Opportunities Master Fund [10]	638	33%
Holders of Greater than 5% of the class as a group (4 Persons)	1,913	100%
Holders of Greater than 5% of the class (Series F-1 Convertible Preferred Shares)		
Aditxt, Inc.[11]	22,280	100%

* Includes beneficial ownership of less than 1% of the outstanding shares of Evofem's common stock.

(1) Consists of 170 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of March 15, 2024.

(2) Consists of (i) 4 shares of common stock held by Mr. O'Brien, and (ii) 169 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of March 15, 2024.
(3) Consists of (i) 5 shares of common stock held by Dr. Rarick, and (ii) 162 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of March 15, 2024.
(4) Consists of 180 shares of common stock that may be acquired by Mr. Rutherford pursuant to the exercise of stock options within 60 days of March 15, 2024.
(5) Consists of (i) 1,493 shares of common stock held by Ms. Pelletier, and (ii) 1,445 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of March 15, 2024.
(6) Consists of (i) 1,502 shares of common stock held by our current executive officers and directors, and (ii) 2,142 shares of common stock that may be acquired by our current executive officers and directors pursuant to the exercise of stock options within 60 days after March 15, 2024.
(7) Consists of shares of Series E-1 Shares, with voting rights equal to 20% of the then issued and outstanding common shares. According to our books and records, the address of Keystone Capital Partners, LLC is 139 Fulton Street, Suite 412, New York, NY, 10038. Keystone Capital Partners, LLC is managed by RANZ Group LLC. Fredric Zaino, the Managing Member of RANZ Group LLC, may be deemed to have investment discretion and voting power over the shares held by Keystone Capital Partners LLC. RANZ Group LLC and Mr. Zaino each disclaim any beneficial ownership of these shares.
(8) Consists of shares of Series E-1 Shares, with voting rights equal to 18% of the then issued and outstanding common shares. According to our books and records, the address of Mercer Street Global Opportunity Fund, LLC is 1111 Brickell Ave., Suite 2920, Miami, FL, 33131. Mercer Street Global Opportunity Fund, LLC is managed by Mercer Street Capital Partners LLC, which is managed by Jonathan Juchno. Mercer Street Capital Partners LLC and Mr. Juchno may be deemed to have investment discretion and voting power over the shares held by Mercer Street Global Opportunity Fund, LLC. Mercer Street Capital Partners LLC and Mr. Juchno each disclaim any beneficial ownership of these shares.
(9) Consists of shares of Series E-1 Shares, with voting rights equal to 6% of the then issued and outstanding common shares. According to our books and records, the address of Seven Knots, LLC is 7 Rose Avenue, Great Neck, NY, 11021. Marissa Welner, the Manager of Seven Knots, LLC, holds voting and dispositive power over the shares held by this stockholder. Ms. Welner disclaims any beneficial ownership of these shares.
(10) Consists of shares of Series E-1 Shares, with voting rights equal to 22% of the then issued and outstanding common shares. According to our books and records, the address of Walleye Opportunities Master Fund, Ltd. is c/o Walleye Capital, LLC 2800 Niagara Lane North, Plymouth, MN, 55447. Walleye Capital LLC is the investment manager of Walleye Opportunities Master Fund Ltd and may be deemed to beneficially own the shares owned by the Walleye Opportunities Master Fund Ltd. Roger Masi is a Portfolio Manager of Walleye Capital LLC and may be deemed to have voting and dispositive power over the shares owned by the Walleye Opportunities Master Fund Ltd. Walleye Capital LLC and Mr. Masi each disclaim any beneficial ownership of these shares.
(11) Consists of 22,280 shares of Series F-1 Shares, with no voting rights. According to our books and records, the address of Aditxt, Inc. is 737 N. Fifth Street, Suite 200, Richmond, VA 23219. Amro Albanna is the Chief Executive Officer of Aditxt, Inc.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Our Audit Committee is responsible for reviewing and approving all transactions in which we are a participant and in which any parties related to us, including our executive officers, directors, beneficial owners of more than 5% of our securities, immediate family members of the foregoing persons, and any other persons whom our Board determines may be considered related parties, has or will have a direct or indirect material interest. If advanced approval is not feasible, the Audit Committee has the authority to ratify a related party transaction at the next Audit Committee meeting. For purposes of our Audit Committee charter, a material interest is deemed to be any consideration received by such a party in excess of the lesser of $0.1 million per year or 1% of the average of our total assets for the last two completed fiscal years.

In reviewing and approving such transactions, the Audit Committee shall obtain, or shall direct our management to obtain on its behalf, all information that our committee believes to be relevant and important to a review of the transaction prior to its approval. Following receipt of the necessary information, a discussion shall be held of the relevant factors if deemed to be necessary by our committee prior to approval. If a discussion is not deemed to be necessary, approval may be given by written consent of our committee. This approval authority may also be delegated to the Chairperson of the Audit Committee in respect of any transaction in which the expected amount is less than $0.5 million.

The Audit Committee or its chairperson, as the case may be, shall approve only those related party transactions that are determined to be in, or not inconsistent with, the best interests of us and our stockholders, taking into account all available facts and circumstances as our committee or the Chairperson determines in good faith to be necessary. These facts and circumstances will typically include, but not be limited to, the material terms of the transaction, the nature of the related party's interest in the transaction, the significance of the transaction to the related party and the nature of our relationship with the related party, the significance of the transaction to us, and whether the transaction would be likely to impair (or create an appearance of impairing) the judgment of a director or executive officer to act in our best interest. No member of the Audit Committee may participate in any review, consideration, or approval of any related party transaction with respect to which the member or any of his or her immediate family members is the related party, except that such member of the Audit Committee will be required to provide all material information concerning the related party transaction to the Audit Committee.

Except as otherwise set forth below, during the years ended December 31, 2023 and 2022 and to-date in 2024 there were no transactions to which we will be a party, nor are there any currently proposed transactions to which we will be a party, in which:

- the amounts involved exceeded or will exceed the lesser of $0.1 million per year or 1% of the average of our total assets for the last two completed fiscal years; and
- any of our directors, nominees for director, executive officers or holders of more than 5% of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

Preferred Stock

Series B and C Convertible Preferred Stock

On October 12, 2021, the Company completed the initial closing of a registered direct offering with Keystone Capital Partners (Keystone Capital) (the Initial October 2021 Registered Direct Offering), whereby the Company issued 5,000 shares of Series B-1 Convertible Preferred Stock, par value $0.0001 per share, at a price of $1,000 per share. The Company received proceeds from the Initial October 2021 Registered Direct Offering of approximately $4.6 million, net of offering expenses.

On October 26, 2021, the Company completed the additional closing of the October 2021 Registered Direct Offering (the Additional October 2021 Registered Direct Offering), whereby the Company issued 5,000 shares of Series B-2 Convertible Preferred Stock, par value $0.0001 per share, at a price of $1,000 per share. The Company received proceeds from the Additional October 2021 Registered Direct Offering of approximately $5.0 million, net of offering expenses.

The Series B-1 and B-2 Convertible Preferred Stock were convertible into shares of common stock at any time at a conversion price per share of the greater of $1,125.00 (Fixed Conversion Price), or the price computed as the product of 0.85 multiplied by the arithmetic average of the closing sale prices of a share of the Company's common stock during the five consecutive trading-day period immediately preceding the conversion date (Variable Conversion Price).

Other Information

On October 12, 2021, Keystone Capital converted their 5,000 shares of B-1 Convertible Preferred Stock at a conversion price of $1,181.25 per share into 4,232 shares of the Company's common stock. Pursuant to the terms of the Series B-2 Convertible Preferred Stock, the Fixed Conversion Price was adjusted during the first quarter of 2022 for certain dilutive issuances. The adjustment period ended on April 25, 2022 and the Fixed Conversion Price was fixed at $332.50 from the sale of common stock pursuant to the Seven Knots Purchase Agreement. During March and April 2022, Keystone Capital converted their 1,200 shares of B-1 Convertible Preferred Stock at a conversion price of $587.50 per share into 2,347 shares of the Company's common stock. Pursuant to the terms of the Series B-2 Convertible Preferred Stock, the Fixed Conversion Price was adjusted during the first quarter of 2022 for certain dilutive issuances.

On March 24, 2022, the Company entered into an exchange agreement with the holder of its Series B-2 Convertible Preferred Stock, pursuant to which the holder agreed to exchange 1,700 shares of the Series B-2 Convertible Preferred Stock in consideration for 1,700 shares of the Company's Series C Convertible Preferred Stock, par value $0.0001 per share, $1,000.00 per share stated value. The Series C and Series B-2 Preferred Stock had substantially similar terms except with respect to voting provisions; the holders of Series C Preferred Stock had the right to cast, at the 2022 Annual Meeting of Stockholders, 50,000 votes per share of Series C Preferred Stock on the proposal that our Amended and Restated Certificate of Incorporation, as amended (the Certificate of Incorporation), be amended to effect a reverse stock split of the issued and outstanding shares of common stock, provided, that such votes must be counted by the Company in the same proportion as the aggregate shares of common stock voted on the proposal.

On May 4, 2022, following the 2022 Annual Meeting of Stockholders and pursuant to the May 2022 Exchange, the remaining 2,100 shares of Series B-2 Convertible Preferred Stock and 1,700 shares of Series C Convertible Preferred Stock were exchanged for Senior Subordinated Notes with an aggregate principal amount of $4.8 million and warrants to purchase up to 6,666 shares of common stock.

Effective December 15, 2021, the Company amended and restated its certificate of incorporation, under which the Company is currently authorized to issue up to 5,000,000 shares of preferred stock, $0.0001 par value per share.

Series D Non-Convertible Preferred Stock

On December 16, 2022, the Company filed a Certificate of Designation of Series D Non-Convertible Preferred Stock, par value $0.0001 per share (the Series D Preferred Shares). An aggregate of 70 shares was authorized. They are not convertible into shares of common stock, have limited voting rights equal to 1% of the total voting power of the then-outstanding shares of common stock entitled to vote per share, are not entitled to dividends, and were subsequently redeemed by us, once our shareholders approved a reverse split, as described in the Certificate of Designation. All 70 shares of the Series D Preferred were subsequently issued in connection with the December 2022 Securities Purchase Agreement as discussed in Note 4 - Debt. Since the Series D Preferred Shares can only be settled in cash, they were recorded as a liability within accrued expenses in the consolidated balance sheets. The amount related to the liability is *de minimus*. All 70 shares of the Series D Preferred were redeemed in July 2023.

Series E-1 Convertible Preferred Stock

On August 7, 2023, the Company filed a Certificate of Designation of Series E-1 Convertible Preferred Stock (Certificate of Designation), par value $0.0001 per share (the Series E-1 Shares). An aggregate of 2,300 shares was authorized. The Series E-1 Shares are convertible into shares of common stock at a conversion price of $0.40 per share and are both counted toward quorum on the basis of and have voting rights equal to the number of shares of common stock into which the Series E-1 Shares are then convertible. The Series E-1 Shares are senior to all common stock with respect to preferences as to dividends, distributions and payments upon a dissolution event. Dividends are payable in shares of common stock and may, at the Company's election, be capitalized and added to the principal monthly. Also on August 7, 2023, certain investors party to the December 2022 Notes and the February 2023 Notes exchanged $1.8 million total in principal and accrued interest under the outstanding convertible promissory notes for 1,800 shares of Series E-1 Shares. Per the Series E-1 Convertible Preferred Stock Certificate of Designation, the conversion rate can also be adjusted in several future circumstances, such as on certain dates after the exchange date and upon the issuance of additional convertible securities with a lower conversion rate or in the instance of a Triggering Event. As such, the conversion price as of December 31, 2023 was adjusted to $0.0615 per share and there were 1,874 Series E-1 Shares issued and outstanding.

Series F-1 Convertible Preferred Stock

On December 11, 2023, the Company filed a Certificate of Designation of Series F-1 Convertible Preferred Stock (F-1 Certificate of Designation), par value $0.0001 per share. An aggregate of 95,000 shares was authorized. The Series F-1 Shares are convertible into shares of common stock at a conversion price of $0.0635 per share and do not have the right to vote on any matters presented to the holders of the Company's common stock. The Series F-1 Shares are senior to all common stock and subordinate to Series E-1 Shares with respect to preferences as to dividends, distributions and payments upon a dissolution event. In the event of a liquidation event, the Series F-1 Shares are entitled to receive an amount per share equal to the Black Scholes Value as of the liquidation event plus the greater of 125% of the conversion amount (as defined in the F-1 Certificate of Designation) and the amount the holder of the Series F-1 Shares would receive if the shares were converted into common stock immediately prior to the liquidation event. If the funds available for liquidation are insufficient to pay the full amount due to the holders of the Series F-1 Shares, each holder will receive a percentage payout. The Series F-1 Shares are not entitled to dividends. The Series F-1 Shares also have a provision that allows them to be converted to common stock at a conversion rate equal to the Alternate Conversion Price (as defined in the F-1 Certificate of Designation) times the number of shares subject to conversion times the 25% redemption premium in the event of a Triggering Event (as defined in the F-1 Certificate of Designation) such as in a liquidation event.

As discussed in Note 4 - Debt, on December 21, 2023, warrants to purchase up to 9,972,074 shares of the Company's common stock were exchanged for 613 shares of the Company's Series F-1 Shares, as defined above. An additional 21,667 Series F-1 Shares were issued in exchange for a partial value of certain purchase rights. The Series F-1 Shares were immediately exchanged by the holders for shares of Aditxt Series A-1 preferred stock and 22,280 Series F-1 Shares were outstanding as of December 31, 2023.

Aditxt Merger Agreement

On December 11, 2023, the Company entered into an Agreement and Plan of Merger, as amended (the Merger Agreement) with Aditxt, Inc., a Delaware corporation (Aditxt), Adicure, Inc., a Delaware corporation, and a wholly-owned Subsidiary of Aditxt (Merger Sub), pursuant to which, and on the terms and subject to the conditions thereof, Merger Sub will merge with and into the Company, with the Company surviving as a wholly owned subsidiary of Aditxt. The Merger is expected to close in the second half of 2024.

Item 14. Principal Accounting Fees and Services.

Change of Independent Registered Public Accounting Firm

On July 11, 2023, the Audit Committee dismissed Deloitte as our independent registered public accounting firm. Deloitte's audit reports on our consolidated financial statements for the fiscal years ended December 31, 2022 and 2021 contained no adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope, or accounting principles, except that, the reports included an explanatory paragraph relating to substantial doubt about the Company's ability to continue as a going concern. During our two most recent fiscal years, which ended December 31, 2022 and December 31, 2021, and the subsequent interim period through July 11, 2023, there were no "disagreements" (within the meaning set forth in Item 304(a)(1)(iv) of Regulation S-K under the Securities Exchange Act of 1934 (Regulation S-K)) with Deloitte on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to Deloitte's satisfaction, would have caused Deloitte to make reference to the subject matter of the disagreements in connection with their reports on the Company's consolidated financial statements. There were no reportable events within the meaning of Item 304(a)(1)(v) of Regulation S-K, and related instructions thereto, during the fiscal years ended December 31, 2022 and 2021, and through the subsequent interim period through July 11, 2023, except that, as previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 (the "2022 10-K") and Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023, the Company reported material weaknesses in its internal control over financial reporting during such period. As disclosed in the 2022 10-K, in connection with the Company's evaluation of the effectiveness of its internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934), the Company concluded that its internal control over financial reporting was not effective as of December 31, 2022.

In accordance with Item 304(a)(3) of Regulation S-K, we requested that Deloitte furnish us with a letter addressed to the SEC stating whether or not Deloitte agrees with the above statements. Deloitte furnished the requested letter stating whether it agrees with the statements above, and, if not, stating the respects in which it does not agree, and a copy is filed as Exhibit 16.1 to our current report on Form 8-K filed with the SEC on July 17, 2023.

On July 11, 2023, based on the recommendation of the Audit Committee, the Board approved the engagement of BPM LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2023, subject to ratification by the Company's stockholders at the Company's 2023 Annual Meeting.

During the fiscal year ended December 31, 2022 and the subsequent interim period through July 11, 2023, neither we, nor any person acting on our behalf, consulted BPM LLP regarding (i) the application of accounting principles to a specified transaction, either completed or proposed, (ii) the type of the audit opinion that might be rendered on our consolidated financial statements, and BPM LLP did not provide any written report or oral advice to us that BPM LLP concluded was an important factor considered by us in reaching a decision as to the accounting, auditing or financial reporting issue, or (iii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K) or a reportable event of the type described in Item 304(a)(1)(v) of Regulation S-K.

Independent Registered Public Accounting Firm's Fees

The following table shows the fees billed by BPM for the audit of our annual consolidated financial statements for the last two fiscal years.

	Year Ended December 31	
	2023	**2022**
Audit Fees [1]	$ 565,681	$ -
Audit Related Fees	-	-
Tax Fees [2]	-	-
All Other Fees	-	-
Total	$ 565,681	$ -

(1) Audit Fees represent fees and out-of-pocket expenses, whether or not yet invoiced, for professional services provided in connection with the audit of the Company's consolidated financial statements, the review of the Company's quarterly consolidated financial statements, and audit services provided in connection with other regulatory filings.
(2) Tax fees represent fees and out-of-pocket expenses for professional services for tax compliance, tax advice or tax return preparations.

The following table shows the fees billed by Deloitte for the audit of our annual financial statements for the last two fiscal years and for other services rendered by Deloitte to the Company during our last two fiscal years.

	Year Ended December 31	
	2023	**2022**
Audit Fees [1]	$ 103,000	$ 1,311,774
Audit Related Fees	-	-
Tax Fees [2]	-	135,030
All Other Fees [3]	-	-
Total	$ 103,000	$ 1,446,804

(1) Audit Fees represent fees and out-of-pocket expenses, whether or not yet invoiced, for professional services provided in connection with the audit of the Company's consolidated financial statements, the review of the Company's quarterly consolidated financial statements, professional services in connection with the Company's registration statements on Form S-3 and S-8 and comfort letters, and audit services provided in connection with other regulatory filings.
(2) Tax fees represent fees and out-of-pocket expenses for professional services for tax compliance, tax advice or tax return preparations.
(3) All Other Fees represent annual licensing fees for an accounting database subscription.

Pre-Approval Policies and Procedures

The Audit Committee annually reviews and pre-approves certain audit and non-audit services that may be provided by our independent registered public accounting firm and establishes and pre-approves the aggregate fee level for these services. Any proposed services that would cause us to exceed the pre-approved aggregate fee amount must be pre-approved by the Audit Committee. All audit services for 2022 and 2023 were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents filed as part of this Annual Report

1. Financial Statements.

The Reports of Independent Registered Public Accounting Firms, the consolidated financial statements and the notes to the financial statements listed above are set forth beginning on page F-1, immediately following the signature pages of this Annual Report.

2. Financial Statement Schedules.

All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

3. Exhibits Required to Be Filed by Item 601 of Regulation S-K.

A list of exhibits is set forth on the following page and is incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Exhibit Title	Filed Herewith	Incorporated by Reference		
			Form	File No.	Date Filed
2.1	Definitive agreement by and between the Company and Aditxt, Inc.		8-K	001-36754	December 12, 2023
2.2	First Amendment to the Merger Agreement, dated January 8, 2024		8-K	001-36754	January 11, 2024
2.3	Second Amendment to the Merger Agreement, dated January 20, 2024		8-K	001-36754	January 31, 2024
3.1	Amended and Restated Certificate of Incorporation		8-K	001-36754	9/15/2023
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation		8-K	001-36754	5/17/2023
3.3	Amended and Restated Bylaws of the Registrant.		8-K	001-36754	07/17/2023
3.4	Certificate of Designation of Series E-1 Preferred Stock.		8-K	001-36754	8/10/2023
3.5	Amendment to the amended and Restated Certificate of Incorporation of Evofem Biosciences, Inc		8-K	001-36754	9/15/2023
3.6	Certificate of Designation of Series F-1 Preferred Stock		8-K	001-36754	12/12/2023
4.1	Form of Warrant.		8-K	001-36754	1/13/2022
4.2	Form of Senior Subordinated Note.		8-K	001-36754	1/13/2022
4.3	Form of Warrant.		8-K	001-36754	3/1/2022
4.4	Form of Senior Subordinated Note.		8-K	001-36754	3/1/2022
4.5	Form of Senior Subordinated Note.		8-K	001-36754	5/5/2022
4.6	Form of Senior Subordinated Note.		8-K	001-36754	5/5/2022
4.7	Form of Warrant.		8-K	001-36754	5/5/2022
4.8	Form of Senior Subordinated Convertible Note.		8-K	001-36754	2/23/2023
4.9	Form of Warrant.		8-K	001-36754	2/23/2023
4.10	Form of Registration Rights Agreement.		8-K	001-36754	2/23/2023
4.11	Form of Senior Subordinated Convertible Note.		8-K	001-36754	3/14/2023
4.12	Form of Warrant.		8-K	001-36754	3/14/2023
4.13	Form of Registration Rights Agreement.		8-K	001-36754	3/14/2023
4.14	Form of Senior Subordinated Convertible Note.		8-K	001-36754	3/24/2023
4.15	Form of Warrant.		8-K	001-36754	3/24/2023
4.16	Form of Registration Rights Agreement.		8-K	001-36754	3/24/2023
4.17	Form of Senior Subordinated Convertible Note.		8-K	001-36754	4/10/2023
4.18	Form of Warrant.		8-K	001-36754	4/10/2023
4.19	Form of Registration Rights Agreement.		8-K	001-36754	4/10/2023
4.20	Form of Warrant.		8-K	001-36754	2/23/2023
4.21	Form of Registration Rights Agreement.		8-K	001-36754	2/23/2023
4.22	Form of Senior Subordinated Convertible Note.		8-K	001-36754	3/14/2023
4.23	Form of Warrant.		8-K	001-36754	3/14/2023
4.24	Form of Registration Rights Agreement.		8-K	001-36754	3/14/2023
4.25	Form of Senior Subordinated Convertible Note.		8-K	001-36754	3/24/2023
4.26	Form of Warrant.		8-K	001-36754	3/24/2023
4.27	Form of Registration Rights Agreement.		8-K	001-36754	3/24/2023
4.28	Form of Senior Subordinated Convertible Note.		8-K	001-36754	4/10/2023
4.29	Form of Warrant.		8-K	001-36754	4/10/2023
4.30	Form of Registration Rights Agreement.		8-K	001-36754	4/10/2023
4.31	Form of Senior Subordinated Convertible Note.		8-K	001-36754	7/10/2023
4.32	Form of Warrant.		8-K	001-36754	7/10/2023
4.33	Form of Registration Rights Agreement.		8-K	001-36754	7/10/2023
4.34	Form of Senior Subordinated Convertible Note.		8-K	001-36754	8/10/2023
4.35	Form of Warrant.		8-K	001-36754	8/10/2023
4.36	Form of Registration Rights Agreement.		8-K	001-36754	8/4/2023
4.37	Form of Senior Subordinated Convertible Note.		8-K	001-36754	10/3/2023
4.38	Form of Warrant.		8-K	001-36754	10/3/2023
4.39	Form of Registration Rights Agreement.		8-K	001-36754	10/3/2023
4.40	Form of Senior Subordinated Convertible Note.		8-K	001-36754	12/7/2023

10.1	^^Securities Purchase Agreement, by and between the Investors therein and the Registrant, dated as of February 17, 2023.		8-K	001-36754	2/23/2023
10.2	^^Securities Purchase Agreement, by and between the Investors therein and the Registrant, dated as of March 13, 2023.		8-K	001-36754	3/14/2023
10.3	^^Securities Purchase Agreement, by and between the Investors therein and the Registrant, dated as of March 20, 2023.		8-K	001-36754	3/24/2023
10.4	^^Securities Purchase Agreement, by and between the Investors therein and the Registrant, dated as of April 5, 2023.		8-K	001-36754	4/10/2023
10.5	^^Securities Purchase Agreement, by and between the Investors therein and the Registrant, dated as of July 3, 2023.		8-K	001-36754	7/10/2023
10.6	^^Securities Purchase Agreement, by and between the Investors therein and the Registrant, dated as of August 4, 2023.		8-K	001-36754	8/10/2023
10.7	^^Equity Exchange Agreement, by and between the Investors therein and the Registrant, dated as of August 7, 2023.		8-K	001-36754	8/10/2023
10.8	Offer Letter, by and between the Registrant and Ivy Zhang, dated as of April 10, 2023.		10-Q	001-36754	6/16/2023
10.9	Securities Purchase and Security Agreement, dated as of April 23, 2020, by and between Evofem Biosciences, Inc., its wholly-owned domestic subsidiaries as guarantors, certain affiliates of Baker Bros. Advisors LP, as purchasers, and Baker Bros. Advisors LP, as designated agent.		8-K	001-36754	4/27/2020
10.10	First Amendment to Securities Purchase and Security Agreement, dated as of November 20, 2021, by and among Evofem Biosciences, Inc., certain affiliates of Baker Bros. Advisors LP, as purchasers, and Baker Bros. Advisors LP, as designated agent.		8-K	001-36754	11/22/2021
10.11	Second Amendment to Securities Purchase and Security Agreement, dated as of April 23, 2020, by and among Evofem Biosciences, Inc., certain affiliates of Baker Bros. Advisors LP, as purchasers, and Baker Bros. Advisors LP, as designated agent.		8-K	001-36754	03/21/2022
10.12	Third Amendment to Securities Purchase and Security Agreement, dated as of September 15, 2022, by and among Evofem Biosciences, Inc., certain institutional investor and their designated agent.		8-K	001-36754	09/16/2022
10.13	^^Fourth Amendment to Securities Purchase and Security Agreement		8-K	001-36754	9/11/2023
10.14	^^Securities Purchase Agreement, by and between the Investors therein and the Registrant, dated as of September 27, 2023.		8-K	001-36754	10/3/2023
10.15	Amended Employment Agreement, by and between the Registrant and Ivy Zhang, dated as of November 8, 2023		10-Q	001-36754	11/14/2023
10.16	Amended Employment Agreement, by and between the Registrant and Saundra Pelletier, dated as of November 8, 2023		10-Q	001-36754	11/14/2023
16.1	Deloitte & Touche LLP letter, dated July 17, 2023.		8-K	001-36754	07/17/2023
19.1*	Insider trading policies and procedures	X			
19.2*	Incentive compensation recoupment policy	X			
21.1*	List of Subsidiaries	X			
23.1*	Consent of BPM, LLP	X			
23.2*	Consent of Deloitte & Touche LLP	X			
31.1	* Certification of Principal Executive Officer 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.	X			
31.2	* Certification of Principal Financial Officer 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.	X			
32.1	* Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101.INS	† Inline XBRL Instance Document	X			
101.SCH	† Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	† Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	† Inline XBRL Definition Linkbase Document	X			
101.LAB	† Inline XBRL Taxonomy Extension Labels Linkbase Document	X			
101.PRE	† Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X			

Δ Management Compensation Plan or arrangement.

