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, 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 22,898,468 shares of common stock, $0.001 par value, outstanding as of November 11, 2024.

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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 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 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 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 establish, maintain, grow or increase sales and revenues;
- our expectations about market trends;
- our ability to continue operating as a going concern;
- our ability to develop and advance our current product candidate, FemBloc and successfully initiate and complete clinical trials;
- the ability of our clinical trials to demonstrate safety and effectiveness of our product candidate, FemBloc and other positive results;
- our ability to enroll subjects in the clinical trials for our product candidate, FemBloc in order to advance the development thereof on a timely basis;
- our ability to obtain U.S. Food and Drug Administration (FDA) approval for our product candidate, FemBloc, for permanent birth control, 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 FemBloc, or the effect of delays in obtaining regulatory authorizations and 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 hire and retain our senior management and other highly qualified personnel;
- FDA or other U.S. or foreign regulatory or governmental 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; and
- the volatility of the trading price of our common stock.

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)

Assets	September 30, 2024	December 31, 2023
Current assets:		
Cash and cash equivalents	$ 7,611,210	21,716,077
Accounts receivable, net	378,290	98,906
Inventory, net	1,937,670	667,118
Prepaid and other current assets	1,370,523	695,879
Total current assets	11,297,693	23,177,980
Property and equipment, at cost:		
Leasehold improvements	1,238,886	1,212,417
Office equipment	67,231	47,308
Furniture and fixtures	433,584	414,303
Machinery and equipment	2,848,833	2,559,356
Construction in progress	548,149	423,077
	5,136,683	4,656,461
Less accumulated depreciation	(3,748,393)	(3,545,422)
Net property and equipment	1,388,290	1,111,039
Long-term assets:		
Lease right-of-use assets, net	1,941,624	2,380,225
Intangible assets, net of accumulated amortization	70,064	—
Other long-term assets	887,410	1,086,581
Total long-term assets	2,899,098	3,466,806
Total assets	$ 15,585,081	27,755,825

(continued)

FEMASYS INC.
Condensed Balance Sheets
(unaudited)

Liabilities and Stockholders' Equity	September 30, 2024	Dece 2
Current liabilities:		
Accounts payable	$ 1,121,873	1
Accrued expenses	1,127,645	1
Clinical holdback – current portion	92,170	
Lease liabilities – current portion	525,752	
Total current liabilities	2,867,440	3
Long-term liabilities:		
Clinical holdback – long-term portion	36,081	
Convertible notes payable, net (including related parties)	5,068,556	4
Lease liabilities – long-term portion	1,643,217	2
Total long-term liabilities	6,747,854	6
Total liabilities	9,615,294	9
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par, 200,000,000 authorized, 22,350,022 shares issued and 22,232,799 outstanding as of September 30, 2024; and 21,774,604 shares issued and 21,657,381 outstanding as of December 31, 2023	22,350	
Treasury stock, 117,223 common shares	(60,000)	
Warrants	2,608,642	2
Additional paid-in-capital	125,473,368	123
Accumulated deficit	(122,074,573)	(108
Total stockholders' equity	5,969,787	18
Total liabilities and stockholders' equity	$ 15,585,081	27

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

FEMASYS INC.
Condensed Statements of Comprehensive Loss
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Sales	$ 554,908	244,361	1,047,532	858,859
Cost of sales (excluding depreciation expense)	190,839	86,186	352,496	301,775
Operating expenses:				
Research and development	2,303,241	2,072,830	6,049,847	5,137,441
Sales and marketing	1,572,189	70,883	2,847,866	444,678
General and administrative	1,530,791	1,970,408	4,645,412	4,642,182
Depreciation and amortization	76,288	125,318	215,144	391,683
Total operating expenses	5,482,509	4,239,439	13,758,269	10,615,984
Loss from operations	(5,118,440)	(4,081,264)	(13,063,233)	(10,058,900)
Other income (expense):				
Interest income	124,028	92,392	532,850	232,133
Interest expense	(413,290)	(8,033)	(1,163,153)	(9,903)
Total other income (expense), net	(289,262)	84,359	(630,303)	222,230
Loss before income taxes	(5,407,702)	(3,996,905)	(13,693,536)	(9,836,670)
Income tax expense (benefit)	1,158	—	(592)	—
Net loss	$ (5,408,860)	(3,996,905)	(13,692,944)	(9,836,670)
Net loss attributable to common stockholders, basic and diluted	$ (5,408,860)	(3,996,905)	(13,692,944)	(9,836,670)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.24)	(0.26)	(0.62)	(0.74)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	22,232,799	15,093,147	22,075,135	13,369,462

