

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 March 31, 2024

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: 001-40492

Femasys Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	11-3713499
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
3950 Johns Creek Court, Suite 100	
Suwanee, GA	30024
(Address of principal executive offices)	(Zip Code)
(770) 500-3910	
(Registrant's telephone number, including area code)	
N/A	
(Former name, former address and former fiscal year, if changed since last report)	

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

Title of each class	Trading symbol	Name of each exchange on which registered
Common stock, \$0.001 par value	FEMY	The Nasdaq Capital Market

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐  
Non-accelerated filer ☒  
Emerging growth company ☒

Accelerated filer ☐  
Smaller reporting 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 Registrant had 22,220,718 shares of common stock, \$0.001 par value, outstanding as of May 8, 2024.

## TABLE OF CONTENTS

		Page
	<b>Part I. Financial Information</b>	
Item 1	<a href="#">Condensed Financial Statements</a>	5
	<a href="#">Condensed Balance Sheets as of March 31, 2024 and December 31, 2023 (unaudited)</a>	6
	<a href="#">Condensed Statements of Comprehensive Loss for the Three months ended March 31, 2024 and 2023 (unaudited)</a>	7
	<a href="#">Condensed Statements of Stockholders' Equity for the Three months ended March 31, 2024 and 2023 (unaudited)</a>	8
	<a href="#">Condensed Statements of Cash Flows for the Three months ended March 31, 2024 and 2023 (unaudited)</a>	9
	<a href="#">Condensed Notes to Financial Statements (unaudited)</a>	10
Item 2	<a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	18
Item 3	<a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	22
Item 4	<a href="#">Controls and Procedures</a>	22
	<b>Part II. Other Information</b>	
Item 1	<a href="#">Legal Proceedings</a>	22
Item 1A	<a href="#">Risk Factors</a>	23
Item 2	<a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	23
Item 3	<a href="#">Defaults Upon Senior Securities</a>	23
Item 4	<a href="#">Mine Safety Disclosures</a>	23
Item 5	<a href="#">Other Information</a>	23
Item 6	<a href="#">Exhibits</a>	23
<a href="#">SIGNATURES</a>		24

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- our ability to develop and advance our current product candidates and programs into, and successfully initiate and complete, clinical trials;
- the ability of our clinical trials to demonstrate safety and effectiveness of our product candidates and other positive results;
- our ability to enroll subjects in the clinical trials for our product candidates in order to advance the development thereof on a timely basis;
- our ability to successfully initiate and grow the commercial launch of FemaSeed®;
- our ability to obtain additional financing to fund the clinical development and commercialization of our product candidate and products and fund our operations;
- estimates regarding the total addressable market for our products and product candidate;
- competitive companies and technologies in our industry;
- our ability to obtain U.S. Food and Drug Administration (FDA) approval for our permanent birth control system, ability to establish and expand sales of our women-specific medical products and develop and commercialize additional products;
- our ability to obtain regulatory approvals for and commercialize our product candidate, or the effect of delays in obtaining regulatory authorizations and commercialize;
- our business model and strategic plans for our products, product candidate, technologies and business, including our implementation thereof;
- commercial success and market acceptance of our products and product candidate;
- our ability to achieve and maintain adequate levels of coverage or reimbursement for FemaSeed, FemBloc® or any future product candidates, and our products we may seek to commercialize;
- our ability to manufacture our products and product candidates in compliance with applicable laws, regulations and requirements and to oversee third-party suppliers, service providers and vendors in the performance of any contracted activities in accordance with applicable laws, regulations and requirements;
- our ability to accurately forecast customer demand for our product candidates, and manage our inventory;
- our ability to build, manage and maintain our direct sales and marketing organization, and to market and sell our artificial insemination product, permanent birth control system, and women-specific medical product solutions in markets in and outside of the United States;
- our ability to hire and retain our senior management and other highly qualified personnel;
- FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry generally, including healthcare reform measures in the United States and international markets;
- the timing or likelihood of regulatory filings and approvals or clearances;
- our ability to establish and maintain intellectual property protection for our product candidates and our ability to avoid claims of infringement;
- the volatility of the trading price of our common stock; and
- our expectations about market trends.

[Table of Contents](#)

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this Quarterly Report on Form 10-Q entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report on 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the Securities and Exchange Commission as exhibits hereto completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. The forward-looking statements contained in this Quarterly Report on 10-Q are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended.

**PART I. FINANCIAL INFORMATION**

**ITEM I. Financial Statements**

**FEMASYS INC.**  
Condensed Balance Sheets  
(unaudited)

	<b>Assets</b>	<b>March 31, 2024</b>	<b>December 31, 2023</b>
Current assets:			
Cash and cash equivalents		\$ 17,835,968	21,716,077
Accounts receivable, net		120,529	98,906
Inventory, net		971,297	667,118
Prepaid and other current assets		955,539	695,879
Total current assets		<u>19,883,333</u>	<u>23,177,980</u>
Property and equipment, at cost:			
Leasehold improvements		1,212,417	1,212,417
Office equipment		47,308	47,308
Furniture and fixtures		417,654	414,303
Machinery and equipment		2,582,220	2,559,356
Construction in progress		569,723	423,077
		<u>4,829,322</u>	<u>4,656,461</u>
Less accumulated depreciation		<u>(3,615,405)</u>	<u>(3,545,422)</u>
Net property and equipment		<u>1,213,917</u>	<u>1,111,039</u>
Long-term assets:			
Lease right-of-use assets, net		2,227,561	2,380,225
Intangible assets, net of accumulated amortization		33,115	
Other long-term assets		1,013,034	1,086,581
Total long-term assets		<u>3,273,710</u>	<u>3,466,806</u>
Total assets		<u>\$ 24,370,960</u>	<u>27,755,825</u>

(continued)

**FEMASYS INC.**  
Condensed Balance Sheets  
(unaudited)

	March 31, 2024	December 31, 2023
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,095,730	1,137,8
Accrued expenses	673,457	1,444,2
Clinical holdback – current portion	93,376	65,3
Lease liabilities – current portion	494,967	406,6
Total current liabilities	<u>2,357,530</u>	<u>3,054,0</u>
Long-term liabilities:		
Clinical holdback – long-term portion	30,389	54,9
Convertible notes payable, net (including related parties)	4,472,456	4,258,1
Lease liabilities – long-term portion	1,902,991	2,036,0
Total long-term liabilities	<u>6,405,836</u>	<u>6,349,1</u>
Total liabilities	<u>8,763,366</u>	<u>9,403,2</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par, 200,000,000 authorized, 22,216,570 shares issued and 22,099,347 outstanding as of March 31, 2024; and 21,774,604 shares issued and 21,657,381 outstanding as of December 31, 2023	22,217	21,7
Treasury stock, 117,223 common shares	(60,000)	(60,0
Warrants	2,631,838	2,787,1
Additional paid-in-capital	124,994,678	123,985,3
Accumulated deficit	<u>(111,981,139)</u>	<u>(108,381,6</u>
Total stockholders' equity	<u>15,607,594</u>	<u>18,352,1</u>
Total liabilities and stockholders' equity	<u>\$ 24,370,960</u>	<u>27,755,3</u>

The accompanying notes are an integral part of these condensed unaudited financial statements.