† 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, as amended.

^ The schedules and exhibits to the Merger Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

^^ Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

* Furnished herewith. This certification is being furnished solely to accompany this Annual 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, as amended, and is 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.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned hereunto duly authorized.

EVOFEM BIOSCIENCES, INC.

March 27, 2024

By: */s/ Saundra Pelletier*
Name: Saundra Pelletier
Title: *President, Chief Executive Officer and Interim Chairperson of the Board*

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Saundra Pelletier Saundra Pelletier	President, Chief Executive Officer and Interim Chairperson of the Board (*Principal Executive Officer*)	March 27, 2024
/s/ Ivy Zhang Ivy Zhang	Chief Financial Officer and Secretary (*Principal Financial Officer and Principal Accounting Officer)*	March 27, 2024
/s/ Kim P. Kamdar, Ph.D. Kim P. Kamdar, Ph.D.	Director	March 27, 2024
/s/ Tony O'Brien Tony O'Brien	Director	March 27, 2024
/s/ Colin Rutherford Colin Rutherford	Director	March 27, 2024
/s/ Lisa Rarick Lisa Rarick	Director	March 27, 2024

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Evofem Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Evofem Biosciences, Inc. and Subsidiaries (the "Company") as of December 31, 2023, and the related consolidated statements of operations, comprehensive operations, convertible and redeemable preferred stock and stockholders' deficit, and cash flows for the year ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for each of the year ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, negative cash flows from operations since inception, has received a notice of default for its convertible notes, and does not have sufficient capital to repay such obligations, which are now currently due and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provide a reasonable basis for our opinion.

Emphasis of the Matter – Restatement of Unaudited Interim Financial Statements

As disclosed in Note 12 of the financial statements, the unaudited interim financial statements as of and for the periods ended June 30, 2023 and September 30, 2023 have been restated to reclassify purchase rights from equity to liability classification.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Critical Audit Matter Description

In April 2020, the Company entered into a Securities Purchase and Security Agreement with certain affiliates of Baker Bros. Advisors LP, as purchasers, pursuant to which the Company agreed to issue and sell senior secured promissory notes (the "Baker Notes") in an aggregate principal amount of up to $25.0 million. The Baker Notes were issued and sold in two separate closings in April and June 2020, were subsequently exchanged with Aditxt, Inc. in December 2023 as described in Note 4 – Debt, and remain outstanding at December 31, 2023. The Company elected the fair value option under ASC 825, *Financial Instruments* ("ASC 825") and recognized the hybrid debt instrument at fair value inclusive of the embedded features. The fair value of the Baker Notes was determined by estimating the fair value of the Market Value of Invested Capital ("MVIC") of the Company from the third quarter of 2022 through the second quarter of 2023. The MVIC was estimated using forms of the cost and market approaches. In the Cost approach, an adjusted net asset value method was used to determine the net recoverable value of the Company, including an estimate of the fair value of the Company's intellectual property. Starting in the third quarter of 2023, the fair value of the Baker Notes, and subsequently the Aditxt Notes, was determined using a Monte Carlo simulation-based model. The Monte Carlo simulation was used to take into account several embedded features and factors, including the exercise of the repurchase right, the Company's future revenues, meeting certain debt covenants, the maturity term of the note and dissolution. For the dissolution scenario, the Cost approach, an adjusted Net Asset Value Method was used to determine the net recoverable value of the Company, including an estimate of the fair value of the Company's intellectual property. The estimated fair value of the Company's intellectual property was valued using a Relief from Royalty Method, which required management to make significant estimates and assumptions related to forecasts of future revenue, and the selection of the royalty and discount rates. The guideline public company method served as another valuation indicator. In this form of the Market approach, comparable market revenue multiples were elected and applied to the Company's forward revenue forecast to ultimately derive a MVIC indication. As of December 31, 2023, the Company recorded the fair value of the Aditxt Notes at $13.5 million.

We identified the Company's estimate of the fair value for the Baker Notes, and subsequently the Aditxt Notes, as a critical audit matter due to the significant estimates and assumptions made by management related to forecasts of future revenue, probability of scenarios used in the Monte Carlo simulation, and the selection of the royalty and discount rates to determine the fair value of the Company's intellectual property. This required a high degree of auditor judgment and an increased extent of effort, including the need to involve our fair value specialists, when performing audit procedures to evaluate the reasonableness of management's forecasts of future revenue, probability of scenarios used in the Monte Carlo simulation, and the selection of the royalty and discount rates for the intellectual property.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the Company's determination of the fair value of the Baker Notes, and subsequently Aditxt Notes, included the following, among others:

- We evaluated management's ability to accurately forecast future revenue by comparing actual revenues to management's historical forecasts.
- We evaluated the reasonableness of management's forecasts of future revenue by comparing the forecasts to (1) historical results, (2) internal communications to management and the Board of Directors, and (3) the overall estimated market size.
- With the assistance of fair value specialists, we evaluated the reasonableness of the probability of scenarios used in the Monte Carlo simulation the royalty and discount rates by (1) testing the underlying source information and mathematical accuracy of the calculations (2) developing a range of independent estimates and comparing those to the probability scenarios and discount rates selected by management and (3) understanding the facts and circumstances around the selected probability weightings for each scenario and selected royalty rate.

We have served as the Company's auditor since 2023.

/s/ BPM, LLP
Walnut Creek, California

March 26, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Evofem Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Evofem Biosciences, Inc. and subsidiaries (the "Company") as of December 31, 2022, the related consolidated statements of operations, comprehensive operations, convertible and redeemable preferred stock and stockholders' deficit and cash flows, for the year ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses, negative cash flows from operations since inception and has received a notice of default for its convertible notes, and does not have sufficient capital to repay such obligations, which are now currently due. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

San Diego, CA
April 27, 2023 (July 7, 2023, as to the effects of the reverse stock split described in Note 1)

We have served as the Company's auditor since 2015. In 2023 we became the predecessor auditor.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value and share data)

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ -	$ 2,769
Restricted cash	580	1,207
Trade accounts receivable, net	5,738	1,126
Inventories	1,697	5,379
Prepaid and other current assets	1,195	2,218
Total current assets	9,210	12,699
Property and equipment, net	1,203	3,940
Operating lease right-of-use assets	106	4,406
Other noncurrent assets	35	4,118
Total assets	$ 10,554	$ 25,163
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 17,020	$ 14,984
Convertible notes payable carried at fair value (Note 4)	14,731	39,416
Convertible notes payable - Adjuvant (Note 4)	28,537	26,268
Accrued expenses	4,227	4,124
Accrued compensation	2,609	2,175
Operating lease liabilities - current	97	2,311
Derivative liabilities	1,926	1,676
Other current liabilities	3,316	2,876
Total current liabilities	72,463	93,830
Operating lease liabilities - non-current	8	3,133
Total liabilities	72,471	96,963
Commitments and contingencies (Note 7)		
Convertible and redeemable preferred stock, $0.0001 par value, Senior to common stock		
Series B-1, B-2, C, E-1, and F-1 convertible preferred stock, 5,000, 5,000, 1,700, 2,300, and 95,000 shares authorized; 1,874 shares of E-1 and 22,280 shares of F-1 issued and outstanding at December 31, 2023; no other shares issued and outstanding at December 31, 2023 or 2022	4,593	-
Stockholders' deficit:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2023 or 2022		-
Common Stock, $0.0001 par value; 3,000,000,000 shares authorized; 20,007,799 and 984,786 shares issued and outstanding as of December 31, 2023 and 2022, respectively	2	-
Additional paid-in capital	823,036	817,367
Accumulated other comprehensive income (loss)	(849)	49,527
Accumulated deficit	(888,699)	(938,694)
Total stockholders' deficit	(66,510)	(71,800)
Total liabilities, convertible and redeemable preferred stock and stockholders' deficit	$ 10,554	$ 25,163

See accompanying notes to the consolidated financial statements.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Years Ended December 31,	
	2023	**2022**
Product sales, net	$ 18,218	$ 16,837
Operating expenses:		
Cost of goods sold	6,512	4,415
Research and development	2,939	25,032
Selling and marketing	11,664	43,951
General and administrative	14,950	27,563
Total operating expenses	36,065	100,961
Loss from operations	(17,847)	(84,124)
Other income (expense):		
Interest income	31	85
Other expense, net	(2,628)	(2,087)
Loss on issuance of financial instruments	(6,776)	(72,993)
Gain (loss) on debt extinguishment	75,337	(24,487)
Change in fair value of financial instruments	4,879	106,952
Total other income, net	70,843	7,470
Income (loss) before income tax	52,996	(76,654)
Income tax expense	(17)	(44)
Net income (loss)	52,979	(76,698)
Deemed dividends	(2,984)	(1,316)
Net income (loss) attributable to common stockholders	$ 49,995	$ (78,014)
Net income (loss) per share attributable to common stockholders:		
Basic (Note 2)	$ 10.36	$ (167.42)
Diluted (Note 2)	$ 0.05	$ (167.42)
Weighted-average shares used to compute net income (loss) per share:		
Basic	4,826,763	465,967
Diluted	984,038,574	465,967

See accompanying notes to the consolidated financial statements.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE OPERATIONS
(In thousands, except share and per share data)

	Years Ended December 31	
	2023	**2022**
Net income (loss)	$ 52,979	$ (76,698)
Other comprehensive income:		
Change in fair value of financial instruments attributed to credit risk change	22,814	44,438
Reclassification adjustment related to debt extinguishment	(73,187)	-
Comprehensive income (loss)	$ 2,606	$ (32,260)

See accompanying notes to consolidated financial statements.

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

	Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Stockholders' Deficit					
					Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	5,000	4,740	-	-	86,666	-	751,276	5,089	(860,680)	(104,315)
Issuance of common stock - Stock Purchase Agreement (Note 8)	-	-	-	-	16,739	-	7,953	-	-	7,953
Issuance of common stock - May 2022 Public Offering (see Note 8)	-	-	-	-	181,320	-	1,239	-	-	1,239
Issuance of common stock upon cash exercise of warrants	-	-	-	-	385,198	-	41,932	-	-	41,932
Issuance of common stock - ESPP	-	-	-	-	601	-	20	-	-	20
Issuance of common stock - a360 Media	-	-	-	-	53,908	-	3,408	-	-	3,408
Issuance of common stock upon noncash exercise of Purchase Rights	-	-	-	-	260,692	-	1,005	-	-	1,005
Conversion of series B-2 convertible preferred stock	(1,200)	(1,143)	-	(72)	2,347	-	1,251	-	-	1,251
Exchange of series B-2 convertible preferred stock (see Note 8)	(1,700)	(1,616)	1,700	1,616	-	-	-	-	-	-
Convertible preferred stock deemed dividends	-	118	-	84	-	-	(81)	-	-	(81)
Restricted stock awards issued	-	-	-	-	1,258	-	-	-	-	-
Restricted stock awards cancelled	-	-	-	-	(1,258)	-	-	-	-	-
May 2022 exchange transaction	(2,100)	(2,099)	(1,700)	(1,628)	(2,600)	-	3,655	-	(1,316)	2,339
Cash repurchase of fractional common stock after the reverse stock split	-	-	-	-	(85)	-	(18)	-	-	(18)
Issuance of December 2022 Notes	-	-	-	-	-	-	1,344	-	-	1,344
Change in fair value of financial instruments attributed to credit risk change	-	-	-	-	-	-	-	44,438	-	44,438
Modification of	-	-	-	-	-	-	1,070	-	-	1,070

Baker Warrants (see Note 4)										
Stock-based compensation	-	-	-	-	-	-	3,313	-	-	3,313
Net loss	-	-	-	-	-	-	-	-	(76,698)	(76,698)
Balance at December 31, 2022	**-**	**$ -**	**-**	**$ -**	**984,786**	**$ -**	**$ 817,367**	**$ 49,527**	**$ (938,694)**	**$ (71,800)**

	Series E-1 Redeemable Convertible Preferred Stock		Series F-1 Redeemable Convertible Preferred Stock		Stockholders' Deficit					
					Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	-	$ -	-	$ -	984,786	$ -	$ 817,367	$ 49,527	$ (938,694)	$ (71,800)
Issuance of common stock upon cash exercise of warrants	-	-	-	-	1,760,544	-	284	-	-	284
Issuance of common stock upon noncash exercise of purchase rights	-	-	-	-	16,534,856	2	424	-	-	426
Issuance of SSNs (See Note 4)	-	-	-	-	-	-	5,420	-	-	5,420
Issuance of common stock upon conversion of notes	-	-	-	-	730,997	-	-	-	-	-
Issuance of convertible and redeemable preferred stock upon exchange of notes with existing equity holders	1,800	1,800	-	-	-	-	(1,797)	(3)	-	(1,800)
Issuance of convertible and redeemable preferred stock upon exchange of partial purchase rights value and warrants (see Note 8)	-	-	22,280	2,719	-	-	(13)	-	(2,748)	(2,761)
Adjustment related to reverse stock split (fractional shares)	-	-	-	-	(3,384)	-	-	-	-	-
Change in fair value of financial instruments attributed to credit risk change (see Note 4)	-	-	-	-	-	-	-	22,814	-	22,814
Adjustment related to downround feature for financial instruments	-	-	-	-	-	-	162	-	(162)	-
Stock-based compensation	-	-	-	-	-	-	1,189	-	-	1,189
Reverse of AOCI upon Baker's 4th Amendment	-	-	-	-	-	-	-	(73,187)	-	(73,187)
Series E-1 Shares dividends	74	74	-	-	-	-	-	-	(74)	(74)
Net income	-	-	-	-	-	-	-	-	52,979	52,979
Balance at December 31, 2023	**1,874**	**$ 1,874**	**22,280**	**$ 2,719**	**20,007,799**	**$ 2**	**$ 823,036**	**$ (849)**	**$ (888,699)**	**$ (66,510)**

See accompanying notes to the consolidated financial statements.

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net income (loss)	$ 52,979	$ (76,698)
Adjustments to reconcile net income (loss) to net cash and restricted cash used in operating activities:		
Loss on issuance of financial instruments	6,776	72,993
Gain on debt extinguishment	(75,337)	24,487
Change in fair value of financial instruments	(4,879)	(106,952)
Financial instrument modification expense	-	1,067
Stock-based compensation	1,189	3,313
Depreciation	477	1,015
Noncash interest expenses	2,270	2,176
Noncash right-of-use amortization	1,304	1,031
Noncash inventory reserve for excess & obsolescence	1,576	(300)
Net gain on lease termination	(466)	-
Noncash instrument exchange expense	-	514
Loss on disposal and write-down of property and equipment	2,511	926
Gain on accounts payable settlements	(2,096)	-
Changes in operating assets and liabilities:		
Trade accounts receivable	(4,612)	5,323
Inventories	2,106	1,566
Prepaid and other assets	3,661	2,593
Accounts payable	4,090	4,474
Accrued expenses and other liabilities	527	(4,106)
Accrued compensation	434	(2,478)
Lease liabilities	(1,478)	(1,354)
Net cash and restricted cash used in operating activities	**(8,968)**	**(70,410)**
Purchases of property and equipment	(4)	(341)
Net cash and restricted cash used in investing activities	**(4)**	**(341)**
Cash flows from financing activities:		
Proceeds from issuance of common stock - exercise of warrants	290	25,211
Proceeds from issuance of common stock and warrants, net of offering costs	-	24,882
Proceeds from issuance of common stock – Public Offering, net of commissions – ATM transactions	-	7,438
Proceeds from issuance of common stock- ESPP and exercise of stock options	-	20
Borrowings under term notes	5,640	11,500
Payments under term notes	(1,154)	(5,892)
Cash repurchase of fractional common stock after reverse stock split	-	(18)
Cash paid for offering costs	-	(1,202)
Net cash and restricted cash provided by financing activities	**4,776**	**61,939**
Net change in cash, cash equivalents and restricted cash	(4,196)	(8,812)
Cash, cash equivalents and restricted cash, beginning of period	4,776	13,588
Cash, cash equivalents and restricted cash, end of period	$ 580	$ 4,776
Supplemental cash flow information:		
Cash paid for interest	338	698
Cash paid for taxes	4	26
Supplemental disclosure of noncash investing and financing activities:		
Exchange of convertible notes to Series E-1 Shares	1,800	-
Exchange of warrants and partial purchase rights value to Series F-1 Shares	2,761	-
Issuance of common stock upon exercise of purchase rights	426	1,007
Series E-1 shares dividends	74	-
Right-of-use assets obtained in exchange for operating lease liabilities	-	219
Purchases of property and equipment included in accounts payable and accrued expenses	-	105
Conversion of series B-2 and B-1 convertible preferred stock to common stock	-	1,187
Exchange of series B-2 convertible preferred stock to series C convertible preferred stock	-	1,616
Issuance of common stock for prepaid advertising	-	3,412
Exchange of Adjuvant Notes for Purchase Rights	-	634
Exchange of term notes for Purchase Rights	-	4,806

See accompanying notes to the consolidated financial statements.

1. Description of Business and Basis of Presentation

Description of Business

Evofem is a San Diego-based, commercial-stage biopharmaceutical company committed to commercializing innovative products to address unmet needs in women's sexual and reproductive health.

The Company's first commercial product, Phexxi® (lactic acid, citric acid, and potassium bitartrate) vaginal gel (Phexxi), was approved by the U.S. Food and Drug Administration (FDA) on May 22, 2020, and is the first and only FDA-approved, hormone-free, woman-controlled, on-demand prescription contraceptive gel for women. The Company commercially launched Phexxi in September 2020. Phexxi net product sales were $16.8 million in 2022 and $18.2 million in 2023.

On December 11, 2023, the Company entered into an Agreement and Plan of Merger, as amended (the Merger Agreement) with Aditxt, Inc., a Delaware corporation (Aditxt), Adicure, Inc., a Delaware corporation, and a wholly-owned Subsidiary of Aditxt (Merger Sub), pursuant to which, and on the terms and subject to the conditions thereof, the Merger Sub will merge with and into the Company, with the Company surviving as a wholly owned subsidiary of Aditxt (the Merger). The Merger is expected to close in the second half of 2024; the accompanying consolidated financial statements do not reflect the potential impact of the Merger Agreement.

Basis of Presentation and Principles of Consolidation

The Company prepared the consolidated financial statements in accordance with accounting principles generally accepted in the US (GAAP) and the rules and regulations of the Securities and Exchange Commission (SEC) related to annual reports on Form 10-K. 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.

Reverse Stock Split

On March 15, 2023, the Company's shareholders approved a reverse stock split between 1-for-20 and not more than 1-for-125 at any time on or prior to March 15, 2024. The Company decided on a ratio of 1-for-125 for the Reverse Stock Split, which became effective on May 18, 2023. The consolidated financial statements are retrospectively adjusted for this Reverse Stock Split.

Risks, Uncertainties and Going Concern

Any disruptions in the commercialization of Phexxi and/or its supply chain could have a material adverse effect on the Company's business, results of operations and financial condition.

The consolidated 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 does 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.

The Company's principal operations have been related to research and development, including the development of Phexxi, and to its commercially related sales and marketing efforts. Additional activities have included raising capital, identifying alternative manufacturing to lower the cost of goods sold (COGS), seeking ex-U.S. licensing partners to commercialize Phexxi outside the U.S. and provide non-dilutive capital to the Company, and establishing and maintaining a corporate infrastructure to support a commercial product. The Company has incurred operating losses and negative cash flows from operating activities since inception. As of December 31, 2023, the Company had cash and cash equivalents, including restricted cash from the Adjuvant Notes (as defined in Note 4 - Debt) of $0.6 million, a working capital deficit of $63.3 million and an accumulated deficit of $888.7 million.

Effective October 3, 2022, the Company's common stock is listed on the OTC Venture Market (the OTCQB) of the OTC Markets Group, Inc., a centralized electronic quotation service for over-the-counter securities, under the symbol "EVFM." The OTCQB imposes, among other requirements, a minimum $0.01 per share bid price requirement (the Bid Price Requirement) for continued inclusion on the OTCQB. The closing bid price for the Company's common stock must remain at or above $0.01 per share to comply with the Bid Price Requirement for continued listing. As of March 21, 2024, the closing price was $0.0158. While the Company's common stock was previously listed on the Nasdaq Capital Market (Nasdaq) under the symbol "EVFM", on August 11, 2022, it was suspended from trading on the Nasdaq due to noncompliance with the Nasdaq's minimum bid price requirement. On October 26, the Company's common stock was formally delisted from Nasdaq. The delisting of the Company's shares from Nasdaq makes shares of the Company's common stock less liquid and makes it more difficult for the Company to raise funds when and as needed to fund its operations.

In October 2022, the Company reported that its Phase 3 clinical trial (*EVOGUARD)* did not achieve its efficacy endpoints. The Company has discontinued investment in this development program.

