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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2025

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	**20-8527075**
(State or other jurisdiction of incorporation)	**(IRS Employer Identification No.)**
7770 Regents Road, Suite 113-618 San Diego, CA 92122	
(Address of Principal Executive Offices)	**92122 (Zip Code)**

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

N/A
(Former name or former address, if changed since last report.)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None		

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

The number of shares of the registrant's Common Stock, $0.0001 par value per share, outstanding as of November 12, 2025 was 126,685,925.

Table of Contents

FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q (Quarterly 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 Quarterly 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;
- risks and uncertainties related to changes in government operations, including a federal government shutdown, which could delay our ability to offer registered securities, FDA reviews, disrupt supply chains, or affect healthcare reimbursement decisions;
- the Notice of Default and cancellation of Forbearance Agreement received by Future Pak, LLC and any potential legal action(s) against the Company, including that its assets that could be taken and potential negative outcome(s) thereof;
- our ability to successfully commercialize SOLOSEC® (secnidazole) 2g oral granules (SOLOSEC);
- 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(s) needing stockholder, FINRA, Nasdaq, 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 if and as needed;
- 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 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 PHEXX® (formerly known as PHEXXI) (lactic acid, citric acid, and potassium bitartrate) vaginal gel (PHEXX) to patients;
- estimates regarding HCPs' recommendations of SOLOSEC to patients suffering from the sexual health infections for which it is indicated;
- the rate and degree of market acceptance of our products;
- our ability to successfully commercialize and distribute our products and continue to develop our sales and marketing capabilities, particularly after any product rebrand;
- changing the name of our hormone-free birth control product from PHEXXI to PHEXX;
- our estimates regarding the effectiveness of our marketing campaigns;
- our strategic plans for our business, including the commercialization of our products;

- 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 our products absent full or partial third-party payer reimbursement;
- the potential substantial negative impact on contraception access and STI treatment, especially for low-income and uninsured women after the passage of the One Big Beautiful Bill Act;
- 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 products;
- our dependence on third parties for the manufacture of our products;
- 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 Quarterly Report, we caution you that these statements are based on our projections of the future that are subject to known and unknown risks and uncertainties and other factors that may cause our actual results, level of activity, performance or achievements expressed or implied by these forward-looking statements, to differ. 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 Quarterly Report and the documents that we have filed as exhibits to this Quarterly Report and incorporated by reference herein completely and with the understanding that our actual 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 Quarterly Report are made as of the date of this Quarterly Report, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

This Quarterly 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.

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

This Quarterly Report includes our trademarks, trade names and service marks, including “EVOFEM®”, “PHEXX®”, “FEMIDENCE™”, and “SOLOSEC®”, 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 Quarterly 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. FINANCIAL INFORMATION
Item 1. Financial Statements

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except par value and share data)

	As of	
	September 30, 2025	**December 31, 2024**
Assets		
Current assets:		
Cash and cash equivalents	$ -	$ -
Restricted cash	840	741
Trade accounts receivable, net	4,435	9,832
Inventories	1,684	1,577
Prepaid and other current assets	959	1,459
Total current assets	7,918	13,609
Property and equipment, net	420	458
Operating lease right-of-use assets	195	89
Intangible asset, net (Note 7)	5,238	9,597
Other noncurrent assets	36	36
Total assets	$ 13,807	$ 23,789
Liabilities, convertible and redeemable preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 11,624	$ 16,172
Notes - carried at fair value (Note 4)	18,509	14,974
Notes - carried at fair value - Related Party (Note 4)	983	-
Convertible notes, net - Adjuvant - Related Party (Note 4)	32,167	30,769
Short term debt	291	135
Accrued expenses	1,363	5,509
Accrued compensation	3,609	3,494
Operating lease liabilities – current	124	82
Derivative liabilities	1,140	1,359
Contingent liabilities - current (Note 7)	215	592
Other current liabilities	8,161	7,362
Total current liabilities	78,186	80,448
Operating lease liabilities - noncurrent	72	7
Contingent liabilities - noncurrent (Note 7)	5,718	9,809
Total liabilities	83,976	90,264
Commitments and contingencies (Note 7)		
Convertible and redeemable preferred stock, $0.0001 par value, senior to Common Stock		
Series E-1, F-1 and G-1 convertible and redeemable preferred stock, 10,000, 95,000 and 5,000 shares authorized; 2,582 and 2,068 shares of E-1 issued and outstanding as of September 30, 2025 and December 31, 2024, respectively; 26,280 shares of F-1 issued and outstanding at both September 30, 2025 and December 31, 2024 1,587 shares of G-1 issued and outstanding at September 30, 2025 and no such shares issued and outstanding at December 31, 2024	4,897	4,782
Stockholders' deficit:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding at both September 30, 2025 and December 31, 2024	-	-
Common Stock, $0.0001 par value; 3,000,000,000 shares authorized; 123,956,354 and 113,356,354 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	12	11
Additional paid-in capital	831,816	829,026
Accumulated other comprehensive loss	(6,718)	(2,630)
Accumulated deficit	(900,176)	(897,664)
Total stockholders' deficit	(75,066)	(71,257)
Total liabilities, convertible and redeemable preferred stock and stockholders' deficit	$ 13,807	$ 23,789

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

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Product sales, net	$ 4,952	$ 4,496	$ 10,622	$ 12,259
Operating Expenses:				
Cost of goods sold	905	869	2,025	2,322
Gain on change in accounting estimates on contingent royalty liability (Note 7)	(1,933)	-	(1,933)	-
Amortization of intangible asset	80	301	410	301
Research and development, net	470	332	(3,819)	1,196
Selling and marketing	2,391	2,382	7,616	6,970
General and administrative	2,088	3,052	6,296	8,143
Total operating expenses	4,001	6,936	10,595	18,932
Income (loss) from operations	951	(2,440)	27	(6,673)
Other income (expense):				
Interest income	3	3	13	13
Other expense, net	(682)	(562)	(1,944)	(1,736)
Loss on issuance of financial instruments	-	-	-	(3,300)
Gain (loss) on debt extinguishment, net	-	(143)	-	977
Change in fair value of financial instruments	(1,845)	769	(490)	4,896
Total other income (expense), net	(2,524)	67	(2,421)	850
Loss before income tax benefit (expense)	(1,573)	(2,373)	(2,394)	(5,823)
Income tax benefit (expense)	4	8	(3)	-
Net loss	(1,569)	(2,365)	(2,397)	(5,823)
Convertible and redeemable preferred stock deemed dividends	(111)	(5)	(115)	(99)
Net loss attributable to common stockholders	$ (1,680)	$ (2,370)	$ (2,512)	$ (5,922)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.01)	$ (0.02)	$ (0.02)	$ (0.09)
Weighted-average shares used to compute net loss per share attributable to common shareholders, basic and diluted	119,578,093	96,459,121	116,229,614	64,924,454

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

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE OPERATIONS
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net loss	$ (1,569)	$ (2,365)	$ (2,397)	$ (5,823)
Other comprehensive income (loss):				
Change in fair value of financial instruments attributed to credit risk change (Note 4)	(4,162)	(1,069)	(4,088)	(1,001)
Reclassification adjustment related to debt extinguishment	-	143	-	143
Comprehensive loss	$ (5,731)	$ (3,291)	$ (6,485)	$ (6,681)

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

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

	Series E-1 Convertible and Redeemable Preferred Stock		Series F-1 Convertible and Redeemable Preferred Stock		Series G1 Convertible and Redeemable Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2024	2,068	$ 1,979	26,280	$ 2,803	-	-	113,356,354	$ 11	$ 829,026	$ (2,630)	$ (897,664)	$ (71,257)
Stock-based compensation	-	-	-	-	-	-	-	-	70	-	-	70
Change in fair value of financial instruments attributed to credit risk change (Note 4)	-	-	-	-	-	-	-	-	-	647	-	647
Series E-1 Shares dividends	53	3	-	-	-	-	-	-	-	-	(3)	(3)
Net income	-	-	-	-	-	-	-	-	-	-	956	956
Balance as of March 31, 2025	**2,121**	**$ 1,982**	**26,280**	**$ 2,803**	-	-	**113,356,354**	**$ 11**	**$ 829,096**	**$ (1,983)**	**$ (896,711)**	**$ (69,587)**
Issuance of Common Stock upon noncash exercise of purchase rights	-	-	-	-	-	-	5,300,000	1	1	-	-	2
Issuance of Aditxt Notes – Related Party (Note 4)	-	-	-	-	-	-	-	-	2,296	-	-	2,296
Stock-based compensation	-	-	-	-	-	-	-	-	31	-	-	31
Change in fair value of financial instruments attributed to credit risk change (Note 4)	-	-	-	-	-	-	-	-	-	(573)	-	(573)
Series E-1 Shares dividends	179	1	-	-	-	-	-	-	-	-	(1)	(1)
Net loss	-	-	-	-	-	-	-	-	-	-	(1,784)	(1,784)
Balance as of June 30, 2025	**2,300**	**$ 1,983**	**26,280**	**$ 2,803**	-	-	**118,656,354**	**$ 12**	**$ 831,424**	**$ (2,556)**	**$ (898,496)**	**$ (69,616)**
Issuance of Common Stock upon noncash exercise of purchase rights	-	-	-	-	-	-	5,300,000	-	-	-	-	-
Issuance of Series G-1												

convertible and redeemable preferred stock upon conversion of convertible notes (Note 8)	-	-	-	-	1,573	-	-	-	369	-	-	369
Stock-based compensation	-	-	-	-	-	-	-	-	23	-	-	23
Change in fair value of financial instruments attributed to credit risk change (Note 4)	-	-	-	-	-	-	-	-	-	(4,162)	-	(4,162)
Series E-1 and G-1 Shares dividends	282	106	-	-	14	5	-	-	-	-	(111)	(111)
Net loss	-	-	-	-	-	-	-	-	-	-	(1,569)	(1,569)
Balance as of September 30, 2025	**2,582**	**$ 2,089**	**26,280**	**$ 2,803**	**1,587**	**$ 5**	**123,956,354**	**$ 12**	**$ 831,816**	**$ (6,718)**	**$ (900,176)**	**$ (75,066)**

	Series E-1 Convertible and Redeemable Preferred Stock		Series F-1 Convertible and Redeemable Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2023	1,874	$ 1,874	22,280	$ 2,719	20,007,799	$ 2	$ 823,036	$ (849)	$ (888,699)	$ (66,510)
Issuance of Common Stock upon exercise of warrants	-	-	-	-	246,153	-	15	-	-	15
Issuance of Common Stock upon noncash exercise of purchase rights	-	-	-	-	17,725,000	2	87	-	-	89
Issuance of Common Stock upon conversion of notes	-	-	-	-	10,731,443	1	34	-	-	35
Stock-based compensation	-	-	-	-	-	-	237	-	-	237
Change in fair value of financial instruments attributed to credit risk change (Note 4)	-	-	-	-	-	-	-	324	-	324
Series E-1 Shares dividends	47	47	-	-	-	-	-	-	(47)	(47)
Net loss	-	-	-	-	-	-	-	-	(4,809)	(4,809)
Balance as of March 31, 2024	**1,921**	**$ 1,921**	**22,280**	**$ 2,719**	**48,710,395**	**$ 5**	**$ 823,409**	**$ (525)**	**$ (893,555)**	**$ (70,666)**
Issuance of Common Stock upon noncash exercise of purchase rights	-	-	-	-	24,350,000	2	66	-	-	68
Issuance of Common Stock upon conversion of notes	-	-	-	-	9,768,291	1	15	-	-	16
Stock-based compensation	-	-	-	-	-	-	219	-	-	219
Change in fair value of financial instruments attributed to credit risk change (Note 4)	-	-	-	-	-	-	-	(256)	-	(256)
Series E-1 Shares dividends	47	47	-	-	-	-	-	-	(47)	(47)
Net loss	-	-	-	-	-	-	-	-	1,351	1,351
Balance as of June 30, 2024	**1,968**	**$ 1,968**	**22,280**	**$ 2,719**	**82,828,686**	**$ 8**	**$ 823,709**	**$ (781)**	**$ (892,251)**	**$ (69,315)**
Issuance of Common Stock upon noncash exercise of purchase rights	-	-	-	-	17,500,000	2	9	-	-	11
Stock-based compensation	-	-	-	-	-	-	203	-	-	203
Extinguishment of Baker Notes (Note 4)	-	-	-	-	-	-	-	143	-	143

Change in fair value of financial instruments attributed to credit risk change (Note 4)	-	-	-	-	-	-	-	(1,069)	-	(1,069)
Series E-1 Shares dividends	49	5	-	-	-	-	-	-	(5)	(5)
Issuance of Series F-1 Shares to Aditxt (Related Party)	-	-	1,260	67	-	-	1,193	-	-	1,193
Allocation of reinstatement proceeds (Related Party)	-	-	-	-	-	-	316	-	-	316
Net loss	-	-	-	-	-	-	-	-	(2,365)	(2,365)
Balance as of September 30, 2024	**2,017**	**$ 1,973**	**23,540**	**$ 2,786**	**100,328,686**	**$ 10**	**$ 825,430**	**$ (1,707)**	**$ (894,621)**	**$ (70,888)**

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

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine months ended September 30,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (2,397)	$ (5,823)
Adjustments to reconcile net loss to net cash, cash equivalents and restricted cash used in operating activities:		
Loss on issuance of financial instruments	-	3,300
Gain on debt extinguishment	-	(977)
Gain on change in accounting estimates on contingent royalty liability	(1,933)	-
Change in fair value of financial instruments	490	(4,896)
Inventory write-down for excess & obsolescence	178	-
Loss on contingent liability	25	840
Stock-based compensation	124	659
Depreciation	14	25
Amortization of intangible asset	410	301
Noncash interest expense	1,760	1,673
Noncash right-of-use amortization	95	69
Net loss on disposal or impairment of property and equipment	20	11
Gain on accounts payable and accrued expenses settlements	(5,618)	-
Changes in operating assets and liabilities:		
Trade accounts receivable	5,397	345
Inventories	(285)	234
Prepaid and other assets	500	195
Accounts payable	(1,365)	(211)
Accrued expenses and other liabilities	1,016	2,234
Accrued compensation	115	613
Contingent liabilities	(475)	-
Operating lease liabilities	(94)	(69)
Net cash, cash equivalents and restricted cash used in operating activities	(2,023)	(1,477)
Cash flows from investing activities:		
Payments related to asset acquisition	(57)	(509)
Purchases of property and equipment	(2)	(14)
Net cash, cash equivalents and restricted cash used in investing activities	(59)	(523)
Cash flows from financing activities:		
Proceeds from issuance of Aditxt Notes – Related Party	2,425	-
Borrowings under short-term debt and Notes – carried at fair value	383	397
Proceeds from reinstatement of Merger Agreement – Related Party	-	1,000
Proceeds from issuance of preferred stock – Related Party	-	1,260
Payments under short term debt and Notes – carried at fair value	(627)	(515)
Net cash, cash equivalents and restricted cash provided by financing activities	2,181	2,142
Net change in cash, cash equivalents and restricted cash	99	142
Cash, cash equivalents and restricted cash, beginning of period	741	580
Cash, cash equivalents and restricted cash, end of period	$ 840	$ 722
Supplemental disclosure of noncash investing and financing activities:		
Net increase/(decrease) in contingent liabilities	$ (3,950)	$ 13,743
Exchange of convertible notes to Series G-1 convertible and redeemable preferred stock	369	-
Addition to ROU asset and lease liability due to new leases	201	90
Purchases of property and equipment included in accounts payable and accrued expenses	78	78
Series E-1 and G-1 Shares deemed dividends	115	99
Issuance of Common Stock upon exercise of purchase rights	2	168
Issuance of Common Stock upon conversion of notes	-	51
Issuance of Common Stock upon exercise of warrants	-	15
Allocation of reinstatement proceeds – Related Party	-	316
Acquisition related amounts included in accounts payable and accrued expenses	-	70

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

EVOFEM BIOSCIENCES, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED 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, PHEXX®, was approved by the FDA on May 22, 2020, for the prevention of pregnancy and launched in the U.S. in September 2020. PHEXX is the first and only non-hormonal prescription contraceptive vaginal gel. Women use it when they have sex, applying PHEXX 0-60 minutes prior to intercourse. Because PHEXX is hormone-free and non-systemic, it is not associated with side effects of hormonal contraceptive methods, which include depression, weight gain, headaches, loss of libido, mood swings and irritability. Taking hormones may not be right for some women, especially those with certain medical conditions including clotting disorders, hormone-sensitive cancers, diabetes, or a BMI over 30, as well as women who are breast feeding, and / or who smoke. Per National Center for Health Statistics (NCHS)-published data, more than 23.3 million women in the U.S. do not want to get pregnant and will not use a hormonal contraceptive.