**FEMASYS INC.**  
Condensed Statements of Comprehensive Loss  
(unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Sales	\$ 271,140	293,984
Cost of sales (excluding depreciation expense)	88,532	105,120
Operating expenses:		
Research and development	1,770,731	1,537,439
Sales and marketing	300,487	244,896
General and administrative	1,502,804	1,315,137
Depreciation and amortization	71,228	133,066
Total operating expenses	3,645,250	3,230,538
Loss from operations	(3,462,642)	(3,041,674)
Other income (expense):		
Interest income	224,684	97,089
Interest expense	(361,552)	(1,672)
Total other income (expense)	(136,868)	95,417
Net loss	\$ (3,599,510)	(2,946,257)
Net loss attributable to common stockholders, basic and diluted	\$ (3,599,510)	(2,946,257)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.17)	(0.25)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	21,775,357	11,872,255

The accompanying notes are an integral part of these condensed unaudited financial statements.

**FEMASYS INC.**  
Condensed Statements of Stockholders' Equity  
(unaudited)

	Common stock		Treasury common stock		Warrants	Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount				
<b>THREE MONTHS ENDED MARCH 31, 2024</b>								
Balance at December 31, 2023	21,774,604	\$ 21,775	117,223	\$ (60,000)	\$ 2,787,137	\$ 123,985,306	\$ (108,381,629)	\$ 18,352,589
Share-based compensation expense	—	—	—	—	—	77,585	—	77,585
Issuance of common stock in connection with at-the-market offering, net of issuance costs	441,966	442	—	—	—	776,488	—	776,930
Expiration of warrant	—	—	—	—	(155,299)	155,299	—	—
Net loss	—	—	—	—	—	—	(3,599,510)	(3,599,510)
Balance at March 31, 2024	<u>22,216,570</u>	<u>\$ 22,217</u>	<u>117,223</u>	<u>\$ (60,000)</u>	<u>\$ 2,631,838</u>	<u>\$ 124,994,678</u>	<u>\$ (111,981,139)</u>	<u>\$ 15,607,594</u>
<b>THREE MONTHS ENDED MARCH 31, 2023</b>								
Balance at December 31, 2022	11,986,927	\$ 11,987	117,223	\$ (60,000)	\$ 567,972	\$ 108,857,065	\$ (94,134,505)	\$ 15,242,519
Issuance of common stock in connection with at-the-market offering, net of issuance costs	2,869	3	—	—	—	3,365	—	3,368
Share-based compensation expense	—	—	—	—	—	56,954	—	56,954
Net loss	—	—	—	—	—	—	(2,946,257)	(2,946,257)
Balance at March 31, 2023	<u>11,989,796</u>	<u>\$ 11,990</u>	<u>117,223</u>	<u>\$ (60,000)</u>	<u>\$ 567,972</u>	<u>\$ 108,917,384</u>	<u>\$ (97,080,762)</u>	<u>\$ 12,356,584</u>

The accompanying notes are an integral part of these condensed unaudited financial statements.



**FEMASYS INC.**  
Condensed Statements of Cash Flows  
(unaudited)

	Three Months ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (3,599,510)	(2,946,257)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	69,983	131,653
Amortization	1,245	1,413
Amortization of right-of-use assets	152,664	75,635
Provision for bad debts	1,000	—
Inventory reserve write-off	1,240	300
Share-based compensation expense	77,585	56,954
Amortization of debt issuance costs and discount	258,802	—
Changes in operating assets and liabilities:		
Accounts receivable	(22,623)	(46,485)
Inventory	(305,419)	(64,318)
Prepaid and other assets	(187,359)	150,654
Accounts payable	(137,753)	3,016
Accrued expenses	(792,239)	78,703
Lease liabilities	(44,745)	(91,211)
Other liabilities	(40,995)	2,306
Net cash used in operating activities	(4,568,124)	(2,647,637)
Cash flows from investing activities:		
Acquisition of patents	(25,603)	—
Purchases of property and equipment	(64,557)	(8,901)
Net cash used in investing activities	(90,160)	(8,901)
Cash flows from financing activities:		
Proceeds from at-the-market sales of common stock	802,242	3,373
Issuance costs for at-the-market sales of common stock	(24,067)	—
Repayment of note payable	—	(141,298)
Payments under lease obligations	—	(6,135)
Net cash provided by (used in) financing activities	778,175	(144,060)
Net change in cash and cash equivalents	(3,880,109)	(2,800,598)
Cash and cash equivalents:		
Beginning of period	21,716,077	12,961,936
End of period	\$ 17,835,968	10,161,338
Supplemental cash flow information		
Cash paid for:		
Interest	\$ —	1,672
Non-cash investing and financing activities:		
Property and equipment costs included in accounts payable and accrued expense	\$ 108,304	12,990
Acquisition of patents included in accounts payable	\$ 8,757	—
Commissions costs relating to certain proceeds from issuance of common stock	\$ —	109
Deferred offering costs reclassified to additional paid-in-capital	\$ 1,245	—

The accompanying notes are an integral part of these condensed unaudited financial statements.

FEMASYS INC.  
Condensed Notes to Financial Statements  
(unaudited)

**(1) Organization, Nature of Business, and Liquidity**

*Organization and Nature of Business*

Femasys Inc. (the Company or Femasys) was incorporated in Delaware on February 19, 2004 and is headquartered in Suwanee, Georgia. The Company is a leading biomedical company focused on addressing significant unmet needs for women worldwide with a broad portfolio of in-office, accessible, and innovative therapeutic and diagnostic products, including a lead revolutionary product candidate and FDA-cleared products. The Company's mission is to provide women with superior minimally-invasive, non-surgical product technologies, accessible in the office, improving patient care and overall health economics focused on servicing the reproductive health needs for those seeking solutions for infertility issues (FemaSeed® and FemVue®) or permanent birth control (FemBloc®). The Company currently operates as one segment with an initial focus on servicing the reproductive health needs for those seeking solutions for infertility issues or permanent birth control.