In March 2023, the Company received a Notice of Event of Default and Reservation of Rights (the Notice of Default) from Baker Bros claiming that the Company failed to maintain the required shares reserved amount per the Third Baker Amendment as defined in Note 4 - Debt. In addition, the Notice of Default resulted in a cross default under all outstanding debt; which became currently due and the Company did not have sufficient capital to repay such obligations during the period of default. As of June 30, 2023, the Company had not met the affirmative covenant requiring achievement of $100.0 million in cumulative net sales of Phexxi by such date as per the First Baker Amendment (as defined in Note 4 – Debt). In September 2023, the Company entered into the Fourth Baker Amendment (as defined in Note 4 – Debt), upon which the cumulative net sales covenant was removed and all defaults existing at the time of signing were cured.

Management's plans to meet its cash flow needs in the next 12 months include generating recurring product revenue, restructuring its current payables and obtaining additional funding through means such as the issuance of its capital stock, non-dilutive financings, or through collaborations or partnerships with other companies, including license agreements for Phexxi in the US or foreign markets, or other potential business combinations, including the Merger.

The Company anticipates it will continue to incur net losses for the foreseeable future. According to management estimates, liquidity resources as of December 31, 2023 and 2022 were not sufficient to maintain the Company's cash flow needs for the twelve months from the date of issuance of these consolidated financial statements.

If the Company is not able to obtain the required funding through a significant increase in revenue, equity or debt financings, license agreements for Phexxi in the US or foreign markets, or other means, or is unable to obtain funding on terms favorable to the Company, or if there is another event of default affecting the notes payable, there will be a material adverse effect on commercialization and development operations and the Company's ability to execute its 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 further reductions in spending, including spending in connection with its commercialization activities, extend payment terms with suppliers, liquidate assets where possible at a potentially lower amount than as recorded in the consolidated financial statements, suspend or curtail planned operations, or cease operations entirely. Any of these could materially and adversely affect the Company's liquidity, financial condition and business prospects, and the Company would not be able to continue as a going concern. The Company has concluded that these circumstances and the uncertainties associated with the Company's ability to obtain additional equity or debt financing on terms that are favorable to the Company, or at all, and otherwise succeed in its future operations raise substantial doubt about the Company's ability to continue as a going concern.

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.

Significant estimates affecting amounts reported or disclosed in the consolidated financial statements include, but are not limited to: the assumptions used in measuring the revenue gross-to-net variable consideration items; the trade accounts receivable credit loss reserve estimate; the discount rate used in estimating the fair value of the right-of-use (ROU) assets and lease liabilities; the assumptions used in estimating the fair value of convertible notes, warrants and purchase rights issued; the useful lives of property and equipment; the recoverability of long-lived assets; clinical trial accruals; the assumptions used in estimating the fair value of stock-based compensation expense; the valuation of inventory; and the valuation of deferred tax assets. These assumptions are more fully described in Note 2 – Summary of Significant Accounting Policies, Note 3 - Revenue, Note 4 - Debt, Note 6 - Fair Value of Financial Instruments, Note 7 - Commitments and Contingencies, Note 9 - Stock-based Compensation, and Note 11 – Income Taxes. 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, 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, the Chief Executive Officer of the Company, 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, cash equivalents and restricted cash. Deposits in the Company's checking and time deposit accounts are maintained in federally insured financial institutions and are subject to federally insured limits or limits set by Securities Investor Protection Corporation. 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 on amounts in excess of federally insured limits due to the financial position of the depository institutions in which these deposits are held. The Company's deposits were primarily held in Silicon Valley Bank prior to their closure by regulators; however, the Company was subsequently able to regain full access to all its deposits and moved these to a different financial institution.

The Company is also subject to credit risk related to its trade accounts receivable from product sales. Its customers are located in the U.S. and consist of wholesale distributors, retail pharmacies, and a mail-order specialty pharmacy. The Company extends credit to its customers in the normal course of business after evaluating their overall financial condition and evaluates the collectability of its accounts receivable by periodically reviewing the age of the receivables, the financial condition of its customers, and its past collection experience. Historically, the Company has not experienced any credit losses. As of December 31, 2023, based on the evaluation of these factors the Company did not record an allowance for doubtful accounts. Phexxi is distributed primarily through three major distributors and a mail-order pharmacy, who receive service fees calculated as a percentage of the gross sales, and a fee per units shipped, respectively. These entities are not obligated to purchase any set number of units and distribute Phexxi on demand as orders are received. For the years ended December 31, 2023, and 2022, the Company's three largest customers combined made up approximately 84% and 77% of its gross product sales, respectively. As of December 31, 2023, the Company's three largest customers combined made up 87% and as of December 31, 2022, the Company's four largest customers combined made up 81% of its trade accounts receivable balance.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents consist of readily available cash in checking accounts and money market funds. Restricted cash consists of cash held in monthly time deposit accounts and letters of credit as described in Note 7 - Commitments and Contingencies. During the twelve months ended December 31, 2023, the Company's letters of credit of $0.3 million for its fleet leases were released. Additionally, the remaining funds of the $25.0 million received from the issuance of Adjuvant Notes (as defined below) in the fourth quarter of 2020 is classified as restricted cash as the Company is contractually obligated to use the funds for specific purposes. Upon receipt of a notice of default from its landlord on March 20, 2023, for failing to pay March 2023 rent timely resulting in a breach under the office lease agreement, the Company's letter of credit in the amount of $0.8 million, in restricted cash, was recovered by the landlord.

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

	Twelve months ended	
	2023	2022
Cash and cash equivalents	$ -	$ 2,769
Restricted cash	580	1,207
Restricted cash included in other noncurrent assets	-	800
Total cash, cash equivalents and restricted cash presented in the consolidated statements of cash flows	$ 580	$ 4,776

Trade Accounts Receivable and Allowance

Trade accounts receivable are amounts owed to the Company by its customers for product that has been delivered. The trade accounts receivable are recorded at the invoice amount, less prompt pay and other discounts, chargebacks and an allowance for credit losses, if any. The allowance for credit losses is the Company's estimate of losses over the life of the receivables. The Company determines the allowance for credit losses based on its historical payment information by customer and the analysis of the trade accounts receivable balance by customer segment. When the collectability of an invoice is no longer probable, the Company will create a reserve for that specific receivable. If a receivable is determined to be uncollectible, it is charged against the general credit loss reserve or the reserve for the specific receivable, if one exists. No allowance was deemed necessary at December 31, 2023 or 2022.

Fair Value of Financial Instruments

The Company defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities that are required to be recorded at fair value, the Company considers the principal or most advantageous market in which to transact and the market-based risk. The Company applies fair value accounting for all assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a recurring basis.

The valuation of assets and liabilities are subject to fair value measurements using a three-tiered approach. Fair value measurement is classified and disclosed by the Company in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents, restricted cash, accounts payable, accrued expenses and accrued compensation approximate their fair values due to their short-term nature.

The Company believes that the Adjuvant Notes bear interest at a rate that approximates prevailing market rates for instruments with similar characteristics. The Company estimates the fair value of other debt carried at fair value (the Baker Notes and the Senior Subordinate Notes) utilizing a specialist using a Monte Carlo methodology as described in Note 6 – Fair Value of Financial Instruments. Based on the assumptions used to value these instruments at fair value, the debt instruments are categorized as Level 3 in the fair value hierarchy.

Inventories

Inventories, consisting of purchased materials, direct labor and manufacturing overheads, are stated at the lower of cost, or net realizable value. Cost is determined on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. At each balance sheet date, the Company evaluates ending inventories for excess quantities, obsolescence, or shelf-life expiration. The evaluation includes an analysis of the Company's current and future strategic plans, anticipated future sales, the price projections of future demand, and the remaining shelf life of goods on hand. To the extent that management determines there are excess or obsolete inventory or quantities with a shelf life that is too near its expiration for the Company to reasonably expect that it can sell those products prior to their expiration, the Company adjusts the carrying value to estimated net realizable value in accordance with the first-in, first-out inventory costing method.

Inventories consist of the following (in thousands) for the period indicated:

	December 31,	
	2023	**2022**
Raw Materials [(1)]	$ 520	$ 758
Work in process	386	4,142
Finished Goods [(1)]	791	1,748
Total [(2)]	$ 1,697	$ 6,648

(1) The raw materials and finished goods balances included a combined estimated reserve on obsolescence and excess inventory which might not be sold prior to expiration of $0.3 million as of December 31, 2023, based upon assumptions about future manufacturing needs and gross sales of Phexxi. Inventory associated with the additional write-down of $1.3 million recorded during the year ended December 31, 2023, was disposed and is no longer in the inventory balance as of December 31, 2023.

(2) A portion of the total inventory balance which relates to inventory not expected to be sold within one year from the balance sheet date is included in other noncurrent assets as of December 31, 2022.

Property and Equipment

Property and equipment generally consist of research equipment, computer equipment and software and office furniture. Property and equipment are recorded at cost and depreciated over the estimated useful lives of the assets (generally three to five years) using the straight-line method. Leasehold improvements are stated at cost and are amortized on a straight-line basis over the lesser of the remaining term of the related lease or the estimated useful lives of the assets. Repairs and maintenance costs are charged to expense as incurred and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheets and any resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

Impairment of Long-lived Assets

The Company reviews property and equipment for impairment on an annual basis and whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to the asset or asset group are less than its carrying amount. An impairment loss is measured as the amount by which the carrying amount of an asset or asset group exceeds its fair value. The Company recognized an immaterial impairment of construction in process in the year ended December 31, 2023 and no such impairment loss was recorded during the year ended December 31, 2022.

Clinical Trial Accruals

As part of the process of preparing the consolidated financial statements, the Company is required to estimate expenses resulting from obligations under contracts with vendors, clinical research organizations (CROs), consultants and under clinical site agreements relating to conducting 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.

The Company's 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. The Company accounts 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. Management determines 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, the Company adjusts the clinical expense recognition if actual results differ from its estimates. The Company makes estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The Company's clinical trial accruals are partially dependent upon accurate reporting by CROs and other third-party vendors. The Company's 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 period.

Fair Value of Warrants

Upon the issuance of warrants, they are initially measured at fair value and reviewed for the appropriate classification (liability or equity). Warrants determined to require liability accounting are subsequently re-measured with changes in fair value being recognized as a component of other income (expense), net in the consolidated statements of operations. Warrants are valued using an option pricing model based on the applicable assumptions, which include the exercise price of the warrants, time to expiration, expected volatility of our peer group, risk-free interest rate, and expected dividends. The Company re-evaluates the classification of its warrants at each balance sheet date to determine the proper balance sheet classification for each warrant. The assumptions used in the Option Pricing Model (OPM) are considered level 3 assumptions and include, but are not limited to, the market value of invested capital, our cumulative equity value as a proxy for the exercise price, the expected term the purchase rights will be held prior to exercise and a risk-free interest rate, and probability of change of control events.

Leases

The Company determines if an arrangement is a lease or implicitly contains a lease as well as if the lease is classified as an operating or finance lease in accordance with ASC 842, *Leases* (ASC 842), at inception based on the lease definition. Operating leases are included in operating lease ROU assets and operating lease liabilities in the Company's consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term. Lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at commencement date or the adoption date for existing leases based on the present value of lease payments over the lease term using an estimated discount rate.

For leases which do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at commencement date or the adoption date in determining the present value of lease payments over a similar term. In determining the estimated incremental borrowing rate, the Company considers a rate obtained from its primary banker for discussion purposes of a potential collateralized loan with a term similar to the lease term; the Company's historical borrowing capability in the market; and the Company's costs incurred for underwriting discounts and financing costs in its previous equity financings. For leases which have an implicit rate, the Company uses the rate implicit in the lease to determine the present value of the lease payments. The ROU assets also include any lease payments made and exclude lease incentives. For operating leases, lease expense is recognized on a straight-line basis over the lease term. Lease and non-lease components within a contract are generally accounted for separately. Short-term leases of 12 months or less, if any, are expensed as incurred which approximates the straight-line basis due to the short-term nature of the leases.

Operating lease ROU assets and lease liabilities were $0.1 million each on December 31, 2023 and were $4.4 million and $5.4 million on December 31, 2022, respectively. See Note 7 - Commitments and Contingencies for more detailed discussions on leases and financial statements information under ASC 842.

Revenue

The Company recognizes revenue from the sale of Phexxi in accordance with ASC 606, *Revenue from Contracts with Customers* (ASC 606). Revenue is recognized when the Company's performance obligation is satisfied by transferring control of the product to a customer. In accordance with the Company's contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is sold to and received by a customer. The amount of revenue recognized by the Company is equal to the amount of consideration that is expected to be received from the sale of product to its customers.

An estimate for variable consideration is made with each sale and is recorded in conjunction with the revenue being recognized. To calculate the variable consideration, the Company uses the expected value method and the amount is recorded either as a reduction to accounts receivable or as a current liability based on the nature of the allowance and the terms of the related arrangements.

Research and Development

Research and development expenses include costs associated with the Company's research and development activities, including, but not limited to, payroll and personnel-related expenses, stock-based compensation expense, materials, laboratory supplies, clinical studies, and outside services. Research and development costs are expensed as incurred, except when accounting for nonrefundable advance payments for goods or services not yet received. These payments, if any, are capitalized at the time of payment and expensed as the related goods are delivered or the services are performed.

Advertising

Costs for producing advertising are expensed when incurred. Costs for communicating advertising, such as television commercial airtime and print media space, are recorded as prepaid expenses and then expensed when the advertisement occurs. Advertising costs were immaterial in both of the presented periods.

Patent Expenses

The Company expenses all costs incurred relating to patent applications, including, but not limited to, direct application fees and the legal and consulting expenses related to making such applications. Such costs are included in general and administrative expenses in the consolidated statements of operations.

Stock-based Compensation

Stock-based compensation expense for stock options issued to employees, non-employee directors and consultants is measured based on estimating the fair value of each stock option on the date of grant using the Black-Scholes (BSM) option-pricing model.

The following table summarizes the Company's stock-based awards expensing policies for employees and non-employees:

	Employees and Nonemployee Consultants
Service only condition	Straight-line based on the grant date fair value
Performance criterion is probable of being met:	
Service criterion is complete	Recognize the grant date fair value of the award(s) once the performance criterion is considered probable of occurrence
Service criterion is not complete	Expense using an accelerated multiple-option approach[(1)] over the remaining requisite service period
Performance criterion is not probable of being met:	No expense is recognized until the performance criterion is considered probable at which point expense is recognized using an accelerated multiple-option approach

(1) The accelerated multiple-option approach results in compensation expense being recognized for each separately vesting tranche of the award as though the award was in substance multiple awards and, therefore, results in accelerated expense recognition during the earlier vesting periods.

Fair Value of Stock Options

The fair value of stock options is determined using the BSM option-pricing model based on the applicable assumptions, which includes the exercise price of options, time to expiration, expected volatility of our peer group, risk-free interest rate and expected dividend. The Company records forfeitures when they occur.

Performance-based Awards

For performance-based RSAs (i) the fair value of the award is determined on the grant date, (ii) the Company assesses the probability of the individual milestone under the award being achieved, and (iii) the fair value of the shares subject to the milestone is expensed over the implicit service period commencing once management believes the performance criteria is probable of being met. If the performance-based RSAs are modified, the Company applies the share-based payment modification accounting in accordance with ASC 718, *Compensation-Stock Compensation* (ASC 718).

Income Taxes

The accounting guidance for uncertainty in income taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities based on the technical merits of the position.

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized. When the Company establishes or reduces the valuation allowance against its deferred tax assets, its provision for income taxes will increase or decrease, respectively, in the period such determination is made.

Net Income (Loss) per Share

Basic net income (loss) per share attributable to common stockholders is calculated by dividing the net income (loss) by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. The net income (loss) available to common stockholders is adjusted for amounts in accumulated deficit related to the deemed dividends triggered for certain financial instruments. Such adjustment was $3.0 million and zero in the years ended December 31, 2023 and 2022, respectively. Diluted net loss per share is computed by dividing the net loss 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 the year ended December 31, 2022. Potentially dilutive securities excluded from the calculation of diluted net loss per share are summarized in the table below. Common shares were calculated for the convertible preferred stock and the convertible debt using the if-converted method.

	Years Ended December 31,	
	2023	**2022**
Options to purchase common stock	3,747	5,672
Warrants to purchase common stock	21,053,694	2,052,367
Series E-1 Shares	30,472,989	-
Series F-1 Shares	370,731,708	-
Purchase rights to purchase common stock	385,312,084	4,490,202
Convertible notes	616,497,236	18,105,684
Total	1,424,071,458	24,653,925

The following table sets forth the computation of net income attributable to common shareholders, weighted average common shares outstanding for diluted net income per share, and diluted net income per share attributable to common shareholders for the year ended December 31, 2023 (in thousands, except share and per share amounts).

	Twelve Months Ended December 31, 2023
Numerator:	
Net income attributable to common stockholders	$ 49,995
Adjustments:	
Change in fair value of purchase rights	1,253
Noncash interest expense on convertible notes, net of tax	1,432
Net income attributable to common stockholders	$ 52,680
Denominator:	
Weighted average shares used to compute net income attributable to common stockholder, basic	4,826,763
Add:	
Pro forma adjustments to reflect assumed conversion of convertible notes	549,963,204
Pro forma adjustments to reflect assumed exercise of outstanding warrants and purchase rights	405,803,188
Pro forma adjustments to reflect the assumed conversion of Series E-1 Shares	12,272,683
Pro forma adjustments to reflect the assumed conversion of Series F-1 Shares	11,172,736
Weighted average shares used to compute net loss attributable to common stockholder, diluted	984,038,574
Net income per share attributable to common stockholders, diluted	$ 0.05

Recently Adopted Accounting Pronouncements

No significant new standards were adopted during the year ended December 31, 2023.

Recently Issued Accounting Pronouncements — Not Yet Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standards setting bodies that are adopted as of the specified effective date.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes: Improvements to Income Tax Disclosures* addressing income tax disclosures, requiring entities to annually disclose specific categories in the rate reconciliation and provide additional information for certain reconciling items and categories. ASU No. 2023-09 will be effective for the Company beginning with the annual filing for the period ended December 31, 2024 and early adoption is allowed. The Company will adopt ASU No. 2023-09 by adding the required disclosures for the December 31, 2024 Annual Report.

The Company does not believe the impact of any other recently issued standards and any issued but not yet effective standards will have a material impact on its consolidated financial statements upon adoption.

3. Revenue

The Company recognizes revenue from the sale of Phexxi in accordance with Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers* (ASC 606). The provisions of ASC 606 require the following steps to determine revenue recognition: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

In accordance with ASC 606, the Company recognizes revenue when its performance obligation is satisfied by transferring control of the product to a customer. In accordance with the Company's contracts with customers, control of the product is transferred upon the conveyance of title, which occurs when the product is sold to and received by a customer. The Company's customers are located in the U.S. and consist of wholesale distributors, retail pharmacies, and a mail-order specialty pharmacy. Payment terms typically range from 31 to 66 days, include prompt pay discounts, and vary by customer. Trade accounts receivable due to the Company from contracts with its customers are stated separately in the consolidated balance sheets, net of various allowances as described in the Trade Accounts Receivable policy in Note 2 - Summary of Significant Accounting Policies.

The amount of revenue recognized by the Company is equal to the amount of consideration that is expected to be received from the sale of product to its customers. Revenue is only recognized when the performance obligation is satisfied. To determine whether a significant reversal will occur in future periods, the Company assesses both the likelihood and magnitude of any such potential reversal of revenue.

Phexxi is sold to customers at the wholesale acquisition cost (WAC), or in some cases at a discount to WAC. However, the Company records product revenue net of reserves for applicable variable consideration. These types of variable consideration reduce revenue and include the following:

- Distribution services fees
- Prompt pay and other discounts
- Product returns
- Chargebacks
- Rebates
- Patient support programs, including our co-pay programs

An estimate for variable consideration is made with each sale and is recorded in conjunction with the revenue being recognized. To calculate the variable consideration, the Company uses the expected value method and the estimated amounts are recorded as a reduction to accounts receivable or as a current liability based on the nature of the allowance and the terms of the related arrangements. An estimated amount of variable consideration may differ from the actual amount. At each balance sheet date, these provisions are analyzed and adjustments are made if necessary. Any adjustments made to these provisions would also affect net product revenue and earnings.

In accordance with ASC 606, the Company must make significant judgments to determine the estimate for certain variable consideration. For example, the Company must estimate the percentage of end-users that will obtain the product through public insurance such as Medicaid or through private commercial insurance. To determine these estimates, the Company relies on historical sales data showing the amount of various end-user consumer types, inventory reports from the wholesale distributors and mail-order specialty pharmacy, and other relevant data reports.

The specific considerations that the Company uses in estimating these amounts related to variable consideration are as follows:

Distribution services fees – The Company pays distribution service fees to its wholesale distributors and mail-order specialty pharmacy. These fees are a contractually fixed percentage of WAC and are calculated at the time of sale based on the purchase amount. The Company considers these fees to be separate from the customer's purchase of the product and, therefore, they are recorded in other current liabilities on the consolidated balance sheets.

Prompt pay and other discounts – The Company incentivizes its customers to pay their invoices on time through prompt pay discounts. These discounts are an industry standard practice, and the Company offers a prompt pay discount to each wholesale distributor and retail pharmacy customer. The specific prompt pay terms vary by customer and are contractually fixed. Prompt pay discounts are typically taken by the Company's customers, so an estimate of the discount is recorded at the time of sale based on the purchase amount. Prompt pay discount estimates are recorded as contra trade accounts receivable on the consolidated balance sheets.

The Company may also give other discounts to its customers to incentivize purchases and promote customer loyalty. The terms of such discounts may vary by customer. These discounts reduce gross product revenue at the time the revenue is recognized.

Chargebacks – Certain government entities and covered entities (e.g., Veterans Administration, 340B covered entities) are able to purchase Phexxi at a price discounted below WAC. The difference between the government or covered entity purchase price and the wholesale distributor purchase price of WAC will be charged back to the Company. The Company estimates the amount of each chargeback channel based on the expected number of claims in each channel and related chargeback that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Estimated chargebacks are recorded as contra trade accounts receivable on the consolidated balance sheets.

Rebates – The Company is subject to mandatory discount obligations under the Medicaid and Tricare programs. The rebate amounts for these programs are determined by statutory requirements or contractual arrangements. Rebates are owed after the product has been dispensed to an end user and the Company has been invoiced. Rebates for Medicaid and Tricare are typically invoiced in arrears. The Company estimates the amount of rebates based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Rebate estimates are recorded as other current liabilities on the consolidated balance sheets.

Patient support programs – One type of patient support program the Company offers is a co-pay program to commercially insured patients whose insurance requires a co-pay to be made when filling their prescription. This is a voluntary program that is intended to provide financial assistance to patients meeting certain eligibility requirements. The Company estimates the amount of financial assistance for these programs based on the expected number of claims and related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Patient support programs estimates are recorded as other current liabilities on the consolidated balance sheets.

Product returns – Customers have the right to return product that is within six months or less of the labeled expiration date or that is past the expiration date by no more than twelve months. Phexxi was commercially launched in September 2020 with a 30-month shelf life. The shelf life increased to 48 months in June 2022. The Company uses historical sales and return data to estimate future product returns. Product return estimates are recorded as other current liabilities on the consolidated balance sheets.

The variable considerations discussed above were recorded in the consolidated balance sheet and consisted of $0.3 million and $0.1 million in contra trade accounts receivable as of December 31, 2023 and 2022, respectively and $3.2 million and $2.6 million in other current liabilities as of December 31, 2023 and 2022, respectively.

4. Debt

Baker Bros. Notes (temporarily owned by Aditxt from December 11, 2023 through February 26, 2024)

On April 23, 2020, the Company entered into a Securities Purchase and Security Agreement (the Baker Bros. Purchase Agreement) with certain affiliates of Baker Bros. Advisors LP, as purchasers (the Baker Purchasers), and Baker Bros. Advisors LP, as designated agent, pursuant to which the Company agreed to issue and sell to the Baker Purchasers (i) convertible senior secured promissory notes (the Baker Notes) in an aggregate principal amount of up to $25.0 million and (ii) warrants to purchase shares of common stock (the Baker Warrants) in a private placement, which closed in two closings (April 24, 2020, the Baker Initial Closing, and June 9, 2020, the Baker Second Closing) As a result of the two closings, the Company issued and sold Baker Notes with an aggregate principal amount of $25.0 million and Baker Warrants exercisable for 2,731 shares of common stock. Upon the completion of the underwritten public offering in June 2020, the exercise price of the Baker Warrants was $4,575 per share. The Baker Warrants have a five-year term with a cashless exercise provision and are immediately exercisable at any time from their respective issuance date.