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					Total stockholders' equity
	Shares	Amount	Shares	Amount	Warrants	Additional paid-in capital	Accumulated deficit	
THREE MONTHS ENDED SEPTEMBER 30, 2024								
Balance at June 30, 2024	22,350,022	$ 22,350	117,223	$ (60,000)	$ 2,608,642	$ 125,344,962	$ (116,665,713)	$ 11,250,241
Issuance of common stock in connection with at-the-market offering, net of issuance costs	—	—	—	—	—	—	—	—
Issuance of common stock in connection with ESPP	—	—	—	—	—	—	—	—
Expiration of warrant	—	—	—	—	—	—	—	—
Share-based compensation expense	—	—	—	—	—	128,406	—	128,406
Net loss	—	—	—	—	—	—	(5,408,860)	(5,408,860)
Balance at September 30, 2024	22,350,022	$ 22,350	117,223	$ (60,000)	$ 2,608,642	$ 125,473,368	$ (122,074,573)	$ 5,969,787
NINE MONTHS ENDED SEPTEMBER 30, 2024								
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
Issuance of common stock in connection with at-the-market offering, net of issuance costs	563,337	563	—	—	—	989,185	—	989,748
Issuance of common stock in connection with ESPP	12,081	12	—	—	—	10,378	—	10,390
Expiration of warrant	—	—	—	—	(178,495)	178,495	—	—
Share-based compensation expense	—	—	—	—	—	310,004	—	310,004
Net loss	—	—	—	—	—	—	(13,692,944)	(13,692,944)
Balance at September 30, 2024	22,350,022	$ 22,350	117,223	$ (60,000)	$ 2,608,642	$ 125,473,368	$ (122,074,573)	$ 5,969,787

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					Total stockholders' equity
	Shares	Amount	Shares	Amount	Warrants	Additional paid-in capital	Accumulated deficit	
THREE MONTHS ENDED SEPTEMBER 30, 2023								
Balance at June 30, 2023	15,190,376	$ 15,190	117,223	$ (60,000)	$ 1,918,103	$ 110,977,150	$ (99,974,270)	$ 12,876,173
Exercise of common warrants	919,716	920			(336,495)	1,395,550		1,059,975
Share-based compensation expense	—	—	—	—	—	504,359	—	504,359
Net loss	—	—	—	—	—	—	(3,996,905)	(3,996,905)
Balance at September 30, 2023	16,110,092	$ 16,110	117,223	$ (60,000)	$ 1,581,608	$ 112,877,059	$ (103,971,175)	$ 10,443,602
NINE MONTHS ENDED SEPTEMBER 30, 2023								
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 and warrants in connection with April 2023 Financing, net of issuance costs	1,318,000	1,318	—	—	2,526,664	818,014	—	3,345,996
Issuance of common stock in connection with at-the-market offering, net of issuance costs	2,869	3	—	—	—	3,365	—	3,368
Issuance of common stock in connection with ESPP	3,858	3	—	—	—	1,694	—	1,697
Exercise of pre-funded warrants	1,878,722	1,879	—	—	(1,176,533)	1,174,842	—	188
Exercise of common warrants	919,716	920	—	—	(336,495)	1,395,550	—	1,059,975
Share-based compensation expense	—	—	—	—	—	626,529	—	626,529
Net loss	—	—	—	—	—	—	(9,836,670)	(9,836,670)
Balance at September 30, 2023	16,110,092	$ 16,110	117,223	$ (60,000)	$ 1,581,608	$ 112,877,059	$ (103,971,175)	$ 10,443,602

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

FEMASYS INC.
Condensed Statements of Cash Flows
(unaudited)