Femasys has an expansive intellectual property portfolio which covers both design and utility patents in the U.S. and significant ex-U.S. markets for each product initiative. Femasys has taken concepts internally conceived and protected through development, including domestic and foreign regulatory approvals, and production, through in-house manufacturing. FemaSeed, a solution which enables directed intratubal insemination to improve on traditional intrauterine insemination (IUI) and provides a lower cost and safer option to in vitro fertilization methods, received approval to sell FemaSeed in Canada in April 2023. In September 2023, the Company received 510(k) clearance from the FDA for FemaSeed for intratubal insemination to market in the United States. A pivotal clinical trial was still ongoing at the time of receiving regulatory clearance, however, enrollment was completed in November 2023. FemVue, a solution that enables fallopian tube assessment with ultrasound as an alternative to the radiologic approach (hysterosalpingogram) for the diagnosis of infertility, is approved for sale in the U.S., Japan, and Canada. FemChec® allows for fallopian tube evaluation after a FemBloc procedure to confirm occlusion (or procedure success). FemCerv® is a solution for complete tissue sampling with minimal contamination of the endocervical canal in a virtually pain-free procedure as an alternative to the single biopsy method and is approved for sale in the U.S. and Canada. FemCath®, allows for selective evaluation of an individual fallopian tube as an alternative to the traditional intrauterine catheter that is undirected, is approved for sale in the U.S. and Canada. FemBloc®, the Company's solution for permanent birth control, is based on the Company's platform technology for delivery and in June 2023 Femasys received FDA approval of our IDE to evaluate the safety and efficacy of FemBloc, our non-surgical, non-implant, non-hormonal in-office solution for permanent birth control in a pivotal clinical trial. In August 2023 Femasys announced the initiation of enrollment in the FINALE [Prospective Multi-Center Trial for FemBloc Intratubal Occlusion for TranscervicAL Permanent Birth Control] pivotal trial designed to evaluate the safety and efficacy of FemBloc. This prospective, multi-center, open-label, single-arm study design includes pregnancy rate as the primary endpoint, which will be analyzed once 401 women have relied on FemBloc for one year for permanent birth control. In addition, the study is designed as a roll-in beginning with enrollment of 50 women for a clinical readout primarily of preliminary safety data prior to enrolling the remaining subjects. An interim analysis of clinical data endpoints is planned once 300 women have used FemBloc for permanent birth control for one year. Follow-up will continue annually for five years post-market.

*Basis of Presentation*

The Company has prepared the accompanying condensed financial statements pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in the annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) have been condensed or omitted pursuant to these rules and regulations. These condensed financial statements should be read in conjunction with the Company's audited financial statements and footnotes related thereto for the year ended December 31, 2023 included in our Annual Report on Form 10K filed with the SEC on March 28, 2024 (the Annual Report). There have been no material changes to the Company's significant accounting policies described in Note 2 to the financial statements included in the Annual Report.

In the opinion of management, the unaudited financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the Company's financial position and the results of its operations and cash flows at the dates for periods presented. The results of operations for such interim periods are not necessarily indicative of the results to be expected for the full year.

*Use of Estimates*

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expense during the reporting periods. Estimates for these and other items are subject to change and are reassessed by management in accordance with U.S. GAAP. Actual results could differ from those estimates.

*Liquidity*

As of March 31, 2024, the Company had cash and cash equivalents of \$17,835,968. The Company plans to finance its operations and development needs with its existing cash and cash equivalents, additional equity and/or debt financing arrangements, and revenue primarily anticipated from the sale of FemVue and FemaSeed to support the Company's research and development activities, largely in connection with FemBloc. There can be no assurance that the Company will be able to obtain additional financing on terms acceptable to the Company, on a timely basis, or at all. If the Company is not able to obtain sufficient funds on acceptable terms when needed, the Company's business, results of operations, and financial condition could be materially adversely impacted.

FEMASYS INC.  
Condensed Notes to Financial Statements  
(unaudited)

For the three months ended March 31, 2024, the Company generated a net loss of \$3,599,510. The Company expects such losses to increase over the next few years as the Company advances FemBloc through clinical development until FDA approval is received and is available to be marketed.

The Company believes that its cash and cash equivalents as of March 31, 2024 and cash received subsequent to quarter end (see Note 16, Subsequent Events) will be sufficient to fund our ongoing operations at least 12 months from the date of filing these condensed financial statements.

*Recently Issued Accounting Pronouncements – Recently Adopted*

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 28): Improvements to Reportable Segment Disclosures*. The ASU improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The ASU improves financial reporting by requiring disclosure of incremental segment information on an annual and interim basis for all public entities to enable investors to develop more decision-useful financial analyses. The amendments in this update are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company will adopt the ASU for the fiscal year ended December 31, 2024 and interim periods in fiscal 2025. The adoption of the ASU will result in additional disclosures to the Company's financial statements and footnote disclosures.

*Recently Issued Accounting Pronouncements – Not Yet Adopted*

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The ASU requires the annual financial statements to include consistent categories and greater disaggregation of information in the rate reconciliation, and income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for the Company's annual reporting periods beginning after December 15, 2024. Adoption is either with a prospective method or a fully retrospective method of transition. Early adoption is permitted. The Company is currently evaluating the effect that adoption of ASU 2023-09 will have on its financial statements and expects to adopt the ASU on January 1, 2025.

No other new accounting pronouncement issued or effective has had, or is expected to have, a material impact on the Company's financial statements.

**(2) Fair Value**

The Company applies a fair value hierarchy that requires the use of observable market data, when available, and prioritizes the inputs to valuation techniques used to measure fair value in the following categories:

Level 1 – Valuation is based upon quoted prices for identical instruments traded in active markets.

Level 2 – Valuation is based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques for which all significant assumptions are observable in the market.

Level 3 – Valuation is generated from model-based techniques that use significant assumptions not observable in the market. These unobservable assumptions reflect the Company's own estimates of assumptions market participants would use in pricing the asset or liability.

Certain of the Company's financial instruments, including cash and cash equivalents, notes payable and other liabilities approximate their fair value because of the short-term maturity of these financial instruments and are based on Level 1 inputs. The Company's equity-classified warrants and stock options are measured at fair value upon grant using the Black-Scholes option pricing model, a Level 2 input. The Company uses unobservable inputs for the model's assumptions, including management's assumptions of the Company's volatility and price of the underlying stock. The fair value of the Company's convertible notes is disclosed at each reporting period based on a discounted cash flow analysis, a Level 3 input.

**(3) Cash and Cash Equivalents**

As of March 31, 2024 and December 31, 2023, money market funds included in cash and cash equivalents on the balance sheets were \$17,503,242 and \$21,278,895, respectively, which represent level 1 within the fair value hierarchy where there are quoted prices in active markets for identical assets.

**(4) Inventories**

Inventory stated at cost, net of reserve, consisted of the following:

	March 31, 2024	December 31, 2023
Materials	\$ 574,199	367,934
Work in progress	131,657	128,993
Finished goods	265,441	170,191
Inventory, net	<u>\$ 971,297</u>	<u>667,118</u>

FEMASYS INC.  
Condensed Notes to Financial Statements  
(unaudited)

**(5) Accrued Expenses**

Accrued expenses consisted of the following:

	March 31, 2024	December 31, 2023
Clinical trial costs	\$ 243,367	276,141
Accrued interest	147,275	—
Incentive and other compensation costs	146,409	1,082,606
Director fees	70,000	60,210
Franchise taxes	12,800	12,160
Other	53,606	13,179
Accrued expenses	<u>\$ 673,457</u>	<u>1,444,296</u>

**(6) Clinical Holdback**

The following table shows the activity within the clinical holdback liability accounts for the three months ended March 31, 2024:

Balance at December 31, 2023	\$ 120,235
Clinical holdback retained	3,530
Clinical holdback paid	—
Balance at March 31, 2024	<u>\$ 123,765</u>
Less: clinical holdback - current portion	<u>(93,376)</u>
Clinical holdback - long-term portion	<u>\$ 30,389</u>

**(7) Revenue Recognition**

Revenue is recognized upon shipment of our goods based upon contractually stated pricing at standard payment terms ranging from 30 to 60 days. All revenue is recognized point in time and no revenue is recognized over time. For the three months ended March 31, 2024 and 2023, there was no revenue recognized from performance obligations satisfied or partially satisfied in prior periods, nor were there any unsatisfied performance obligations as of March 31, 2024 or 2023.