The Company acquired global rights to SOLOSEC® on July 14, 2024 and relaunched the brand in November 2024. SOLOSEC is an FDA-approved single-dose oral antimicrobial agent that provides a complete course of therapy for the treatment of two common sexual health infections – bacterial vaginosis (BV) and trichomoniasis. This acquisition aligns with and advances the Company's mission to commercialize innovative and differentiated products for women's sexual and reproductive health.

Outside the U.S., the Company's strategy is to commercialize its products in global markets through commercial partnerships and/or license agreements.

- The Company licensed commercial rights to PHEXX and SOLOSEC in the Middle East and North Africa (MENA) to Pharma 1 Drug Store, LLC, an emerging Emirati health care company (Pharma 1), in July 2024 and May 2025, respectively. Pharma 1 filed for regulatory approval of PHEXX in the United Arab Emirates (UAE) in June 2025 and of SOLOSEC in the UAE in September 2025.
- PHEXX was approved in Nigeria on October 6, 2022, as Femidence™ by the National Agency for Food and Drug Administration and Control.
- PHEXX has also been submitted for approval in Mexico, Ethiopia and Ghana.

Basis of Presentation and Principles of Consolidation

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

The Company's financial statements are presented on a consolidated basis, which include the accounts of the Company and its wholly-owned subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation. The unaudited interim condensed consolidated financial statements do not include all information and disclosures required by GAAP for annual audited financial statements and should be read in conjunction with the Company's consolidated financial statements and notes thereto for the year ended December 31, 2024 included in its Annual Report on Form 10-K as filed with the SEC on March 24, 2025 as amended on March 28, 2025 (the 2024 Audited Financial Statements).

The unaudited interim condensed consolidated financial statements included in this report have been prepared on the same basis as the Company's audited consolidated financial statements and include all adjustments (consisting only of normal recurring adjustments) necessary for a fair statement of the financial position, results of operations, cash flows, and statements of convertible and redeemable preferred stock and stockholders' deficit for the periods presented. The results for the three and nine months ended September 30, 2025 are not necessarily indicative of the results expected for the full year. The condensed consolidated balance sheet as of December 31, 2024 was derived from the 2024 Audited Financial Statements.

Risks, Uncertainties and Going Concern

Any disruptions in the commercialization of PHEXX or SOLOSEC and/or the products' supply chains could have a material adverse effect on the Company's business, results of operations and financial condition.

The condensed 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 are related to the commercialization of PHEXX and, since July 2024, SOLOSEC. Additional activities have included raising capital, identifying alternative manufacturing to lower PHEXX cost of goods sold (COGS), seeking ex-U.S. licensing partners to add non-dilutive capital to the balance sheet and geographically diversify the revenue stream, seeking product in-licensing/acquisition opportunities to expand and diversify the U.S. revenue stream, and establishing and maintaining a corporate infrastructure to support commercial products. The Company has incurred operating losses and negative cash flows from operating activities since inception. As of September 30, 2025, the Company had a working capital deficit of $70.3 million and an accumulated deficit of $900.2 million.

On January 6, 2025, the Company received a written notice from the OTC Markets notifying the Company that, because the closing bid price for the Company's Common Stock was below $0.01 per share for 30 consecutive calendar days, the Company was not compliant with the minimum bid price requirement for continued listing on the OTCQB, as set forth in the OTCQB listing standards, section 2.3 (the Minimum Bid Price Requirement). In accordance with OTCQB Listing Standards, Section 4.1, to regain compliance with the Minimum Bid Price Requirement the Company's closing bid price was required to be equal to or greater than $0.01 for ten consecutive trading days during the 90-day compliance period which ended April 6, 2025.

On April 22, 2025, the Company received a written notice from the OTC Markets that it did not regain compliance with the Minimum Bid Price Requirement during the specified period, and as such, its Common Stock was removed from OTCQB and began trading on the OTC Pink Current (OTCPK) at market open on April 23, 2025. OTC Markets concurrently notified the Company that if the closing bid price for the Company's Common Stock is $0.01 or higher for 30 consecutive calendar days, and the Company meets all of the eligibility requirements listed under Section 1 of the OTCQB Rules, Evofem may request to be moved back to OTCQB.

The Company's Common Stock was moved to and began trading on the Over-the-Counter Integrated Disclosure (OTCID), the new basic reporting market tier launched by the OTC Markets Group, at market open on July 1, 2025.

Management's plans to meet its cash flow needs in the next 12 months include generating recurring product revenue from PHEXX and SOLOSEC, earning milestone payments by achieving certain regulatory milestone under the License and Supply Agreement with Pharma 1 for SOLOSEC, restructuring its current payables, and obtaining additional funding through non-dilutive or dilutive financings, collaborations or partnerships with other companies, including license agreements for PHEXX and/or SOLOSEC in the U.S. or foreign markets, or through other potential business combinations.

The Company anticipates it will continue to incur net losses for the foreseeable future. According to management estimates, liquidity resources as of September 30, 2025, were not sufficient to maintain the Company's cash flow needs for the twelve months from the date of issuance of these unaudited interim condensed 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 PHEXX and/or SOLOSEC, 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 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 condensed 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 interim condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the interim condensed consolidated financial statements and the notes thereto.

Significant estimates affecting amounts reported or disclosed in the interim condensed consolidated financial statements include, but are not limited to: the assumptions used in measuring the revenue gross-to-net variable consideration items; the allowance for expected credit losses estimate; the assumptions used in estimating the fair value of convertible notes, preferred stock, warrants and purchase rights issued; the assumptions used in the valuation of inventory, intangible asset, and contingent liabilities; the useful lives and recoverability of long-lived assets; the assumptions used to estimate the amount due under the contingent Rush Royalty liability; and the valuation of deferred tax assets. 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 (CODM), 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. The Company's CODM assesses performance and decides how to allocate resources for the Company's one operating segment based on consolidated net loss that is reported on the interim condensed consolidated statements of operations. The Company has also evaluated the significant segment expenses incurred by the single segment that are regularly provided to the CODM. The significant segment expenses regularly provided to the CODM are consistent with those reported on the interim condensed consolidated statements of operations and include cost of goods sold, research and development, selling and marketing, and general and administrative. The CODM uses these expense categories, along with data on product sales, net, to make key operating decisions, such as the strategic direction of the Company, pursuing and/or approving product acquisitions, decisions about key personnel, and approving annual operating budgets. The Company manages assets on a consolidated basis as reported on the interim condensed consolidated balance sheets.

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, time deposit and investment 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 condensed 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 is also subject to credit risk related to its trade accounts receivable from product sales. Its customers are located in the U.S. and, expected to begin in the fourth quarter of 2025, in the UAE, and consist of wholesale distributors, retail pharmacies, mail-order specialty pharmacies and, in the UAE, its licensee Pharma 1. 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. As of September 30, 2025 and December 31, 2024, based on the evaluation of these factors, the Company did not record an allowance for expected credit losses.

In the U.S., products are distributed primarily through three major distributors and mail-order pharmacies, which receive service fees calculated as a percentage of the gross sales and a fee-per-unit shipped, respectively. These entities are not obligated to purchase any set number of units; they distribute products on demand as orders are received.

For the three and nine months ended September 30, 2025, the Company's three largest customers combined made up approximately 75% and 74% of its gross product sales, respectively. For the three and nine months ended September 30, 2024, the Company's three largest customers combined made up approximately 80% and 79% of its gross product sales, respectively. As of September 30, 2025 and December 31, 2024, the Company's three largest customers combined made up 83% and 89%, respectively, of its trade accounts receivable balance.

Significant Accounting Policies

There have been no changes to the significant accounting policies that were described in Note 2 – Summary of Significant Accounting Policies of the 2024 Audited Financial Statements in the Company's Annual Report.

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.

Net Loss Per Share

Basic net loss per share attributable to Common Stockholders is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. The net 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 $0.1 million in each of the three and nine months ended September 30, 2025. Such adjustment was immaterial and $0.1 million in the three and nine months ended September 30, 2024, 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 each of the three and nine months ended September 30, 2025 and 2024. 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.

	September 30,	
	2025	**2024**
Options to purchase Common Stock	3,372	3,747
Warrants to purchase Common Stock	263,062,099	20,807,539
Purchase rights to purchase Common Stock	1,508,548,899	1,529,448,899
Convertible debt	2,923,775,388	2,577,050,313
Series E-1 Shares	167,654,737	131,023,274
Series F-1 Shares	1,706,493,507	1,528,571,429
Series G-1 Shares	103,029,458	-
Total[(1)]	6,672,567,460	5,786,905,201

(1) The potentially dilutive securities in the table above include all potentially dilutive securities that are not included in the diluted net loss per share as per GAAP, whereas the total Common Stock reserved for future issuance in Note 8 – Convertible and Redeemable Preferred Stock and Stockholders' Deficit includes the shares that must legally be reserved based on the applicable instruments' agreements.

Recently Adopted Accounting Pronouncements

No significant new standards were adopted during the nine months ended September 30, 2025.

Recently Issued Accounting Pronouncements — Not Yet Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standards setting bodies that are adopted as of the specified effective date.

In October 2023, the FASB issued Accounting Standards Update (ASU) 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*, designed to clarify or improve disclosure and presentation requirements on a variety of topics and align the requirements in the FASB Accounting Standards Codification (ASC) with the SEC regulations. This guidance is effective for the Company no later than June 30, 2027. The Company is still evaluating the impact of ASU 2023-06.

In December 2023, the FASB issued ASU 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 2023-09 will be effective for the Company beginning with the annual filing for the period ending December 31, 2025 and early adoption is allowed. The Company is still evaluating the impact of ASU 2023-09.

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*, which primarily requires disaggregation of specific expense categories in disclosures within the footnotes on an annual and interim basis. ASU 2024-03 is effective for the Company's annual period ending December 31, 2027 and interim periods thereafter. Early adoption is permitted. In January 2025, the FASB issued ASU 2025-01 to clarify the effective date of ASU 2024-03. The Company is still evaluating the impacts of ASU 2024-03 and ASU 2025-01.

In November 2024, the FASB issued ASU 2024-04, *Debt - Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments*, designed to clarify the requirements for accounting for the settlement of a debt as an induced conversion versus as an extinguishment. This guidance is effective for the Company no later than January 1, 2026. The Company is still evaluating the impact of ASU 2024-04.

In July 2025, the FASB issued ASU 2025-05, *Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*, to provide a practical expedient related to the estimation of expected credit losses for current accounts receivable and current contract assets that arise from transactions accounted for under ASC 606. This guidance is effective for the Company no later than January 1, 2026. The Company is still evaluating the impact of ASU 2025-05.

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 condensed consolidated financial statements upon adoption.

3. Revenue

The Company recognizes revenue from the sale of PHEXX and SOLOSEC 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; 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. Any payments received before the Company satisfies its performance obligations are considered deferred revenue until the obligations are satisfied. 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 primarily located in the U.S., and expected to begin in the fourth quarter of 2025, in the UAE, and consist of wholesale distributors, retail pharmacies, and mail-order specialty pharmacies. 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 condensed consolidated balance sheets, net of various allowances as described in the Trade Accounts Receivable policy in Note 2 – Summary of Significant Accounting Policies to the 2024 Audited Financial Statements.

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.

Our products are sold to domestic 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 pharmacies. 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 condensed 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 customers. 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 condensed 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.

Product returns – Domestic 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. PHEXX has a shelf life of 48 months. SOLOSEC has a shelf life of 60 months. The Company uses historical sales and return data to estimate future product returns. Product return estimates are recorded as other current liabilities on the condensed consolidated balance sheets.

Chargebacks – Certain government entities and covered entities (e.g., Veterans Administration, 340B covered entities, group purchasing organizations) are able to purchase products 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 condensed 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 invoiced in arrears. The Company also has a commercial rebate program whereby certain customers receive a rebate as contractually arranged. 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 condensed consolidated balance sheets.

Patient support programs – The Company voluntarily offers a co-pay program 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 associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Patient support program estimates are recorded as other current liabilities on the condensed consolidated balance sheets.

The variable consideration discussed above was recorded in the condensed consolidated balance sheets and consisted of $0.1 million and $0.3 million in contra trade accounts receivable as of September 30, 2025 and December 31, 2024, respectively, and $8.0 million and $7.2 million in other current liabilities as of September 30, 2025 and December 31, 2024, respectively.

4. Debt

Baker Notes (temporarily owned by Aditxt from December 11, 2023 through February 26, 2024 and owned by Future Pak, LLC since July 23, 2024)

On April 23, 2020, the Company entered into a Securities Purchase and Security Agreement (the Baker Bros. SPA) 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 had a five-year term with a cashless exercise provision and were immediately exercisable at any time from their respective issuance date. The April 2020 Baker Warrants expired on April 24, 2025. The June 2020 Baker Warrants expired on June 9, 2025.

The Baker Notes have 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 periods 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 three and nine months ended September 30, 2025 was approximately $2.9 million and $8.5 million, respectively, which was added to the outstanding principal balance. Interest pertaining to the Baker Notes for the three and nine months ended September 30, 2024 was approximately $2.7 million and $7.8 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 at a call price equal to 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 extended, effective upon the Company's achievement of the Financing Threshold, the affirmative covenant to achieve $100.0 million in cumulative net sales of PHEXX by June 30, 2022 to June 30, 2023. Additionally per the First Baker Amendment, if the Company were to issue warrants to purchase capital stock of the Company (or other similar consideration) in any equity financing that closed on or prior to the date on which the Company met the Financing Threshold, 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 to the Baker Purchasers (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 – Convertible and Redeemable Preferred Stock and 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. The exercise price was $0.0154 per share as of September 30, 2025.

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 (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) disclosed top-line results from the *EVOGUARD* clinical trial (the Clinical Trial Milestone) on or before 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 PHEXX 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 (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 waiver of 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 ex-U.S. license agreements 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 achieve $100 million in cumulative net PHEXX 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.

The Company paid the required $1.0 million upfront payment in September 2023 and is required to make 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 PHEXX according to the table below.

Quarterly global net revenue	Quarterly cash payment
≤ $5.0 million	3% of such global net revenues
>$5.0 million and ≤ $7.0 million	3% on net revenue ≤ $5.0 million; 4% on the net revenue over $5.0 million
Greater than $7.0 million	3% on the net revenue ≤ $5.0 million; 4% on the net revenue over $5.0 million and up to $7.0 million; 5% on net revenue over $7.0 million

The quarterly cash payments became payable beginning in the fourth quarter of 2023 and have been timely paid since.

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. Quarterly cash payments that will be treated as Applicable Reductions paid to date as of September 30, 2025, amount to $1.1 million.

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 loss in the condensed consolidated balance sheets. All other changes in fair value were recognized in the condensed consolidated statements of operations.

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 execution of the 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. The Baker Notes were re-assigned back to the Baker Purchasers on February 26, 2024 (the February Assignment Agreement).

Due to the execution of the February Assignment Agreement, the Company reviewed the Baker Notes in accordance with ASC 470. The Baker Notes, having been effectively terminated, were extinguished on February 26, 2024, resulting in removing the fair value of the old Baker Notes of $13.5 million. The newly re-assigned Baker Notes were subsequently recorded at fair value using the valuation methods discussed in Note 6 – Fair Value of Financial Instruments.

On July 23, 2024, the Company consented to the transfer of ownership of the Baker Notes from Baker Brothers Life Sciences, 667, L.P., and Baker Bros. Advisors, LP, each a Delaware limited partnership (collectively, Baker) to Future Pak, LLC (the Assignee) (the July 2024 Assignment). The terms of the Baker Notes were not changed in connection with the assignment from Baker to the Assignee. Due to the July 2024 Assignment, the Company reviewed the Baker Notes in accordance with ASC 470. The Baker Notes, having been effectively terminated, were extinguished on July 23, 2024, resulting in removing the fair value of the old Baker Notes of $12.3 million and the related accumulated other comprehensive income of $0.1 million as of the date of the extinguishment. The newly re-assigned Baker Notes were subsequently recorded at fair value using the valuation methods discussed in Note 6 – Fair Value of Financial Instruments.