	Nine Months ended Sep 30	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (13,692,944)	(9,836,670)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	202,971	388,777
Amortization	12,173	2,906
Amortization of right-of-use assets	438,601	274,158
Loss on disposal of assets	—	44,538
Accounts receivable reserve	6,000	—
Inventory reserve	2,830	4,972
Share-based compensation expense	310,004	626,529
Amortization of debt issuance costs and discount	854,902	—
Changes in operating assets and liabilities:		
Accounts receivable	(285,384)	(26,086)
Inventory	(1,273,382)	(170,917)
Prepaid and other assets	(266,518)	313,154
Accounts payable	(51,799)	341,119
Accrued expenses	(316,651)	112,728
Lease liabilities	(273,734)	(304,004)
Other liabilities	(36,509)	(15,770)
Net cash used in operating activities	(14,369,440)	(8,244,566)
Cash flows from investing activities:		
Acquisition of patents	(82,237)	—
Purchases of property and equipment	(654,914)	(99,018)
Net cash used in investing activities	(737,151)	(99,018)
Cash flows from financing activities:		
Proceeds from the issuance of common stock and warrants in April 2023 Financing	—	3,899,813
Equity issuance costs for April 2023 Financing	—	(547,764)
Proceeds from exercise of pre-funded warrants	—	188
Proceeds from exercise of common warrants	—	1,059,975
Proceeds from common stock issued through ESPP and exercised options	10,390	1,697
Proceeds from at-the-market sales of common stock	1,021,994	3,373
Issuance costs for at-the-market sales of common stock	(30,660)	—
Repayment of note payable	—	(327,006)
Payments under lease obligations	—	(16,193)
Net cash provided by financing activities	1,001,724	4,074,083
Net change in cash and cash equivalents	(14,104,867)	(4,269,501)
Cash and cash equivalents:		
Beginning of period	21,716,077	12,961,936
End of period	$ 7,611,210	8,692,435
Supplemental cash flow information		
Cash paid for:		
Interest	$ —	9,903
Taxes	5,708	4,550
Non-cash investing and financing activities:		
Property and equipment costs included in accounts payable and accrued expense	35,849	—
Commissions costs relating to certain proceeds from issuance of common stock	—	6,163
Deferred offering costs reclassified to additional paid-in-capital	1,586	—
Right-of-use asset obtained in exchange for a lease liability	—	2,496,968
Prepaid insurance financed with promissory notes	—	283,334

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 utility and design 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. The Company received approval to sell FemaSeed, a solution which enables directed intratubal insemination to improve on historic intrauterine insemination (IUI) and provides a lower cost and safer option to in vitro fertilization (IVF) methods, from Health Canada, the Public Health Agency of Canada (Health Canada) in April 2023. In September 2023, the Company received 510(k) clearance from the FDA for FemaSeed 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. In June 2024, the Company received European Union Medical Device Regulation (EU MDR) certificates and CE Mark certification for four products: FemaSeed, FemVue, FemCerv® and FemCath®. 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. 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 for diagnosis of cervical cancer 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. In August 2024, the Company announced receipt of CE Mark certification and product approval from Health Canada for our compact, eco-friendly FemVue® MINI for fallopian tube assessment. In September 2024, the Company announced receipt of 510(k) clearance from FDA for FemChec®, a controlled contrast generating device. The Company received CE mark approval for FemChec in September 2024.

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.

FEMASYS INC.
Condensed Notes to Financial Statements
(unaudited)

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 September 30, 2024, the Company had cash and cash equivalents of $7,611,210. 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 FemaSeed and FemVue to support the Company's research and development activities, primarily focused on 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.

For the nine months ended September 30, 2024, the Company generated a net loss of $13,692,944. The Company expects such losses to increase over the next few years as the Company advances FemBloc through clinical development if and until FDA approval is received and is available to be marketed.

The financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net operating losses in every year since inception and has an accumulated deficit as of September 30, 2024 of $122,074,573 and expects to incur additional losses and negative operating cash flows for at least the next twelve months. The Company's ability to meet its obligations is dependent upon its ability to generate sufficient cash flows from operations and future financing transactions. Although management expects the Company will continue as a going concern, there is no assurance that management's plans will be successful since the availability and amount of such funding is not certain. Accordingly, substantial doubt exists about the Company's ability to continue as a going concern for at least one year from the issuance of these financial statements. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability of assets or the amounts and classifications of liabilities that may result from the possible inability of the Company to continue as a going concern.

FEMASYS INC.
Condensed Notes to Financial Statements
(unaudited)

Recently Issued Accounting Pronouncements

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 other liabilities approximate their fair value because of the short-term maturity of these financial instruments. The fair value of stock options, convertible notes and warrants are based on Level 3 inputs.

(3) Cash and Cash Equivalents

As of September 30, 2024 and December 31, 2023, money market funds included in cash and cash equivalents on the balance sheets were $6,809,936 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.

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(4) Inventories

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

	September 30, 2024	December 31, 2023
Materials	$ 1,043,045	367,934
Work in progress	509,217	128,993
Finished goods	385,408	170,191
Inventory, net	$ 1,937,670	667,118

(5) Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2024	December 31, 2023
Accrued interest	$ 352,775	—
Clinical trial costs	350,208	276,141
Incentive and other compensation costs	297,897	1,082,606
Director fees	70,000	60,210
Franchise taxes	3,150	12,160
Other	53,615	13,179
Accrued expenses	$ 1,127,645	1,444,296

(6) Clinical Holdback

The following table shows the activity within the clinical holdback liability accounts for the nine months ended September 30, 2024:

Balance at December 31, 2023	$ 120,235
Clinical holdback retained	14,465
Clinical holdback paid	(6,449)
Balance at September 30, 2024	$ 128,251
Less: clinical holdback - current portion	(92,170)
Clinical holdback - long-term portion	$ 36,081

(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 and nine months ended September 30, 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 September 30, 2024 or December 31, 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.

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The following table summarizes our sales by geographic region as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Primary geographical markets	**2024**	**2023**	**2024**	**2023**
U.S.	$ 262,458	244,361	755,082	800,814
International	292,450	—	292,450	58,045
Total	$ 554,908	244,361	1,047,532	858,859

(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 September 30, 2024 and December 31, 2023.

(9) Notes Payable

AFCO Credit Corporation (AFCO)

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 was $48,423, which represents principal and interest. The Promissory Note was paid in full without penalty in November 2023.

As of September 30, 2024, and December 31, 2023, there was no principal balance on the AFCO. Interest expense in connection with the AFCO promissory notes was $0 and $9,317 for the three and nine months ended September 30, 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.

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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 September 30, 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.

For the convertible notes for the three months e nded September 30, 2024, the Company recognized total interest expense of $413,290, including coupon interest expense of $ 102,750 and amortization of debt discount and issuance costs of $310,540. For the nine months ended September 30, 2024, the Company recognized total interest expense of $1,163,153, including coupon interest expense of $ 308,250 and amortization of debt discount and issuance costs of $ 854,902. 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 September 30, 2024, the Notes principal balance as $ 6,850,000, unamortized discount was $1,781,444 and accrued interest was $ 352,775. The fair value of the convertible notes on September 30, 2024, calculated using a discounted cash flow analysis, was $6,399,810.

(11) Stockholders' Equity

On July 1, 2022, the Company filed a shelf registration statement to sell up to $150 million in common and preferred stock, debt securities and warrants. Additionally, the Company 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 the Company may offer and sell shares of 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 September 30, 2024, 3.9 million shares of common stock have been sold for aggregate proceeds of approximately $8.7 million under the Equity Distribution Agreement pursuant to the prospectus. As of September 30, 2024, the amount we are authorized to sell is subject to baby-shelf limitations.

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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.

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 September 30, 2024, 68,809 placement agent warrants remain outstanding.

As of September 30, 2024, the Company had 22,232,799 shares of common stock outstanding, and no dividends have been declared or paid.