The majority of products sold directly to U.S. customers are shipped via common carrier, and the customer pays for shipping and handling and assumes control Free on Board (FOB) shipping point. Products shipped to our international distributors are in accordance with their respective agreements; however, the shipping terms are generally EX-Works, reflecting that control is assumed by the distributor at the shipping point. Returns are only accepted with prior authorization from the Company. Items to be returned must be in original unopened cartons and are subject to a 30% restocking fee. Throughout the periods presented, the Company has not had a history of significant returns.

The following table summarizes our sales, primarily from FemVue, by geographic region as follows:

	Three Months Ended March 31,	
Primary geographical markets	2024	2023
U.S.	\$ 271,140	293,984
International	—	—
Total	<u>\$ 271,140</u>	<u>293,984</u>

**(8) Commitments and Contingencies**

*Legal Claims*

Occasionally, the Company may be a party to legal claims or proceedings of which the outcomes are subject to significant uncertainty. In accordance with Accounting Standards Codification (ASC) 450, *Contingencies*, the Company will assess the likelihood of an adverse judgment for any outstanding claim as well as ranges of probable losses. When it has been determined that a loss is probable and the amount can be reasonably estimated, the Company will record a liability. For both periods presented, there were no material legal contingencies requiring accrual or disclosure.

The Company, as permitted under Delaware law and in accordance with its bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The Company entered into employment agreements with its officers, which provides for indemnification protection in the executive's capacity as an officer for actions taken within the scope of employment. The maximum amount of potential future indemnification is unlimited; however, the Company has obtained director and officer insurance that limits its exposure. The Company believes the fair value for these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations as of March 31, 2024 and December 31, 2023.

FEMASYS INC.  
Condensed Notes to Financial Statements  
(unaudited)

**(9) Notes Payable**

*AFCO Credit Corporation (AFCO)*

In June 2022, the Company executed a Promissory Note with AFCO to finance certain insurance premiums totaling \$ 465,380, requiring the Company to pay \$ 47,539 in a down payment and make monthly installment payments. The annual interest rate was 5.7% and the monthly installment payment was \$47,539, which represents principal and interest. The final installment payment was paid in March of 2023.

In July 2023, the Company executed a Promissory Note with AFCO to finance certain insurance premiums totaling \$ 469,042, requiring the Company to pay \$ 48,423 in a down payment and make monthly installment payments. The annual interest rate was 8.6% and the monthly installment is \$48,423, which represents principal and interest. The Promissory Note was paid in full without penalty in November 2023.

As of March 31, 2024, and December 31, 2023, there was no principal balance on the AFCO note in the accompanying balance sheets. Interest expense in connection with the AFCO promissory notes was \$0 and \$1,319 for the three months ended March 31, 2024 and 2023, respectively.

**(10) Convertible Notes with Warrants (November 2023 Financing)**

On November 21, 2023, the Company issued (i) senior unsecured convertible notes in an aggregate principal amount of \$ 6,850,000, convertible into shares of common stock at a conversion price of \$ 1.18 per share, (ii) Series A Warrants to purchase up to an aggregate of 5,805,083 shares of common stock at an exercise price of \$1.18 per share, and (iii) Series B Warrants, together with the Series A Warrants, and, together with the convertible notes, to purchase up to an aggregate of 5,805,083 shares of common stock at an exercise price of \$1.475 per share. The financing resulted in aggregate gross proceeds of \$ 6,850,000, before \$525,144 of transaction costs. The Company intends to use the net proceeds from the offering for general corporate purposes.

The Notes accrue interest at a rate of 6.0% per annum, payable annually, in cash or shares of common stock at the Company's option, and mature on November 21, 2025, unless earlier converted or redeemed.

The Notes are convertible into shares of common stock at the election of the holder at any time at an initial conversion price of \$ 1.18. The Company has agreed not to issue or sell any equity securities of the Company at a price below the then-current conversion price for a period of 18 months after closing, subject to certain exceptions. Beginning six months after issuance, the Company may require holders to convert their Notes into conversion shares if the closing price of the common stock exceeds \$2.36 per share for 10 consecutive trading days and the daily dollar trading volume of the common stock exceeds \$ 1,000,000 per day during the same period and certain equity conditions described in the Notes are satisfied. The Notes provide for certain events of default, whereby each holder of Notes will be able to require the Company to redeem in cash any or all of the holder's Notes at a premium of 115%. The conversion feature did not meet the requirements for separate accounting and is not accounted for as a derivative instrument. As of March 31, 2024, the Convertible Notes have not been converted into shares of common stock.

*The Warrants*

The Series A Warrants are exercisable immediately and expire five years from the date of issuance. The Company has the right to call the exercise of the Series A Warrants if the closing price of the common stock exceeds 200% of the Series A Exercise Price for 10 consecutive trading days and the daily dollar trading volume of the common stock exceeds \$1,000,000 per day during the same period and certain equity conditions are satisfied.

The Series B Warrants are exercisable immediately, together with the Series A Warrant Shares, and expire one year from the date of issuance. The Company has the right to call the exercise of the Series B Warrants if the closing price of the common stock exceeds 200% of the Series B exercise price for 10 consecutive trading days and the daily dollar trading volume of the common stock exceeds \$1,000,000 per day during the same period and certain equity conditions are satisfied. There is no established public trading market for the warrants and the Company does not intend to list the Warrants on any national securities exchange or nationally recognized trading system.

The Series A Warrants and Series B Warrants are classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock from which they are issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise.

FEMASYS INC.  
Condensed Notes to Financial Statements  
(unaudited)

The Series A and Series B Warrants were valued using the relative fair value method and the following Black-Scholes assumptions:

	Series A Warrants	Series B Warrants
Expected term (in years)	5	1
Risk-free interest rate	4.55%	5.24%
Dividend yield	—%	—%
Expected volatility	104.89%	113.84%
Exercise price	\$ 1.18	\$ 1.48
Stock price	\$ 0.95	\$ 0.95
Black-Scholes value	\$ 0.55	\$ 0.28

The November 2023 Financing proceeds of \$6,850,000 net of \$525,144 in transaction costs were allocated to the convertible notes and Series A and Series B Warrants using the relative fair value method. The valuation of the warrants was \$2,219,165 and was recorded as a component of stockholders' equity, and a total debt discount of \$2,744,309. The convertible notes are recorded as a long-term liability, net of discount and issuance costs.