The Company did not repurchase the Baker Notes prior to September 8, 2025. As of September 30, 2025, the Baker Notes are recorded at fair value in the condensed consolidated balance sheet as short-term Notes – carried at fair value with a total fair value of $15.2 million, and the total outstanding balance including principal and accrued interest is $117.6 million. As of December 31, 2024, the Baker Notes were recorded at fair value in the condensed consolidated balance sheet as short-term Notes – carried at fair value with a total balance of $13.8 million, and the total outstanding balance including principal and accrued interest was $109.5 million.

On September 27, 2024, the Assignee, as agent for the Purchasers (in such capacity, the Designated Agent), provided a Notice of Event of Default and Reservation of Rights (the September 2024 Notice of Default) relating to the Securities Purchase and Security Agreement dated April 23, 2020, as amended, by and among the Company, Designated Agent, as certain guarantors and the purchasers (each a Purchaser and collectively Purchasers). The September 2024 Notice of Default claims that by entering into arrangements to pay certain existing obligations, including obligations owed to the U.S. Department of Health and Human Services, an Event of Default has occurred under Section 9.1(e) of the Baker Bros. SPA.

According to the Notice of Default, the Designated Agent has accelerated repayment of the outstanding principal balance owed by the Company under the Securities Purchase Agreement. If all Purchasers exercise the Section 5.7 Option (as defined below), the repurchase price would be equal to the total outstanding balance, including principal and accrued interest. Pursuant to Section 5.7(b) of the Baker Bros. SPA, upon the occurrence of an Event of Default, each Purchaser may elect, at its option, to require the Company to repurchase the Note held by such Purchaser (or any portion thereof) at a repurchase price equal to two times the sum of the outstanding principal balance and all accrued and unpaid interest thereon, due within three business days after such Purchaser delivers a notice of such election (the Section 5.7 Option).

On October 27, 2024, the Designated Agent sent an amended and supplemental notice to the Initial Notice of Default (the Amended Notice of Default) which added new claims of default based on the Company's payment agreements of existing obligations, including obligations owed to the U.S. Department of Health and Human Services; allegedly triggering an Event of Default under Section 9.1(e) of the Baker Bros. Purchase Agreement, as amended. Furthermore, the Amended Notice stated that, because the events of default described in the Amended Notice of Default are not the certain prior events of default listed in the Forbearance Agreement (Specified Defaults), the Designated Agent and the holders of the senior secured promissory notes described in the Baker Bros. SPA thereby provided notice to the Company that the Forbearance Agreement was terminated as of October 27, 2024.

On November 8, 2024, the Designated Agent sent an amended and supplemental notice to the Notices (the Third Amended Notice of Default) which added new claims of default based on (i) the Company's failure to maintain a cash position of $1.0 million or greater, as required under Section 5(b) of the Forbearance Agreement (ii) the Company's failure to deliver financial and operating reports in accordance with the timeline required under the Section 8.1(n) of the Baker Stock Purchase Agreement, and (iii) to clarify the outstanding balance under the notes of the Baker Stock Purchase Agreement plus all accrued and unpaid interest thereon, in the sum of approximately is $107.0 million as opposed to the Repurchase Price as defined in the Fourth Amendment.

The Events of Defaults have not been waived or cured. The Company strongly disagrees with the Designated Agent's claim that an Event of Default has occurred. The Company intends to vigorously contest any attempt by the Designated Agent and the Purchasers to exercise their default rights and remedies under the Baker Bros. SPA.

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 or Adjuvant), 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 nine months ended September 30, 2025 was 7.5%.

Interest expense for the Adjuvant Notes consists of the following, and is included in convertible notes, net – Adjuvant on the condensed consolidated balance sheets as of September 30, 2025 and December 31, 2024 and in other expense, net on the condensed consolidated statements of operations for the three and nine months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Coupon interest	$ 599	$ 556	$ 1,763	$ 1,637
Amortization of issuance costs	-	-	-	28
Total	$ 599	$ 556	$ 1,763	$ 1,665

The Adjuvant Notes are convertible, subject to customary 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 volume-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 PHEXX 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 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 volume-weighted average price of the Company's Common Stock is $18,750 per share, or (ii) the Company achieves cumulative net sales of PHEXX 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.

Also on September 15, 2022, the Company 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 (e.g. $2.9 million of the Adjuvant Notes) for rights to receive 109,842 shares of Common Stock (the Adjuvant Purchase Rights). The number of shares for each Adjuvant Purchase Right was initially fixed, but is subject to certain customary adjustments and, until the second anniversary of issuance (i.e., October 14, 2022), adjustments for certain dilutive Company equity issuances. Refer to Note 8 – Convertible and Redeemable Preferred Stock and 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 September 30, 2025, all Adjuvant Purchase Rights remain outstanding and the conversion price of the Adjuvant Notes was $0.0154. Assuming this conversion price per share, the Adjuvant Notes could be converted into 2,088,759,258 shares of Common Stock.

The Adjuvant Notes are accounted for in accordance with authoritative guidance for convertible debt instruments and are classified as current liabilities in the condensed 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 evaluated and is classified as part of stockholders' deficit in accordance with ASC 815, *Derivatives and Hedging* (ASC 815) as of September 30, 2025. See Note 6 - Fair Value of Financial Instruments for a description of the accounting treatment for the Adjuvant Purchase Rights.

The Company was in default of the Adjuvant Notes as of September 30, 2023, due to the failure to meet the cumulative net sales requirement. However, Adjuvant forbore such default in October 2023 and therefore the Company is no longer in default.

As of September 30, 2025, the Adjuvant Notes are recorded in the condensed consolidated balance sheet as convertible notes, net – Adjuvant with a total balance of $32.2 million. The balance is comprised of $22.5 million in principal and $9.7 million in accrued interest. As of December 31, 2024, the Adjuvant Notes were recorded in the condensed consolidated balance sheet as convertible notes, net – Adjuvant with a total balance of $30.8 million. The balance was comprised of $22.5 million in principal and $8.3 million in accrued interest.

On April 10, 2025, Aditxt, the Company and Adjuvant entered into a Call Option Agreement wherein Adjuvant granted to Aditxt, a call option to purchase, at the sole discretion of Aditxt, all of the convertible Adjuvant Notes and Rights to receive Common Stock (the Securities) held by Adjuvant for an aggregate purchase price of $13.0 million. The call option expired on June 30, 2025.

As described in Note 8 – Convertible and Redeemable Preferred Stock and Stockholders' Deficit, on August 22, 2025, the Company entered into an Exchange Agreement with Adjuvant providing for the exchange of a portion of the Adjuvant Notes due in the aggregate original principal and accrued interest amount of approximately $0.4 million into an aggregate 365 shares of Series G-1 Preferred Stock, par value $0.0001 per share (the Series G-1 Shares). The exchange was accounted for as a partial debt extinguishment via delivery of other financial assets and the difference between the carrying value of the extinguished debt and the fair value of the Series G-1 Shares at issuance of approximately $0.4 million was recorded as an increase to capital contribution during the three months ended September 30, 2025.

On October 13, 2025 the Company and the Adjuvant Purchasers entered into a third amendment to the Adjuvant Purchase Agreement (the Adjuvant Third Amendment).

The Adjuvant Third Amendment amends certain provisions including updating the date that the Adjuvant Notes will be payable in full to the earlier of (a) six months after the October 13, 2025, (b) at the election of Adjuvant, the date of a consummation of a Change of Control (as defined in the Adjuvant Purchase Agreement), and (c) the date of any acceleration of the Adjuvant Notes in accordance with Section 8 (the Maturity Date, as per the Adjuvant Purchase Agreement). The Adjuvant Notes may not be prepaid prior to the date that is six months after October 13, 2025 without prior written consent of Adjuvant.

Term Notes

Original SSNs and Exchanged SSNs

The Company entered into eight Securities Purchase Agreements (SPAs) between December 2022 and September 2023 with certain investors; each of the agreements was materially similar. 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) and (iii) Series D Preferred Stock (the Preferred Shares; December 2022 SPA only) (collectively, the Original Senior Subordinated Notes, or Original SSNs). Additionally, the conversion rate and warrant strike price are subject to adjustment upon the issuance of other securities (as defined) below the stated conversion rate and strike price at issuance.

On December 1, 2023, the Company entered into restructuring agreements with the holders of the Original SSNs, pursuant to which the Company and each holder agreed to, among other things, to (i) change the governing law and jurisdiction of the Notes from New York to Delaware and (ii) reissue the Notes (the Exchanged SSNs) under Section 3(a)(9) exemption of the Securities Act of 1993, as amended (the Restructuring Agreements). The maturity date of the Exchanged SSNs is December 1, 2026. No new consideration was paid and, other than the maturity date, no other terms of the Original SSNs were changed in conjunction with the Restructuring Agreements.

Assuming the applicable conversion price per share, the Exchanged SSNs could be converted into 584,994,694 shares of Common Stock as of September 30, 2025.

The Exchanged SSNs' interest rates are subject to increase to 12% upon an event of default and the Exchanged SSNs have no Company right to prepayment prior to maturity; however, the Company has the option to redeem the Exchanged SSNs at a redemption premium of 32.5%. The purchasers of the Exchanged SSNs can also require the Company to redeem their respective Exchanged SSNs a) at the respective premium rate tied to the occurrence of certain subsequent transactions, and b) in the event of subsequent placements (as defined). Also, pursuant to the terms of the Restructuring Agreement, Purchasers have certain rights to participate in subsequent issuances of the Company's securities, subject to certain exceptions. The conversion price for the Exchanged SSNs was $0.0154 as of September 30, 2025.

The Company evaluated the Original SSNs in accordance with ASC 480 and determined that the Original SSNs were all liability instruments at issuance. The applicable Original SSNs 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 Original SSNs.

Pursuant to the Restructuring Agreement, the Company evaluated the Exchanged SSNs under ASC 470 – *Debt* (ASC 470), and concluded that the exchange represented a non-substantial modification of the Original SSNs. Accordingly, the Company accounted for the Exchanged SSNs as a modification of the Original SSNs rather than as an extinguishment which would require derecognizing the fair value of Original SSNs and related accumulated other comprehensive loss and replacing them with the fair Exchanged SSNs.

The Company also evaluated the warrants in accordance with ASC 480 and ASC 815 and as of both September 30, 2025 and December 31, 2024, the warrants are 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 for Aditxt series A-1 preferred stock; 26,280 Series F-1 Shares were outstanding as of both September 30, 2025 and December 31, 2024; these shares are held by Aditxt.

As described in Note 8 – Convertible and Redeemable Preferred Stock and Stockholders' Deficit, on August 22, 2025, the Company entered into Exchange Agreements with certain SSN holders providing for the exchange of a portion of the SSNs due in the aggregate original principal and accrued interest amount of approximately $1.2 million into an aggregate 1,208 shares of Series G-1 Shares. The exchange was accounted for as a partial debt extinguishment via delivery of other financial assets and the difference between the fair value of the extinguished debt and the fair value of the Series G-1 Shares at issuance of an immaterial amount was recorded as a deemed dividend during the three months ended September 30, 2025.

Aditxt Notes and Warrants

On April 8, 2025, the Company entered into a securities purchase agreement (the Aditxt April SPA) with Aditxt providing for the sale and issuance of senior subordinated convertible notes due in the aggregate original principal amount of $2.3 million (the Aditxt April Note) and warrants to purchase an aggregate of 149,850,150 shares (the Aditxt April Warrants) of Common Stock of the Company, par value $0.0001 (collectively, the Aditxt April Offering). The Company waived Aditxt's default under the terms of the A&R Merger Agreement due to the full Fifth Parent Investment, as defined in the Fifth Amendment to the A&R Merger Agreement, entered into on March 22, 2025 (the Fifth Amendment) not being made by the deadline set forth in the Fifth Amendment.

On June 26, 2025, the Company entered into a securities purchase agreement (the Aditxt June SPA) with Aditxt providing for the sale and issuance of senior subordinated convertible notes due in the aggregate original principal amount of $1.4 million (the Aditxt June Note, or together with the Aditxt April Note, the Aditxt Notes) and warrants to purchase an aggregate of 92,407,592 shares (the Aditxt June Warrants) of Common Stock of the Company, par value $0.0001 (collectively, the Aditxt June Offering).

In both the Aditxt April Offering and the Aditxt June Offering, Aditxt paid approximately $650 for each $1,000 of the principal amount of the Notes and Warrants and the Company issued a total of 242,257,742 warrants to purchase shares of Common Stock with an exercise price of $0.0154. In each of the Aditxt April Notes and the Aditxt June Notes, the notes are unsecured senior subordinated notes, have an interest rate of 8%, and mature three years from the respective issuance dates. The net proceeds after the offering costs to the Company from the Aditxt April Offering and Aditxt June Offering were approximately $2.4 million. Assuming the applicable conversion price per share, the Aditxt Notes could be converted into 250,021,436 shares of Common Stock as of September 30, 2025.

The Aditxt April Notes' and the Aditxt June Notes' interest rates are subject to increase to 12% upon an event of default and they have no Company right to prepayment prior to maturity; however, the Company has the option to redeem the respective notes at a redemption premium of 32.5%. Aditxt can also require the Company to redeem the notes a) at the respective premium rate tied to the occurrence of certain subsequent transactions, and b) in the event of subsequent placements (as defined). Also, pursuant to the terms of the respective SPAs, Aditxt has certain rights to participate in subsequent issuances of the Company's securities, subject to certain exceptions, and the shares of Company Common Stock underlying the Aditxt April Offering and the Aditxt June Offering are unregistered. Additionally, the conversion rate and warrant strike price are subject to adjustment upon the issuance of other securities (as defined) below the stated conversion rate and strike price at issuance.

The Company evaluated the Aditxt April Notes and Aditxt June Notes in accordance with ASC 480 and determined that the notes were all liability instruments at issuance. The 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 Aditxt Notes.

The Company also evaluated the Aditxt April Warrants and the Aditxt June Warrants in accordance with ASC 480 and ASC 815 and as of September 30, 2025 the warrants are recorded in equity.

Summary of SSNs and Warrants at Issuance (December 2022 to September 2023 and April to June 2025):

Notes	Principal At Issuance (in Thousands)	Net Proceeds Before Issuance costs (in Thousands)	Common Warrants	Preferred Shares	Original Maturity Date	Current Maturity Date
December 2022 Notes[4]	$ 2,308	$ 1,500	369,230	70 - Series D	12/21/2025 (4)	12/1/2026
February 2023 Notes[1][4]	1,385	900	653,538	-	2/17/2026 (4)	12/1/2026
March 2023 Notes[4]	600	390	240,000	-	3/17/2026 (4)	12/1/2026
March 2023 Notes[2][4]	538	350	258,584	-	3/20/2026 (4)	12/1/2026
April 2023 Notes[4]	769	500	615,384	-	3/6/2026 (4)	12/1/2026
July 2023 Notes[4]	1,500	975	1,200,000	-	3/6/2026 (4)	12/1/2026
August 2023 Notes[4]	1,000	650	799,999	-	8/4/2026 (4)	12/1/2026
September 2023 Notes[3][4]	2,885	1,875	26,997,041	-	9/26/2026 (4)	12/1/2026
Aditxt April Note	2,308	1,500	149,850,150	-	4/8/2028	4/8/2028

Aditxt June Note	1,423	925	92,407,592	-	6/26/2028	6/26/2028
Total Offerings	$ 14,716	$ 9,565	273,391,518			

(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 at issuance and 4,807,692 pre-funded warrants exercisable at $0.001 per share.
(4) As described above, for accounting purposes, the Company accounted for the Exchanged SSNs as a modification of the Original SSNs rather than as an extinguishment which would require derecognizing the fair value of Original SSNs and related accumulated other comprehensive loss and replacing them with the fair Exchanged SSNs. The maturity date under the Exchanged SSNs is December 1, 2026.

Short-term Debt

Insurance Premium Finance Agreement

In June 2024, the Company entered into an insurance premium finance agreement with First Insurance Funding (FIF) to finance a portion of the year's D&O and general insurance policies. The total amount financed was $0.4 million at an annual interest rate of 8.57%. The Company made nine equal payments, commencing in July 2024. The Company recorded the total financed amount as a short-term debt on the condensed consolidated balance sheet as of December 31, 2024. The interest expense, included in other income (expense), net, in the condensed consolidated statement of operations, was immaterial for the three and nine months ended September 30, 2024.