The Baker Notes had a five-year term, with no pre-payment ability during the first three years. Interest on the unpaid principal balance of the Baker Notes (the Baker Outstanding Balance) accrues at 10.0% per annum with interest accrued during the first year from the two respective closing dates recognized as payment-in-kind. The effective interest rate for the period was 10.0%. Accrued interest beyond the first year of the respective closing dates is to be paid in arrears on a quarterly basis in cash or recognized as payment-in-kind, at the direction of the Baker Purchasers. As discussed below, with the amendment to the Baker Bros. Purchase Agreement, interest payments were paid-in kind. Interest pertaining to the Baker Notes for the twelve months ended December 31, 2023 and 2022 was approximately $8.7 million and $3.3 million, respectively, which was added to the outstanding principal balance. The Company accounts for the Baker Notes under the fair value method as described below and, therefore, the interest associated with the Baker Notes is included in the fair value determination.

The Baker Notes were callable by the Company on 10 days' written notice beginning on the third anniversary of the initial closing date of April 24, 2020. The call price equals 100% of the Baker Outstanding Balance plus accrued and unpaid interest if the Company's common stock as measured using a 30-day volume weighted average price (VWAP) was greater than the benchmark price of $9,356.25 as stated in the Baker Bros. Purchase Agreement, or 110% of the Baker Outstanding Balance plus accrued and unpaid interest if the VWAP was less than such benchmark price. The Baker Purchasers also had the option to require the Company to repurchase all or any portion of the Baker Notes in cash upon the occurrence of certain events. In a repurchase event, as defined in the Baker Bros. Purchase Agreement, the repurchase price will equal 110% of the Baker Outstanding Balance plus accrued and unpaid interest. In the event of default or the Company's change of control, the repurchase price would equal to the sum of (x) three times of the Baker Outstanding Balance plus (y) the aggregate value of future interest that would have accrued. The Baker Notes were convertible at any time at the option of the Baker Purchasers at the conversion price of $4,575 per share prior to the First and Second Baker Amendments (as defined below).

On November 20, 2021, the Company entered into the first amendment to the Baker Bros. Purchase Agreement (the First Baker Amendment), in which each Baker Purchaser had the right to convert all or any portion of the Baker Notes into common stock at a conversion price equal to the lesser of (a) $4,575 and (b) 115% of the lowest price per share of common stock (or, as applicable with respect to any equity securities convertible into common stock, 115% of the applicable conversion price) sold in one or more equity financings until the Company has met a qualified financing threshold defined as one or more equity financings resulting in aggregate gross proceeds to the Company of at least $50 million (the Financing Threshold).

The First Baker Amendment also extended, effective upon the Company's achievement of the Financing Threshold, the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2022 to June 30, 2023. Additionally per the First Baker Amendment, if in any equity financing closing on or prior to the date the Company has met the Financing Threshold the Company issued warrants to purchase capital stock of the Company (or other similar consideration), the Company was required to issue to the Baker Purchasers an equivalent coverage of warrants (or other similar consideration) on the same terms as if the Baker Purchasers had participated in the financing in an amount equal to the then outstanding principal of Baker Notes held by the Baker Purchasers. In satisfaction of this requirement and in connection with the closing of the May 2022 Public Offering, the Company issued warrants to purchase 582,886 shares of the Company's common stock at an exercise price of $93.75 per share (the June 2022 Baker Warrants). As required by the terms of the First Baker Amendment, the June 2022 Baker Warrants have substantially the same terms as the warrants issued in the May 2022 Public Offering. Refer to Note 8 - Stockholders' Deficit for further information. The exercise price of the initial Baker Warrants and the June 2022 Baker Warrants was reset multiple times as a result of various Notes issuances in accordance with the agreement and the exercise price as of December 31, 2023 was $0.0615 per share.

On March 21, 2022, the Company entered into the second amendment to the Baker Bros. Purchase Agreement (the Second Baker Amendment), which granted each Baker Purchaser the right to convert all or any portion of the Baker Notes into common stock at a conversion price equal to the lesser of (a) $725.81 or (b) 100% of the lowest price per share of common stock (or as applicable with respect to any equity securities convertible into common stock, 100% of the applicable conversion price) sold in any equity financing until the Company has (i) met the qualified financing threshold by June 30, 2022, defined as a single underwritten financing resulting in aggregate gross proceeds to the Company of at least $20 million (Qualified Financing Threshold) and (ii) the disclosure of top-line results from the *EVOGUARD* clinical trial (the Clinical Trial Milestone) by October 31, 2022. The Second Baker Amendment also provided that the exercise price of the Baker Warrants will equal the conversion price of the Baker Notes. The Company met the Qualified Financing Threshold upon the closing of the May 2022 Public Offering, and as of September 30, 2022, the conversion price and exercise price of the Baker Warrants was reset to $93.75. The Company achieved the Clinical Trial Milestone in October 2022. Also, with the achievement of the Qualified Financing Threshold and the Clinical Trial Milestone, the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi was extended to June 30, 2023, which was subsequently waived via the Baker Fourth Amendment as discussed below.

On September 15, 2022, the Company entered into the third amendment to the Baker Bros. Purchase Agreement (the Third Baker Amendment), pursuant to which the conversion price was amended to $26.25, subject to adjustment for certain dilutive Company equity issuance adjustments for a two-year period; an interest make-whole payment due in certain circumstances was removed; and certain change of control and liquidation payment amounts were reduced from three times the outstanding amounts of the Baker Notes to two times the outstanding amounts. In addition, the Third Baker Amendment provided that the Company may make future interest payments to the Baker Purchasers in kind or in cash, at the Company's option. On the same day, the Company also entered into a Secured Creditor Forbearance Agreement with the Baker Purchasers (Baker Forbearance Agreement), according to which the Baker Purchasers agreed to forebear the defaults that existed at that time.

On December 19, 2022, the Company entered into the First Amendment to the Forbearance Agreement (the Amendment) effective as of December 15, 2022 to amend certain provisions of the Forbearance Agreement dated September 15, 2022. The Amendment revised the Forbearance Agreement to (i) amend the Fifth Recital Clause to clarify that the Purchasers consent to any additional indebtedness *pari passu*, but not senior to that of the Purchasers, in an amount not to exceed $5.0 million, and (ii) strike and entirely replace Section 4 to clarify the terms of the Purchasers' consent to Interim Financing (as defined therein). No other revisions were made to the Forbearance Agreement.

On March 7, 2023, Baker Bros. Advisors, LP (the Designated Agent) provided a Notice of Event of Default and Reservation of Rights (the Notice of Default) relating to the Baker Bros. Purchase Agreement. The Notice of Default claimed that the Company failed to maintain the "Required Reserve Amount" as required by the Third Baker Amendment. The Designated Agent, at the direction of the Baker Purchasers, accelerated repayment of the outstanding balance payable. As a result, approximately $92.7 million, representing two times the sum of the outstanding balance and all accrued and unpaid interest thereon and all other amounts due under the Baker Bros. Purchase Agreement and other documents, was due and payable within three business days of receipt of the Notice of Default. In addition, the Company did not meet the $100.0 million cumulative net sales threshold by June 30, 2023 and as such was in default as of that date. As discussed below, all existing defaults were cured upon the signing of the Fourth Baker Amendment.

On September 8, 2023, the Company entered into the Fourth Amendment to the Baker Bros. Purchase Agreement (the Fourth Baker Amendment) with the Baker Purchasers. The Fourth Amendment amends certain provisions within the Baker Bros. Purchase Agreement including:

(i) the rescission of the Notice of Default delivered to the Company on March 7, 2023 and waiving the Events of Default named therein;

(ii) the waiver of any and all other Events of Default existing as of the Fourth Amendment date;

(iii) the removal of the conversion feature into shares of Company common stock, including the removal of any requirement to reserve shares of common stock for conversion of the Baker Notes as well as any registration rights related thereto;

(iv) the clarification that for the sole purpose of enabling an ex-U.S. license agreement for such assets, any Patents, Trademarks or Copyrights acquired after the Effective Date shall be excluded from the definition of Collateral; and,

(v) the removal of the requirement for the Company to obtain $100 million in cumulative net Phexxi sales in the specified timeframe.

The outstanding balance of the Baker Notes will continue to accrue interest at 10% per annum and, in the event of a default in the agreement or a failure to pay the Repurchase Price (as defined below) on or before September 8, 2028 (the Maturity Date), the Baker Purchasers may collect on the full principal amount then outstanding. Additionally, the Company was required to make a $1.0 million upfront payment by October 1, 2023 (which payment was made in late September 2023) as well as quarterly cash payments based upon a percentage of the Company's global net product revenue. The cash payments will be determined based upon the quarterly global net revenue of Phexxi such that if the global net revenue is less than or equal to $5.0 million, the Company will pay 3% of such global net revenues; if the global net revenue is over $5.0 million and less than or equal to $7.0 million, the Company will continue to pay 3% on net revenue up to $5.0 million and 4% on the net revenue over $5.0 million; and if the global net revenue is over $7.0 million, the Company will pay 3% on the net revenue up to $5.0 million, 4% on the net revenue over $5.0 million up to $7.0 million, and 5% on net revenue over $7.0 million. The cash payments were payable beginning in the fourth quarter of 2023. Regardless of the percentage paid, the quarterly cash payment amounts, along with the $1.0 million upfront payment, will be deducted from the Repurchase Price as Applicable Reductions.

The Fourth Amendment also granted the Company the ability to repurchase the principal amount and accrued and unpaid interest of the Baker Notes for up to a five-year period for the one-time Repurchase Price designated below:

Date of Notes' Repurchase	Repurchase Price
On or prior to September 8, 2024	$14,000,000 (less Applicable Reductions)
September 9, 2024-September 8, 2025	$16,750,000 (less Applicable Reductions)
September 9, 2025-September 8, 2026	$19,500,000 (less Applicable Reductions)
September 9, 2026-September 8, 2027	$22,250,000 (less Applicable Reductions)
September 9, 2027-September 8, 2028	$25,000,000 (less Applicable Reductions)

The Company evaluated whether any of the Embedded Features required bifurcation as a separate component. The Company elected the fair value option (FVO) under ASC 825, *Financial Instruments* (ASC 825), as the Baker Notes are qualified financial instruments and are, in whole, classified as liabilities. Under the FVO, the Company recognized the debt instrument at fair value, inclusive of the Embedded Features with changes in fair value related to changes in the Company's credit risk being recognized as a component of accumulated other comprehensive income in the consolidated balance sheets. All other changes in fair value were recognized in the consolidated statements of operations.

Due to the execution of the Fourth Baker Amendment, the Company reviewed the Baker Notes in accordance with ASC 470, *Debt* (ASC 470). Because the Baker Notes were recorded under the FVO, the Fourth Amendment was outside the scope of ASC 470-60 and as such did not qualify as a troubled debt restructuring (TDR). The Baker Notes were evaluated in accordance with ASC 470 and were determined to have failed certain qualitative factors to qualify as a modification and, therefore, were accounted for as an extinguishment. The Company removed the fair value of the old Baker Notes of $15.6 million and the related accumulated other comprehensive income of $73.2 million as of the date of extinguishment and recorded the fair value of the new Baker Notes, as measured on the date of the Baker Fourth Amendment as $12.5 million, and recognized a gain of approximately $75.3 million within the consolidated statements of operations, in the gain (loss) on issuance of financial instruments line item, upon extinguishment. The gain includes recognizing $73.2 million that had previously been a component of other comprehensive income as part of the prior quarterly revaluations using the valuation methods discussed in Note 6 – Fair Value of Financial Instruments.

As part of the consideration for the Merger, on December 11, 2023, the Baker Purchasers signed an agreement to assign the Baker Notes to Aditxt (the December Assignment Agreement). Upon this December Assignment Agreement, Aditxt assumed all terms under the Baker Notes, with Aditxt becoming the new senior secured debtholder of the Company, governed by the requirements under the Fourth Baker Amendment. As described in Note 13 – Subsequent Events, the Baker Notes were re-assigned back to the Baker Purchasers on February 26, 2024.

Due to the execution of the December Assignment Agreement, the Company reviewed the Baker Notes in accordance with ASC 470. The Baker Notes, having been effectively terminated were extinguished on December 11, 2023, resulting in removing the fair value of the old Baker Notes of $12.5 million. The temporarily assigned Baker Notes were subsequently recorded at fair value using the valuation methods discussed in Note 6 – Fair Value of Financial Instruments.

As of December 31, 2023, the Baker Notes are recorded at fair value in the consolidated balance sheet as short-term convertible notes payable with a total balance of $13.5 million, and the total outstanding balance including principal and accrued interest is $99.5 million.

Adjuvant Notes

On October 14, 2020, the Company entered into a Securities Purchase Agreement (the Adjuvant Purchase Agreement) with Adjuvant Global Health Technology Fund, L.P., and Adjuvant Global Health Technology Fund DE, L.P. (together, the Adjuvant Purchasers), pursuant to which the Company sold unsecured convertible promissory notes (the Adjuvant Notes) in aggregate principal amount of $25.0 million.

The Adjuvant Notes have a five-year term, and in connection with certain Company change of control transactions, the Adjuvant Notes may be prepaid at the option of the Company or will become payable on the date of the consummation of a change of control transaction at the option of the Adjuvant Purchasers. The Adjuvant Notes have interest accruing at 7.5% per annum on a quarterly basis in arrears to the outstanding balance of the Adjuvant Notes and are recognized as payment-in-kind. The effective interest rate for the year ended December 31, 2023 was 8.8%.

Interest expense for the Adjuvant Notes consist of the following, and is included in short-term convertible notes payable on the consolidated balance sheet as of December 31, 2023 and 2022 and in other expense, net on the consolidated statements of operations for the years ended December 31, 2023 and 2022 (in thousands):

	Years Ended December 31,	
	2023	2022
Coupon interest	$ 2,046	$ 2,048
Amortization of issuance costs	224	129
Total [4]	$ 2,270	$ 2,177

The Adjuvant Notes are convertible, subject to customary 4.99% and 19.99% beneficial ownership limitations, into shares of the Company's common stock, par value $0.0001 per share, at any time at the option of the Adjuvant Purchasers at a conversion price of $6,843.75 per share. In connection with certain Company change of control transactions, the Adjuvant Notes may be prepaid at the option of the Company or will become payable at the option of the Adjuvant Purchasers. To the extent not previously prepaid or converted, the Adjuvant Notes were originally automatically convertible into shares of the Company's common stock at a conversion price of $6,843.75 per share immediately following the earliest of the time at which the (i) 30-day value-weighted average price of the Company's common stock was $18,750 per share, or (ii) the Company achieved cumulative net sales of $100.0 million, provided such net sales were achieved prior to July 1, 2022.

On April 4, 2022, the Company entered into the first amendment to the Adjuvant Purchase Agreement (the Adjuvant Amendment). The Adjuvant Amendment extended the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2022 to June 30, 2023. The Adjuvant Amendment also provided for an adjustment to the conversion price of the Adjuvant Notes such that the conversion price (the Conversion Price) for these Notes, effective as of the May 2023 reverse stock split, will now be the lesser of (i) $678.49 and (ii) 100% of the lowest price per share of common stock (or with respect to securities convertible into common stock, 100% of the applicable conversion price) sold in any equity financing until the Company has met the Qualified Financing Threshold. Effective as of the Company's achievement of the Qualified Financing Threshold, the automatic conversion provisions in the Agreement were further amended to provide that the Adjuvant Notes will automatically convert into shares of the Company's common stock at the Conversion Price immediately following the earliest of the time at which the (i) 30-day value-weighted average price of the Company's common stock is $18,750 per share, or (ii) the Company achieves cumulative net sales of Phexxi of $100.0 million, provided such net sales were achieved prior to July 1, 2023.

The Adjuvant Notes contain various customary affirmative and negative covenants agreed to by the Company. On September 12, 2022, the Company was in default of the Adjuvant Notes due to the default with the Baker Notes under the cross-default provision. On September 15, 2022, the Company entered into a Forbearance Agreement (the Adjuvant Forbearance Agreement) with the Adjuvant Purchasers, pursuant to which the Adjuvant Purchasers agreed to forbear from exercising any of their rights and remedies during the Forbearance Period as defined in therein, but solely with respect to the specified events of default provided under the Adjuvant Forbearance Agreement.

On September 15, 2022, the Company also entered into the second amendment to the Adjuvant Purchase Agreement (the Second Adjuvant Amendment), pursuant to which the conversion price per share was reduced to $26.25, subject to adjustment for certain dilutive Company equity issuance adjustments for a two-year period. In addition, the Company entered into an exchange agreement, pursuant to which the Adjuvant Purchasers agreed to exchange 10% of the outstanding amount of the Adjuvant Notes as of September 15, 2022 (or $2.9 million) for rights to receive 109,842 shares of common stock (the Adjuvant Purchase Rights). The number of shares for each Adjuvant Purchase Right is initially fixed, but is subject to certain customary adjustments, and, until the second anniversary of issuance, adjustments for certain dilutive Company equity issuances. Refer to Note 8 - Stockholders' Deficit for discussion regarding additional issuances of purchase rights under this provision. The Adjuvant Purchase Rights expire on June 28, 2027 and do not have an exercise price per share and, therefore, will not result in cash proceeds to the Company. As of December 31, 2023, all Adjuvant Purchase Rights remain outstanding. The conversion price of the Adjuvant Notes was reset several times during 2023 along with various financing and equity transactions; as of December 31, 2023, the conversion price was $0.0615.

The Adjuvant Notes are accounted for in accordance with authoritative guidance for convertible debt instruments and are classified as current liabilities in the consolidated balance sheets. The aggregate proceeds of $25.0 million were initially classified as restricted cash for financial reporting purposes due to contractual stipulations that specify the types of expenses the money can be spent on and how it must be allocated. The conversion feature was required to be bifurcated as an embedded derivative because the Company did not have sufficient number of shares reserved upon conversion as of December 31, 2022; however, the fair value of such feature was immaterial as of December 31, 2022. As of June 30, 2023, the Company had a sufficient number of shares reserved and the conversion feature was reclassified to stockholders' deficit in accordance with ASC 815, *Derivatives and Hedging* (ASC 815) at that time. As of December 31, 2023 and 2022, $0.6 million and $0.9 million, respectively in proceeds remained, which are included in restricted cash on the consolidated balance sheets. See Note 6 - Fair Value of Financial Instruments for a description of the accounting treatment for the Adjuvant Purchase Rights.

Due to the execution of the Adjuvant Forbearance and the Second Adjuvant Amendment, the Company reviewed the Adjuvant Notes in accordance with ASC 470. The Company concluded that although changes in the structure of the debt met certain qualitative factors to qualify as a TDR, the effective interest rate post changes was greater than the original effective interest rate and, therefore, failed the quantitative test to be a TDR. The Adjuvant Notes were evaluated in accordance with ASC 470 and were determined to have failed certain qualitative factors to qualify as a modification and, therefore, were accounted for as an extinguishment. The Company removed the old debt from its financial records and recorded the new, revised debt and concurrently recognized a gain of approximately $2.5 million upon extinguishment, included in change in fair value of financial instruments within the consolidated statements of operations for the third quarter of 2022. As discussed above, the Company was in default of the Adjuvant Notes at September 30, 2023, due to the failure to meet the cumulative net sales requirement. However, Adjuvant forebeared such default in October 2023 and therefore the Company is no longer in default.

As of December 31, 2023, the Adjuvant Notes are recorded in the consolidated balance sheet as short-term convertible notes payable with a total balance of $28.5 million. The balance is comprised of $22.5 million in principal, net of unamortized debt issuance costs, and $6.1 million in accrued interest. As of December 31, 2022, the Adjuvant Notes were recorded in the consolidated balance sheet as short-term convertible notes payable with a total balance of $26.3 million. The balance was comprised of $22.3 million in principal, net of unamortized debt issuance costs, and $4.0 million in accrued interest.

As of December 31, 2023, and assuming the current conversion price of $0.0615 per share, the Adjuvant Notes could be converted into 464,027,724 shares of common stock.

Term Notes

January and March 2022 Notes

On January 13, 2022, the Company entered into a Securities Purchase Agreement (the January 2022 Purchase Agreement) with institutional investors (the January 2022 Notes Purchasers) pursuant to which the Company agreed to sell in a registered direct offering (i) unsecured 5.0% Senior Subordinated Notes due 2025 with an aggregate issue price of $5.9 million (the January 2022 Notes), which included an original issue discount of $0.9 million, and (ii) warrants (the January 2022 Warrants) to purchase up to 8,003 shares of the Company's common stock, $0.0001 par value per share. The January 2022 Warrants had an exercise price of $735.00 per share and were initially exercisable beginning on July 15, 2022 with a five-year term. Pursuant to the terms of the March 2022 Purchase Agreement (as defined below), the January 2022 Warrants became exercisable on March 1, 2022, as described in more detail below.

On March 1, 2022, the Company entered into a Securities Purchase Agreement (the March 2022 Purchase Agreement) with institutional investors (the March 2022 Notes Purchasers) pursuant to which the Company agreed to sell in a registered direct offering (i) unsecured 5.0% Senior Subordinated Notes due 2025 with an aggregate issue price of approximately $7.5 million (the March 2022 Notes), which included an original issue discount of approximately $2.5 million, and (ii) warrants (the March 2022 Warrants) to purchase up to 8,303 shares of the Company's common stock, $0.0001 par value per share. The March 2022 Warrants have an exercise price of $897.56 per share and are immediately exercisable with a five-year term.

The January and March 2022 Notes carried an interest rate of 5% per annum, which was subject to increase to 18% upon an event of default. The January and March 2022 Notes were able to be prepaid, in whole or in part, at the Company's option together with all accrued and unpaid interest and fees as of the date of repayment. The holders of the January and March 2022 Notes were able to require the Company to redeem their respective notes upon the occurrence of an event of default with a redemption premium of 25%. The holders of the January and March 2022 Notes were also able to require the Company to redeem their respective notes upon the occurrence of certain subsequent transactions.

Pursuant to the terms of the January and March 2022 Purchase Agreements, the Company agreed to certain restrictions on effecting variable rate transactions so long as the January and March 2022 Notes were outstanding. Also, pursuant to the terms of the January and March 2022 Purchase Agreements, the January and March 2022 Purchasers had certain rights to participate in subsequent issuances of the Company's securities, subject to certain exceptions.

The Company evaluated the January and March 2022 Notes to determine if any embedded components qualified as a derivative requiring bifurcation in accordance with ASC 815. The Company determined that the embedded put option and interest rate increase feature would both require bifurcation and separate accounting. Therefore, the Company elected to use the fair value option under ASC 825, *Financial Instruments* (ASC 825) for the January and March 2022 Notes inclusive of the embedded features.

The Company evaluated the January and March 2022 Warrants and determined that in accordance with ASC 815 the warrants should be recorded at fair value and classified as a derivative liability in the consolidated balance sheet. Both the January and March 2022 Notes and Warrants were marked-to-market at each reporting date.

Under the valuation methods as described in Note 6 - Fair Value of Financial Instruments, the Company recorded the following in the consolidated financial statements related to the January and March 2022 Notes and Warrants during the year ended December 31, 2022: (i) $0.2 million in notes at issuance; (ii) $10.6 million in warrants at issuance as a derivative liability; and (iii) a $0.9 million loss on issuance. During the year ended December 31, 2022, the Company recognized gains in fair value of financial instruments as a result of the mark-to-market adjustment on the January and March 2022 Warrants of $10.6 million.