For the convertible notes for the quarter ended March 31, 2024, the Company recognized total interest expense of \$ 361,552, including coupon interest expense of \$ 102,750 amortization of debt discount and issuance costs of \$258,802. As of December 31, 2023, the Notes principal balance as \$6,850,000, unamortized discount was \$2,636,346 and accrued interest was \$44,525. As of March 31, 2024, the Notes principal balance as \$ 6,850,000, unamortized discount was \$2,377,544 and accrued interest was \$147,275. The fair value of the convertible notes on March 31, 2024, calculated using a discounted cash flow analysis, was \$6,185,934.

**(11) Stockholders' Equity**

On July 1, 2022, we filed a prospectus including an offering to sell up to \$ 150 million in common and preferred stock, debt securities and warrants. Additionally, we entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Piper Sandler & Co. ("Piper Sandler" or the "Sales Agent") and filed a related prospectus establishing an "at-the-market" facility, pursuant to which we may offer and sell shares of our common stock from time to time through the Sales Agent. In October 2023, the Sales Agent was authorized to sell shares for aggregate proceeds up to \$16.7 million at current market prices until all shares are sold. As of March 31, 2024, 3.9 million shares of common stock have been sold for aggregate proceeds of \$8.7 million under the Equity Distribution Agreement pursuant to the prospectus. As of March 31, 2024, the amount we are authorized to sell is subject to baby-shelf limitations.

In April 2023, the Company sold an aggregate of (i) 1,318,000 shares of common stock and (ii) pre-funded warrants to purchase up to 1,878,722 shares of common stock in a registered direct offering ("pre-funded warrants") and, in a concurrent private placement, warrants to purchase up to 3,196,722 shares of common stock ("common warrants"). Additionally, common warrants were issued to the placement agent to purchase up to 191,803 shares of common stock as compensation for services ("placement agent warrants"), collectively the ("April 2023 Financing"). The purchase price per share for the common stock, pre-funded warrants was \$1.22 and \$1.2199, respectively. The gross proceeds from the offering were \$3,899,813, less placement agent fees and offering expenses of \$547,764. The Company intends to use the net proceeds from the offering for general corporate purposes.

As of March 31, 2024, the Company had 22,099,347 shares of common stock outstanding, and no dividends have been declared or paid.

FEMASYS INC.  
Condensed Notes to Financial Statements  
(unaudited)

**(12) Equity Incentive Plans and Warrants**

*Stock-Based Awards*

*(a) Stock Option Plans*

Activity under the Company's stock option plans for the three months ended March 31, 2024 was as follows:

	Number of options	Weighted average exercise price
Outstanding at December 31, 2023	2,102,030	\$ 2.00
Granted	708,821	0.97
Forfeited	(62,618)	2.59
Outstanding at March 31, 2024	2,748,233	\$ 1.72
Vested and exercisable at March 31, 2024	1,208,627	\$ 2.63

Options granted under our 2021 Stock Option Plan for the three months ended March 31, 2024 to employees and nonemployees were 706,321 and 2,500, respectively and the weighted average exercise prices were \$ 0.97 and \$0.79, respectively. The weighted-average fair values of the options granted to employees and nonemployees were \$0.83 and \$0.39, respectively and were estimated using the following Black-Scholes assumptions:

	Employee	Nonemployee
Expected term (in years)	6.25	1.50
Risk-free interest rate	3.87%	4.53%
Dividend yield	—%	—%
Expected volatility	109.65%	105.34%

No options were exercised for the three months ended March 31, 2024 under our stock option plans.

As of March 31, 2024, the total number of shares of common stock reserved for future awards under the 2021 Stock Option Plan was 849,647.

*(b) Inducement Grants*

On February 12, 2024, the Company awarded, outside the 2021 Plan, our Chief Commercial Officer a stock option grant for the right to purchase 100,000 shares of common stock at an exercise price of \$ 1.10 per share (inducement grant), which was approved by the Compensation committee. The inducement grant will vest in equal installments over four years provided the employee remains employed by the Company on the vesting date. The fair value of the inducement grant was \$0.94 and was estimated using the following assumptions:

	Inducement
Expected term (in years)	6.25
Risk-free interest rate	4.10%
Dividend yield	—%
Expected volatility	109.64%

As of March 31, 2024, inducement grant awards of 250,000 shares were outstanding with a weighted average exercise price of \$ 1.89, and 62,500 shares were vested and exercisable with a weighted average exercise price of \$2.64.

FEMASYS INC.  
Condensed Notes to Financial Statements  
(unaudited)

(c) *Share-Based Compensation Expense*

The following table shows the share-based compensation expense related to vested stock option grants to employees and nonemployees by financial statement line item on the accompanying condensed statement of comprehensive loss:

	Three Months Ended March 31,	
	2024	2023
Research and development	\$ 30,327	25,059
Sales and marketing	6,199	(2,544)
General and administrative	41,059	34,439
Total share-based compensation expense	\$ 77,585	56,954

As March 31, 2024, the remaining share-based compensation expense that is expected to be recognized in future periods for employees and nonemployees is \$1,411,405, which includes \$155,222 of compensation expense to be recognized upon achieving certain performance conditions. For service-based awards, the \$1,256,183 of unrecognized expense is expected to be recognized over a weighted average period of 3.3 years.

(d) *Employee Stock Purchase Plan (ESPP)*

For the three months ended March 31, 2024, no shares of common stock were issued under the Company's ESPP Plan. As of March 31, 2024, the total number of shares of common stock reserved for future awards under the ESPP Plan was 603,518.

(e) *April 2023 Financing*

On April 20, 2023, the Company entered into a securities purchase agreement pursuant to which the Company sold (i) 1,318,000 shares of common stock (see Note 11, *Stockholders' Equity*), (ii) pre-funded warrants to purchase 1,878,722 shares of common stock, (iii) common warrants to purchase 3,196,722 shares of common stock. Additionally, common warrants to purchase 191,803 shares of common stock were issued to the placement agent compensation for services performed.

The pre-funded warrants, common warrants and placement agent warrants were exercisable immediately following the closing date of the offering. The pre-funded warrants have an unlimited term and an exercise price of \$0.0001 per share. The common warrants have a 5.5 year term and an exercise price of \$1.095 per share. The placement agent warrants have a 5 year term and exercise price of \$1.525 per share. The offering resulted in aggregate gross proceeds of \$3,899,813, before \$547,764 of transaction costs.

The pre-funded warrants and common warrants are classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise.

The common stock was valued at \$1,133,480, based on the Company's stock price. The pre-funded warrants and common warrants were valued at \$ 1,615,701 and \$1,854,099, respectively, using the following Black-Scholes assumptions:

	Pre-funded warrants	Common warrants
Expected term (in years)	4	4
Risk-free interest rate	3.83%	3.83%
Dividend yield	—%	—%
Expected volatility	100.25%	100.25%
Exercise price	\$ 0.0001	\$ 1.095
Stock price	\$ 0.86	\$ 0.86
Black-Scholes value	\$ 0.86	\$ 0.58

The net proceeds of \$3,352,049 were allocated to the common stock, pre-funded warrants and common warrants using the relative fair value method. The valuations were recorded to stockholders' equity.