In June 2025, the Company entered into an insurance premium finance agreement with First Insurance Funding (FIF) to finance a portion of its current policy year's Directors and Officers (D&O) and general insurance policies. The total amount financed was $0.4 million at an annual interest rate of 7.82%. The Company will make eight equal payments, commencing in August 2025. The Company recorded the total financed amount as a short-term debt on the condensed consolidated balance sheets. The interest expense, included in other expense, net, in the condensed consolidated statement of operations, was immaterial for the three and nine months ended September 30, 2025.

5. Balance Sheet Details

Inventories

Inventories consist of the following (in thousands):

	September 30, 2025	December 31, 2024
Raw materials	$ 134	$ 350
Work in process	792	982
Finished goods	758	245
Total	$ 1,684	$ 1,577

Prepaid and Other Current Assets

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

	September 30, 2025	December 31, 2024
Insurance	$ 650	$ 391
Prescription Drug User Fee Act (PDUFA) fees	-	606
Outside service retainers	70	160
Short-term deposits	127	127
Other	112	175
Total	$ 959	$ 1,459

Property and Equipment, Net

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

	Useful Life	September 30, 2025	December 31, 2024
Research equipment	5 years	$ 96	$ 585
Computer equipment and software	3 years	34	145
Construction in-process	-	402	429
		532	1,159
Less: accumulated depreciation		(112)	(701)
Total, net		$ 420	$ 458

Depreciation expense for property and equipment was immaterial in each of the three and nine months ended September 30, 2025 and 2024, respectively.

Intangible Asset, Net

Intangible asset, net, acquired in July 2024, consists of the following (in thousands):

	Useful Life	September 30, 2025	December 31, 2024
Intellectual property	16 years	$ 6,267	$ 10,216
Less: accumulated amortization		(1,029)	(619)
Total, net		$ 5,238	$ 9,597

The intangible asset relates entirely to the asset acquired with the SOLOSEC asset acquisition and, as described further in Note 7 – Commitments and Contingencies, the useful life is based on the SOLOSEC IP patent expiration. Amortization expense was $0.1 million and $0.4 million in the three and nine months ended September 30, 2025, respectively. Amortization expense is expected to be approximately $0.1 million for the remainder of 2025 and $0.4 million in each subsequent year until the intangible asset is fully amortized, which will be in approximately 14.9 years. As described in Note 2 – Summary of Significant Accounting Policies, the intangible asset value is adjusted at each reporting date in conjunction with the mark-to-market adjustment of the contingent liabilities, which could impact the expected amortization. The initial intangible asset fair value was $16.1 million at acquisition; this was reduced by $5.9 million for the year ended December 31, 2024. The net adjustment for the nine months ended September 30, 2025 was a reduction to the intangible balance of $3.9 million.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2025	December 31, 2024
Clinical trial related costs	$ -	$ 2,498
Accrued royalty	39	1,976
Accrued compensation for non-employee directors	697	505
Other	627	530
Total	$ 1,363	$ 5,509

6. Fair Value of Financial Instruments

Fair Value of Financial Liabilities

The following tables summarize the Company's debt instruments as of September 30, 2025 and December 31, 2024, respectively (in thousands):

As of September 30, 2025	Principal Amount	Accrued Interest	Net Carrying Amount	Fair Value Amount	Fair Value Leveling
Baker Notes[1][2]	$ 117,634	$ -	$ 117,634	$ 15,174	Level 3
Adjuvant Notes[3]	22,500	9,667	32,167	N/A	N/A
December 2022 Notes[1] [4]	629	-	629	233	Level 3
February 2023 Notes [1] [4]	946	-	946	350	Level 3
March 2023 Notes [1] [4]	1,100	-	1,100	407	Level 3
April 2023 Notes [1] [4]	707	-	707	262	Level 3
July 2023 Notes [1] [4]	1,380	-	1,380	511	Level 3
August 2023 Notes [1] [4]	963	-	963	357	Level 3
September 2023 Notes [1] [4]	3,283	-	3,283	1,215	Level 3
Aditxt Notes[1]	3,850	-	3,850	983	Level 3
Totals	$ 152,992	$ 9,667	$ 162,659	$ 19,492	N/A

As of December 31, 2024	Principal Amount	Accrued Interest	Net Carrying Amount	Fair Value Amount	Fair Value Leveling
Baker Notes[1][2]	$ 109,488	$ -	$ 109,488	$ 13,801	Level 3
Adjuvant Notes[3]	22,500	8,269	30,769	N/A	N/A
December 2022 Notes[1] [4]	973	-	973	118	Level 3
February 2023 Notes [1] [4]	980	-	980	120	Level 3
March 2023 Notes [1] [4]	1,209	-	1,209	147	Level 3
April 2023 Notes [1] [4]	883	-	883	108	Level 3
July 2023 Notes [1] [4]	1,322	-	1,322	161	Level 3
August 2023 Notes [1] [4]	1,119	-	1,119	136	Level 3
September 2023 Notes [1] [4]	3,147	-	3,147	383	Level 3
Totals	$ 141,621	$ 8,269	$ 149,890	$ 14,974	N/A

(1) These liabilities are/were carried at fair value in the condensed 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 $33.4 million and $24.9 million of interest paid in-kind as of September 30, 2025 and December 31, 2024, respectively.

(3) The Adjuvant Notes are recorded in the condensed consolidated balance sheets at their net carrying amount which includes principal and accrued interest.

(4) For accounting purposes, the Company accounted for the Exchanged SSNs as a modification of the Original SSNs rather than as an extinguishment which would require derecognizing the fair value of Original SSNs and related accumulated other comprehensive loss and replacing them with the fair Exchanged SSNs.

The following tables summarize the Company's derivative liabilities as of September 30, 2025 and December 31, 2024 as discussed in Note 8 – Convertible and Redeemable Preferred Stock and Stockholders' Deficit (in thousands):

	Fair Value		
	September 30, 2025	December 31, 2024	Leveling
Purchase rights	$ 1,140	$ 1,359	Level 3
Total derivative liabilities	$ 1,140	$ 1,359	

Change in Fair Value of Level 3 Financial Liabilities

The following table summarizes the changes in Level 3 financial liabilities related to Baker Notes, SSNs, and Aditxt Notes measured at fair value on a recurring basis for the three and nine months ended September 30, 2025 (in thousands):

	Baker Notes (Assigned to Future Pak; Note 4)	Total SSNs and Aditxt Notes (Note 4)	Total
Balance at June 30, 2025	$ 14,609	$ 172	$ 14,781
Extinguishment/conversion	-	(16)	(16)
Payments	(143)	-	(143)
Change in fair value presented in the condensed consolidated statements of operations	708	-	708
Change in fair value presented in the condensed consolidated statements of comprehensive operations	-	4,162	4,162
Balance at September 30, 2025	$ 15,174	$ 4,318	$ 19,492

	Baker Notes (Assigned to Future Pak; Note 4)	Total SSNs and Aditxt Notes (Note 4)	Total
Balance at December 31, 2024	$ 13,801	$ 1,173	$ 14,974
Balance at issuance	-	129	129
Extinguishment/conversion	-	(16)	(16)
Payments	(391)	-	(391)
Change in fair value presented in the condensed consolidated statements of operations	708	-	708
Change in fair value presented in the condensed consolidated statements of comprehensive operations	1,056	3,032	4,088
Balance at September 30, 2025	$ 15,174	$ 4,318	$ 19,492

The following table summarizes the changes in Level 3 financial liabilities related to Baker Notes and SSNs measured at fair value on a recurring basis for the three and nine months ended September 30, 2024 (in thousands):

	Baker Notes (Assigned to Future Pak; Note 4)	Total SSNs (Note 4)	Total
Balance at June 30, 2024	$ 12,280	$ 959	$ 13,239
Balance at issuance	12,280	-	12,280
Extinguishment/conversion	(12,280)	-	(12,280)
Payments	(125)	-	(125)
Change in fair value presented in the condensed consolidated statements of comprehensive operations	1,721	(652)	1,069
Balance at September 30, 2024	$ 13,876	$ 307	$ 14,183

	Baker Notes (Assigned to Future Pak; Note 4)	Total SSNs (Note 4)	Total
Balance at December 31, 2023	$ 13,510	$ 1,221	$ 14,731
Balance at issuance	24,670	-	24,670
Extinguishment/conversion	(25,790)	(51)	(25,841)
Payments	(378)	-	(378)
Change in fair value presented in the condensed consolidated statements of comprehensive operations	1,864	(863)	1,001

Balance at September 30, 2024	$ 13,876	$ 307	$ 14,183

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 three and nine months ended September 30, 2025 (in thousands):

	Purchase Rights	Derivative Liabilities Total
Balance at June 30, 2025	$ 3	$ 3
Exercises	-	-
Change in fair value presented in the condensed consolidated statements of operations	1,137	1,137
Balance at September 30, 2025	$ 1,140	$ 1,140

	Purchase Rights	Derivative Liabilities Total
Balance at December 31, 2024	$ 1,359	$ 1,359
Exercises	(1)	(1)
Change in fair value presented in the condensed consolidated statements of operations	(218)	(218)
Balance at September 30, 2025	$ 1,140	$ 1,140

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 three and nine months ended September 30, 2024 (in thousands):

	Purchase Rights	Derivative Liabilities Total
Balance at June 30, 2024	$ 942	$ 942
Exercises	(11)	(11)
Change in fair value presented in the condensed consolidated statements of operations	(769)	(769)
Balance at September 30, 2024	$ 162	$ 162

	Purchase Rights	Derivative Liabilities Total
Balance at December 31, 2023	$ 1,926	$ 1,926
Balance at issuance	3,300	3,300
Exercises	(168)	(168)
Change in fair value presented in the condensed consolidated statements of operations	(4,896)	(4,896)
Balance at September 30, 2024	$ 162	$ 162

Valuation Methodology

Baker Notes

The fair value of the Baker Notes is determined using a Monte Carlo simulation-based model and is subject to uncertainty due to the assumptions used in the model. The fair value of the Baker Notes is sensitive to these estimated inputs made by management that are used in the calculation. The Monte Carlo simulation takes into account several embedded features and factors and management inputs, including the exercise of the repurchase rights, 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.

Exchanged SSNs and Aditxt Notes

The fair value of the Exchanged SSNs and Aditxt Notes issued, as described in Note 4 – Debt, were determined by estimating the fair value of the Market Value of Invested Capital (MVIC) of the Company on a going-concern basis. This was estimated using a form of the market approach where comparable market revenue multiples were selected and applied to the Company's forward revenue forecast to ultimately derive a MVIC indication. An option-pricing model (OPM) was then applied to value the Exchanged SSNs by allocating the estimated MVIC through the Company's capital structure including the more senior notes payoff in a hypothetical exit event. Under the OPM, each debt or equity class is modeled as a call option with a distinct claim on the total value of the Company. The option's exercise price is based on the Company's total value available for each participating security holder. By constructing a series of options in which the exercise price is set at incremental levels of value, which correspond to the value necessary for each level of equity to participate, we determined the incremental option value of each series. When multiplied by the percentage of ownership of each equity class participating, the result is the incremental value allocated to each class under that series.

Purchase Rights

The Adjuvant Purchase Rights and the May Note Purchase Rights (collectively Purchase Rights) are recorded as derivative liabilities in the condensed consolidated balance sheets. The Purchase Rights are valued using an OPM, like a Black-Scholes model, with changes in the fair value being recorded in the condensed 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

Warrants are classified as equity and the Company re-evaluates 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, because 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.

SOLOSEC Asset Acquisition Intangible Asset and Contingent Liabilities

The total consideration for the SOLOSEC asset acquisition included an up-front payment (paid at closing), sales-based payments to be paid over the next 15 years (the Earnout Term) in each year in which SOLOSEC adjusted net revenue is over a specified threshold, a $10.0 million one-time payment once the cumulative SOLOSEC adjusted net revenues reach $100 million, and assumption of quarterly royalty payments based on SOLOSEC net revenue. As discussed in Note 7 – Commitments and Contingencies, the fair value of the consideration is attributed to the SOLOSEC product line and was therefore recorded as an intangible asset.

The fair value of the total consideration, including cash paid and future sales-based payments, is determined using a Monte Carlo simulation model, which assumes the Company's revenue follows a geometric Brownian motion. Using specific revenue factors, including expected growth, risk adjustments, and revenue volatility, future revenues were simulated through the Earnout Term to assess whether sales-based payments would be triggered in each relevant period, as stipulated by the SOLOSEC Asset Purchase Agreement. The average output of the Monte Carlo simulations for each period provides the expected payment value, which is then discounted to its present value to derive the fair value of future sales-based payments and recorded as contingent liabilities. The discount rate is a market index rate based on the Company's credit risk.

The fair value of the SOLOSEC contingent liabilities is subject to uncertainty due to the assumptions made by management that are used in the Monte Carlo simulation-based model. These factors include the estimated future SOLOSEC net revenue, the risk-neutral revenue calculation and simulation assumptions, payment timing, and the discount rate.

The fair value of the SOLOSEC contingent liabilities will be updated at each reporting period using the methodology described above. Any changes to the fair value will be recorded as an adjustment to the carrying value of both the contingent liabilities and the SOLOSEC IP intangible asset as per ASC 323, *Investments – Equity Method and Joint Ventures* (ASC 323). Periodic intangible amortization will also be prospectively updated based on the new fair value of the SOLOSEC IP.

7. Commitments and Contingencies

SOLOSEC

The Company reviewed the SOLOSEC acquisition in accordance with ASC 805, *Business Combinations* (ASC 805), including applying the screen test. In accordance with ASC 805, the Company engaged a third-party valuation specialist to estimate the fair value for the SOLOSEC IP as well as for the total consideration. Per the valuation, the fair value of the SOLOSEC IP exceeded 90% of the total consideration, which indicates that the screen test failed. Further, the Company did not acquire any substantive processes, which indicates that the acquisition is an asset acquisition rather than a business combination. The Company recorded the fair value of the future sales-based payments as contingent liabilities in accordance with ASC 450, *Contingencies* (ASC 450) and the fair value of the total consideration plus the transaction costs as an intangible asset in accordance with ASC 350, *Intangibles* (ASC 350).

Per the Transition Services Agreement (TSA) entered into in conjunction with the SOLOSEC asset acquisition, the Company is committed to purchasing finished goods inventory from the seller through a transition period ending in November 2026 at a pre-defined unit price. The total expected commitment is approximately $3.5 million; however, the quantities to be purchased can be negotiated if both parties agree. The Company concluded that the inventory purchase commitment does not meet the definition of a derivative under ASC 815. During the three and nine months ended September 30, 2025, there were approximately $0.4 million and $0.8 million in purchases under this commitment, respectively. The Company expects to purchase approximately $0.6 million in the remainder of the year ending December 31, 2025, and $1.9 million in the year ended December 31, 2026 under this commitment. The TSA also required the seller to provide transitional support services until the Company fully established SOLOSEC operations; the Company was obligated to pay an immaterial amount quarterly for these services.

The Company is also obligated to pay a quarterly royalty, in amounts equal to a certain percentage of the SOLOSEC net revenue, beginning July 14, 2024. There are no minimum quarterly or annual royalty payment amounts. Such royalty costs were immaterial and $0.1 million for the three and nine months ended September 30, 2025, respectively. As of September 30, 2025, $0.2 million and $5.4 million related to the future payments related to the SOLOSEC acquisition, including sales-based payments, one-time payment, and quarterly royalty payments, was included in contingent liabilities – current and contingent liabilities – noncurrent, respectively, in the condensed consolidated balance sheet. Such amounts were $0.7 million and $9.7 million, respectively, as of December 31, 2024.

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 September 30, 2025, there were a total of 18 leased vehicles.

The Company determined that the leased vehicles are accounted for as operating leases under ASC 842, *Leases* (ASC 842). In May and June 2024, the Company extended the lease term by an additional 12 months for vehicles with initial terms of 24 months. The Company determined that such extensions were accounted for as modifications; the Company reassessed the lease classification and the incremental borrowing rate on the modification date and accounted for these modifications accordingly.

In the second and third quarter of 2025, the Company replaced the leased vehicles; the vehicles have a lease term of 24 months. In conjunction with the new leases, the Company assessed the incremental borrowing rate and also determined that the leased vehicles should be accounted for as operating leases under ASC 842.