On May 4, 2022, the January and March 2022 Notes were exchanged pursuant to the May 2022 Exchange, as defined below.

May 2022 Notes

On May 4, 2022, the Company entered into amendment and exchange agreements (the May 2022 Exchange) with the holder of issued and outstanding Series B-2 and C Preferred Stock, Seven Knots, and the January and March 2022 Notes Purchasers (collectively, the May 2022 Notes Purchasers), pursuant to which they agreed to exchange all of the January and March 2022 Notes, 2,100 shares of Series B-2 Convertible Preferred Stock, 1,700 shares of Series C Convertible Preferred Stock, and 4,266 shares of the Company's Common Stock for (i) new 5.0% Senior Subordinated Notes with an aggregate principal amount of $22.3 million (the May 2022 Notes), (ii) 1,666 new shares of Common Stock and (iii) new warrants to purchase up to 6,666 shares of Common Stock (the May 2022 Warrants). The May 2022 Warrants have an exercise price of $309.56 per share and were exercisable immediately with a five-year term. The 2,100 shares of Series B-2 Convertible Preferred Stock, 1,700 shares of Series C Convertible Preferred Stock, and 4,266 shares of the Company's Common Stock that were exchanged in the May 2022 Exchange were retired by the Company. All aforementioned exchange transactions were cashless.

The May 2022 Notes were substantially similar to the January and March 2022 Notes, except that (i) the maturity date of the May 2022 Notes was August 1, 2022 and (ii) the holders of the May 2022 Notes may require the Company to redeem or exchange up to 100% of the May 2022 Notes upon the occurrence of certain subsequent transactions (each, a Subsequent Transaction Optional Redemption). Pursuant to the terms of the May 2022 Notes and subject to certain conditions described in the May 2022 Notes, if the Company completed an underwritten public offering of at least $20 million complying with certain conditions (a Qualified Underwritten Offering) and the holder of the May 2022 Notes did not participate in the Qualified Underwritten Offering, then the holder would have forfeited their right to Subsequent Transaction Optional Redemption solely with respect to that Qualified Underwritten Offering and amounts that may have been due pursuant to the May 2022 Notes would not have been due and payable until the three-month anniversary of the Qualified Underwritten Offering.

The May 2022 Public Offering qualified as the Qualified Underwritten Offering and, in connection with the May 2022 Public Offering, the holders of the May 2022 Notes waived certain of their preemptive and redemption rights and the Company redeemed $5.9 million of the May 2022 Notes. The holders of the May 2022 Notes also waived the maturity date of the May 2022 Notes until October 31, 2022.

The May 2022 Notes contain various customary affirmative and negative covenants agreed to by the Company. The May 2022 Notes also include other customary events of default, which include the suspension of trading of shares of the Company's common stock on the Nasdaq Capital Market for a period of more than five trading days. On September 12, 2022, the Company was in default of the May Notes due to the default with the Baker Notes under the cross-default provision. As a result, the interest rate was increased to 18% for the duration of the default and the holders of the May 2022 Notes had the right to request redemption for 125% of the amounts then owed pursuant to the May 2022 Notes.

On September 15, 2022, the Company entered into exchange agreements with each of the May 2022 Notes Purchasers (the May 2022 Notes Exchange Agreements), pursuant to which the May 2022 Notes Purchasers agreed to exchange all outstanding balances of the May Notes as of September 15, 2022 using the higher interest rate and redemption premium aforementioned for purchase rights (the May Note Purchase Rights) to receive 832,237 shares of common stock. As a result, the May Notes were no longer outstanding as of December 31, 2022. The number of right shares for each May Note Purchase Right was initially fixed, but is subject to certain customary adjustments, and, until the second anniversary of issuance, adjustments for certain dilutive Company equity issuances, as further discussed in Note 8 - Stockholders' Deficit, and expire on June 28, 2027. The May 2022 Notes Purchasers also waived certain anti-dilution share adjustment provisions with respect to shares underlying the May 2022 Warrants.

The Company evaluated the May 2022 Notes and determined that in accordance with ASC 470 the notes should be accounted for as a modification of the January and March 2022 Notes. The Company further evaluated the May 2022 Notes to determine if any embedded components qualified as a derivative requiring bifurcation in accordance with ASC 815. The Company determined that the embedded put options and interest rate increase features would all require bifurcation and separate accounting. Therefore, the Company elected to use the fair value option under ASC 825, *Financial Instruments* (ASC 825) for the May 2022 Notes inclusive of the embedded features.

The Company evaluated the May 2022 Warrants and determined that, in accordance with ASC 815, the warrants should be recorded at fair value and classified as a derivative liability in the consolidated balance sheet. Both the May 2022 Notes and Warrants are marked-to-market at each reporting date before the exchange as described above.

Under the valuation methods as described in Note 6 - Fair Value of Financial Instruments, the Company recorded the following in the consolidated financial statements related to the May 2022 Notes and Warrants during the year ended December 31, 2022: (i) $22.3 million in notes at issuance; and (ii) $1.6 million in warrants at issuance as a derivative liability. During the year ended December 31, 2022, the Company recognized losses in fair value of financial instruments as a result of the mark-to-market adjustment on the May 2022 Notes of $10.3 million and gains in fair value of financial instruments as a result of the mark-to-market adjustment on the May 2022 Warrants of $1.6 million.

December 2022 and February, March, April, July, August, and September 2023 Notes

The Company entered into eight similar Securities Purchase Agreements (SPAs) between December 2022 and September 2023 with certain investors. Each of the agreements were materially similar. The variable details of each SPA, such as the principal amount of each note offering, net proceeds, and maturity date are outlined in the table below. Pursuant to each SPA, the Company agreed to sell in a registered direct offering (i) unsecured 8.0% senior subordinated notes with the maturity dates and aggregate issue prices (ii) warrants to purchase the listed number of shares of the Company's common stock, $0.0001 par value per share (including prefunded common stock Warrants as a part of the September 2023 SPA) (iii) Series D Preferred Stock (the Preferred Shares; December 2022 SPA only) (collectively, the Senior Subordinated Notes, or SSNs). The SSNs had net proceeds to the Company from and are convertible at the amounts listed below.

The SSNs interest rates are subject to increase to 12% upon an event of default and the Notes have no Company right to prepayment prior to maturity; however, the Company can redeem the respective SSNs at a redemption premium of 32.5%. The Purchasers can also require the Company to redeem their notes at the respective premium rate tied to the occurrence of certain subsequent transactions, as well as require the Company to redeem the SSNs in the event of subsequent placements (as defined). Also, pursuant to the terms of the SPAs, Purchasers have certain rights to participate in subsequent issuances of the Company's securities, subject to certain exceptions. Additionally, the conversion rate and warrant strike price are subject to adjustment upon the issuance of other securities (as defined) less than the stated conversion rate and strike price at issuance. The strike prices adjusted as discussed in the table below. Additionally, subsequent to December 31, 2023, the conversion price of the SSNs was adjusted to $0.0158 per share due to the price reset requirements in the SPA.

The Company evaluated the SSNs in accordance with ASC 480 and determined that the Notes were all liability instruments at issuance. The applicable Notes were then evaluated in accordance with the requirements of ASC 825 and the Company concluded that they were not precluded from electing the fair value option for the applicable Notes.

The Company also evaluated the Warrants in accordance with ASC 480 and determined that the Warrants issued before the Reverse Stock Split in May 2023 were required to be recorded as liabilities at fair value in the Company's consolidated balance sheets. The applicable SSNs were marked-to-market at each reporting date with changes in fair value recognized in the consolidated statement of operations, unless the change is concluded to be related to changes in the Company's credit rating, in which case the change was recognized as a component of accumulated other comprehensive income in the consolidated balance sheets. As a result of the Reverse Stock Split, the Company had sufficient shares available for issuance to cover the potential exercises; therefore, the Warrants that were previously classified as liabilities were marked-to-market and reclassified to equity in May 2023. For the Warrants issued after the Reverse Stock Split, the Company determined they were required to be recorded in equity.

On December 21, 2023, warrants to purchase up to 9,972,074 shares of the Company's common stock were exchanged for 613 shares of the Company's series F-1 convertible and redeemable preferred stock (Series F-1 Shares, as defined below). The Series F-1 Shares, some of which were also issued based on the partial value of certain purchase rights, as described above, were immediately exchanged to Aditxt series A-1 preferred stock and 22,280 Series F-1 Shares were outstanding as of December 31, 2023 and held by Aditxt. The Series F-1 Shares will be cancelled at such time that the Merger is successfully closed, as applicable.

Summary of SSNs and Warrants (December 2022 to September 2023):

						Conversion Price					
Notes	**Principal at issuance (in thousands)**	**Gross proceeds before issuance costs (in thousands)**	**Warrants at issuance (common stock)**	**Preferred Shares**	**Maturity Date**	**At Issuance**	**At 12/31/2022**	**At 3/31/2023**	**At 6/30/2023**	**At 9/30/2023**	**At 12/31/2023**
December 2022 Notes	$ 2,308	$ 1,500	369,230	70 - Series D	12/21/2025	$ 6.25	$ 6.25	$ 1.625	$ 0.8125	$ 0.0845	$ 0.0615
February 2023 Notes[1]	1,385	900	653,538	-	2/17/2026	$ 2.50	N/A	$ 1.625	$ 0.8125	$ 0.0845	$ 0.0615
March 2023 Notes	600	390	240,000	-	3/17/2026	$ 2.50	N/A	$ 1.625	$ 0.8125	$ 0.0845	$ 0.0615
March 2023 Notes[2]	538	350	258,584	-	3/20/2026	$ 2.50	N/A	$ 1.625	$ 0.8125	$ 0.0845	$ 0.0615
April 2023 Notes	769	500	615,384	-	3/6/2026	$ 1.25	N/A	N/A	$ 0.8125	$ 0.0845	$ 0.0615
July 2023 Notes	1,500	975	1,200,000	-	3/6/2026	$ 1.25	N/A	N/A	N/A	$ 0.0845	$ 0.0615
August 2023 Notes	1,000	650	799,999	-	8/4/2026	$ 1.25	N/A	N/A	N/A	$ 0.0845	$ 0.0615
September 2023 Notes[3]	2,885	1,875	26,997,041	-	9/26/2026	$ 0.13	N/A	N/A	N/A	$ 0.13	$ 0.0615
Total Senior Subordinate Notes	$ 10,985	$ 7,140	31,133,776								

(1) Warrants include 99,692 issued to the placement agent.
(2) Warrants include 43,200 issued to the placement agent.
(3) Warrants include 22,189,349 common warrants at $0.13 per share and 4,807,692 pre-funded warrants exercisable at $0.001 per share.

5. Balance Sheet Details

Prepaid and Other Current Assets

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

	December 31,	
	2023	2022
Insurance	$ 777	$ 1,387
Research & development costs	13	403
Other	405	428
Total	$ 1,195	$ 2,218

Property and Equipment, Net

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

		December 31,	
	Useful Life	2023	2022
Research equipment	5 years	$ 586	$ 653
Computer equipment and software	3 years	647	639
Office furniture	5 years	-	881
Leasehold improvements	5 years or less	-	3,388
Construction in-process	—	1,156	1,568
		2,389	7,129
Less: accumulated depreciation		(1,186)	(3,189)
Total, net		$ 1,203	$ 3,940

Depreciation and amortization expense for property and equipment is disclosed in the consolidated statements of cash flows.

Other Noncurrent Assets

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

	December 31,	
	2023	2022
Restricted cash included in noncurrent assets	$ -	$ 800
Inventories, long-term	-	1,270
Prepaid directors & officers' insurance	-	1,717
Other	35	331
Total	$ 35	$ 4,118

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2023	2022
Clinical trial related costs	$ 2,498	$ 2,574
Accrued royalty	1,146	674
Other	583	876
Total	$ 4,227	$ 4,124

6. Fair Value of Financial Instruments

Fair Value of Financial Assets

The fair values of the Company's assets, including money market funds, investments in marketable fixed income debt securities classified as cash and cash equivalents measured on a recurring basis as of December 31, 2022, are summarized in the following tables (in thousands). There are no such instruments as of December 31, 2023.

	As of December 31, 2022				
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (level 2)	Significant Unobservable Inputs (Level 3)	Significant Unobservable Inputs (Level 3)	Total
Money market funds [1]	$ 2,612	$ -	$ -	$ -	$ 2,612
Total assets	$ 2,612	$ -	$ -	$ -	$ 2,612

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

Fair Value of Financial Liabilities

The following table is a summary of the Company's convertible debt instruments as of December 31, 2023 and 2022, respectively (in thousands):

					Fair Value	
As of December 31, 2023	Principal Amount	Unamortized Issuance Costs	Accrued Interest	Net Carrying Amount	Amount	Leveling
Baker Notes[1][2]	$ 99,460	$ -	$ -	$ 99,460	$ 13,510	Level 3
Adjuvant Notes[3]	22,500	(27)	6,064	28,537	N/A	N/A
December 2022 Notes[1]	940	-	-	940	118	Level 3
February 2023 Notes [1]	905	-	-	905	118	Level 3
March 2023 Notes [1]	1,204	-	-	1,204	157	Level 3
April 2023 Notes [1]	816	-	-	816	106	Level 3
July 2023 Notes [1]	1,534	-	-	1,534	202	Level 3
August 2023 Notes [1]	1,033	-	-	1,033	136	Level 3
September 2023 Notes [1]	2,945	-	-	2,945	384	Level 3

(1) These liabilities are/were carried at fair value in the consolidated balance sheets. As such, the principal and accrued interest was included in the determination of fair value. The related debt issuance costs were expensed.

(2) The Baker Notes principal amount includes $13.7 million of interest paid-in kind as of December 31, 2023.

(3) The Adjuvant Notes are recorded in the consolidated balance sheets at their net carrying amount which includes principal and accrued interest, net of unamortized issuance costs.

As of December 31, 2022	Principal Amount	Unamortized Issuance Costs	Accrued Interest	Redemption Amount	Amount Exchanged	Net Carrying Amount	Fair Value	
							Amount	Leveling
Baker Notes[1][2]	$ 45,528	$ -	$ -	$ -	$ -	$ 45,528	$ 39,260	Level 3
Adjuvant Notes[3][4]	22,500	(252)	4,020	-	-	26,268	-	N/A
May 2022 Notes[1]	16,376	-	1,101	4,369	(21,846)	-	-	N/A
December 2022 Notes [1]	2,308	-	-			2,308	156	Level 3

(1) These liabilities are/were carried at fair value in the consolidated balance sheets. As such, the principal and accrued interest was included in the determination of fair value. The related debt issuance costs were expensed.

(2) The Baker Notes principal amount includes $5.6 million of interest paid-in kind as of December 31, 2022.

(3) The Adjuvant Notes are recorded in the consolidated balance sheets at their net carrying amount which includes principal and accrued interest, net of unamortized issuance costs.

(4) The principal amount and accrued interest of the Adjuvant Notes are net of the 10% reduction in principal and interest of $2.5 million and $0.4 million, respectively, received in exchange for the issuance of purchase rights.

The following tables summarize the Company's derivative liabilities as of December 31, 2023 and 2022 as discussed in Note 8 - Stockholders' Deficit (in thousands):

	Fair Value		
	December 31, 2023 [2]	December 31, 2022[1]	Leveling
April and June 2020 Baker Warrants	$ N/A	$ 1	Level 3
May 2022 Public Offering Warrants	N/A	303	Level 3
June 2022 Baker Warrants	N/A	170	Level 3
December 2022 Warrants	N/A	107	Level 3
Purchase Rights	1,926	1,095	Level 3
Total Derivative Liabilities	$ 1,926	$ 1,676	

(1) As of December 31, 2022, all warrants issued by the Company are subject to liability accounting due to potential settlement in cash, an insufficient number of authorized shares and other adjustment mechanics. However, warrants with an exercise price greater than $6.25 per share were considered to be significantly out of the money and therefore the value ascribed to those warrants was considered to be *de minimus* and is therefore excluded from the above table.

(2) Upon the effectuation of the reverse split on May 18, 2023, the Company has a sufficient number of authorized shares. As a result, during the second quarter of 2023, all warrants in the table above were marked-to-market on May 18, 2023, and then reclassified to equity.

Change in Fair Value of Level 3 Financial Liabilities

The following tables summarize the changes in Level 3 financial liabilities related to Term Notes, Baker Notes and SSNs measured at fair value on a recurring basis for the year ended December 31, 2023 (in thousands):

	Baker First Closing Notes	Baker Second Closing Notes	Baker Notes- Fourth Amendment	Baker Notes (Assigned to Aditxt; Note 4)	Total SSNs (Note 4)	Total
Balance at December 31, 2022	$ 23,556	$ 15,704	$ -	$ -	$ 156	$ 39,416
Balance at issuance	-	-	13,450	13,510	220	27,180
Payments	-	-	(1,154)	-	-	(1,154)
Extinguishment/conversion	(9,360)	(6,240)	(11,082)	-	(1)	(26,683)
Change in fair value presented in the Consolidated Statements of Operations	-	-	(1,214)	-	-	(1,214)
Change in fair value presented in the Consolidated Statements of Comprehensive Operations	(14,196)	(9,464)	-	-	846	(22,814)
Balance at December 31, 2023	$ -	$ -	$ -	$ 13,510	$ 1,221	$ 14,731

The following table summarizes the changes in Level 3 financial liabilities related to Term Notes, Baker Notes and December 2022 Notes measured at fair value on a recurring basis for the year ended December 31, 2022 (in thousands):

	Term Notes - January 2022 Notes	Term Notes - March 2022 Notes	Term Notes - May 2022 Notes	Baker First Closing Notes	Baker Second Closing Notes	Total Senior Subordinate Notes (Note 4)	Total
Balance at December 31, 2021	$ -	$ -	$ -	$ 49,030	$ 32,687	$ -	$ 81,717
Balance at issuance	116	149	447	-	-	156	868
Payments	-	-	(5,892)	-	-	-	(5,892)
Change in fair value presented in the Consolidated Statements of Operations	4	2	10,251	1,189	792	-	12,238
Change in fair value presented in the Consolidated Statements of Comprehensive Operations	-	-	-	(26,663)	(17,775)	-	(44,438)
Exchange of notes (noncash)	(120)	(151)	(4,806)	-	-	-	(5,077)
Balance at December 31, 2022	$ -	$ -	$ -	$ 23,556	$ 15,704	$ 156	$ 39,416

The following table summarizes the changes in Level 3 financial liabilities related to derivative liabilities measured at fair value on a recurring basis for the year ended December 31, 2023 (in thousands):

	April and June 2020 Baker Warrants	May 2022 Public Offering Common Warrants	June 2022 Baker Warrants	December 2022 Warrants	February and March 2023 Warrants	Purchase Rights	Derivative Liabilities Total
Balance at December 31, 2022	$ 1	$ 303	$ 170	$ 107	$ -	$ 1,095	$ 1,676
Balance at issuance	-	-	-	-	6	5,556	5,562
Exercises	-	(7)	-	-	-	(424)	(431)
Change in fair value presented in the Consolidated Statements of Operations	(1)	(295)	(169)	(107)	(6)	(4,301)	(4,879)
Reclassified to equity	-	(1)	(1)	-	-	-	(2)
Balance at December 31, 2023	$ -	$ -	$ -	$ -	$ -	$ 1,926	$ 1,926

The following table summarizes the changes in Level 3 financial liabilities related to derivative liabilities measured at fair value on a recurring basis for the year ended December 31, 2022 (in thousands):

	Convertible Preferred Stock Conversion Feature	Derivative Liabilities Previously Classified as Equity Instruments	January 2022 Warrants	March 2022 Warrants	May 2022 Warrants	May 2022 Public Offering Common Warrants	May 2022 Public Offering Pre-Funded Warrants	June 2022 Baker Warrants	December 2022 Warrants	Purchase Rights	Derivative Liabilities Total
Balance at December 31, 2021	$ 202	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 202
Balance at issuance	-	-	4,562	6,025	1,613	18,074	4,633	70,238	107	6,284	111,536
Exercises	-	-	-	-	-	(12,086)	(4,633)	-	-	(1,007)	(17,726)
Change in fair value presented in the Consolidated Statements of Operations	(83)	-	(4,562)	(6,025)	(1,613)	(5,685)	-	(70,068)	-	(4,182)	(92,218)
Conversion of series B-2 convertible preferred stock	(46)	-	-	-	-	-	-	-	-	-	(46)
Loss on re-valuation of derivative liabilities presented in the consolidated statement of operations.	-	1	-	-	-	-	-	-	-	-	1
May 2022 exchange transaction	(73)	-	-	-	-	-	-	-	-	-	(73)
Balance at December 31, 2022	$ -	$ 1	$ -	$ -	$ -	$ 303	$ -	$ 170	$ 107	$ 1,095	$ 1,676

Valuation Methodology

Baker Notes

Through June 30, 2022, the fair value of the Baker Notes issued, and the change in fair value of the Baker Notes at the reporting date, were determined using a Monte Carlo simulation-based model. The Monte Carlo simulation was used to take into account several embedded features and factors, including the future value of our common stock, a potential change of control event, the probability of meeting certain debt covenants, the maturity term of the Baker Notes, the probability of an event of voluntary conversion of the Baker Notes, the probability of the failure to meet the affirmative covenant to achieve $100.0 million in cumulative net sales of Phexxi by June 30, 2023, the probability of exercise of the put right and the probability of exercise of the call right.

The fair value of the Baker Notes is subject to uncertainty due to the assumptions that are used in the Monte Carlo simulation-based model. These factors include but are not limited to the future value of the Company's common stock, the probability and timing of a potential change of control event, the probability of meeting certain debt covenants, the probability of an event of voluntary conversion of the Baker Notes, exercise of the put right, and exercise of the Company's call right. The fair value of the Baker Notes is sensitive to these estimated inputs made by management that are used in the calculation.

From the third quarter of 2022 through the second quarter of 2023, the fair value of the Baker Notes issued as described in Note 4 - Debt, and subsequent changes in fair value recorded at each reporting date, was determined by estimating the fair value of the Market Value of Invested Capital ("MVIC") of the Company. This was estimated using forms of the cost and market approaches. In the Cost approach, an adjusted net asset value method was used to determine the net recoverable value of the Company, including an estimate of the fair of the Company's intellectual property. The estimated fair value of the Company's intellectual property was valued using a relief from royalty method which required management to make significant estimates and assumptions related to forecasts of future revenue, and the selection of the royalty and discount rates. The guideline public company method served as another valuation indicator. In this form of the Market approach, comparable market revenue multiples were selected and applied to the Company's forward revenue forecast to ultimately derive a MVIC indication. If the resulting fair value from these approaches was not estimated as greater than the contractual payout, the fair value of the Baker Notes became only the Company MVIC available for distribution to this first lien note holder.

Starting in the third quarter of 2023, the fair value of the Baker Notes, issued as described in Note 4 - Debt is determined using a Monte Carlo simulation-based model. The Monte Carlo simulation was used to take into account several embedded features and factors, including the exercise of the repurchase right, the Company's future revenues, meeting certain debt covenants, the maturity term of the note and dissolution. For the dissolution scenario, the cost approach, an adjusted net asset value method was used to determine the net recoverable value of the Company, including an estimate of the fair value of the Company's intellectual property. The estimated fair value of the Company's intellectual property was valued using a relief from royalty method which required management to make significant estimates and assumptions related to forecasts of future revenue, and the selection of the royalty (5.0%) and discount (15.0%) rates.

The fair value of the Baker Notes is subject to uncertainty due to the assumptions that are used in the Monte Carlo simulation-based model. These factors include but are not limited to the Company's future revenue, and the probability and timing of the exercise of the repurchase right. The fair value of the Baker Notes is sensitive to these estimated inputs made by management that are used in the calculation.

January, March and May 2022 Notes

The fair value of the January and March 2022 as well as the May 2022 Notes issued as described in Note 4 - Debt, and subsequent changes in fair value recorded at each reporting date, were determined using a probability weighted expected return method (PWERM) model. PWERM was used to take into account several factors, including the future value of the Company's common stock, a potential change of control event, the probability of meeting certain debt covenants, the maturity term of the January and March 2022 Notes, exercise of the put right and exercise of the Company's call right.