In June 2023, all pre-funded warrants were exercised for shares of common stock. In September and October 2023, all common warrants and 122,994 placement agent warrants were exercised for cash proceeds of \$3,687,976. As of March 31, 2024, 68,809 placement agent warrants remain outstanding.

(13) *Related-Party Transactions*

In November 2023, the Company issued unsecured convertible notes and accompanying Series A and Series B Warrants (see Note 9). The transaction included issuance of a \$5 million convertible note and Series A and Series B Warrants to PharmaCyte Biotech, Inc. The interim CEO, President and Director of PharmaCyte Biotech, Inc., Joshua Silverman, serves on the Company's board of directors.



FEMASYS INC.  
Condensed Notes to Financial Statements  
(unaudited)

During the year ended December 31, 2023 and quarters ended March 31, 2024 and 2023, a family member of the CEO was employed by the Company.

**(14) Net Loss per Share Attributable to Common Stockholders**

The following table sets forth the computation of the basic and diluted net loss per share:

	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Net loss attributable to common stockholders, basic & diluted	\$ (3,599,510)	(2,946,257)
Weighted average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted	21,775,357	11,872,255
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.17)	(0.25)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding because they would be anti-dilutive:

	<b>March 31, 2024</b>	<b>March 31, 2023</b>
Options to purchase common stock	2,998,233	1,036,495
Warrants to purchase common stock, in connection with April 2023 financing	68,809	—
Warrants to purchase common stock, in connection with November 2023 financing	11,610,166	—
Warrants to purchase common stock	201,578	233,460
Total potential shares	14,878,786	1,269,955

**(15) Income Taxes**

The effective tax rate of 0% for the three months ended March 31, 2024 and 2023 was lower than the statutory rate due to the Company remaining in a full valuation allowance position.

**(16) Subsequent Events**

In April 2024, the Company sold 121,371 shares under the at-the-market facility, resulting in gross cash proceeds of \$219,752.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or the SEC, on March 28, 2024. This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "goal," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential" and similar expressions intended to identify forward-looking statements and reflect our beliefs and opinions on the relevant subject. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Quarterly Report on Form 10-Q. The forward-looking statements included in this Quarterly Report on Form 10-Q are made only as of the date hereof. These statements are based upon information available to us as of the filing date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

### Overview

We are a leading biomedical company focused on addressing significant unmet needs for women worldwide with a broad portfolio of in-office, accessible, and innovative therapeutic and diagnostic solutions, including a lead revolutionary product candidate and FDA-cleared products. Our mission is to provide women with superior minimally-invasive, non-surgical product technologies, accessible in the office, improving patient care and overall health economics focused on servicing the reproductive health needs for those seeking solutions for infertility issues (FemaSeed and FemVue) or permanent birth control (FemBloc). We are a woman-founded and led company with an expansive, internally created intellectual property portfolio with over 180 patents globally, in-house chemistry, manufacturing, and controls (CMC) and device manufacturing capabilities and proven ability to develop and commercialize products. Our suite of products and product candidates address what we believe are multi-billion dollar global market segments in which there has been little advancement for many years, helping women avoid pharmaceutical solutions, implants and surgery that can be expensive and expose women to harm.

### Corporate Update

On October 26, 2023, we announced the completion of the European Union Medical Device Regulation (MDR) final audit which is the last step in obtaining an MDR certificate and CE marking.

On November 15, 2023, we secured a \$6.85 million financing with a strategic investment from investors led by PharmaCyte Biotech.

On November 28, 2023, we announced the completion of enrollment of FemaSeed pivotal trial in support of commercial launch.

On January 23, 2024 and January 26, 2024, we announced initiation of enrollment in pivotal trial (NCT05977751) of our permanent birth control candidate FemBloc at two academic sites, for a total of six active sites, the maximum number permitted in the first stage.

On February 6, 2024, we announced the appointment of Richard Spector to new position of Chief Commercial Officer.

On March 6, 2024, we announced the first in-office commercial procedure with FDA-cleared FemaSeed infertility solution at a former investigative site.

On March 20, 2024, we announced positive topline data from pivotal trial for FDA-cleared FemaSeed for the treatment of infertility.

### Clinical Update

**FemaSeed – Our Intrauterine Artificial Insemination Solution.** In September 2023 we announced 510(k) clearance from the FDA for FemaSeed for intrauterine insemination. The clinical trial was still ongoing at the time of receiving U.S. regulatory clearance from the FDA, however, the study was concluded with enrollment completed in November 2023. Topline results of the clinical trial were announced in March 2024. The trial demonstrated that 24% of women became pregnant after FemaSeed with male factor infertility (1 million to 20 million total motile sperm count (TMSC)). In contrast, the historical control indicated a 6.7% pregnancy rate by cycle for intrauterine insemination (IUI) with male factor infertility (greater than 1 million TMSC). Although subjects were permitted to have multiple FemaSeed attempts, the majority of women who became pregnant did so after the first FemaSeed procedure. The majority of adverse events were reported as mild (n=127 subjects, 216 cycles). No new safety concerns were observed through the seven-week follow-up. All adverse events were consistent with those known for IUI. The approved labeling includes women or couples wishing to become pregnant by way of intrauterine insemination. The recruitment of the commercial team began with the hire of the Chief Commercial Officer in February 2024. In March 2024, the first commercial use of FemaSeed at a former investigative site was announced. Recruitment of the commercial team is underway.

**FemBloc – Our Permanent Birth Control Solution.** In June 2023 we received FDA approval of our IDE to evaluate the safety and efficacy of FemBloc, our non-surgical, non-implant, in-office solution for permanent birth control in a pivotal clinical trial. In August 2023 we announced the initiation of enrollment in the FINALE [Prospective Multi-Center Trial for FemBloc (Intrauterine Occlusion for Transcervical Permanent Birth Control)] pivotal trial designed to evaluate the safety and efficacy of FemBloc. This prospective, multi-center, open-label, single-arm study design includes pregnancy rate as the primary endpoint, which will be analyzed once 401 women have used FemBloc for one year for permanent birth control. In addition, the study is designed as a roll-in beginning with enrollment of 50 women for a clinical readout primarily of preliminary safety data prior to enrolling the remaining subjects. An interim analysis of clinical data endpoints is planned once 300 women have used FemBloc for permanent birth control for one year. Follow-up will continue annually for five years post-market. All six sites permitted in the initial stage of the trial were announced as actively enrolling subjects in January 2024.