Supplemental Financial Statement Information

		Three Months Ended September 30,		Nine Months Ended September 30,	
Lease Cost (in thousands)	**Classification**	**2025**	**2024**	**2025**	**2024**
Operating lease expense	Research and development	$ 1	$ -	$ 3	$ 2
Operating lease expense	Selling and marketing	11	40	86	135
Operating lease expense	General and administrative	2	3	8	8
Total		$ 14	$ 43	$ 97	$ 145

Lease Term and Discount Rate	**September 30, 2025**	**December 31, 2024**
Weighted Average Remaining Lease Term (in years)	1.65	0.77
Weighted Average Discount Rate	12%	12%

Maturity of Operating Lease Liabilities (in thousands)	**September 30, 2025**
Remainder of 2025 (3 months)	$ 34
Year ending December 31, 2026	127
Year ending December 31, 2027	52
Total lease payments	213
Less imputed interest	(17)
Total	$ 196

	Nine Months Ended September 30,	
Other information (in thousands)	**2025**	**2024**
Operating cash outflows in operating leases	$ 94	$ 218
Non-cash addition to ROU assets and lease liabilities due to new leases	$ 201	$ 90

Other Contractual Commitments

In November 2019, the Company entered into a supply and manufacturing agreement with a third-party to manufacture PHEXX, with potential to manufacture other product candidates, in accordance with all applicable current good manufacturing practice regulations. There were $0.3 million and $1.1 million in purchases under the supply and manufacturing agreement for the three and nine months ended September 30, 2025, respectively, and $0.8 million and $1.0 million in purchases during each of the three and nine month periods ended September 30, 2024.

Related Party Transactions

Windtree

On March 20, 2025, Windtree Therapeutics, Inc. (Windtree) and the Company entered into a License and Supply Agreement, as amended on March 28, 2025 (collectively, the Windtree License and Supply Agreement), wherein Windtree agreed to become a manufacturer and supplier of PHEXX. The Company expects to significantly reduce its COGS once the Company begins selling PHEXX manufactured under the Windtree License and Supply Agreement. The Company will not have any financial obligations until submitting a binding forecast six months prior to the scheduled manufacturing date. Because Saundra Pelletier, the Company's CEO, is also on the board of Windtree, the Company evaluated the relationship between the entities and determined that Windtree is a related party of the Company. Due to the related party nature of the entities, the Company will add additional disclosures around any transactions that occur between the companies under the Windtree License and Supply Agreement once they begin; as of the date of this Quarterly Report, no transactions have been started.

Aditxt

Aditxt was considered a related party of the Company during the three and nine months ended September 30, 2025 because Saundra Pelletier, the

Company's Chief Executive Officer, served as a member of Aditxt's Board of Directors from June 9, 2025 until September 23, 2025. Ms. Pelletier's term expired on that date.

Merger

On July 14, 2024, the Company entered into an Amended and Restated Agreement and Plan of Merger (the "A&R Merger Agreement") with Aditxt, Inc. ("Aditxt"), pursuant to which Aditxt was expected to acquire the Company in an all-stock transaction. The A&R Merger Agreement was amended several times, including the Sixth Amendment to the A&R Merger Agreement, entered into on August 26, 2025 (the Sixth Amendment). The Sixth Amendment was entered into to (i) amend section 1.5 and 3.1(b)(ii) to update the definition of "Unconverted Company Preferred Stock" to include Series G-1 Shares; (ii) amend section 1.6 to update the definition of "Company Shareholder Approval" to include the outstanding shares of Company Common Stock (including all of the Company's Preferred Stock, on the basis and to the extent it is permitted to so vote) entitled to vote thereon and each series of the Unconverted Company Preferred Stock; (iii) amend section 6.23 to clarify that the Company will assist in obtaining Exchange Agreements (as defined in the A&R Merger Agreement, as amended) to exchange Company convertible notes and purchase rights for an aggregate of not more than 89,021 shares of Parent Preferred Stock from the applicable Company shareholders; (iv) amend section 7.2(j) to change the number of dissenting shares to no more than 5,932,818 shares of Common Stock or 202 shares of Preferred Stock; (v) add a new section 7.2(k) to require waivers from each holder of the Company's E-1 Convertible Preferred Stock, with respect to the last sentence of Section 2, the entirety of Section 6, any price adjustment provisions that may be triggered under Section 8(a)(ii), Section 12(c), and Section 12(d) of the Series E-1 Certificate of Designations; and (vi) to replace, in its entirety, the Certificate of Designations for Exchanged Parent Preferred Stock included as Exhibit C to the A&R Merger Agreement.

On October 20, 2025, the Company terminated the A&R Merger Agreement after the proposed merger was not approved by the Company's stockholders. No termination fee or other cash consideration was paid by either party, and no further obligations remain under the agreement.

Notes

As discussed in Note 4 – Debt, on April 8, 2025 and June 26, 2025, the Company entered into two securities purchase agreements with Aditxt (the Aditxt April Note and the Aditxt June Note). Under these agreements the Company issued senior subordinated convertible notes in the aggregate original principal amount of $3.7 million and warrants to purchase up to 242,257,742 shares of the Company's Common Stock. The notes bear interest at 8%, mature three years from issuance, and were issued at a discount of $650 per $1,000 of principal. Net cash proceeds to the Company were approximately $2.4 million. The warrants have an exercise price of $0.0154 per share.

Adjuvant

Because Adjuvant has significant voting power due to its increased beneficial ownership limitation, the Company evaluated the relationship between the entities and determined that Adjuvant is a related party of the Company. Except for the exchange from the Adjuvant Notes to Series G-1 Shares during the third quarter of 2025 as described in Note 8 – Convertible and Redeemable Preferred Stock and Stockholders' Deficit, and the Adjuvant Third Amendment as described and defined in Note 10 – Subsequent Events, there was no other transaction occurred between two entities in 2025.

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. As of September 30, 2025, there were no other claims or actions pending against the Company which management believes have a probable, or a reasonably possible, probability of an unfavorable outcome other than the TherapeuticsMD, Inc. (TherapeuticsMD) dispute as described below.

During the nine months ended September 30, 2025, the Company settled a portion of its trade payables with numerous vendors, which resulted in a $3.1 million reduction in trade payables and a $2.5 million reduction in accrued expenses. However, the Company may receive trade payable demand letters from other vendors that could lead to potential litigation. As of September 30, 2025, approximately 75% 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 U.S. 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 were required to be performed by July 2024 (the Settlement Timeline), including changing the name of PHEXX. The Company failed to meet the terms of the settlement agreement by the Settlement Timeline. As a result, the Company is currently working with TherapeuticsMD on resolution of this issue. In September 2024, the Company filed an application for a new name, which was approved by the FDA in April 2025. The Company is advancing its re-branding plans and timeline. In accordance with ASC 450, the Company has accrued the present value of the probable settlement amounts remaining payable over the next several years, which was $0.4 million and $0.8 million as of September 30, 2025 and December 31, 2024, respectively, as a component of contingent liabilities in the condensed consolidated balance sheets.

As of September 30, 2025, the Company has received multiple letters from purported Company stockholders demanding that the Company's board of directors take action on behalf of the Company to remedy allegations regarding the Company's disclosures to shareholders with respect to various alleged omissions of material information in both its preliminary proxy statement filed September 23, 2024 and definitive proxy statement filed September 8, 2025 relating to the A&R Merger Agreement, as amended, and demands made under Section 220 of the DGCL for books and records related to the transaction and disclosures in the proxy statement. The Company believes all such demands are without merit. Furthermore, on October 20, 2025, the Company terminated the A&R Merger Agreement after the Merger was not approved by the required number of shareholders at the Special Meeting as further discussed in Note 10 – Subsequent Events. The Company continues to work with each of the firms representing the stockholders to resolve.

On September 27, 2024, Future Pak, LLC, as agent for the Purchasers (in such capacity, the Designated Agent) provided a Notice of Event of Default and Reservation of Rights (the Notice of Default) relating to the Baker Bros. SPA, as amended, by and among the Company, Designated Agent, as certain guarantors and the purchasers (each a Purchaser and collectively Purchasers). The Notice of Default claims that by entering into arrangements to repay certain existing obligations, including obligations owed to the U.S. Department of Health and Human Services, an Event of Default has occurred under Section 9.1(e) of the Baker Bros. SPA. According to the Notice of Default, the Designated Agent has accelerated repayment of the outstanding principal balance owed by the Company under the Securities Purchase Agreement. If all Purchasers exercise the Section 5.7 Option (as defined below), the repurchase price would be equal to $106.8 million. Pursuant to Section 5.7(b) of the Baker Bros. SPA, upon the occurrence of an Event of Default, each Purchaser may elect, at its option, to require the Company to repurchase the Note held by such Purchaser (or any portion thereof) at a repurchase price equal to two times the sum of the outstanding principal balance and all accrued and unpaid interest thereon, due within three business days after such Purchaser delivers a notice of such election (the Section 5.7 Option).

On October 27, 2024, the Designated Agent sent an amended and supplemented notice to the Notice of Default which adds additional claims of default based on the Company's current repayment agreements of existing obligations, including obligations owed to the U.S. Department of Health and Human Services, an Event of Default has occurred under Section 9.1(e) of the Securities Purchase and Security Agreement dated April 23, 2020, as amended. Furthermore, the Amended Notice stated that, because the events of default described in the Amended Notice of Default are not the certain prior events of default listed in the Forbearance Agreement (the Specified Defaults), the Designated Agent and the holders of the senior secured promissory notes described in the Baker Bros. SPA thereby provided notice to the Company that the Forbearance Agreement is terminated as of October 27, 2024. The Company strongly disagrees with the Designated Agent's claim that any Event of Default has occurred.

On November 8, 2024, the Designated Agent sent an amended and supplemented notice to the Notices (the Third Amended Notice of Default) which adds new claims of default based on (i) the Company's failure to maintain a cash position of $1.0 million or greater, as required under Section 5(b) of the Forbearance Agreement (ii) the Company's failure to deliver financial and operating reports in accordance with the timeline required under the Section 8.1(n) of the Baker Stock Purchase Agreement, and (iii) to clarify the outstanding balance under the notes of the Baker Stock Purchase Agreement plus all accrued and unpaid interest thereon, in the sum of approximately $107.0 million as opposed to the Repurchase Price as defined in the Fourth Amendment. The Company intends to vigorously contest any attempt by the Designated Agent and the Purchasers to exercise their default rights and remedies under the Baker Bros. SPA.

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 a patent and certain know-how related to its vaginal pH modulator technology (US6706276, the Rush Patent). Pursuant to the Rush License Agreement, until the expiration of the Rush Patent, the Company was obligated to pay Rush University an earned royalty during the patent term, calculated as a mid-single digit percentage of PHEXX net sales (the Rush Royalty). In September 2020, the Company entered into the first amendment to the Rush License Agreement, pursuant to which the Company agreed to pay a minimum annual royalty amount of $0.1 million to the extent the earned royalties did not equal or exceed $0.1 million commencing January 1, 2021 until the expiration of the patent, including any granted Patent Term Extensions (PTEs).

The Rush Patent would expire on March 6, 2021 (the Original Expiration Date) if no PTE was obtained. Rush University filed an application for PTE in July 2020, which would extend the expiration date of the Rush Patent to March 6, 2026 if granted. Multiple Orders Granting Interim Extension (OGIEs) were received from the U.S. Patent and Trademark Office (USPTO) while the PTE was under evaluation. The last OGIE expired on March 6, 2025.

Because the USPTO had granted multiple OGIEs to Rush University, between the date of the original PTE application (July 2020) and the final OGIE expiration (March 2025), the Company determined it was probable that the PTE extending the expiration to March 6, 2026 would be granted. Therefore, the Company accrued a total of $2.8 million related to the Rush Royalty as a contingent liability after the Original Expiration Date in accordance with ASC 450, of which $0.9 million was paid in good faith and $1.9 million was unpaid and included in accrued expenses in the condensed consolidated balance sheet as of December 31, 2024.

During the first quarter of 2025, the Company's legal counsel ascertained that no further OGIEs were granted after March 6, 2025 and the PTE had also still not been granted. As a result, the Company discontinued accruing the Rush Royalty since, based on the new information, the Company deemed it remote that the PTE would ultimately be granted. Amounts previously accrued under the rush License Agreement were still being assessed at that time and as such, no adjustments were made. No royalty costs were recorded for the three and nine months ended September 30, 2025. For the three and nine months ended September 30, 2024, $0.2 million and $0.6 million, respectively, of Rush Royalty costs were recorded in cost of goods sold.

Furthermore, in August 2025 the FDA confirmed that the relevant active ingredient covered by the Rush Patent had previously been used in other FDA-approved products and, as such, no PTE should be granted, the Company and its legal counsel determined that the Rush Patent expired on the Original Expiration Date and as such it is no longer probable that the Company will be required to pay any expenses related to the Rush Royalty accrued after that date. The Company reversed the outstanding accrued Rush Royalty contingent liability of $1.9 million during the three months ended September 30, 2025. Because the gain was material to cost of goods sold, the amount was presented separately on the condensed consolidated statement of operations as a gain on change in accounting estimates on contingent royalty liability.

If the Company determines to pursue a refund of the estimated royalties paid but not earned per its current analysis, it could potentially receive a refund of $0.9 million from Rush University (the amount paid for royalties accrued after the Original Expiration Date). Conversely, if Rush University pursues payment of the amounts accrued but not paid for the time covered by the OGIEs, the maximum liability that the Company could incur is approximately $2.3 million. Based on the current analysis, the Company could have an additional gain of up to $0.9 million or a loss of up to $2.3 million.

Our vaginal pH modulator (PHEXX) remains protected in the U.S. by four *Orange Book* patents which are solely-owned by Evofem.

8. Convertible and Redeemable Preferred Stock and 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 2,731 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 $0.0154 per share as of September 30, 2025.

In May 2022, the Company completed an underwritten public offering (the May 2022 Public Offering) which included the issuance of common warrants to purchase 362,640 shares of Common Stock at a price to the public of $93.75 and the issuance of common warrants to purchase 205,360 shares of Common Stock at a price to the public of $93.63 (the May 2022 Common Stock Warrants). The May 2022 Common Stock Warrants were exercisable beginning on May 24, 2022 and have a five-year term. Due to features in the May 2022 Common Stock Warrants, including dilution adjustments requiring strike price resets, additional warrants have been periodically issued as required in the warrant agreements. As of September 30, 2025, there were 894,194 May 2022 Common Stock Warrants outstanding with an exercise price of $0.0154.

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 was $0.0154 per share as of September 30, 2025.

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 was $0.0154 per share as of September 30, 2025. During the second quarter of 2025, pursuant to the Aditxt Notes, as discussed in Note 4 – Debt, the Company issued warrants to purchase up to 242,257,742 shares of the Company's Common Stock at an exercise price of $0.0154 per share.

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 September 30, 2025, warrants to purchase up to 263,062,099 shares of the Company's Common Stock remain outstanding at a weighted average exercise price of $0.18 per share. In accordance with ASC 815, the warrants are classified as equity instruments as of both September 30, 2025 and December 31, 2024. During the first quarter of 2024, the Company obtained waivers from a majority of the convertible instrument holders, removing the requirement for shares to be reserved for conversion of their instruments, which will prevent the instruments from needing to be liability classified due to an insufficient number of authorized shares going forward. 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	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	8,003	$ 735.00	January 13, 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	$ 0.0154	May 24, 2022	May 24, 2022 to May 24, 2027
Common Warrants	582,886	$ 0.0154	June 28, 2022	May 24, 2022 to June 28, 2027
Common Warrants	49,227	$ 0.0154	December 21, 2022	December 21, 2022 to December 21, 2027
Common Warrants	130,461	$ 0.0154	February 17, 2023	February 17, 2023 to February 17, 2028
Common Warrants	258,584	$ 0.0154	March 20, 2023	March 20, 2023 to March 20, 2028
Common Warrants	369,231	$ 0.0154	April 5, 2023	April 5, 2023 to April 5, 2028
Common Warrants	349,463	$ 0.0154	July 3, 2023	July 3, 2023 to July 3, 2028
Common Warrants	615,384	$ 0.0154	August 4, 2023	August 4, 2023 to August 4, 2028
Common Warrants	12,721,893	$ 0.0154	September 27, 2023	September 27, 2023 to September 27, 2028
Common Warrants	149,850,150	$ 0.0154	April 8, 2025	April 8, 2025 to April 8, 2030
Common Warrants	92,407,592	$ 0.0154	June 26, 2025	June 26, 2025 to June 26, 2030
Prefunded Common Warrants	4,807,694	$ 0.0010	September 27, 2023	September 27, 2023 to September 27, 2028
Total	263,062,099			

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. The certificate of incorporation was further amended several times, most recently on August 22, 2025 in order to authorize various series of convertible and redeemable preferred stock; authorized series currently include convertible and redeemable preferred stock designated for Series B-1 and B-2, Series C, Series E-1, Series F-1, Series G-1, and nonconvertible and redeemable preferred stock (Series D), par value $0.0001 per share.