SSNs

The fair value of the SSNs issued as described in Note 4 - Debt, were determined using the methods described above in Valuation Methodology, using the residual value of the Company after the fair value of the Baker Notes. The quarterly valuation adjustments for the year ended December 31, 2023 were recorded as a $0.8 million change in fair value of financial instruments attributed to credit risk change in the consolidated comprehensive statement of operations.

Purchase Rights

The Adjuvant Purchase Rights and the May Note Purchase Rights (collectively Purchase Rights) are recorded as derivative liabilities in the consolidated balance sheets. The Purchase Rights are valued using an OPM, like a Black-Scholes Methodology with changes in the fair value being recorded in the consolidated statements of operations. The assumptions used in the OPM are considered level 3 assumptions and include, but are not limited to, the market value of invested capital, the cumulative equity value of the Company as a proxy for the exercise price and the expected term the Purchase Rights will be held prior to exercise and a risk-free interest rate.

Warrants

The warrants contain a provision, under which the holders can force settlement in cash if the Company does not have sufficient shares authorized to satisfy the warrants. As such, the warrants were recorded as derivative liabilities in the consolidated balance sheet as of December 31, 2022. In accordance with ASC 815, warrants previously classified as equity instruments were determined to be liability classified (the Reclassified Warrants) due to the Company having an insufficient number of authorized shares as of December 31, 2022; however, the impacted warrants were reclassified as equity instruments during the second quarter of 2023 as a result of the Reverse Stock Split. The Company will continue to re-evaluate the classification of its warrants at the close of each reporting period to determine their proper balance sheet classification. The warrants are valued using an OPM based on the applicable assumptions, which include the exercise price of the warrants, time to expiration, expected volatility of our peer group, risk-free interest rate, and expected dividends. The assumptions used in the OPM are considered level 3 assumptions and include, but are not limited to, the market value of invested capital, the cumulative equity value of the Company as a proxy for the exercise price, the expected term the warrants will be held prior to exercise, a risk-free interest rate and probability of change of control event. Additionally, as the warrants are re-priced under certain provisions in the agreements, at each re-pricing event, the Company must value the warrants using a Black-Scholes model immediately prior to and immediately following the re-pricing event. The incremental fair value is recorded as an increase to accumulated deficit and additional paid-in-capital, in accordance with ASC 470.

The Company recorded a $0.2 million adjustment into accumulated deficit in the consolidated statement of convertible and redeemable preferred stock and stockholders' deficit during the year ended December 31, 2023 in accordance with ASC 260, *Earnings per Share* (ASC 260), related to the down round features triggered due to reset of exercise price for equity classified warrants.

7. Commitments and Contingencies

Operating Leases

Fleet Lease

In December 2019, the Company and Enterprise FM Trust (the Lessor) entered into a Master Equity Lease Agreement whereby the Company leases vehicles to be delivered by the Lessor from time to time with various monthly costs depending on whether the vehicles are delivered for a term of 24 or 36 months, commencing on each corresponding delivery date. The leased vehicles are for use by eligible employees of the Company's commercial operations team. As of December 31, 2023, there was a total of 21 leased vehicles. The Company maintained a letter of credit as collateral in favor of the Lessor, which was included in restricted cash in the consolidated balance sheet as December 31, 2022. This letter of credit was $0.3 million, which was released by the Lessor during the first quarter of 2023. The Company determined that the leased vehicles are accounted for as operating leases under ASC 842, *Leases* (ASC 842). In September 2022, the Company extended the lease term for an additional 12 months for the vehicles with a term of 24 months. The Company determined that such extension is accounted for as a modification, for which the Company reassessed the lease classification and the incremental borrowing rate on the modification date and accounted for accordingly.

2020 Lease and the First Amendment

On October 3, 2019, the Company entered into an office lease for approximately 24,474 square feet (the High Bluff Premises) pursuant to a non-cancelable lease agreement (the 2020 Lease). The 2020 Lease commenced on April 1, 2020 with an expiry of September 30, 2025, unless terminated earlier in accordance with its terms. The Company provided the landlord with a $0.8 million security deposit in the form of a letter of credit for the High Bluff Premises.

On April 14, 2020, the Company entered into the first amendment to the 2020 Lease for an additional 8,816 rentable square feet of the same office location (the Expansion Premises), which commenced on September 1, 2020 with an expiry of September 30, 2025. The Company provided an additional $0.05 million in a letter of credit for the Expansion Premises. As of December 31, 2022, restricted cash maintained as collateral for the Company's security deposit was $0.8 million.

On March 20, 2023, the Company received a notice of default from its landlord for failing to timely pay March 2023 rent, resulting in a breach under the agreement. As a result, the Company's letter of credit in the amount of $0.8 million, in restricted cash, was recovered by the landlord. In June 2023, the Company reached a settlement with the landlord. As a result of such settlement, the Company reversed its associated remaining ROU assets of $3.3 million and lease liabilities of $4.2 million and recognized a gain of $0.2 million.

2022 Sublease

On May 27, 2022, the Company entered into a sublease agreement with AMN Healthcare, Inc. (AMN), pursuant to which the Company agreed to sublease 16,637 rentable square feet of the High Bluff Premises to AMN for a term commencing on June 15, 2022 and ending coterminous with the 2020 Lease on September 30, 2025, in exchange for the sum of approximately $0.1 million per month, subject to an annual 3.5% increase each year. Gross sublease income was $0.3 million and $0.6 million for the years ended December 31, 2023 and 2022, respectively. The sublease was terminated along with the settlement of the 2020 Lease in June 2023.

Lease Cost (in thousands)	Classification	Years Ended December 31, 2023	2022
Operating lease expense	Research and development	$ 127	$ 210
Operating lease expense	Selling and marketing	360	886
Operating lease expense	General and administrative	339	597
Total		$ 826	$ 1,693

Lease Term and Discount Rate	Years Ended December 31, 2023	2022
Weighted Average Remaining Lease Term (in years)	0.75	2.68
Weighted Average Discount Rate	12%	12%

Maturity of Operating Lease Liabilities (in thousands)	December 31, 2023
Year ending December 31, 2024	$ 47
Year ending December 31, 2025	62
Year ending December 31, 2026	5
Total lease payments	114
Less imputed interest	(9)
Total	$ 105

Other information (in thousands)	Years Ended December 31, 2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows in operating leases	$ 1,524	$ 2,639

Other Contractual Commitments

In November 2019, the Company entered into a supply and manufacturing agreement with a third-party to manufacture Phexxi, with potential to manufacture other product candidates, in accordance with all applicable current good manufacturing practice regulations. There were no purchases under the supply and manufacturing agreement for the year ended December 31, 2023 and $1.0 million for the year ended December 31, 2022.

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. During the year ended December 31, 2023, the Company settled a portion of its trade payables with numerous vendors, which resulted in a $2.1 million reduction in trade payables. As of December 31, 2023, there were no claims or actions pending against the Company which management believes has a probable or reasonably possible probability of an unfavorable outcome. However, the Company may receive trade payable demand letters from its vendors that could lead to potential litigation. As of December 31, 2023, approximately 90% of the Company's trade payables were greater than 90 days past due.

On December 14, 2020, a trademark dispute captioned TherapeuticsMD, Inc. v Evofem Biosciences, Inc., was filed in the US District Court for the Southern District of Florida against the Company, alleging trademark infringement of certain trademarks owned by TherapeuticsMD under federal and state law (Case No. 9:20-cv-82296). On July 18, 2022, the Company settled the lawsuit with TherapeuticsMD, with certain requirements which may need to be performed within two years.

In April 2023, the Company received a Paragraph IV certification notice letter regarding an Abbreviated New Drug Application ("ANDA") submitted to the FDA by Padagis Israel Pharmaceuticals Inc. (Padagis). The ANDA sought approval from the FDA to commercially manufacture, use, or sell a generic version of Phexxi® under 21 U.S.C. § 355(j) prior to the expiration of US Patent Nos. 10,568,855; 11,337,989; and 11,439,610 listed in the FDA's Orange Book (collectively the "Phexxi Patents").

On June 1, 2023, the Company filed a complaint for patent infringement in the US District Court for the District of New Jersey. The complaint alleges that Padagis' proposed generic version of Phexxi infringes the Phexxi Patents. The Company subsequently filed a substantively identical action in the US District Court for the District of Delaware.

On August 7, 2023, Padagis filed its Answer and Defenses to Complaint for Patent Infringement and Defendant's Counterclaims.

On September 18, 2023, Padagis withdrew the Paragraph IV certification in the previously-submitted ANDA and instead converted to a Paragraph III certification. With the pivot to Paragraph III certification, rather than challenging the Phexxi patents and seeking approval of the ANDA prior to expiration of any of these patents, Padagis is instead now asking the FDA to wait until after all the Phexxi patents expire before issuing final approval of the ANDA. The latest-expiring Phexxi patents do not expire until 2033.

Both companies requested dismissal on September 21, 2023. The case was dismissed on September 22, 2023.

Intellectual Property Rights

In 2014, the Company entered into an amended and restated license agreement (the Rush License Agreement) with Rush University Medical Center (Rush University) pursuant to which Rush University granted the Company an exclusive, worldwide license of certain patents and know-how related to its multipurpose vaginal pH modulator technology. For the U.S. patent that the Company licensed from Rush University, three Orders Granting Interim Extension (OGIEs) were received from the USPTO, extending the expiration of this patent to March 2024. Pursuant to the Rush License Agreement, the Company is obligated to pay Rush University an earned royalty based upon a percentage of net sales in the range of mid-single digits until the expiration of this patent. In September 2020, the Company entered into the first amendment to the Rush License Agreement, pursuant to which the Company is also obligated to pay a minimum annual royalty amount of $0.1 million to the extent the earned royalties do not equal or exceed $0.1 million commencing January 1, 2021. Such royalty costs, included in cost of goods sold, were $0.7 million and $1.1 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, approximately $1.1 million and $0.6 million were included in accrued expenses in the consolidated balance sheets.

8. Stockholders' Deficit

Warrants

In April and June 2020, pursuant to the Baker Bros. Purchase Agreement, as discussed in Note 4 - Debt, the Company issued warrants to purchase up to 2,732 shares of common stock in a private placement at an exercise price of $4,575 per share. The Second Baker Amendment provides that the exercise price of the Baker Warrants will equal the conversion price of the Baker Notes. The exercise price of the Baker warrants was multiple times in 2023 and to $0.0615 per share as of December 31, 2023.

In January 2022, pursuant to the January 2022 Securities Purchase Agreement as discussed in Note 4 - Debt, the Company issued warrants to purchase up to 8,003 shares of the Company's common stock in a registered direct offering at an exercise price of $735 per share. In March 2022, pursuant to the March 2022 Securities Purchase Agreement as discussed in Note 4 - Debt, the Company issued warrants to purchase up to 8,303 shares of common stock in a registered direct offering at an exercise price of $897.56 per share.

In May 2022, pursuant to the exchange agreement as described in Note 4 - Debt, the Company issued common warrants to purchase up to 6,666 shares of common stock at an exercise price of $309.56 per share. The warrants have a five-year term and were exercisable beginning on May 4, 2022.

In May 2022, pursuant to the May 2022 Public Offering as described below, the Company issued common warrants to purchase up to 568,000 shares of common stock at an exercise price of $93.75 per share, and pre-funded warrants to purchase up to 102,680 shares of common stock at an exercise price of $0.125 per share. The warrants have a five-year term and were exercisable beginning May 24, 2022. The common warrants contain (and the pre-funded warrants contained) customary 4.99% and 19.99% limitations on exercise provisions. The exercise price and number of shares issuable upon exercise of the common warrants is subject to adjustment for certain dilutive issuances, stock splits and similar recapitalization transactions. During the year ended December 31, 2022, all pre-funded warrants were exercised for an immaterial amount of cash and 282,518 shares of common warrants were exercised for total proceeds of $25.2 million.

In June 2022, as required by the Second Baker Amendment, the Company issued the June 2022 Baker Warrants to purchase up to 582,886 shares of the Company's common stock, $0.0001 par value per share. The June 2022 Baker Warrants have an exercise price of $93.75 per share and a five-year term and were exercisable beginning June 28, 2022. The June 2022 Baker Warrants also contain customary 4.99% and 19.99% limitations on exercise provisions. The exercise price and number of shares issuable upon exercise of the June 2022 Baker Warrants is subject to adjustment for certain dilutive issuances, stock splits and similar recapitalization transactions. The exercise price of these warrants reset multiple times in 2023 and to $0.0615 per share as of December 31, 2023.

In February, March, April, July, August, and September 2023, pursuant to the SSNs as discussed in Note 4 - Debt, the Company issued warrants to purchase up to 1,152,122 shares of the Company's common stock at an exercise price of $2.50 per share, up to 2,615,383 shares of the Company's common stock at an exercise price of $1.25 per share and up to 22,189,349 shares of the Company's common stock at an exercise price of $0.13 per share. The exercise price of these warrants reset multiple times in 2023 and to $0.0615 per share as of December 31, 2023.

On December 21, 2023, warrants to purchase up to 9,972,074 shares of the Company's common stock were exchanged for 613 shares of the Company's Series F-1 Shares.

As of December 31, 2023, warrants to purchase up to 21,053,694 shares of the Company's common stock remain outstanding at a weighted average exercise price of $2.43 per share. In accordance with ASC 815, certain warrants previously classified as equity instruments were determined to be liability classified (the Reclassified Warrants) due to the Company having an insufficient number of authorized shares as of December 31, 2022; however, the impacted warrants were reclassified back to as equity instruments during the second quarter of 2023 as a result of the May 2023 Reverse Stock Split. The Company will continue to re-evaluate the classification of its warrants at the close of each reporting period to determine the proper balance sheet classification for them. These warrants are summarized below:

Type of Warrants	Underlying common stock to be Purchased		Exercise Price	Issue Date	Exercise Period
Common Warrants	4	$	6,918.75	June 11, 2014	June 11, 2014 to June 11, 2024
Common Warrants	451	$	14,062.50	May 24, 2018	May 24, 2018 to May 24 2025
Common Warrants	888	$	11,962.50	April 11, 2019	October 11, 2019 to April 11, 2026
Common Warrants	1,480	$	11,962.50	June 10, 2019	December 10, 2019 to June 10, 2026
Common Warrants	1,639	$	0.0615	April 24, 2020	April 24, 2020 to April 24, 2025
Common Warrants	1,092	$	0.0615	June 9, 2020	June 9, 2020 to June 9, 2025
Common Warrants	8,003	$	735.00	January 31, 2022	March 1, 2022 to March 1, 2027
Common Warrants	8,303	$	897.56	March 1, 2022	March 1, 2022 to March 1, 2027
Common Warrants	6,666	$	309.56	May 4, 2022	May 4, 2022 to May 4, 2027
Common Warrants	894,194	$	0.0615	May 24, 2022	May 24, 2022 to May 24, 2027
Common Warrants	582,886	$	0.0615	June 28, 2022	May 24, 2022 to June 28, 2027
Common Warrants	49,227	$	0.0615	December 21, 2022	December 21, 2022 to December 21, 2027
Common Warrants	130,461	$	0.0615	February 17, 2023	February 17, 2023 to February 17, 2028
Common Warrants	258,584	$	0.0615	March 20, 2023	March 20, 2023 to March 20, 2028
Common Warrants	615,384	$	0.0615	April 5, 2023	April 5, 2023 to April 5, 2028
Common Warrants	164,848	$	0.0615	July 3, 2023	July 3, 2023 to July 3, 2028
Common Warrants	799,999	$	0.0615	August 4, 2023	August 4, 2023 to August 4, 2028
Common Warrants	12,721,893	$	0.0615	September 27, 2023	September 27, 2023 to September 27, 2028
Prefunded Warrants	4,807,692	$	0.0010	September 27, 2023	September 27, 2023 to September 27, 2028
Total	21,053,694				

Preferred Stock

Effective December 15, 2021, the Company amended and restated its certificate of incorporation, under which the Company is currently authorized to issue up to 5,000,000 shares of total preferred stock, including the authorized convertible and redeemable preferred stock designated for Series B-1 and B-2, Series C, Series E-1, and Series F-1, and nonconvertible and redeemable preferred stock (Series D), par value $0.0001 per share.

Convertible and Redeemable Preferred Stock

In October 2021, the Company issued 5,000 shares of Series B-1 Convertible Preferred Stock, par value $0.0001 per share, at a price of $1,000.00 per share, and 5,000 shares of Series B-2 Convertible Preferred Stock, par value $0.0001 per share, at a price of $1,000.00 per share to Keystone Capital Partners (Keystone Capital) through a registered direct offering.

The Series B-1 and B-2 Convertible Preferred Stock were convertible into shares of common stock at any time at a conversion price per share of the greater of Fixed Conversion Price or Variable Conversion Price as defined. All 5,000 shares of B-1 Convertible Preferred Stock were converted into 4,232 shares of the Company's common stock in 2021 at a conversion price of $1,181.25. Pursuant to the terms of the Series B-2 Convertible Preferred Stock, the Fixed Conversion Price was adjusted during the first quarter of 2022 for certain dilutive issuances. The adjustment period ended on April 25, 2022 and the Fixed Conversion Price was fixed at $332.50 from the sale of common stock pursuant to the Seven Knots Purchase Agreement. During March and April 2022, Keystone Capital converted their 1,200 shares of B-2 Convertible Preferred Stock into 2,347 shares of the Company's common stock at a conversion price of $587.50 per share.

On March 24, 2022, the Company, entered into an exchange agreement with the holder of its Series B-2 Convertible Preferred Stock, pursuant to which the holder agreed to exchange 1,700 shares of the Series B-2 Convertible Preferred Stock in consideration for 1,700 shares of the Company's Series C Convertible Preferred Stock, par value $0.0001 per share, $1,000.00 per share stated value. Except with respect to voting provisions, the Series C and Series B-2 Preferred Stock had substantially similar terms.

On May 4, 2022, pursuant to the May 2022 Exchange, the remaining 2,100 shares of Series B-2 Convertible Preferred Stock and 1,700 shares of Series C Convertible Preferred Stock were exchanged for Senior Subordinated Notes with an aggregate principal amount of $4.8 million and warrants to purchase up to 6,666 shares of common stock.

On August 7, 2023, the Company filed a Certificate of Designation of Series E-1 Convertible Preferred Stock (Certificate of Designation), par value $0.0001 per share (the Series E-1 Shares). An aggregate of 2,300 shares was authorized. The Series E-1 Shares are convertible into shares of common stock at a conversion price of $0.40 per share and are both counted toward quorum on the basis of and have voting rights equal to the number of shares of common stock into which the Series E-1 Shares are then convertible. The Series E-1 Shares are senior to all common stock with respect to preferences as to dividends, distributions and payments upon a dissolution event. In the event of a liquidation event, the Series E-1 Shares are entitled to receive an amount per share equal to the Black Scholes Value as of the liquidation event plus the greater of 125% of the conversion amount (as defined in the Certificate of Designation) and the amount the holder of the Series E-1 Shares would receive if the shares were converted into common stock immediately prior to the liquidation event. If the funds available for liquidation are insufficient to pay the full amount due to the holders of the Series E-1 Shares, each holder will receive a percentage payout. The Series E-1 Shares are entitled to dividends at a rate of 10% per annum or 12% upon a triggering event. Dividends are payable in shares of common stock and may, at the Company's election, be capitalized and added to the principal monthly. The Series E-1 Shares also have a provision that allows them to be converted to common stock at a conversion rate equal to the Alternate Conversion Price (as defined in the Certificate of Designation) times the number of shares subject to conversion times the 25% redemption premium in the event of a Triggering Event (as defined in the Certificate of Designation) such as in a liquidation event. The Series E-1 Shares are mandatorily redeemable in the event of bankruptcy.

On August 7, 2023, certain investors party to the December 2022 Notes and the February 2023 Notes exchanged $1.8 million total in principal and accrued interest under the outstanding convertible promissory notes for 1,800 shares of Series E-1 Shares (the August 2023 Preferred Stock Transaction). Per the Series E-1 Convertible Preferred Stock Certificate of Designation, the conversion rate can also be adjusted in several future circumstances, such as on certain dates after the exchange date and upon the issuance of additional convertible securities with a lower conversion rate or in the instance of a Triggering Event. As such, the conversion price as of December 31, 2023 was adjusted to $0.0615 per share. The Series E-1 Shares are classified as mezzanine equity within the consolidated balance sheets in accordance with ASC 480 because of a fixed 25% redemption premium upon a Triggering Event and no mandatory redemption feature. During the year ended December 31, 2023, $1.8 million was recorded as an increase to additional paid-in-capital for the preferred shares in the consolidated statement of convertible and redeemable preferred stock and stockholders' deficit related to the August 2023 Preferred Stock Transaction and a dividend of $0.1 million was recorded as an increase to the number of Series E-1 Shares outstanding.

On December 11, 2023, the Company filed a Certificate of Designation of Series F-1 Convertible Preferred Stock (F-1 Certificate of Designation), par value $0.0001 per share (the Series F-1 Shares). An aggregate of 95,000 shares was authorized. The Series F-1 Shares are convertible into shares of common stock at a conversion price of $0.0635 per share and do not have the right to vote on any matters presented to the holders of the Company's common stock. The Series F-1 Shares are senior to all common stock and subordinate to the Series E-1 Shares with respect to preferences as to dividends, distributions and payments upon a dissolution event. In the event of a liquidation event, the Series F-1 Shares are entitled to receive an amount per share equal to the Black Scholes Value as of the liquidation event plus the greater of 125% of the conversion amount (as defined in the F-1 Certificate of Designation) and the amount the holder of the Series F-1 Shares would receive if the shares were converted into common stock immediately prior to the liquidation event. If the funds available for liquidation are insufficient to pay the full amount due to the holders of the Series F-1 Shares, each holder will receive a percentage payout. The Series F-1 Shares are not entitled to dividends. The Series F-1 Shares also have a provision that allows them to be converted to common stock at a conversion rate equal to the Alternate Conversion Price (as defined in the F-1 Certificate of Designation) times the number of shares subject to conversion times the 25% redemption premium in the event of a Triggering Event (as defined in the F-1 Certificate of Designation) such as in a liquidation event. The Series F-1 Shares are mandatorily redeemable in the event of bankruptcy.

On December 21, 2023, the Company issued a total of 22,280 Series F-1 Shares to certain investors, including 613 shares exchanged for warrants to purchase up to 9,972,074 shares of the Company's common stock and 21,667 shares to exchange a partial value of the outstanding purchase rights. The holders of the Series F-1 Shares immediately exchanged their Series F-1 Shares to Aditxt's Series A-1 preferred stock, and as a result, Aditxt currently holds the Company's Series F-1 Shares. The Series F-1 Shares will be cancelled upon the consummation of the Merger.

Effective December 15, 2021, the Company amended and restated its certificate of incorporation, under which the Company is currently authorized to issue up to 5,000,000 shares of preferred stock, $0.0001 par value per share.

Nonconvertible and Redeemable Preferred Stock

On December 16, 2022, the Company filed a Certificate of Designation of Series D Non-Convertible Preferred Stock, par value $0.0001 per share (the Series D Preferred Shares). An aggregate of 70 shares was authorized; these shares were not convertible into shares of common stock, had limited voting rights equal to 1% of the total voting power of the then-outstanding shares of common stock entitled to vote, were not entitled to dividends, and were required to be redeemed by the Company once its shareholders approved a reverse split, as described in the Certificate of Designation. All 70 shares of the Series D Preferred were subsequently issued in connection with the December 2022 Securities Purchase Agreement as discussed in Note 4 - Debt. The Series D Preferred Shares, which were classified as liabilities as of December 31, 2022, were redeemed in July 2023.

Common Stock

Effective September 14, 2023, the Company further amended its amended and restated certificate of incorporation to increase the number of authorized shares of common stock to 3,000,000,000 shares.