## Results of Operations

### Comparison of the Three Months Ended March 31, 2024 and 2023

The following table shows our results of operations for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,		Change	% Change
	2024	2023		
Sales	\$ 271,140	293,984	(22,844)	-7.8%
Cost of sales (excluding depreciation expense)	88,532	105,120	(16,588)	-15.8%
Operating expenses:				
Research and development	1,770,731	1,537,439	233,292	15.2%
Sales and marketing	300,487	244,896	55,591	22.7%
General and administrative	1,502,804	1,315,137	187,667	14.3%
Depreciation and amortization	71,228	133,066	(61,838)	-46.5%
Total operating expenses	3,645,250	3,230,538	414,712	12.8%
Loss from operations	(3,462,642)	(3,041,674)	(420,968)	13.8%
Other income (expense):				
Interest income	224,684	97,089	127,595	131.4%
Interest expense	(361,552)	(1,672)	(359,880)	21523.9%
Other income (expense)	(136,868)	95,417	(232,285)	-243.4%
Net loss	\$ (3,599,510)	(2,946,257)	(653,253)	22.2%

#### Sales

Sales decreased by \$22,844, or 7.8%, to \$271,140 for the three months ended March 31, 2024 from \$293,984 for the three months ended March 31, 2023, attributable entirely to U.S. sales. Units sold decreased by 5.1% for the comparable periods, while maintaining a consistent average selling price.

#### Cost of sales

Cost of sales decreased by \$16,588 or 15.8%, to \$88,532 for the three months ended March 31, 2024 from \$105,120 for the three months ended March 31, 2023. The decrease is primarily attributed to reduced sales and certain manufacturing efficiencies.

#### Research and development

The following table summarizes our R&D expenses incurred during the periods presented:

	Three Months Ended March 31,	
	2024	2023
Compensation and related personnel costs	\$ 989,057	900,288
Clinical-related costs	438,775	366,360
Material and development costs	143,699	167,161
Professional and outside consultant costs	168,182	91,935
Other costs	31,018	11,695
Total research and development expenses	\$ 1,770,731	1,537,439

R&D expenses increased by \$233,292 or 15.2%, to \$1,770,731 for the three months ended March 31, 2024 from \$1,537,439 for the three months ended March 31, 2023. The increase relates primarily to increased compensation costs, clinical-related costs, and professional and outside consultant costs, partially offset by reduced material and development costs.

**Sales and marketing**

Sales and marketing expenses increased by \$55,591 or 22.7%, to \$300,487 for the three months ended March 31, 2024 from \$244,896 for the three months ended March 31, 2023. The increase is largely due to increased compensation costs as we began hiring commercial team members.

**General and administrative**

General and administrative expenses increased by \$187,667, or 14.3%, to \$1,502,804 for the three months ended March 31, 2024 from \$1,315,137 for the three months ended March 31, 2023. The increase was largely due to increased facility, overhead and compensation costs.

**Depreciation and amortization**

Depreciation and amortization expenses decreased by \$61,838, or 46.5%, to \$71,228 for the three months ended March 31, 2024 from \$133,066 for the three months ended March 31, 2023. The decrease is due to a reduction of amortization expense associated with our intangible assets and depreciation expense associated with our fixed assets.

**Other income (expense), net**

Other income (expense), net decreased by \$232,285, or 243.4%, to \$136,868 of expense for the three months ended March 31, 2024 from \$95,417 of income for the three months ended March 31, 2023. The decrease relates to interest expense and non-cash discount amortization related to the convertible notes payable, partially offset by an increase in interest income.

**Liquidity and Capital Resources**

**Sources of liquidity**

Since our inception through March 31, 2024, our operations have been financed primarily by net proceeds from the sale of our common stock and convertible preferred stock, indebtedness and, to a lesser extent, product revenue. As of March 31, 2024, we had \$17,835,968 of cash and cash equivalents and an accumulated deficit of \$111,981,139.

On July 1, 2022, we entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Piper Sandler & Co. (the "Sales Agent") and filed a related prospectus establishing an "at-the-market" facility, pursuant to which we may offer and sell shares of our common stock from time to time through the Sales Agent. In October 2023, the Sales Agent was authorized to sell shares of common stock for an aggregate price up to \$16.7 million pursuant to the prospectus. As of March 31, 2024, approximately 3.8 million shares of common stock have been sold for aggregate proceeds of \$8.5 million under the Equity Distribution Agreement pursuant to the prospectus. As of March 31, 2024, the amount we are authorized to sell is subject to baby-shelf limitations.

In April 2023, we sold an aggregate of (i) 1,318,000 shares of common stock and (ii) pre-funded warrants to purchase up to 1,878,722 shares of common stock in a registered direct offering and, in a concurrent private placement, warrants to purchase up to 3,196,722 shares of common stock. Additionally, common warrants were issued to the placement agent in this transaction to purchase up to 191,803 shares of common stock as compensation for services, collectively the ("April 2023 Financing"). The purchase price per share for the common stock, pre-funded warrants was \$1.22 and \$1.2199, respectively. The net proceeds from the April 2023 Financing at closing were approximately \$3.4 million. The pre-funded and common warrants in the April 2023 Financing were fully exercised for cash for additional proceeds of \$3.5 million. Placement agent warrants of 68,809 remain outstanding as of March 31, 2024.

In November 2023, we entered into a securities purchase agreement with certain accredited investors pursuant to which we sold (i) senior unsecured convertible notes in an aggregate principal amount of \$6,850,000, convertible into shares of common stock at a conversion price of \$1.18 per share, (ii) Series A Warrants to purchase up to an aggregate of 5,805,083 shares of common stock at an exercise price of \$1.18 per share, and (iii) Series B Warrants to purchase up to an aggregate of 5,805,083 shares of common stock at an exercise price of \$1.475 per share (collectively, the "November Private Placement"). Net proceeds from the November Private Placement were \$6.3 million. If exercised for cash, the warrants issued in the November Private Placement could result in proceeds of up to an additional \$15.4 million.

**Funding requirements**

Based on our current operating plan, our current cash and cash equivalents are expected to be sufficient to fund our ongoing operations into the second half of 2025. Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate.

Our cash and cash equivalents as of March 31, 2024 will not be sufficient to fund all of our product candidates through regulatory approval, and we anticipate needing to raise additional capital to complete the development and commercialization of our product candidates. However, we can give no assurances that we will be able to secure additional sources of funds to support our operations, or if such funds will be available to us, that such additional financing will be sufficient to meet our needs or be on terms acceptable to us. This risk may increase if economic and market conditions deteriorate. If we are unable to obtain additional financing when needed, we may need to terminate, significantly modify, or delay the development of our product candidates, or we may need to obtain funds through collaborations or otherwise on terms that may require us to relinquish rights to our technologies or product candidates that we might otherwise seek to develop or commercialize independently. If we are unable to raise adequate additional capital as and when required in the future, we could be forced to cease development activities and terminate our operations, and you could experience a complete loss of your investment.

**Cash Flows****Comparison of the Three months ended March 31, 2024 and 2023**

The following table summarizes our cash flows for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
Net cash used in operating activities	\$ (4,568,124)	(2,647,637)
Net cash used in investing activities	(90,160)	(8,901)
Net cash provided by (used in) financing activities	778,175	(144,060)
Net change in cash and cash equivalents	<u>\$ (3,880,109)</u>	<u>(2,800,598)</u>

**Operating activities**

For the three months ended March 31, 2024, cash used in operating activities was \$4,568,124, attributable to a net loss of \$3,599,510 and a net change in our net operating assets and liabilities of \$1,531,133, partially offset by non-cash charges of \$562,519. Non-cash charges primarily consisted of \$258,802 in amortization of the discount on convertible notes, \$152,664 in right-of-use amortization, \$77,585 in share-based compensation and \$71,228 in depreciation and amortization. The change in our net operating assets and liabilities was primarily due to a decrease in accounts payable and accrued expenses of \$929,992, increases in accounts receivable and prepaid and other assets of \$209,982 and inventory of \$305,419.