Convertible and Redeemable Preferred Stock

On August 7, 2023, the Company filed a Certificate of Designation of Series E-1 Convertible Preferred Stock (E-1 Certificate of Designation), par value $0.0001 per share (the Series E-1 Shares). On June 30, 2025, the holders of a majority of issued and outstanding shares of the Series E-1 Shares approved by written consent in lieu of a meeting the Amended and Restated Certificate of Designations of Series E-1 Convertible Preferred Stock (the A&R E-1 Certificate of Designations). The Company's Board of Directors also approved the A&R E-1 Certificate of Designations on June 30, 2025. The A&R E-1 Certificate of Designations increases the number of total authorized shares from 2,300 to 10,000 in order to authorize a sufficient number of shares for the payment of dividends in kind in the form of additional shares of Series E-1 Shares and update certain definitions. The A&R E-1 Certificate of Designations became effective on September 30, 2025. The Series E-1 Shares are convertible into shares of Common Stock at a conversion price of $0.40 per share, as adjusted, 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 were entitled to dividends at a rate of 10% per annum (which increased as per the provision below as of April 1, 2025) or 12% upon a triggering event. On the 18-month anniversary of the initial issuance date for the Series E-1 convertible preferred stock, the dividend rate increased by 30% and will remain at that rate until no E-1 Shares remain outstanding. Dividends are payable in shares of Common Stock and may, at the Company's election, be capitalized and added to the principal balance of Series E-1 Shares 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. Series E-1 Shares rank higher than all shares of the Company's Common Stock and Series F-1 Shares (defined below) with respect to the preferences as to dividends and any distributions and payments upon the liquidation, dissolution, and winding up of the Company.

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 has been adjusted several times and was $0.0154 as of September 30, 2025. The Series E-1 Shares are classified as mezzanine equity within the condensed 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 three and nine months ended September 30, 2025, $0.1 million in deemed dividends were recorded as an increase to the Series E-1 Shares outstanding for each period. During the three and nine months ended September 30, 2024, an immaterial amount and $0.1 million, respectively, in deemed dividends were 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 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. In June 2024, the Required Holders, as defined in the F-1 Certificate of Designation, approved an amended and restated certificate of designation (the Amended F-1 Certificate of Designation) to the Company's certificate of designation designating the rights, preferences, and limitations of the Company's Series F-1 Shares. Series F-1 Shares rank higher than all shares of the Company's Common Stock with respect to the preferences as to dividends and any distributions and payments upon the liquidation, dissolution, and winding up of the Company. The Amended F-1 Certificate of Designation provides for the removal of the conversion price adjustment provisions previously included and changed the conversion price to $0.0154.

On December 21, 2023, the Company issued a total of 22,280 Series F-1 Shares to certain investors pursuant to an exchange transaction, 613 of the Series F-1 Shares were issued in exchange for warrants to purchase up to 9,972,074 shares of the Company's Common Stock and 21,667 Series F-1 Shares to exchange a partial value of the outstanding purchase rights. Immediately subsequent to the exchange transaction, the holders of the Series F-1 Shares exchanged their Series F-1 Shares for Aditxt's Series A-1 preferred stock, and as a result, Aditxt currently holds the Company's Series F-1 Shares.

During the second half of 2024, as part of the funding requirement by Aditxt pursuant to the A&R Merger Agreement, the Company issued a total of 4,000 Series F-1 Shares to Aditxt for an aggregate purchase price of $4.0 million. Additionally, Aditxt also paid the Company $1.0 million in May 2024 in conjunction with signing the Reinstatement and Fourth Amendment to the Merger Agreement. The 4,000 Series F-1 Shares were recorded at fair value with the variance between the immaterial fair value and the total $5.0 million cash received being recorded as additional paid-in-capital in the condensed consolidated balance sheet. As discussed in Note 7 – Related Party Transactions, Aditxt currently holds all outstanding Series F-1 Shares. Accordingly, transactions related to the Series F-1 Preferred Stock are considered related-party transactions under ASC 850.

On August 22, 2025, the Company filed a Certificate of Designations creating the Series G-1 Preferred Stock (G-1 Certificate of Designations), par value $0.0001 per share (the Series G-1 Shares). The Company's Board of Directors approved the G-1 Certificates of Designations on August 22, 2025 and the G-1 Certificate of Designations became effective upon filing with the State of Delaware on the same day. Subsequently on August 22, 2025, the Company entered into Exchange Agreements with certain investors (the G-1 Investors) providing for the exchange of certain SSNs and a portion of the Adjuvant Notes due in the aggregate original principal and accrued interest amount of approximately $1.6 million into an aggregate 1,573 shares of Series G-1 Shares (collectively, the G-1 Offering). The Series G-1 Preferred Shares entitles the holder thereof to vote together with the common shareholders as a single class and to cast that number of votes per share as is equal to the number of shares of Common Stock into which it is then convertible. Each of the Series G-1 Shares has a stated value of $1,000 per share and is convertible into shares of Common Stock at a rate determined by dividing (i) the stated value of such Series G-1 Shares plus any declared and unpaid dividends on such shares by (ii) the conversion price of $0.0154 per share, subject to adjustment as provided in the Certificate of Designations. The Certificate of Designations also provides that in the event of certain Triggering Events (as defined below), any holder may, at any time, convert any or all of such holder's Series G-1 Shares at a conversion rate equal to the product of (i) the Alternate Conversion Price (as defined below) and (ii) the quotient of (x) the 25% redemption premium multiplied by (y) the amount of Series G-1 Preferred Stock subject to such conversion. Triggering Events include, among others, (i) a failure to timely deliver shares of Common Stock, upon a conversion, (ii) a suspension of trading or the failure to be traded or listed on an eligible market for five consecutive days or more, (iii) the failure to pay any dividend to the holders of Series G-1 Preferred Stock when required, (iv) the failure to remove restrictive legends when required, (v) proceedings for a bankruptcy, insolvency, reorganization or liquidation, which are not dismissed with 30 days, (vi) commencement of a voluntary bankruptcy proceeding, and (vii) final judgments against the Company for the payment of money in excess of $0.1 million. Alternate Conversion Price means the lowest of (i) the applicable conversion price the in effect, (ii) 80% of the volume weighted average price (VWAP) of the Common Stock on the trading day immediately preceding the delivery of the applicable conversion notice, (iii) 80% of the VWAP of the Common Stock on the trading day of the delivery of the applicable conversion notice and (iv) 80% of the price computed as the quotient of (I) the sum of the VWAP of the Common Stock for each of the three (3) trading days with the lowest VWAP of the Common Stock during the fifteen (15) consecutive trading day period ending and including the trading day immediately preceding the delivery of the applicable conversion notice, divided by (II) three (3). Each holder of Series G-1 Shares is entitled to receive dividends at a rate of 8% per annum, paid in the form of Common Stock or paid-in-kind as additional shares of Series G-1 Shares, at the Company's discretion (the Series G-1 Dividends) payable to the holders of the Series G-1 Shares on a monthly basis.

The fair value of the G-1 Shares issued was determined by estimating the fair value of the MVIC of the Company on a going-concern basis. This was estimated using a form of the market approach where comparable market revenue multiples were selected and applied to the Company's forward revenue forecast to ultimately derive a MVIC indication. An OPM was then applied to value the G-1 Shares by allocating the estimated MVIC through the Company's capital structure including the more senior notes payoff in a hypothetical exit event. Under the OPM, each debt or equity class is modeled as a call option with a distinct claim on the total value of the Company. The option's exercise price is based on the Company's total value available for each participating security holder. By constructing a series of options in which the exercise price is set at incremental levels of value, which correspond to the value necessary for each level of equity to participate, we determined the incremental option value of each series. When multiplied by the percentage of ownership of each equity class participating, the result is the incremental value allocated to each class under that series.

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.

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. 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.

In connection with the SSNs issuances, during the three and nine months ended September 30, 2024, the Company increased the number of outstanding Purchase Rights by zero and 1,161,636,815, respectively, due to the reset of their exercise price. This was recorded as a loss on issuance of financial instruments as an immaterial amount in the condensed consolidated statements of operations for each period. No such exercise price reset occurred during the three and nine months ended September 30, 2025. The exercise price will be further adjusted if any other convertible instruments have price resets. In addition, the Company issued 5,300,000 and 10,600,000 shares of Common Stock upon the exercise of certain Purchase Rights during the three and nine months ended September 30, 2025, respectively. The Company issued 17,500,000 and 59,575,000 such shares upon the exercise of certain Purchase Rights during the three and nine months ended September 30, 2024, respectively. As of September 30, 2025, Purchase Rights to receive 1,508,548,899 shares of the Company's Common Stock remained outstanding.

Common Stock Reserved for Future Issuance

Common Stock reserved for future issuance is as follows in common equivalent shares as of September 30, 2025:

Common Stock issuable upon the exercise of stock options outstanding	3,372
Common Stock issuable upon the exercise of Common Stock warrants	10,595,019
Common Stock available for future issuance under the 2019 ESPP	509
Common Stock available for future issuance under the Amended Inducement Plan	609
Common Stock reserved for the exercise of purchase rights	741,490,642
Common Stock reserved for the conversion of convertible notes	421,784,555
Common Stock reserved for the conversion of series E-1 preferred stock	46,570,761
Total Common Stock reserved for future issuance[(1)]	1,220,445,467

(1) The potentially dilutive securities in Note 2 – Summary of Significant Accounting Policies includes all potentially dilutive securities that are not included in the diluted EPS as per U.S. GAAP, whereas the total Common Stock reserved for future issuance in the table above includes the shares that must legally be reserved based on the applicable instruments' agreements.

9. Stock-based Compensation

Equity Incentive Plans

No equity awards were issued in either period presented. The following table summarizes stock-based compensation expense related to stock options granted to employees, non-employee directors and consultants included in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	$ -	$ 5	$ 1	$ 31
Selling and marketing	2	18	7	77
General and administrative	21	180	116	551
Total	$ 23	$ 203	$ 124	$ 659

Stock Options

As of September 30, 2025, unrecognized stock-based compensation expense for employee stock options was approximately $0.1 million, which the Company expects to recognize over a weighted-average remaining period of 0.2 years, assuming all unvested options become fully vested.

10. Subsequent Events

Termination of Aditxt Merger

On October 20, 2025, the Company held a Special Meeting of Stockholders. After the Company's stockholders did not approve the transactions contemplated by the A&R Merger Agreement, the Company delivered a notice of termination to Aditxt notifying it that the Company was exercising its right to terminate the A&R Merger Agreement effective October 20, 2025. The termination was in accordance with (i) Section 8.1(b)(ii), which allows either party to terminate the A&R Merger Agreement if the Merger shall not have been consummated on or before 5:00 p.m. Eastern Time, on September 30, 2025, and (ii) as per Section 8.1(b)(iv), which allows either party to terminate the A&R Merger Agreement if the Company Shareholder Approval shall not have been obtained at a duly held Company Shareholders Meeting at which a vote was taken on the approval of the Agreement and the Transactions, including the Merger.

As a result of the termination of the A&R Merger Agreement, all other ancillary agreements related to the A&R Merger Agreement, with the exception of the obligations under the Non-Disclosure Agreement, entered into by and between the Company and Aditxt, as of October 23, 2023, terminated concurrently with the termination of the A&R Merger Agreement. No consideration was paid in connection with the termination.

Adjuvant Third Amendment

On October 13, 2025 the Company and the Adjuvant Purchasers entered into the Adjuvant Third Amendment, which amends certain provisions within the Adjuvant Purchase Agreement including updating the date that the Notes will be payable in full to the earlier of (a) six months after the October 13, 2025, (b) at the election of Adjuvant, the date of a consummation of a Change of Control (as defined in the Adjuvant Purchase Agreement), and (c) the date of any acceleration of the Adjuvant Notes in accordance with Section 8 (the Maturity Date, as per the Adjuvant Purchase Agreement). The Adjuvant Notes may not be prepaid prior to the date that is six months after October 13, 2025 without prior written consent of Adjuvant.

2025 Equity Incentive Plan

On October 3, 2025, our board of directors approved, and recommended our stockholders to approve at our annual meeting to be held on November 26, 2025, the 2025 Equity Incentive Plan (the "2025 Plan"), with a maximum of 50,000,000 shares available for issuance. No grants have been made under the 2025 Plan.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The terms "we," "us," "our," "Evofem" or the "Company" refer collectively to Evofem Biosciences, Inc. and its wholly-owned subsidiaries, unless otherwise stated. All information presented in this quarterly report on Form 10-Q (Quarterly Report) is based on our fiscal year. Unless otherwise stated, references to particular years, quarters, months or periods refer to our fiscal years ending December 31 and the associated quarters, months and periods of those fiscal years.

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report. Some of the information contained in this discussion and analysis is set forth elsewhere in this Quarterly 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 Quarterly 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. We currently commercialize two FDA-approved products: PHEXX® (lactic acid, citric acid and potassium bitartrate) vaginal gel and SOLOSEC® (secnidazole) 2 g oral granules.

Approved by the FDA on May 22, 2020, PHEXX is the first and only non-hormonal prescription contraceptive gel. It is locally acting, with no systemic activity, and used on-demand by women only when they have sex. Because PHEXX is a non-hormonal contraceptive, it is not associated with side effects of exogenous hormone use, which include depression, weight gain, headaches, loss of libido, mood swings and irritability. Taking hormones may not be right for some women, especially those with certain medical conditions, including clotting disorders hormone-sensitive cancer, diabetes, or a BMI over 30, or those who are breast feeding or who smoke. Per the National Center for Health Statistics (NCHS), more than 23.3 million women in the U.S. will not use a hormonal contraceptive.

Evofem has delivered PHEXX net sales growth in each consecutive year since it was launched in September 2020. Key growth drivers for 2025 include social media campaigns, participation in strategic medical conferences, and initiatives to expand use of PHEXX in women who take oral birth control pills in conjunction with GLP-1 prescription medications like Ozempic, Mounjaro and Zepbound for weight loss. These drugs may make oral birth control pills less effective at certain points in the dosing schedule. Per the United States Prescribing Information (USPI), prescribers are instructed to "advise patients using oral contraceptives to switch to a non-oral contraceptive method or add a barrier method" to prevent unintended pregnancy during these times.

In July 2024 we acquired global rights to SOLOSEC. This FDA-approved single-dose oral antimicrobial agent provides a complete course of therapy for the treatment of two common sexual health infections – bacterial vaginosis (BV) and trichomoniasis. The SOLOSEC acquisition aligns with and advances our mission to improve access to innovative and differentiated options that impact women's daily lives. We expect commercialization of SOLOSEC will benefit from our commercial infrastructure and strong physician relationships.

We intend to expand the global reach of our products and further increase our global potential through ex-U.S. partnerships or licensing agreements for PHEXX and SOLOSEC.

We licensed exclusive commercial rights for PHEXX in MENA to Pharma 1 Drug Store, an emerging Emirati health care company. Under the License and Supply Agreement dated on July 17, 2024, as amended on May 3, 2025, the licensed territory includes the UAE, Kuwait, Saudi Arabia, Qatar, Oman, and Jordan, with potential to expand into 15 other countries in the region. Pharma 1 is responsible for obtaining and maintaining any regulatory approvals required to market and sell PHEXX, and will handle all aspects of distribution, sales and marketing, pharmacovigilance and all other commercial functions in these countries. Evofem will supply product to Pharma 1 at cost-plus. Pharma 1 filed for regulatory approval of PHEXX in the UAE in June 2025.

The Company also licensed commercial rights to SOLOSEC in MENA to Pharma 1 on May 19, 2025. Under this agreement, the licensed territory includes the UAE, Kuwait, Saudi Arabia, Qatar, Oman, and Jordan, with potential to expand into 15 other countries in the region. Pharma 1 is responsible for obtaining and maintaining any regulatory approvals required to market and sell SOLOSEC, and will handle all aspects of distribution, sales and marketing, pharmacovigilance and all other commercial functions in these countries. Evofem will supply product to Pharma 1 at a specified cost per unit. Pharma 1 filed for regulatory approval of SOLOSEC in the UAE in September 2025.

Additionally, PHEXX was approved in Nigeria on October 6, 2022, as Femidence™ by the National Agency for Food and Drug Administration and Control. PHEXX has also been submitted for approval in Mexico, Ethiopia and Ghana.