Public Offerings

In May 2022, the Company completed an underwritten public offering (the May 2022 Public Offering), whereby the Company issued 181,320 shares of common stock and common warrants (the May Common Stock Warrants) to purchase 362,640 shares of common stock at a price to the public of $93.75. The common warrants have an exercise price of $93.75 per share, a five-year term, and were exercisable beginning on May 24, 2022. In the May 2022 Public Offering the Company also issued pre-funded warrants to purchase 102,680 shares of common stock and common warrants to purchase 205,360 shares of common stock at a price to the public of $93.63. The pre-funded warrants had an exercise price of $0.125 per share, were exercisable beginning on May 24, 2022, and were fully exercised after completion of this offering. The Company received proceeds from the May 2022 Public Offering of $18.1 million, net of $5.9 million debt repayment, underwriting discounts and offering expenses. As discussed above in *Warrants*, the May Common Stock Warrants were impacted by dilution adjustments and the strike price was reset to $0.0615 in December 2023.

Common Stock Purchase Agreement

On February 15, 2022, the Company entered into a common stock purchase agreement (the Stock Purchase Agreement) with Seven Knots, LLC (Seven Knots), pursuant to which Seven Knots agreed to purchase from the Company up to $50.0 million in shares of the Company's common stock. Sales made to Seven Knots were at the Company's sole discretion, and the Company controlled the timing and amount of any and all sales. The price per share was based on the market price of the Company's common stock at the time of sale as computed under the Stock Purchase Agreement. As consideration for Seven Knots' commitment to purchase shares of common stock, the Company issued 1,025 shares of common stock to Seven Knots as commitment fee shares.

Sales of common stock to Seven Knots were subject to customary 4.99% and 19.99% beneficial ownership limitations. The Stock Purchase Agreement had a termination date of the earliest of March 1, 2024, or when Seven Knots has purchased from the Company $50.0 million in shares of the Company's common stock, or as otherwise determined by the Stock Purchase Agreement at the Company's option.

Effective May 18, 2022, the Company and Seven Knots elected to terminate the Stock Purchase Agreement without any penalty or additional cost to the Company. Prior to termination, the Company issued a total of 15,714 shares of common stock under the Stock Purchase Agreement for aggregate net proceeds of $7.4 million.

Unregistered shares

On June 8, 2022, the Company entered into an agreement for services with a360 Media, LLC (a360 Media), pursuant to which a360 Media will provide professional media support and advertising services in exchange for, at a360 Media's option, either (a) $860,119 in cash, or (b) 18,547 shares of the Company's common stock at a value of $46.38 per share. On July 18, 2022, the Company and a360 Media entered into a similar agreement for professional media support and advertising services in exchange for, at a360 Media's option, either (a) $1,409,858 in cash, or (b) 12,802 shares of the Company's common stock at a value of $110.13 per share. On August 15, 2022, the Company and a360 Media entered into a similar agreement for professional media support and advertising services in exchange for, at a360 Media's option, either (a) $1,142,048 in cash, or (b) 22,558 shares of the Company's common stock at a value of $50.63 per share. Pursuant to these three agreements, the company issued an aggregate 53,908 unregistered shares of the Company's common stock to a360 Media. These shares were issued in reliance upon an exemption from registration afforded by Section 4(a)(2) promulgated under the Securities Act of 1933, as amended. The Company evaluated the a360 Media agreement and determined that in accordance with ASC 480 and ASC 718, *Compensation-Stock Compensation* (ASC 718), the common stock issued to a360 should be equity classified and recorded as a prepaid asset in the consolidated balance sheets. As the requisite service condition was met throughout 2022, the Company recognized the noncash stock-based compensation expense during the year ended December 31, 2022 and no prepaid asset related to these shares remained as of December 31, 2022.

Purchase Rights

On September 15, 2022, the Company entered into certain exchange agreements with the Adjuvant Purchasers and the May 2022 Notes Purchasers to exchange, upon request, the Purchase Rights for an aggregate of 942,080 shares of the Company's common stock. The number of right shares for each Purchase Right is initially fixed at issuance, but subject to certain customary adjustments for certain dilutive Company equity issuances until the second anniversary of issuance. These Purchase Rights expire on June 28, 2027. Refer to Note 6 - Fair Value of Financial Instruments for the accounting treatment of the Purchase Rights. In 2023, the Company subsequently signed an additional agreement with the holders of the Purchase Rights upon which the total aggregate value of the Purchase Rights is fixed at $24.7 million, to be paid in a variable number of shares based on the current exercise price.

In connection with the SSNs issuances, during the year ended December 31, 2023, the Company increased the number of outstanding Purchase Rights by 380,821,882 due to the reset of its exercise price, recorded as a loss on issuance of financial instruments in the amount of $4.3 million in the Consolidated Statements of Operations. The exercise price will also be adjusted if any other convertible instruments have price resets. In addition, the Company issued 16,534,856 shares of common stock upon the exercises of certain Purchase Rights during the year ended December 31, 2023.

On December 21, 2023, the Company issued 21,667 shares of the Series F-1 Shares in exchange for a partial value of certain purchase rights, as described above.

As of December 31, 2023, Purchase Rights of 385,312,084 shares of the Company's common stock remained outstanding.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance, on a one-for-one basis, is as follows in common equivalent shares as of December 31, 2023:

Common stock issuable upon the exercise of stock options outstanding	3,747
Common stock issuable upon the exercise of common stock warrants	21,053,694
Common stock available for future issuance under the 2019 ESPP	509
Common stock available for future issuance under the Amended and Restated 2014 Plan	5,789
Common stock available for future issuance under the Amended Inducement Plan	609
Common stock reserved for the exercise of purchase rights	385,312,084
Common stock reserved for the conversion of convertible notes	616,497,236
Common stock reserved for the conversion of series E-1 Shares	30,472,989
Common stock reserved for the conversion of Series F-1 Shares	370,731,708
Total common stock reserved for future issuance	1,424,078,365

9. Stock-based Compensation

Equity Incentive Plans

The following table summarizes stock-based compensation expense related to stock options, restricted stock awards (RSAs) and RSUs granted to employees, non-employee directors and consultants, and the 2019 ESPP (as defined below) included in the consolidated statements of operations as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Research and development	$ 117	$ 553
Sales and marketing	188	497
General and administrative	884	2,263
Total	$ 1,189	$ 3,313

The 2012 Equity Incentive Plan (the 2012 Plan) provides for the issuance of RSAs, RSUs, 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. No further awards may be issued under the 2012 Plan.

On September 15, 2014, the Company's board of directors adopted, and stockholders approved, the 2014 Equity Incentive Plan (the 2014 Plan), which was amended and restated on each of May 2018 and February 26, 2019 (the Amended and Restated 2014 Plan). Per the terms of the Amended and Restated 2014 Plan, the shares reserved will automatically increase on each January 1 through 2024, by an amount equal to the smaller of (i) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31; or (ii) an amount determined by our board of directors. There was no increase to the shares reserved under the plan on January 1, 2023 or 2024.

On July 24, 2018, upon the recommendation by the Compensation Committee, the Company's board of directors adopted the Evofem Biosciences, Inc. 2018 Inducement Equity Incentive Plan (the Inducement Plan). Under the Inducement Plan, as amended, the number of authorized shares total 666 shares. The only persons eligible to receive awards under the Inducement Plan are individuals who satisfy the standards for inducement grant recipients under Nasdaq Marketplace Rule 5635(c)(4), generally, a person not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with the Company.

Stock Options

The following table summarizes share option activity for the years ended December 31, 2023:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	5,672	$ 7,761.25	5.1	-
Granted	-	$ -	-	-
Exercised	-	$ -	-	-
Forfeited	(1,925)	$ 9,363.75	-	-
Outstanding as of December 31, 2023	3,747	$ 6,950.00	6.3	-
Options expected to vest as of December 31, 2023	3,747	$ 6,950.00	6.3	-
Options vested and exercisable as of December 31, 2023	3,153	$ 7,798.75	6.1	-

The following table summarizes certain information regarding stock options for the year ended December 31, 2022 (in thousands, except per share data). No such activities occurred during the year ended December 31, 2023.

	2022
Weighted average grant date fair value per share of options granted during the period	645.00
Cash received from options exercised during the period	-
Intrinsic value of options exercised during the period	-

As of December 31, 2023, unrecognized stock-based compensation expense for employee stock options was approximately $1.1 million, which the Company expects to recognize over a weighted-average remaining period of 1.7 years, assuming all unvested options become fully vested.

Summary of Assumptions

The fair value of noncash stock-based compensation for stock options granted to employees and non-employees was estimated on the date of grant using the Black-Scholes option pricing model based on the following weighted-average assumptions for options granted for the periods indicated.

	Year Ended December 31, 2022
Expected volatility	102.5%
Risk-free interest rate	2.0%
Expected dividend yield	—%
Expected term (years)	6.0

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* (ASC 718), which is the midpoint between the requisite service period and the contractual term of the option.

Restricted Stock Awards

There were no shares of performance-based RSAs granted in 2023 to the Company's executive management team.

For performance-based RSAs, (i) the fair value of the award is determined on the grant date; (ii) the Company assesses the probability of achieving each individual milestone associated with the award using reasonable assumptions based on the Company's operation performance towards each milestone; (iii) the fair value of the shares subject to the milestone is expensed over the implicit service period commencing once management believes the performance criteria is probable of being met; and (iv) the Company reassesses the probability of achieving each individual milestone at each reporting date, and (v) any change in estimate is accounted for through a cumulative adjustment in the period when the change in estimate occurs. Non-performance based RSAs are valued at the fair value on the grant date and the associated expenses will be recognized over the vesting period.

As of December 31, 2023, there was no unrecognized noncash stock-based compensation expense related to unvested RSAs.

Of the total RSAs granted during the year ended December 31, 2022, no shares vested in accordance with the Company's achievement of the Performance-based RSAs milestones. The following table summarizes RSAs activity for the year ended December 31, 2022:

	Shares (RSAs)	Weighted Average Fair Value per Share
Unvested as of December 31, 2021	—	$ —
Granted	1,258	$ 917.50
Forfeited	(1,258)	$ 917.50
Released	—	$ —
Unvested as of December 31, 2022	—	$ —

Employee Stock Purchase Plan

On May 7, 2019, the board of directors approved a 2019 Employee Stock Purchase Plan (the 2019 ESPP), which was approved by stockholders at the 2019 annual meeting held on June 5, 2019. The 2019 ESPP initially authorized the issuance of 266 shares of common stock pursuant to purchase rights were granted to employees. In addition, the number of shares available for issuance under the 2019 ESPP will increase on January 1 of each year until the first day of 2029, in an amount equal to the lesser of (i) 533 shares, (ii) 2% of the shares of common stock outstanding on the preceding December 31, or (iii) such lesser number of shares as is determined by the board of directors. This provision resulted in an additional 133 shares added to the total number of authorized shares on January 1, 2022. The 2019 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 2019 ESPP enables eligible full-time and part-time employees to purchase shares of the Company's common stock through payroll deductions of between 1% and 15% of eligible compensation during an offering period. A new offering period begins around June 15 and December 15 of each year. At the last business day of each offering period, the accumulated contributions made during the offering period will be used to purchase shares. The purchase price is 85% of the lesser of the fair market value of the common stock on the first or the last business day of an offering period. The maximum number of shares of common stock that may be purchased by any participant during an offering period will be equal to $25,000 divided by the fair market value of the common stock on the first business day of an offering period. During the year ended December 31, 2022, there were 601 shares of common stock purchased under the 2019 ESPP. In October 2022, the Board terminated the current offering period ending December 15, 2022, refunded all employee contributions, and suspended future offering periods.

The Company did not recognize any stock-based compensation expense related to the 2019 ESPP for the year ended December 31, 2023 and $0.1 million in noncash stock-based compensation expense for the year ended December 31, 2022. There were no shares of common stock purchased under the 2019 ESPP during the year ended December 31, 2023.

The fair value of shares to be issued to employees under the 2019 ESPP is estimated using a Black-Scholes option-pricing model at the grant date, which requires the use of subjective and complex assumptions, including (i) the expected stock price volatility, (ii) the calculation of the expected term of the award, (iii) the risk-free interest rate and (iv) the expected dividend yield. The following weighted average assumptions were used in the calculation of fair value of shares under the 2019 ESPP at the grant dates for the year ended December 31, 2022.

	Year Ended December 31,
	2022
Expected volatility	177.2%
Risk-free interest rate	2.3%
Expected dividend yield	—%
Expected term (years)	0.5

10. Employee Benefits

The Company has a defined contribution 401(k) plan (401(k) Plan) for all qualifying employees. Employees are eligible to participate in the plan beginning on the first day of the month following their three-month anniversary of employment. Under the terms of the 401(k) Plan, employees may make voluntary contributions as a percentage of their compensation. The Company makes a safe-harbor contribution of three percent (3.0%) of each employee's gross earnings, subject to Internal Revenue Service limitations. In the years ended December 31, 2023 and 2022, the Company made safe-harbor contributions of approximately $0.2 million and $0.6 million, respectively.

11. Income Taxes

The Company is subject to taxation in the US and various states jurisdictions. Tax years since inception remain open to examination by the major taxing jurisdictions. The Company's consolidated pretax income (loss) for the years ended December 31, 2023 and 2022 were generated by domestic as follows (in thousands). There are no consolidated pretax losses generated by foreign operations for the periods indicated.

	2023	2022
US	$ 52,996	$ (76,654)
Total	$ 52,996	$ (76,654)

The income tax provision for the years ended December 31, 2023 and 2022 consisted of the following (in thousands):

	2023	2022
US	$ -	$ -
State	(17)	(44)
Total current tax provision	(17)	(44)
Total deferred tax provision	-	-
Total	$ (17)	$ (44)

The reconciliation between the Company's effective tax rate on income (loss) before income tax and the statutory tax rate for the years ended December 31, 2023 and 2022 was as follows:

	2023	2022
Statutory rate	21.00%	21.00%
State income tax, net of federal benefit	(0.39)%	2.12%
Nondeductible expenses	0.23%	(0.41)%
Equity-based expenses	3.04%	(1.82)%
Change in fair value of purchase rights	(1.93)%	22.60%
Change in fair value of financial instruments	(27.17)%	(20.00)%
Return to provision	0.18%	(0.47)%
Tax credits	(0.44)%	1.41%
Uncertain tax positions	0.12%	(0.39)%
Change in valuation allowance	5.37%	(24.11)%
Effective tax rate	(0.01)%	(0.07)%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's net deferred tax assets arising from its taxable subsidiaries consisted of the following components as of December 31, 2023 and 2022 (in thousands):

	2023	2022
Deferred tax assets:		
Net loss carryforwards	$ 130,746	$ 126,056
Fixed assets and intangibles	246	338
Research and development capitalization	4,067	4,951
Research and development credits	6,320	6,136
Stock-based compensation	2,513	3,367
Other	1,098	2,247
Total deferred tax assets	144,990	143,095
Deferred tax liabilities		
Lease assets	(22)	(1,011)
Fixed assets	(156)	(113)
Other	(27)	(29)
Less: valuation allowance	(144,785)	(141,942)
Net deferred tax assets	$ -	$ -

In assessing the ability to realize deferred tax assets, management considers whether it is more likely than not that some portion or all the deferred tax assets will be realized. Generally, the ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based on historical performance and future expectations, management has determined a valuation allowance is needed in respect to its ending deferred tax assets.

As of December 31, 2023, the Company had net operating loss (NOL) carryforwards for federal income tax purposes of approximately $569.4 million, which will begin to expire in 2029 if not utilized. As of December 31, 2023, the Company had NOL carryforwards in various states of approximately $226.8 million. The state carryforwards have varying expiration dates beginning in 2029.

As of December 31, 2023, the Company had federal and state research and development (R&D) tax credit carryforwards of approximately $6.4 million and $2.5 million, respectively. The federal R&D tax credits begin to expire in 2031, unless utilized, and the state credits do not expire.

For the tax years beginning on or after January 1, 2022, the Tax Cuts and Jobs Act of 2017 ("TCJA") eliminates the option to currently deduct research and development expenses and requires taxpayers to capitalize and amortize them over five years for research activities performed in the US and 15 years for research activities performed outside the US pursuant to IRC Section 174. Although Congress is considering legislation that would repeal or defer this capitalization and amortization requirement, it is not certain that this provision will be repealed or otherwise modified. If the requirement is not repealed or replaced, it will decrease our tax deduction for research and development expense in future years.

The following table summarized the activity related to the Company's gross unrecognized tax benefits as of December 31, 2023 and 2022 (in thousands):

	2023	2022
Balance at the beginning of the year	$ 2,988	$ 2,679
Adjustments related to prior year tax positions	55	5
Increases related to current year tax positions	8	304
Decreases due to statute of limitation expiration	-	-
Balance at end of year	$ 3,051	$ 2,988

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits, and uncertain income tax positions must meet a more likely than not recognition threshold to be recognized. The Company recognizes interest and penalties related to unrecognized tax benefits within the income tax expense line in the consolidated statements of operations. There were no accrued interest and penalties associated with unrecognized tax benefits as of December 31, 2023. The Company does not anticipate a significant change in its uncertain tax benefits over the next 12 months.

Management believes it is more likely than not that all significant tax positions taken to date would be sustained by the relevant taxing authorities. Furthermore, the Company has not recognized any tax benefits to date because the Company has established a full valuation allowance for its deferred tax assets due to uncertainties as to their ultimate realization.

Pursuant to Internal Revenue Code (IRC) sections 382 and 383, use of the Company's NOLs and R&D credit carryforwards may be limited if a cumulative change in ownership of more than 50.0% (by value) occurs within a rolling three-year period. The Company completed a formal Section 382 analysis through the period ending December 31, 2019, and determined it experienced ownership changes in 2010 and 2018. Accordingly, the Company has reduced its deferred tax asset for NOLs and R&D tax credits by the estimated impact of IRC sections 382 and 383 as of December 31, 2019. Any future ownership changes could further impact the utilization of the NOLs and R&D tax credits, however given the full valuation allowance this would not result in an impact to the Company's tax expense.

12. Out of Period Adjustments

In connection with the preparation of the Annual Report on Form 10-K for the year ended December 31, 2023, the Company discovered an error related to the classification of Purchase Rights in the interim condensed consolidated financial statements for the three and six months ended June 30, 2023 and the three and nine months ended September 30, 2023 (the Interim Periods). The Annual Report on Form 10-K for the year ended December 31, 2022 and the three months ended March 31, 2023 were not impacted by the error.

The Purchase Rights were appropriately classified as a derivative liability as of December 31, 2022 and March 31, 2023. When the Company completed the Reverse Stock Split in May 2023, all derivative liabilities were reclassified to equity as the common stock reservation requirement deficit that had previously prevented several instruments from being classified as equity was remedied. However, the Purchase Rights should have remained liability classified due to a subsequent agreement signed with the holders of the Purchase Rights upon which the Purchase Rights have a fixed value, to be paid in a variable number of shares based on the current exercise price, which requires liability treatment per ASC 480. Upon discovery, the Company reclassified the previously recorded carrying value of the Purchase Rights back to derivative liability in the fourth quarter of 2023 and subsequently marked the instruments to fair value as of December 31, 2023 (see Note 6 – Fair Value of Financial Instruments for more information about the current balances and valuation methodology).

Adjustments have been retrospectively made to the comparative periods as of and for the six months ended June 30, 2023 and nine months ended September 30, 2023 to reflect the adjustments described herein and will be presented in subsequent interim filings. The correction of this classification error does not have any impact on the Company's revenues, operating expenses, cash balance, or liquidity. The net impact of the adjustment on the Condensed Consolidated Balance Sheet as of June 30, 2023 was an reclassification to increase derivative liabilities and decrease additional paid-in capital. There was no impact to the Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2023. The net impact of the adjustment on the Condensed Consolidated Balance Sheet as of September 30, 2023 was an increase of $5.4 million to derivative liabilities, a reduction of additional paid-in capital of $5.8 million, an increase to accumulated other comprehensive income (loss) of $0.9 million and an increase to accumulated deficit of $0.4 million.

13. Subsequent Events

On February 26, 2024, Aditxt and the Baker Purchasers entered into an Assignment Agreement (the February Assignment Agreement), pursuant to which the Company consented to the assignment of all remaining amounts due under the Baker Notes back to the original Holders, the Baker Purchasers.

On February 29, 2024, the Company entered into the third amendment to the Merger Agreement to (i) Amend and restate Section 6.10 in its entirety as follows: "Parent Equity Investment. On or prior to (a) April 1, 2024, Parent shall purchase 2,000 shares of the Company's Series F-1 Shares, par value $0.0001 per share for an aggregate purchase price of $2.0 million (the Initial Parent Equity Investment) and (b) April 30, 2024, Parent shall purchase 1,500 shares of F-1 Preferred Stock for an aggregate purchase price of $1.5 million (the Subsequent Parent Equity Investment). (ii) the provision in Section 6.16 was deleted in its entirety, (iii) the date to file a Joint Proxy Statement was extended to April 30, 2024, (iv) a new Section 7.2(i) was added as follows "(i) *Repurchase Price*. No defaults shall have occurred and be continuing under the Loan Documents and the Outstanding Balance (as defined in the Securities Purchase Agreement) plus all accrued and unpaid interest thereon, in an amount not to exceed the Repurchase Price (as defined in the Securities Purchase Agreement) shall have been paid in full." and (v), Section 8.1(f) is amended and restated to allow for termination of the Merger Agreement by the Company if (a) the Initial Parent Equity Investment has not been made by April 1, 2024, or (b) the Subsequent Parent Equity Investment has not been made by April 30, 2024.

EVOFEM BIOSCIENCES, INC.

INSIDER TRADING POLICY

1. Purpose of this Policy. The purchase or sale of securities while possessing material non-public information or the disclosure of inside information to others who may trade in such securities is sometimes referred to as "insider trading" and is prohibited by federal and state securities laws. As an essential part of your work, you may have access to material non-public information about Evofem Biosciences, Inc., its divisions and majority-owned or controlled subsidiaries (collectively, "***Evofem***"), including information about other companies with which Evofem does, or may do, business. Evofem has adopted this Insider Trading Policy (the "***Policy***") to assist Evofem in preventing illegal insider trading and to avoid even the appearance of improper conduct on the part of any Evofem's director, officer, employee or contractor. This Policy is designed to protect and further Evofem's reputation for integrity and ethical conduct. However, the ultimate responsibility for complying with the securities laws, adhering to this Policy and avoiding improper transactions rest with you. It is imperative that you use your best judgment and that you ask questions where you are uncertain how to handle a particular situation.

2. Policy Statement. This memorandum sets forth the Policy of Evofem regarding the trading in Evofem's securities as described below and the disclosure or use of information concerning Evofem. Employees, consultants, contractors, officers, members of the Board of Directors and entities (such as trusts, limited partnerships and corporations) over which such individuals have or share voting control (individually referred to as a "***person***" and collectively referred to as "***persons***") are prohibited, while aware of material non-public information, directly, or indirectly through family members or other persons or entities, from engaging in transactions involving Evofem securities, except as otherwise provided for under this Policy.

3. Penalties for Insider Trading. The penalties for violating the insider trading laws include imprisonment, disgorgement of profits gained or losses avoided, and substantial civil and criminal fines. As of the effective date of this policy civil fines can reach up to three times the profit gained or loss avoided, and criminal fines can reach up to $5.0 million for individuals and $25.0 million for entities. Individuals and entities considered to be "control person" who knew or recklessly disregarded the fact that a "controlled person" was likely to engage in insider trading also may be civilly liable. As of the effective date of this policy the civil liability of "control persons" can be the greater of (i) $1.0 million or (iii) three times the amount of the profit gained or loss avoided. For this purpose, a "control person" is an entity or person who directly or indirectly controls another person, and could include Evofem, its directors and officers. Under some circumstances, individuals who trade on inside information may also be subjected to private civil lawsuits. Moreover, as the material non-public information of Evofem is the property of Evofem, trading on or tipping Evofem confidential information could result in serious employment sanctions, including dismissal.