For the three months ended March 31, 2023, cash used in operating activities was \$2,647,637, attributable to a net loss of \$2,946,257, offset by a net change in our net operating assets and liabilities of \$32,666 and non-cash charges of \$265,955. Non-cash charges largely consisted of \$133,066 in depreciation and amortization, \$75,635 in right-of-use amortization, and \$56,954 in share-based compensation. The change in our net operating assets and liabilities was primarily due to a decrease of \$104,169 in accounts receivable and prepaid and other assets, an increase in accounts payable and accrued expenses of \$81,719, partially offset by an increase of \$64,318 in inventory and decrease of \$91,211 in lease liabilities.

**Investing activities**

For the three months ended March 31, 2024, cash used in investing activities for the purchase of property and equipment and acquisition of patents was \$90,160.

For the three months ended March 31, 2023, cash used in investing activities for the purchase of property and equipment was \$8,901.

**Financing activities**

For the three months ended March 31, 2024, cash provided by financing activities was \$778,175, attributable to proceeds from sales under the at-the-market facility, net of issuance costs.

For the three months ended March 31, 2023, cash used in financing activities was \$144,060, attributable to repayments on notes payable of \$141,298, payments under lease obligations of \$6,135, offset by proceeds from issuance of common stock of \$3,373.

**Critical Accounting Estimates**

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing the Annual Report on Form 10-K for the year ended December 31, 2023 as filed on March 28, 2024, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

**Revenue recognition**

Our policy is to recognize revenue when a customer obtains control of the promised goods under Accounting Standards Update (ASU) 2020-05, *Revenue from Contracts with Customers* (Topic 606), which we adopted effective January 1, 2018. The amount of revenue recognized reflects the consideration to which we expect to be entitled to receive in exchange for these goods, and we have elected to exclude amounts collected from customers for all sales (and other similar) taxes from the transaction price. We do not have multiple performance obligations in our customer orders, so revenue is recognized upon shipment of our goods based upon contractually stated pricing at standard payment terms ranging from 30 to 60 days. All revenue is recognized point in time and no revenue is recognized over time.

The majority of products sold directly to U.S. customers are shipped via common carrier, and the customer pays for shipping and handling and assumes control Free on Board (FOB) shipping point. Products shipped to our international distributors are in accordance with their respective agreements; however, the shipping terms are generally EX-Works, reflecting that control is assumed by the distributor at the shipping point. Returns are only accepted with prior authorization from the Company. Items to be returned must be in original unopened cartons and are subject to a 30% restocking fee. As of March 31, 2024, we have not had a history of significant returns.

**Accrued expenses**

We accrue expenses for estimated costs of R&D activities conducted by our third-party service providers, which include the conduct of preclinical studies and clinical trials. We record the estimated costs of R&D activities based upon the estimated amount of services provided but not yet invoiced. These costs, at times, may be a significant component of the research and development expenses and the Company makes estimates in determining the accrued expense each period. As actual costs become known, the Company adjusts its accrual. These accrued R&D costs are included in accrued expenses on the balance sheet and within R&D expense on the statement of comprehensive loss.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable.

**Item 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act are (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (2) accumulated and communicated to our management, including to our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial and accounting officer), has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our management has concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of March 31, 2024.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Inherent Limitations on Effectiveness of Controls**

Our management, including our Chief Executive Officer and Chief Financial Officer (principal financial and accounting officer), does not expect that our disclosure controls and procedures or internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and implemented, can provide only reasonable, not absolute, assurance that the control system's objectives will be 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 within a company are detected. The inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

From time to time we may be involved in legal proceedings arising in connection with our business. Based on information currently available, we believe that the amount, or range, of reasonably possible losses in connection with any pending actions against us in excess of established reserves, in the aggregate, is not material to our financial condition or cash flows. However, losses may be material to our operating results for any particular future period, depending on the level of income for such period.

**Item 1A. Risk Factors**

As of the date of this report, there are no material changes to our risk factors as previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023.

**Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

During the period covered by this Quarterly Report, none of the Company's directors or executive officers have adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (each as defined in Item 408 of Regulation S-K under the Securities Exchange Act of 1934, as amended).

**Item 6. Exhibits**

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
<a href="#">3.1</a>	Eleventh Amended and Restated Certificate of Incorporation of Femasys Inc.	Form 8-K	001-40492	3.1	June 22, 2021
<a href="#">3.2</a>	Amended and Restated Bylaws of Femasys Inc.	Form 8-K	001-40492	3.2	June 22, 2021
<a href="#">3.3</a>	First Amendment to the Amended and Restated Bylaws of Femasys Inc.	Form 8-K	001-40492	3.1	March 30, 2023
<a href="#">31.1*</a>	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
<a href="#">31.2*</a>	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
<a href="#">32.1*</a>	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
<a href="#">32.2*</a>	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS*	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)				

\*Filed herewith

**SIGNATURES**

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Suwanee, State of Georgia, on this 9<sup>th</sup> day of May 2024.

**FEMASYS INC.**

Dated: May 9, 2024

By: /s/ Kathy Lee-Sepsick  
Kathy Lee-Sepsick  
Chief Executive Officer and President

Dated: May 9, 2024

By: /s/ Dov Elefant  
Dov Elefant  
Chief Financial Officer



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

I, Kathy Lee-Sepsick, certify that:

1. I have reviewed this Report on Form 10-Q for Femasys 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 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, which involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

**FEMASYS INC.**

Date: May 9, 2024

By: /s/ Kathy Lee-Sepsick  
Kathy Lee-Sepsick  
Chief Executive Officer and President  
(principal executive officer)

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

I, Dov Elefant, certify that:

1. I have reviewed this Report on Form 10-Q for Femasys 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 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, which involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

**FEMASYS INC.**

By: /s/ Dov Elefant  
Dov Elefant  
Chief Financial Officer  
(principal financial and accounting officer)

Date: May 9, 2024

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Femasys Inc., a Delaware Corporation, (the "Company") on Form 10-Q for the quarter ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certify the following pursuant to Section 18, U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002:

1. The 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 report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**FEMASYS INC.**

By: /s/ Kathy Lee-Sepsick  
Kathy Lee-Sepsick  
Chief Executive Officer and President  
(principal executive officer)

Date: May 9, 2024

---

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Femasys Inc., a Delaware Corporation, (the "Company") on Form 10-Q for the quarter ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certify the following pursuant to Section 18, U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002:

1. The 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 report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**FEMASYS INC.**

By: /s/ Dov Elefant  
Dov Elefant  
Chief Financial Officer  
(principal financial and accounting officer)

Date: May 9, 2024

---