We halted clinical development of our investigational product candidates in October 2022 to focus resources on growing domestic sales of PHEXX for the prevention of pregnancy.

In the second quarter of 2025, enrollment commenced in an investigator-led randomized, open-label, parallel Phase 4 clinical trial to evaluate the efficacy and cost-effectiveness of secnidazole (SOLOSEC® 2 g, one dose administered one time) versus metronidazole (Flagyl® 500 mg, administered twice daily for seven days) for the treatment of trichomoniasis in men and women. Study investigators hypothesize that, in the current clinical trial, the rate of repeat infections with *T. vaginalis* will be 1.75 lower in the SOLOSEC arm versus the multi-dose oral metronidazole arm and that single-dose SOLOSEC will have higher initial cost but will be more cost effective compared to multi-dose metronidazole, largely due to lower breakthrough rates of infection. This trial is funded directly by the National Institutes of Health (NIH).

In an investigator-led clinical study of SOLOSEC in 24 women with recurrent bacterial vaginosis (BV), once-weekly dosing with demonstrated

efficacy matching or potentially surpassing outcomes of current CDC-recommended suppressive treatments. These promising results underscore SOLOSEC's potential to redefine the standard of care for recurrent BV – offering a simpler treatment option for long-term symptom control. The study was presented at the 2025 American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting.

PHEXX as a Contraceptive; Commercial Strategies

In September 2020, we commercially launched PHEXX in the United States. Our sales force promotes PHEXX 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, two business directors and a Senior Vice President of Commercial Operations. Additionally, we offer women direct access to PHEXX via a telehealth platform. Using this platform, women can directly meet with an HCP to determine their eligibility for a PHEXX prescription and, if eligible, have the prescription written by the HCP, then filled and mailed directly to them by a third-party pharmacy.

Our comprehensive commercial strategy for PHEXX includes marketing and product awareness campaigns targeting HCPs and 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 oral birth control pill users, may be ready to move to an FDA-approved, non-invasive, non-systemic 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.

Key growth drivers for 2025 include social media campaigns, participation in strategic medical conferences, and initiatives to expand use of PHEXX in women who take oral birth control pills in conjunction with GLP-1 prescription medications like Ozempic, Mounjaro and Zepbound for weight loss. These drugs may make oral birth control pills less effective at certain points in the dosing schedule. Per the USPI, prescribers are instructed to “advise patients using oral contraceptives to switch to a non-oral contraceptive method or add a barrier method” to prevent unintended pregnancy during these times.

We continue working to increase the number of lives covered and to gain a preferred formulary position for PHEXX.

Previous contracting efforts have validated our access strategy. With PHEXX approval rates consistently above 80%, the Company has shifted from broad payer contracting to strengthening pharmacy partnerships. In 2025, we expanded our network in two of our highest-volume markets — California and the Northeast — by adding new partners in California and a regional distributor with more than 90 pharmacies in the Northeast. These targeted partnerships represent low-hanging fruit in high-demand areas, improving patient access while supporting more cost-effective and scalable pull-through.

Since the second quarter of 2022, we have been under contract with one of the largest pharmacy benefit managers (PBMs) in the nation, which added PHEXX 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 PHEXX on January 1, 2021. As of May 2025, Medicaid provides health coverage to approximately 70.5 million members; nearly two-thirds of adult women enrolled in Medicaid are in their reproductive years (19-44). Additionally, we began participating in a 340B Group Purchasing Organization (GPO) that serves safety-net clinics throughout the U.S. in June 2024. This GPO has over 6,500 members, which expands our reach among safety-net providers.

As of July 2025, approximately 86% of commercial and Medicaid PHEXX prescriptions are being approved by payers.

PHEXX 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.”

Effective as of January 1, 2023, most insurers and 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 PHEXX, prescribed by healthcare providers.

To comply with these federal guidelines, payers are increasingly covering PHEXX by:

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

In 2022, Evofem developed and introduced a new contraceptive 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 contraceptive educational tool has been extremely well received and has had a positive impact with HCPs and patients alike.

SOLOSEC

In July 2024, we expanded our commercial portfolio by acquiring global rights to SOLOSEC® (secnidazole) 2 g oral granules, a single-dose oral antimicrobial agent that provides a complete course of therapy with just one dose for the treatment of two common sexual health infections. SOLOSEC is FDA-approved for the treatment of:

1) Bacterial vaginosis (BV), a common vaginal infection, in females 12 years of age and older, and
2) *Trichomonas vaginalis*, a common sexually transmitted infection (STI), in people 12 years of age and older.

SOLOSEC has the same call point as PHEXX, enabling us to leverage our commercial infrastructure and strong physician relationships. We re-launched the brand in November 2024.

Bacterial Vaginosis

Bacterial vaginosis (BV) affects an estimated 21 million women in the U.S., approximately 29% of the U.S. population, making it the most common vaginal condition in women ages 15-44. It results from an overgrowth of bacteria, which upsets the balance of the natural vaginal microbiome and can lead to symptoms including odor and discharge. Of interest, BV raises the pH of the vagina, making it a more friendly environment for trichomoniasis and other STIs; approximately 20% of BV patients also have trichomoniasis.

If left untreated, BV can have serious health consequences. Untreated or improperly treated BV is associated with increased risk of infection with STIs like HPV, herpes, trichomoniasis, chlamydia, gonorrhea, and HIV, as well as transmission of STIs to a partner. Additional risks include developing pelvic inflammatory disease (PID), which can threaten a woman's fertility, and complications with gynecological surgery.

Research has shown that as many as 50% of patients with BV do not adhere to a full course of metronidazole treatment (500mg BID x 7d) 14 doses. 58% of women who do not complete therapy will have a recurrence within one year. Noncompliance to a multiple-day metronidazole regimen is a contributing factor to persistent BV.

In clinical trials, SOLOSEC demonstrated clinically and statistically significant efficacy in the treatment of BV with just one dose; 68% of patients treated with SOLOSEC did not require any additional treatment for BV. Guidelines from the American College of Obstetricians and Gynecologists (ACOG) in 2020 and the U.S. Centers for Disease Control (CDC) in 2021 each include single dose SOLOSEC for the treatment of BV.

In May 2025, an investigator-led clinical trial entitled 'Once Weekly Secnidazole Granules for the Treatment of Recurrent Bacterial Vaginosis' was presented at the 2025 ACOG Annual Clinical and Scientific Meeting; the abstract was subsequently published in *Obstetrics & Gynecology*. In this focused clinical study of 24 women with recurrent BV, once-weekly dosing with SOLOSEC demonstrated efficacy matching or potentially surpassing outcomes of current CDC-recommended suppressive treatments. These promising results underscore SOLOSEC's potential to redefine the standard of care for recurrent BV by offering a simpler treatment option for long-term symptom control.

Trichomoniasis

Trichomoniasis (Trich) is the most common non-viral STI in the world. It is caused by a parasite called *Trichomonas vaginalis* and affects both women and men. All sexual partners of an infected person must be treated to prevent reinfection with the parasite. In 2018, there were an estimated 6.9 million new *T. vaginalis* infections in the U.S. According to the CDC, the U.S. prevalence of *T. vaginalis* is 2.1% among females and 0.5% among males, with the highest rates among Black females (9.6%) and Black males (3.6%). A study of STD clinic attendees in Birmingham, Alabama, identified a prevalence of 27% among women and 9.8% among men. Approximately 70% of women with trichomoniasis are also infected with the bacteria that cause BV.

In clinical trials, a single dose of SOLOSEC demonstrated a cure rate of 92.2% for Trich in women, while reported cure rates in males range from 91.7%-100%.

SOLOSEC's one-and-done dosing and the resulting high level of compliance is believed to be a significant differentiator. Non-compliance to a multi-day metronidazole regimen is a contributing factor to persistent Trich or BV; and ACOG and the CDC no longer recommend single dose metronidazole to treat Trich in women.

A Phase 4 investigator-led randomized, open-label, parallel arm clinical trial is underway to evaluate the efficacy and cost-effectiveness of secnidazole (SOLOSEC 2 g, one dose administered one time) versus metronidazole (Flagyl® 500 mg, administered twice daily for seven days) for the treatment of trichomoniasis in men and women. Study investigators hypothesize that, in the current clinical trial, the rate of repeat infections with *T. vaginalis* will be 1.75 lower in the SOLOSEC arm versus the multi- dose oral metronidazole arm and that single-dose SOLOSEC will have higher initial cost but will be more cost effective compared to multi-dose metronidazole, largely due to lower breakthrough rates of infection. This trial is funded by the National Institutes of Health (NIH).

Recent Developments

Aditxt Merger Termination

On July 12, 2024, the Company entered into an Agreement and Plan of Merger, as amended, (the A&R Merger Agreement) with Aditxt, Inc., a Delaware corporation (Aditxt), and Adifem, Inc., a Delaware corporation and 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).

On October 20, 2025, the Company held a Special Meeting of Stockholders. After the Company's stockholders did not approve a proposal to approve the transactions contemplated by the A&R Merger Agreement, the Company delivered a notice of termination to Aditxt notifying it that the Company was exercising its right to terminate the A&R Merger Agreement effective October 20, 2025. The termination was in accordance with (i) Section 8.1(b)(ii), which allows either party to terminate the A&R Merger Agreement if the Merger shall not have been consummated on or before 5:00 p.m. Eastern Time, on September 30, 2025, and (ii) as per Section 8.1(b)(iv), which allows either party to terminate the A&R Merger Agreement if the Company Shareholder Approval shall not have been obtained at a duly held Company Shareholders Meeting at which a vote was taken on the approval of the Agreement and the Transactions, including the Merger.

As a result of the termination of the A&R Merger Agreement, all other ancillary agreements related to the A&R Merger Agreement, with the exception of the obligations under the Non-Disclosure Agreement, entered into by and between the Company and Aditxt, as of October 23, 2023, terminated concurrently with the termination of the A&R Merger Agreement. No consideration was paid in connection with the termination.

We are now pursuing a new path, including aiming to re-list our stock on the Nasdaq Capital Market or a comparable national market and complete a fundraising round to provide critical capital for sales and marketing initiatives designed to catalyze our net sales growth over the next 18-24 months.

Adjuvant Amendment

On October 13, 2025, we entered into a Third Amendment to our Securities Purchase Agreement with Adjuvant Global Health Technology Fund, which extended the maturity and payment terms of the Adjuvant Notes. See Note 10 — Subsequent Events.

2025 Equity Incentive Plan

On October 3, 2025, our Board approved the 2025 Equity Incentive Plan authorizing up to 50 million shares, subject to stockholder approval at the 2025 Annual Meeting. No awards have been granted under the plan to date.

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 U.S. since the commercial launch of PHEXX in September 2020; SOLOSEC net product sales were added to our revenue beginning in July 2024. Gross revenues, as discussed in Note 3 - Revenue, are adjusted for variable consideration, including our patient support programs.

Operating Expenses

Cost of Goods Sold

Inventory costs include all purchased materials, direct labor, and manufacturing overhead. In addition, in prior years we accrued quarterly royalty amounts that would have been due pursuant to our license agreement with Rush University had their application for PTE been granted. The royalty expense accrued were 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. Due to the patent expiration, no royalty costs were recorded for the three and nine months ended September 30, 2025, while $0.2 million and $0.6 million were recorded for the three and nine months ended September 30, 2024 and were included in the costs of goods sold in the condensed consolidated statements of operations. As described in Note 7 – Commitments and Contingencies, no further royalties are due to Rush University now that the patent has expired and the amounts that had been previously accrued but were unpaid as of December 31, 2024 were reversed in the current period, which had a favorable impact on the total operating expenses during the three months ended September 30, 2025 of approximately $1.9 million that is not expected to be repeated in further periods. Due to the materiality and the one-time nature of the reversal, the amount was included in the gain on change in accounting estimates on contingent royalty liability in the condensed consolidated statements of operations.

We are obligated to pay quarterly royalties under the SOLOSEC Asset Purchase Agreement dated July 14, 2024; this royalty is based on a percentage of SOLOSEC net sales, adjusted for co-pay program costs. There are no minimum quarterly or annual royalty amounts. Such royalty costs were immaterial and approximately $0.1 million for the three and nine months ended September 30, 2025, respectively.

Research and Development Expenses

Our research and development expenses primarily consist of costs associated with ongoing improvements related to our products. These expenses include:

- continuous improvements of manufacturing and analytical efficiency;
- ongoing 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.

We expense internal and third-party research and development expenses as incurred. We do not anticipate significant investment in clinical development for the foreseeable future.

Selling and Marketing Expenses

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

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.

Other Income (Expense)

Other income (expense) consists primarily of interest expense and the fair value adjustments of financial instruments issued in various capital raise transactions, including loss on issuance of financial instruments, quarterly change in fair value adjustments, and gains or losses on debt extinguishment. The change in fair value of financial instruments was recognized as a result of mark-to-market adjustments for those financial instruments.

Results of Operations

Three Months Ended September 30, 2025 Compared to Three Months Ended September 30, 2024 (in thousands):

Net Product Sales

	Three Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Product sales, net	$ 4,952	$ 4,496	$ 456	10%

The increase in product sales, net, primarily reflects a full quarter of SOLOSEC in the current year period as well as the increased PHEXX WAC that took effect January 1, 2025.

Cost of Goods Sold

	Three Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Cost of goods sold	$ 905	$ 869	$ 36	4%

The immaterial increase in cost of goods sold was in line with the increased product sales, net, partially offset by the lack of accrual for the Rush Royalty contingent liability in the current year.

Gain on Change in Accounting Estimates on Contingent Royalty Liability

	Three Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Gain on change in accounting estimates on contingent royalty liability	$ (1,933)	$ -	$ (1,933)	(100)%

The $1.9 million gain on change in accounting estimates on contingent royalty liability was due to the reversal of previously accrued but unpaid amounts related to the Rush Royalty as a result of the additional information obtained during the three months ended September 30, 2025, including clarification by the FDA that no PTE should be granted. See Note 7 – Commitments and Contingencies for more information regarding this reversal.

Amortization of Intangible Asset

	Three Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Amortization of intangible asset	$ 80	$ 301	$ (221)	(73)%

The decrease in amortization of intangible asset was primarily due to the decrease in the intangible value due to the prior quarterly valuation of the SOLOSEC contingent liability.

Research and Development Expenses

	Three Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Research and development, net	$ 470	$ 332	$ 138	42%

The increase in research and development expenses was primarily due to a $0.1 million increase in personnel costs.

Selling and Marketing Expenses

	Three Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change

Selling and marketing	$ 2,391	$ 2,382	$ 9	0%

The immaterial increase in selling and marketing expenses reflects a $0.1 million increase in personnel costs, partially offset by a decrease in business development and outside services expenses.

General and Administrative Expenses

	Three Months Ended September 30,		2025 vs. 2024	
	2025	**2024**	**$ Change**	**% Change**
General and administrative	$ 2,088	$ 3,052	$ (964)	(32)%

The decrease in general and administrative expenses was primarily due to an approximately $0.8 million decrease in professional services costs and a reduction of approximately $0.2 million in personnel costs.

Total Other Income (Expense), Net

	Three Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Total other income (expense), net	$ (2,524)	$ 67	$ (2,591)	(3,867)%

Total other expense, net, for the three months ended September 30, 2025 primarily included $0.7 million of interest expense related primarily to the Adjuvant Note and a loss of $1.8 million related to the change in fair value of financial instruments including adjustments related to the purchase rights of $1.1 million and those related to the Baker Notes of $0.7 million. Historically the changes in fair value related to the Baker Notes have been recorded in the condensed consolidated statements of comprehensive operations as the changes were determined to be related to changes in the Company's credit risk. However, in the three months ended September 30, 2025, the primary driver for the increase in the fair value of the Baker Notes is related to the Company not retiring the notes by September 8, 2025, which caused the total amount legally payable to repurchase the notes to increase by approximately $2.8 million.

Total other income, net, for the three months ended September 30, 2024 primarily included a $0.8 million gain on the change in fair value of financial instruments, partially offset by $0.6 million in interest expense related to the Adjuvant Note and loss on the debt extinguishment of $0.1 million.

Nine Months Ended September 30, 2025 Compared to Nine Months Ended September 30, 2024 (in thousands):

Net Product Sales

	Nine Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Product sales, net	$ 10,622	$ 12,259	$ (1,637)	(13)%

The decrease in product sales, net, was primarily due to lower PHEXX sales volume, partially offset by the addition of SOLOSEC in the current year and the increased PHEXX WAC that took effect January 1, 2025.