You should be aware that the surveillance techniques of the stock markets and the Financial Industry Regulatory Authority ("***FINRA***") are becoming more sophisticated all the time, and the chance that authorities will detect and prosecute even a small insider trading violation is a significant one.

4. Questions and Delivery of the Policy. To the extent you have any questions related to this Policy or the topics addressed hereby, please contact Evofem's Chief Financial Officer.

This Policy will be delivered to all existing persons covered by the Policy upon its adoption by Evofem, and to all new directors, employees, officers and where appropriate, contractors and consultants, at the commencement of their employment or association with Evofem. Thereafter, the Policy shall be distributed annually or posted on Evofem's internal website where it is accessible to all regular full-time employees. All persons covered under this Policy must certify their understanding of, and intent to comply with, this Policy. A copy of the certification that all persons covered by this Policy must sign is attached hereto as Exhibit A.

5. This Policy Also Applies to Trading in Other Companies' Securities. In addition, the restrictions imposed by this Policy extend to transactions involving securities of other public companies, such as customers or suppliers of Evofem and companies with which Evofem may be negotiating major transactions, such as an acquisition, joint venture, collaboration, investment or sale. Information that is not material to Evofem may nevertheless be material to the other company. Therefore, a person who is aware of material non-public information about another public company, whether or not the person obtained the information in the course of working for or providing services to Evofem, is subject to restrictions on trading in securities of that company or communicating that information to others.

6. Transactions Covered. "***Trading***" includes purchases and sales of securities such as stock, bonds, debentures, options, puts, calls and any other securities. Examples of the types of covered transactions include:

(a) Open Market Transactions. A person is prohibited from trading, while aware of material non-public information, in any securities in the open market.

(b) Stock Options. A person is prohibited, while aware of material non-public information, from selling in the open market (e.g., in a broker-assisted cashless exercise or any other market sale for the purpose of generating the cash needed to pay the exercise price or taxes or for any other purpose) any of the underlying shares of the stock option.

However, while aware of material non-public information about Evofem, a person may receive a stock option grant and grants of stock options may vest. In addition, a person may exercise a stock option while aware of material non-public information, but only if the person pays the exercise price and applicable taxes in cash or via a net exercise with Evofem (i.e., that does not involve a sale of shares in the market place) or if you deliver stock you hold in Evofem as payment for the exercise price, if such options allow for a net exercise.

(c) Restricted Stock and Restricted Share Units. A person is prohibited, while aware of material non-public information, from selling in the open market any of the underlying shares of restricted stock or restricted share units awarded to that person.

However, while aware of material non-public information about Evofem, a person may receive an award of restricted stock or restricted share units. In addition, awards of restricted stock or restricted share units may vest while a person is aware of material non-public information, and Evofem may withhold shares to cover taxes due upon vesting.

7. No Trading by Others on a Person's Behalf. When a person is prohibited from trading in Evofem securities because he or she is aware of material non-public information, he or she may not have a third-party trade in securities on his or her behalf or disclose such information to any third party, other than on a need-to-know basis. Any trades made by a third party on behalf of a person will be attributed to that person. Thus, trades in Evofem shares held in street name in a person's account or for his or her benefit at a brokerage firm are also prohibited if the person is otherwise prohibited from trading in Evofem securities. If a person invests in a "managed account" or arrangement (other than a Rule 10b5-1 plan discussed below), he or she should instruct the broker or advisor not to trade in Evofem securities on his or her behalf.

8. No Tipping. When a person is prohibited from trading in Evofem securities because he or she is aware of material non-public information, he or she may not disclose material non-public information about Evofem to a third party unless the third party (i) owes a duty of confidence to Evofem (e.g., an attorney, auditor or investment banker retained by Evofem) or (ii) is subject to a confidentiality agreement in favor of Evofem in which the person has agreed or is obligated to keep the information confidential. If that third party trades in Evofem securities, the person who communicated the information (as well as the third party) may be held personally liable under federal (or state) law for violation of securities laws. This practice, known as "***tipping***," violates the securities laws and also can result in the same civil and criminal penalties that apply to insider trading, whether or not the person personally derives any benefit from the third party's actions. This prohibition includes giving trading advice without actually disclosing material non-public information, such as a general statement that, "I would sell now if I were you, but I can't tell you why." As with each of the prohibitions on trading while aware of material non-public information discussed in this Policy, the prohibition on tipping also applies to material non-public information regarding securities of other public companies. Regardless of whether a person covered by this Policy is aware of material non-public information, they are prohibited from posting messages about Evofem or its securities in Internet chat rooms, bulletin boards, blogs or other similar means of electronic distribution, whether under actual or fictitious names.

9. Persons Covered. The same restrictions on insider trading that apply to a person also apply to a person's family members who reside with the person, anyone else who lives in his or her household, and any family members who do not live in his or her household but whose transactions in Evofem or other securities are directed by the person or are subject to his or her influence or control (such as parents or children who consult the person before they trade in Evofem or other securities). Every person is responsible to ensure that trading in any securities by any such third party complies with this Policy.

10. Definition of Material Non-public Information.

(a) Material Information. Information is material if there is a substantial likelihood that a reasonable investor would consider it important in making an investment decision (i.e., deciding whether to buy, hold or sell a security). Therefore, any information that could reasonably be expected to affect the price of the security is potentially material. Both positive and negative information can be material. Common examples of information that may be material are:

(i) Projections of future earnings or losses;

(ii) Earnings that are inconsistent with external guidance from Evofem or with market expectations;

(iii) News of a pending or proposed merger, acquisition or tender offer;

(iv) News of a significant sale of assets or the expansion or curtailment of operations (including a significant new contract or loss of business);

(v) Significant changes in dividend policies or the declaration of a stock split;

(vi) Significant changes in senior management or membership of the Board of Directors;

(vii) Significant new products or discoveries;

(viii) Significant regulatory actions, including receipt or denial of a significant regulatory application for clearance or approval of products;

(ix) The gain or loss of, or a significant change to the terms of Evofem's relationship with, a substantial customer or supplier;

(x) The commencement of, or significant development regarding, any significant litigation;

(xi) A decision by Evofem to borrow a significant amount of money;

(xii) A decision by Evofem to offer securities in a public or private offering or repurchase or redeem any Evofem securities currently owned by the public;

(xiii) A significant change in Evofem's capital expenditure program; and

(xiv) Significant shifts in operating or financial circumstances.

The foregoing are merely examples and should not be treated as an all-inclusive list. There may be other developments not listed above that may be material as well.

The materiality of information is determined on a case-by-case basis in light of all the facts and circumstances. All securities transactions will be viewed after-the–fact with the benefit of hindsight. As a result, before engaging in any transaction, a person should carefully consider how regulators and others might view his or her transaction in hindsight.

(b) Non-public Information. "***Non-public***" information is information that Evofem, or another company if applicable has not released publicly, either by a press release or a filing with the U.S. Securities and Exchange Commission, or is not otherwise available publicly. As a general rule, information is not considered to be "***public***" until the end of the second-trading day after an announcement by Evofem is broadly disseminated. Therefore, a person who was aware of the material information prior to its public release should not engage in any open market transactions in Evofem's securities until at least the opening of trading on the NASDAQ Stock Exchange (***"NASDAQ"***) or other applicable national stock exchange (collectively, "***Applicable Exchange***"), as applicable, on the third-trading day after such information is publicly released (i.e., the next trading day after two full trading days has elapsed since the release of such information), whether through a report filed with the SEC or through major news wire services, or recognized news services. For example, if an announcement is made on a Monday before trading on the Applicable Exchange opens (i.e., before 9:00 a.m. (EST)), a person who was aware of the information in the announcement prior to its public release would not be able to trade until the opening of trading on the Applicable Exchange on Wednesday. If an announcement is made after trading on the Applicable Exchange closes on a Monday, but before trading on the Applicable Exchange opens on Tuesday (i.e., before 9:30 a.m. (EST)), such person would not be able to trade until the opening of trading on the Applicable Exchange on Thursday.

11. Short-Term, Speculative, Hedging and Margin Transactions are Prohibited. All persons covered by this Policy, including, Directors, Section 16 officers, employees, consultants, contractors and related entities are strictly prohibited from engaging in short-term or speculative transactions involving Evofem securities, such as publicly traded options, short sales, puts and calls, and hedging transactions, the Chief Financial Officer or one of his or her designees provides prior written approval. This prohibition also applies to holding Evofem securities in a margin account and "short sales against the box," which are sales of Evofem securities where a person does not deliver the shares he or she owns to settle the transaction but instead delivers other shares that his or her broker has borrowed from others. All persons subject to this Policy must obtain the specific prior written authorization of the Chief Financial Officer before engaging in short-term or speculative transactions involving Evofem securities.

12. Material Non-Public Information Must Be Kept Confidential. Material non-public information about Evofem or its business partners is the property of Evofem, and unauthorized disclosure or use of that information is prohibited. That information should be maintained in strict confidence and should be discussed, even within Evofem, only with persons who have a "need to know." You should exercise the utmost care and circumspection in dealing with information that may be material non-public information. Conversations in public places, such as hallways, elevators, restaurants and airplanes, involving information of a sensitive or confidential nature should be avoided. Written information should be appropriately safeguarded and should not be left where it may be seen by persons not entitled to the information. The unauthorized disclosure of information could result in serious consequences to Evofem, whether or not the disclosure is made for the purpose of facilitating improper trading in securities.

13. Participation in Electronic Bulletin Boards, Chat Rooms, Blogs or Websites Must Be Consistent with this Policy. Any written or verbal statement that would be prohibited under the law or under this policy is equally prohibited if made on electronic bulletin boards, chat rooms, blogs, websites or any other form of social media, including the disclosure of material non-public information about Evofem or material non-public information with respect to other companies that you come into possession of as an associate of Evofem.

14. Public Disclosures Made By Designated Persons Only. No individuals other than specifically authorized personnel should release material information to the public or respond to inquiries from the media, analysts, investors or any others outside of Evofem. You should not respond to these inquiries unless expressly authorized to do so, and should refer any inquiries to Evofem's Chief Financial Officer, or Head of Investor Relations.

15. Post-Employment Transactions. If a person is aware of material non-public information about Evofem when his or her employment terminates, this Policy's restrictions on trading and communicating material non-public information will continue to apply. Such a person may not trade in Evofem securities until that information has become public or is no longer material. In addition, since stock options generally expire 90 days after termination, the person should refer to the stock option section above for guidance regarding exercising stock options that may expire while he or she is aware of material non-public information. A person also may contact the Chief Financial Officer or his or her designee to further discuss their alternatives in this circumstance.

16. Blackout Period. Directors, Section 16 officers and certain other persons designated by the Chief Financial Officer ("***Blackout Covered Individuals***") may not trade in securities in the open market during a no-trade period ("***Blackout Period***"). Each person designated by the Chief Financial Officer as a Blackout Covered Individual shall be notified of such designation, and Evofem shall maintain a list of all Blackout Covered Individuals. An exception to this prohibition may apply for transactions effected pursuant to a pre-approved Rule 10b5-1 plan as discussed below. The quarterly Blackout Period begins on the twentieth (20^{th}) of the last month of every fiscal quarter and continues until the second-trading day after Evofem's earnings for that quarter are publicly released. The Chief Financial Officer may impose additional Blackout Periods for all or some Blackout Covered Individuals and other employees when Evofem may be aware of material non-public information as the Chief Financial Officer deems necessary or appropriate. All Blackout Covered Individuals also are subject to all other restrictions in this Policy.

In addition, the Sarbanes-Oxley Act of 2002 prohibits all trades of Evofem securities by Directors and Section 16 officers of Evofem during a "***pension fund blackout period***." A pension fund blackout period exists whenever 50% or more of the participants in a Evofem benefit plan are unable to conduct transactions in their Evofem common stock accounts for more than three (3) consecutive business days. These blackout periods typically occur when there is a change in the benefit plan's trustee, record keeper or investment manager. Individuals that are subject to these blackout periods will be contacted when these periods are instituted from time to time.

17. Pre-Clearance for Directors, Section 16 Officers and Section 16 Filings.

(a) Each Director and Section 16 officer must obtain pre-clearance from the Chief Financial Officer or one of his or her designees before engaging in the following transactions (including any transactions by their immediate family members) in Evofem securities: purchases; sales; transactions in his or her 401(k) plan or deferred compensation plan; transactions in an IRA or Roth IRA; and for Section 16 officers, any other transactions that are required to be reported under Section 16 of the Securities Exchange Act. Such Director and Section 16 Officer must obtain pre-clearance in the manner set forth in Paragraph 15 below.

(b) Each Director and Section 16 officer must file with the SEC a Form 3 within ten (10) days of becoming an insider to report his or her beneficial ownership of Evofem's securities, including unvested options and restricted stock units. The Chief Financial Officer will prepare and manage the filing of the Form 3 for new Directors, if requested, and Section 16 officers.

(c) SEC Form 4 must be filed within two (2) business days of a reportable transaction by all Directors and Section 16 officers. Reportable transactions do not include gifts, inheritances and transfers to trusts which do not involve a transaction between the Director or Section 16 officer, as applicable, and Evofem. Directors and Section 16 officers may obtain the Form 4 from the Chief Financial Officer, and should have a signed power of attorney on file with the Chief Financial Officer prior to entering into any Section 16 transactions. The Chief Financial Officer will file the completed and signed Form 4 with the SEC electronically, unless instructed otherwise by the Director or Section 16 officer. Directors and Section 16 officers should notify the Chief Financial Officer if they wish to file the Form 4 themselves, to avoid duplicate filings. Evofem must disclose in its periodic reports filed with the SEC any transactions by Directors and Section 16 officers which were not timely reported.

18. Pre-Clearance for Directors, Section 16 Officers and Other Insiders.

(a) Insiders who are Directors, Section 16 Officers and other individuals designated by the Chief Financial Officer as "***Covered Individual Requiring Pre-Clearance for Trades***," must obtain pre-clearance from the Chief Financial Officer or one of his or her designees before trading in Evofem securities.

(b) The Covered Individual Requiring Pre-Clearance for Trades must notify the Chief Financial Officer of the amount and nature of the proposed trade(s) using the Pre-Clearance Request form attached in substantially the form hereto as Exhibit B.

(c) If practicable, the Pre-Clearance Form should be submitted to the Chief Financial Officer at least two business days prior to the date of the intended trade date.

(d) The existence of this approval process does not obligate the Chief Financial Officer to approve any particular trade requested by a Covered Individual Requiring Pre-Clearance for Trades. From time to time, an event may occur that is material to Evofem and is known by only a few Directors or Executives. So long as the event remains material and non-public, the Chief Financial Officer may determine not to approve any transactions in Evofem's securities. If a Covered Individual Requiring Pre-Clearance for Trades requests clearance to trade in Evofem's securities during the pendency of such an event, the Chief Financial Officer may reject the trading request without disclosing the reason.

(e) After receiving written clearance to engage in a trade by the Chief Financial Officer, a Covered Individual Requiring Pre-Clearance for Trades must complete the proposed trade within five (5) business days of the intended date disclosed on the Pre-Clearance Form or make a new trading request.

(f) Each person designated by the Chief Financial Officer as a Covered Individual Requiring Pre-Clearance for Trades shall be notified of such designation, and Evofem shall maintain a list of all Covered Individual Requiring Pre-Clearance for Trades

19. Rule 10b5-1 Plans. Under SEC Rule 10b5-1, a person may have an affirmative defense to insider trading liability for transactions in Evofem securities that are effected pursuant to a written contract or plan meeting certain requirements. In short, the rule presents an opportunity for a person to pre-arrange a sale or purchase of Evofem securities (including an option exercise), provided that, at the time the person establishes such a plan, he or she is not aware of material non-public information.

In order to satisfy Rule 10b5-1, a plan must:

(a) Be documented in writing to instruct another person who is not aware of material non-public information to execute the transactions;

(b) Be established in good faith and at a time when the person is not aware of material non-public information; and

(c) Specify objective criteria (date, price threshold, etc.) used to determine the timing and terms of the purchase or sale, and otherwise not be subject to any influence or discretion from the person establishing the plan.

In addition, Evofem requires pre-approval by the Chief Financial Officer or one of his or her designees of all Rule 10b5-1 plans relating to Evofem securities established by Directors, Section 16 officers and other Covered Individuals. Such Rule 10b5-1 plan must comply with the terms of the Evofem Biosciences, Inc. Rule 10b5-1 Trading Plan Policy.

20. Responsible party. Evofem's Chief Financial Officer is responsible for administering this Policy.

21. Short-Swing Profits. Note that in addition to this Policy, under Section 16(b) of the Securities Exchange Act of 1934, any "short-swing profits" realized by a Section 16 Officer or a director of the Company (or by a beneficial owner of more than 10% of the Company's securities) from a "matching" purchase and sale or "matching" sale and purchase of Company stock occurring within a six-month period is subject to disgorgement to the Company. Note that under Section 16(b), the highest sale price is matched with the lowest purchase price in determining the maximum recoverable profit, and purchases and sales that result in a loss are ignored— meaning that under these rules, you could be deemed to have a profit to be disgorged even though you actually lose money on your trades in the aggregate. There is an active group of lawyers that track purchases and sales by Section 16 Officers and Directors for violation of these rules.

Revised: March 2024

Exhibit A

CERTIFICATION

I hereby certify that:

- I have read and understand the Insider Trading Policy of Evofem Biosciences, Inc. (the "Company").
- I understand that the Company's Chief Financial Officer is available to answer any questions that I have regarding this Insider Trading Policy, or in his/her absence I should contact the Company's Head of Investor Relations.
- I will continue to comply with the Insider Trading Policy for as long as I am a director, officer, employee, consultant or contractor of the Company.
- I understand that insider trading is a crime, may subject me to serious financial penalties and termination of employment, and is strictly prohibited by the Insider Trading Policy.

Signature | Date

Printed Name (Please print legibly)

Title

Exhibit B

PRE-CLEARANCE FORM

M E M O R A N D U M

To: Ivy Zhang, Chief Financial Officer
From:
Date: _____, 20__
Subject: Proposed Transaction in Company Securities by Directors, Section 16 Officers, and other "Insider" Employees, Consultants and Contractors

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This memorandum is to advise you that the undersigned intends to execute a transaction in the Company's securities on _____, and does hereby request that the Company pre-clear the transaction as required by the Company's Insider Trading Policy for directors, executive officers, senior management, and other "Insider" employees (the "Policy").

The general nature of the transaction is as follows:

( ) Purchase up to _____ shares of Evofem common stock (excludes the exercise of stock options to hold shares)
( ) Sell up to _____ shares of Evofem common stock (includes the exercise of stock options with same day sales)
( ) Other (please describe): _____

_____

_____

I have reviewed and considered the Policy and I represent that am NOT in possession of any material non-public information (as defined in the Policy) about the Company and will not enter into the transaction if I come into possession of material non-public information about the Company between the date hereof and the proposed transaction execution date. Accordingly, I intend to trade securities only during an open window as described in the Policy.

I have read and understand the Policy and certify that the above transaction will not violate the Policy. I understand that certain types of transactions are prohibited and agree not to participate in these types of trades.

I agree to advise the Company promptly if, as a result of future developments, any of the foregoing information becomes inaccurate or incomplete in any respect. If I do not effect the above transaction within three days of the date that the transaction has been approved by the Chief Financial Officer, I agree to resubmit a new pre-clearance request. I also agree to report any stock trades to the Chief Financial Officer.

Signature

Print Name

Date

Approved by the Chief Financial Officer of Evofem Biosciences, Inc.:

Name:

Title:

Date

Exhibit 19.2

EVOFEM BIOSCICENCES, INC.

Incentive Compensation Recoupment Policy

In the event Evofem Biosciences, Inc., (the "Company") determines it must restate its financial results as reported in a Form 10-K, Form 10-Q or other report filed with the Securities and Exchange Commission to correct an accounting error due to material noncompliance with any financial reporting requirement under the U. S. federal securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, (a "Restatement"), the Company will seek to recover, at the direction of the Compensation Committee of the Board of Directors (the "Committee") after it has reviewed the facts and circumstances that led to the requirement for the Restatement, incentive compensation (cash and equity-based) awarded or paid within one year following the filing of the financial report giving rise to the Restatement to a covered officer whose intentional misconduct caused or contributed to the need for the Restatement for a fiscal period if a lower award or payment would have been made to such covered officer based upon the restated financial results. The Committee will determine in its discretion the amount, if any, the Company will seek to recover from such covered officer. The Company may offset the recoupment amount against current incentive and non-incentive compensation otherwise owed to the covered officer and through cancellation of unvested or vested equity awards. In addition, the Committee may, to the extent permitted by law, take other remedial and recovery action, as determined by the Committee. The recoupment of incentive compensation under this Policy is in addition to any other right or remedy available to the Company. The Company shall not indemnify any covered officer against the loss of any incorrectly awarded incentive compensation

For purposes of this Policy, the term "covered officer" shall mean executive officers of the Company as defined under the Securities Exchange Act of 1934, as amended, and such other senior executives as may be determined by the Committee. This Policy extends to individuals who were covered officers on or after adoption of the Policy but ceased being a covered officer before a Restatement triggering recoupment under this Policy occurs. This Policy shall be binding and enforceable against all covered officers and their beneficiaries, heirs, executors, administrators or other legal representatives.

The Committee shall have full and final authority to make all determinations under this Policy. The Company shall take such action as it deems necessary or appropriate to implement this Policy, including requiring all covered officers to acknowledge the rights and powers of the Company and the Committee hereunder.

This Policy shall be effective as of the date adopted by the Board of Directors as set forth below and shall apply to incentive compensation that is approved, awarded or granted on or after that date.

Adopted: By the Board of Directors on February 25, 2021.

Exhibit 21.1

Subsidiaries of Evofem Biosciences, Inc.

Evofem Biosciences Operations, Inc.

Evofem, Inc.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333- 258321, 333-253881, 333-234769, 333-232303, 333-231126 and 333-230191 on Form S-3 and Registration Statement Nos. 333-200409, 333-203059, 333-225366, 333-226517, 333-231991, 333-231993, 333-237119, 333-237126, 333-238228, 333-252516 and 333-263422 on Form S-8 of our report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) dated March 26, 2024, relating to the consolidated financial statements of Evofem Biosciences, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2023.

/s/ BPM, LLP
Walnut Creek, California
March 26, 2024

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333- 258321, 333-253881, 333-234769, 333-232303, 333-231126 and 333-230191 on Form S-3 and Registration Statement Nos. 333-200409, 333-203059, 333-225366, 333-226517, 333-231991, 333-231993, 333-237119, 333-237126, 333-238228, 333-252516 and 333-263422 on Form S-8 of our report dated April 27, 2023 (July 7, 2023, as to the effects of the reverse stock split described in Note 1), relating to the financial statements of Evofem Biosciences, Inc. appearing in the Annual Report on Form 10-K for the year ended December 31, 2023.

/s/ DELOITTE & TOUCHE LLP

San Diego, California

March 26, 2024

Exhibit 31.1

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, Saundra Pelletier, certify that:

1 I have reviewed this annual report on Form 10-K 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

(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: March 27, 2024

By: */s/ Saundra Pelletier*
Saundra Pelletier
President, Chief Executive Officer, and Interim Chairperson of the Board
(Principal Executive Officer)

Exhibit 31.2

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, Ivy Zhang, certify that:

1 I have reviewed this annual report on Form 10-K 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

(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: March 27, 2024

By: */s/ Ivy Zhang*
Ivy Zhang
Chief Financial Officer and Secretary
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Evofem Biosciences, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Annual Report"), each of the undersigned officers of the Company, does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of such officer's knowledge:

(1) The Annual Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2024

By: */s/ Saundra Pelletier*
Saundra Pelletier
President, Chief Executive Officer, and Interim Chairperson of the Board
(Principal Executive Officer)

Date: March 27, 2024

By: */s/ Ivy Zhang*
Ivy Zhang
Chief Financial Officer and Secretary
(Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Evofem Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.