Cost of Goods Sold

	Nine Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Cost of goods sold	$ 2,025	$ 2,322	$ (297)	(13)%

The decrease in cost of goods sold in the current year was due primarily to the lower product sales, net as well as the lack of expense related to the Rush Royalty liability in the current year, which was an expense in the prior year.

Gain on Change in Accounting Estimates on Contingent Royalty Liability

	Nine Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Gain on change in accounting estimates on contingent royalty liability	$ (1,933)	$ -	$ (1,933)	(100)%

The gain on change in accounting estimates on contingent royalty liability was due to the reversal of previously accrued but unpaid amounts related to the Rush Royalty as a result of the additional information obtained during the three months ended September 30, 2025, including clarification by the FDA that no PTE should be granted. See Note 7 – Commitments and Contingencies for more information regarding this reversal.

Amortization of Intangible Asset

	Nine Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Amortization of intangible asset	$ 410	$ 301	$ 109	36%

The increase in amortization of intangible asset was primarily due to the timing of the SOLOSEC acquisition. Because the acquisition closed in July 2024, the prior year amortization was therefore only for a partial portion of the nine-month period while the current year is for the entire nine-month period.

Research and Development Expenses

	Nine Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Research and development, net	$ (3,819)	$ 1,196	$ (5,015)	(419)%

The decrease in research and development expenses was primarily due to the negotiation of a portion of the Company's trade payables and accrued liabilities, which resulted in a $5.6 million reduction in research and development expenses in the current period. The decrease was partially offset by an increase of $0.7 million in facilities and outside services costs.

Selling and Marketing Expenses

	Nine Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Selling and marketing	$ 7,616	$ 6,970	$ 646	9%

The increase in selling and marketing expenses was primarily due to a $0.3 million increase related to the PDUFA fee for SOLOSEC as well as an increase in facilities and outside services costs of $0.3 million.

General and Administrative Expenses

	Nine Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
General and administrative	$ 6,296	$ 8,143	$ (1,847)	(23)%

The decrease in general and administrative expenses was primarily due to a $1.0 million decrease in professional services, a $0.4 million decrease in personnel costs, and a $0.4 million reduction in facilities costs.

Total Other Income (Expense), Net

	Nine Months Ended September 30,		2025 vs. 2024	
	2025	2024	$ Change	% Change
Total other income (expense), net	$ (2,421)	$ 850	$ (3,271)	(385)%

Total other expense, net, for the nine months ended September 30, 2025 primarily included a $1.9 million interest expense related to the Adjuvant Note and a loss on the change in fair value of financial instruments of $0.5 million, including a gain related to the purchase rights of $0.2 million and a loss related to the Baker Notes of $0.7 million. Historically the changes in fair value related to the Baker Notes have been recorded in the condensed consolidated statements of comprehensive operations as the changes were determined to be related to changes in the Company's credit risk. However, in the three months ended September 30, 2025, the primary driver for the increase in the fair value of the Baker Notes is related to the Company not retiring the notes by September 8, 2025, which caused the total amount legally payable to repurchase the notes to increase by approximately $2.8 million.

Total other income, net, for the nine months ended September 30, 2024 primarily included a $4.9 million gain on the change in fair value of financial instruments and a gain of $1.0 million related to the Baker Notes extinguishment. The gains were partially offset by a $3.3 million loss on the issuance of financial instruments related to the anti-dilution adjustment for the purchase rights and $1.7 million of interest expense related to the Adjuvant Note.

Liquidity and Capital Resources

Overview

As of September 30, 2025, we had a working capital deficit of $70.3 million and an accumulated deficit of $900.2 million. We have financed our operations to date primarily through the issuance of preferred stock, Common Stock, warrants and convertible and term notes; cash received from private placement transactions; and, to a lesser extent, product sales. As of September 30, 2025, we had approximately $0.8 million in cash and cash equivalents, all of which is 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 September 30, 2025 are insufficient to fund operations for at least the next 12 months from the date on which this Quarterly Report on Form 10-Q is filed with the SEC.

We have incurred losses and negative cash flows from operating activities since inception. In 2024, we focused on further improving and increasing PHEXX access, acquired global rights to SOLOSEC, and delivered our fourth consecutive year of PHEXX net sales growth. In 2025, we continue to focus on top-line growth while maintaining a lean operating structure. We will continue to explore opportunities for organic growth, entry into new markets including those covered by our license and supply agreements with Pharma 1, and potential expansion of our product offerings beyond PHEXX and SOLOSEC.

As of September 30, 2025, the Company's significant commitments include the Baker Notes, Adjuvant Notes, SSNs, and Aditxt Notes as described in Note 4 - Debt and fleet leases, SOLOSEC contingent liability, and the potential settlement amount with TherapeuticsMD as described in Note 7 - Commitments and Contingencies. The purpose of these commitments is to further the commercialization of PHEXX and SOLOSEC. Management's plans to meet the Company's cash flow needs in the next 12 months include generating revenue from the sale of PHEXX and SOLOSEC, further restructuring of the Company's current payables, and obtaining additional funding through means such as the issuance of its capital stock, non-dilutive or dilutive financings, or through collaborations or partnerships with other companies, including license agreements for PHEXX and/or SOLOSEC in the U.S. or foreign markets, or other potential business combinations.

If the Company is not able to obtain the required funding through a significant increase in revenue, equity or debt financings, license agreements for our products in the U.S. 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 condensed 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 condensed 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 condensed 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, 2024 and 2023 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 unaudited condensed consolidated financial statements as of September 30, 2025 and December 31, 2024 and for the three and nine months ended September 30, 2025 and 2024 included in this Quarterly 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.

The Company expects future equity-based compensation expense to increase following stockholder approval of the 2025 Equity Incentive Plan, which authorizes up to 50 million additional shares.

Potential Impact of Federal Government Shutdown

Certain functions of the U.S. federal government, including the Food and Drug Administration (FDA) and other agencies that regulate or reimburse our products, may be limited or delayed in the event of a government shutdown. A prolonged shutdown could delay FDA reviews or other regulatory interactions, temporarily slow processing of payor or government program reimbursements, or defer implementation of new coverage or public-health initiatives. At this time, management does not expect any material adverse impact on our ongoing commercial operations, but we continue to monitor the situation.

Summary Statement of Cash Flows

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

	Nine Months Ended September 30,		2025 vs. 2024	
	2025	**2024**	**$ Change**	**% Change**
Net cash, cash equivalents and restricted cash used in operating activities	$ (2,023)	$ (1,477)	$ (546)	(37)%
Net cash, cash equivalents and restricted cash used in investing activities	(59)	(523)	464	89%
Net cash, cash equivalents and restricted cash provided by in financing activities	2,181	2,142	39	2%
Net change in cash, cash equivalents and restricted cash	$ 99	$ 142	$ (43)	(30)%

Cash Flows from Operating Activities. During the nine months ended September 30, 2025, the primary use of cash, cash equivalents and restricted cash in operating activities was driven by net loss of $2.4 million plus net adjustments to reconcile net loss to net cash, cash equivalents, and restricted cash used in operating activities of $4.4 million. The increase in cash used in operating activities was also driven by the payment of trade payables of $1.4 million, contingent liabilities of $0.5 million, and the purchase of inventory of $0.3 million. The use of cash, cash equivalents, and restricted cash in operating activities was partially offset by the collection of $5.4 million of accounts receivable and increases in accrued expenses and other liabilities of $1.0 million and prepaid expenses of $0.5 million.

During the nine months ended September 30, 2024, the primary use of cash, cash equivalents and restricted cash in operating activities was driven by net loss of $5.8 million offset by net adjustments to reconcile net loss to net cash, cash equivalents, and restricted cash used in operating activities of $1.0 million. The cash used in operating activities was also driven by the payment of trade payables of $0.2 million, partially offset by the collection of $0.3 million of accounts receivable, $0.2 million fewer inventory purchases, and increases in accrued expenses and other liabilities of $2.2 million, accrued compensation of $0.6 million, and prepaid expenses of $0.2 million.

Cash Flows from Investing Activities. During the nine months ended September 30, 2025, the primary use of cash, cash equivalents and restricted cash was the payment of legal and accounting fees related to the acquisition of SOLOSEC which had previously been recorded as accounts payable. During the nine months ended September 30, 2024, the primary use of cash, cash equivalents and restricted cash was the acquisition of the SOLOSEC asset.

Cash Flows from Financing Activities. During the nine months ended September 30, 2025, the primary source of cash, cash equivalents and restricted cash was related to the Aditxt Notes and the financing agreement with First Insurance Funding for total net proceeds to the Company of approximately $2.8 million, partially offset by the payment of short-term debt and quarterly cash payments due under the Fourth Baker Amendment of $0.6 million. During the nine months ended September 30, 2024, the primary source of cash, cash equivalents, and restricted cash was from the $1.0 million received from Aditxt in order to reinstate the Merger Agreement as described above as well as the $1.3 million in Series F-1 Preferred Stock purchased by Aditxt, and the finance agreement with First Insurance Funding for $0.4 million. These inflows were partially offset by $0.5 million of payments under the Baker Notes and short-term debt.

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 2025, while we expect to maintain a lean operating structure at approximately the same level as 2024; should resources

become available we may increase marketing spend to drive further sales growth.

Contractual Obligations and Commitments

Operating Leases

Operating lease right-of-use assets and lease liabilities were $0.2 million and $0.1 million on September 30, 2025 and December 31, 2024, respectively. 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 PHEXX, with potential to manufacture other product candidates, in accordance with all applicable current good manufacturing practice regulations. There were $0.3 million and $1.1 million in purchases under the supply and manufacturing agreement for the three and nine months ended September 30, 2025, respectively, and $0.8 million and $1.0 million in such purchases during the three and nine months ended September 30, 2024.

As described in Note 7 - Commitments and Contingencies, the Company also has commitments related to the SOLOSEC asset acquisition, including a commitment to purchase inventory from the seller through November 2026 at a pre-defined unit price. The Company is further obligated to pay contingent liabilities and quarterly royalties based on SOLOSEC net revenue over the Earnout Term as described in Note 7 - Commitments and Contingencies.

Intellectual Property Rights

As described in Note 7 - Commitments and Contingencies, royalty costs estimated to be payable to Rush University pursuant to the Rush License Agreement were $0.2 million and $0.6 million for the three and nine months ended September 30, 2024. No such amounts were incurred for the three and nine months ended September 30, 2025 due to the expiration of the Rush patent. As of December 31, 2024, approximately $1.9 million were included in accrued expenses in the condensed consolidated balance sheets and no such accrual existed at September 30, 2025 due to the gain on change in accounting estimates on contingent royalty liability recorded during the nine months ended September 30, 2025.

Other Matters

Recently Issued Accounting Pronouncements

For information with respect to recent accounting pronouncements, see Note 2 - Summary of Significant Accounting Policies to our condensed consolidated financial statements appearing in Part I, Item 1 of this Quarterly Report.

Critical Accounting Policies

There have not been any material changes to the critical accounting policies disclosed in our Form 10-K for the year ended December 31, 2024**.**

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended (the Exchange Act) is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

As described in our Annual Report on Form 10-K for the year ended December 31, 2024, we identified material weaknesses in our internal control over financial reporting. As a result of these material weaknesses, our Chief Executive Officer (CEO) and Chief Financial Officer (CFO) have concluded that our disclosure controls and procedures are not effective to provide reasonable assurance that information required to be disclosed in the reports we file and submit under the Securities and Exchange Act is recorded, processed, summarized, and reported as and when required.

Notwithstanding the conclusion by our CEO and CFO that our Disclosure Controls as of September 30, 2025 were not effective, and notwithstanding the material weaknesses in our internal control over financial reporting described more fully under Item 9A in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, management believes that the condensed consolidated financial statements and related financial information included in this Quarterly Report on Form 10-Q fairly present in all material respects our financial condition, results of operations and cash flows as of the date presented, and for the periods ended on such dates, in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP).

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.

Changes in Internal Control over Financial Reporting

Except for ongoing remediation activities described in the preceding paragraph, there were no changes in our internal control over financial reporting that occurred during our latest fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Internal Controls

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.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Refer to Note 7 - Commitments and Contingencies to the unaudited condensed consolidated financial statements in this Form 10-Q for any required disclosure.

Item 1A. Risk Factors

There have not been any material changes to the risk factors disclosed in our Form 10-K for the year ended December 31, 2024, as filed with the SEC on March 24, 2025 and amended on March 28, 2025.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(a) None.

(b) None.

(c) Rule 10b5-1 Trading Plans

During the three months ended September 30, 2025, none of our directors or officers entered into, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," that were intended to satisfy the affirmative defense conditions of Rule 10b5-1, in each case as defined in Item 408 of Regulation S-K.

Item 6. Exhibits

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

EXHIBIT INDEX

Exhibit No.	Exhibit Title	Filed Herewith	Incorporated by Reference		
			Form	File No.	Date Filed
2.1	Amended and Restated Plan of Merger, by and between the Company, Aditxt, Inc. and Adifem, Inc.		8-K	001-36754	7/18/2024
2.2	First Amendment to the Amended and Restated Agreement and Plan of Merger, by and between the Company, Aditxt, Inc., and Adifem, Inc., dated August 16, 2024		8-K	001-36754	8/20/2024
2.3	Second Amendment to the Amended and Restated Agreement and Plan of Merger, by and between the Company, Aditxt, Inc., and Adifem, Inc., dated September 6, 2024		8-K	001-36754	9/6/2024
2.4	Third Amendment to the Amended and Restated Agreement and Plan of Merger, by and among the Company, Aditxt, Inc. and Adifem, Inc., dated October 2, 2024		8-K	001-36754	10/3/2024
2.5	Fourth Amendment to the Amended and Restated Agreement and Plan of Merger, by and among the Company, Aditxt, Inc. and Adifem, Inc., dated November 19, 2024		8-K	001-36754	11/25/2024
2.6	Fifth Amendment to the Amended and Restated Agreement and Plan of Merger by and among the Company, Aditxt, Inc. and Adifem, Inc., dated March 22, 2025		10-K	001-36754	3/24/2025
2.7	Sixth Amendment to the Amended and Restated Merger Agreement, dated August 26, 2025		8-K	001-36754	8/26/2025
3.1	Certificate of Designations of the Series G-1 Preferred Stock		8-K	001-36754	8/26/2025
10.1	License and Supply Agreement dated March 20, 2025		8-K	001-36754	3/26/2025
10.2	Amendment No. 1 to License and Supply Agreement dated March 20, 2025		8-K	001-36754	4/3/2025

10.3		Form of Securities Purchase Agreement		8-K	001-36754	7/2/2025
10.4		Form of Senior Subordinated Convertible Note		8-K	001-36754	7/2/2025
10.5		Form of Warrant		8-K	001-36754	7/2/2025
10.6		Form of Call Option Agreement		8-K	001-36754	4/14/2025
10.7		First Amendment to Development and Supply Agreement dated May 3, 2025		8-K	001-36754	5/8/2025
10.8		License Agreement by and between the Company and Pharma 1 Drug Store, L.L.C		8-K	001-36754	5/22/2025
10.9		Form of Exchange Agreement		8-K	001-36754	8/26/2025
10.10		Third Amendment to Securities Purchase Agreement dated as of October 13, 2025		8-K	001-36754	10/17/2025
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			

* Furnished herewith. This certification is being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, 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.

† The financial information of Evofem Biosciences, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2025 filed on November 13, 2025 formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) Parenthetical Data to the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Operations, (iv) the Condensed Consolidated Statements of Convertible and Redeemable Preferred Stock and Stockholders' Deficit, (v) the Condensed Consolidated Statements of Cash Flows, and (vi) Notes to Unaudited Condensed Consolidated Financial Statements, is furnished electronically herewith.

^^ 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EVOFEM BIOSCIENCES, INC.

Date: November 13, 2025

By: */s/ Ivy Zhang*
Ivy Zhang
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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 quarterly report on Form 10-Q of Evofem Biosciences, Inc.;

2 Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3 Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4 The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5 The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(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: November 13, 2025

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 quarterly report on Form 10-Q of Evofem Biosciences, Inc.;

2 Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3 Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4 The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5 The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(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: November 13, 2025

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 Quarterly Report of Evofem Biosciences, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Quarterly 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 Quarterly 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 Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2025

By: */s/ Saundra Pelletier*
Saundra Pelletier
President, Chief Executive Officer, and Interim Chairperson of the Board
(Principal Executive Officer)

Date: November 13, 2025

By: */s/ Ivy Zhang*
Ivy Zhang
Chief Financial Officer and Secretary
(Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.