(12) Equity Incentive Plans and Warrants

Stock-Based Awards

(a) Stock Option Plans

Activity under the Company's stock option plans for the nine months ended September 30, 2024 was as follows:

	Number of options	Weighted average exercise price
Outstanding at December 31, 2023	2,102,030	$ 2.00
Granted	1,259,421	1.07
Forfeited	(359,807)	1.96
Outstanding at September 30, 2024	3,001,644	$ 1.61
Vested and exercisable at September 30, 2024	1,295,956	$ 2.36

Options granted under our 2021 Stock Option Plan for the nine months ended September 30, 2024 to employees and nonemployees were 1,186,521 and 72,900, respectively and the weighted average exercise prices were $ 1.06 and $1.13, respectively. The weighted-average fair values of the options granted to employees and nonemployees were $0.91 and $0.93, respectively and were estimated using the following Black-Scholes assumptions:

	Employee	Nonemployee
Expected term (in years)	6.25	5.36
Risk-free interest rate	4.05%	4.09%
Dividend yield	—%	—%
Expected volatility	110.29%	111.97%

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No options were exercised for the nine months ended September 30, 2024 under our stock option plans.

As of September 30, 2024, the total number of shares of common stock reserved for future awards under the 2021 Stock Option Plan was 596,236.

(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 September 30, 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.

(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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 49,800	79,561	114,437	131,812
Sales and marketing	18,895	623	43,659	(1,319)
General and administrative	59,711	424,175	151,908	496,036
Total share-based compensation expense	$ 128,406	504,359	310,004	626,529

As September 30, 2024, the remaining share-based compensation expense that is expected to be recognized in future periods for employees and nonemployees is $ 1,487,486, which includes $155,222 of compensation expense to be recognized upon achieving certain performance conditions. For service-based awards, the $1,332,264 of unrecognized expense is expected to be recognized over a weighted average period of 3.0 years.

(d) Employee Stock Purchase Plan (ESPP)

For the nine months ended September 30, 2024, 12,081 shares of common stock were issued under the Company's ESPP Plan at a fair value of $10,390. For the nine months ended September 30, 2023, 3,858 shares of common stock were issued under the ESPP plan at a fair value of $1,697. As of September 30, 2024, the total number of shares of common stock reserved for future awards under the ESPP Plan was 591,437.

(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, (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. See Note 11, *Stockholders' Equity*.

The pre-funded warrants, common warrants and placement agent warrants were exercisable immediately following the closing date of the offering. The pre-funded warrants had an unlimited term and an exercise price of $0.0001 per share. The common warrants had 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 September 30, 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 10). The transaction included the 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. In addition, during the year ended December 31, 2023 and nine months ended September 30, 2024 and 2023, a family member of the CEO was employed by the Company.

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(14) Net Loss per Share Attributable to Common Stockholders

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss attributable to common stockholders, basic & diluted	$ (5,408,860)	(3,996,905)	(13,692,944)	(9,836,670)
Weighted average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted	22,232,799	15,093,147	22,075,135	13,369,462
Net loss per share attributable to common stockholders, basic and diluted	$ (0.24)	(0.26)	(0.62)	(0.74)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Options to purchase common stock	3,251,644	2,229,271	3,251,644	2,229,271
Warrants to purchase common stock, in connection with April 2023 financing	68,809	2,468,809	68,809	2,468,809
Warrants to purchase common stock, in connection with November 2023 financing	11,610,166	—	11,610,166	—
Warrants to purchase common stock	196,816	233,460	196,816	233,460
Total potential shares	15,127,435	4,931,540	15,127,435	4,931,540

(15) Income Taxes

The effective tax rate of 0% for the three and nine months ended September 30, 2024 and 2023 was lower than the statutory rate due to the Company remaining in a full valuation allowance position.

(16) Subsequent Events

In October 2024, the Company sold 665,669 shares under the at-the-market facility, resulting in gross cash proceeds of $900,317.

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, and Canadian and European Union approved 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 200 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 candidate 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 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 November 30, 2023, we announced the appointment of James Liu, M.D. as Chief Medical Officer.

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.

On April 18, 2024, we announced that our CEO met with members of Congress to raise awareness of the Company and discuss women's healthcare initiatives.

On May 16, 2024, we announced that our CEO met with the White House's Gender Policy Council.

On May 17, 2024, we announced that our CEO met with the White House's Office of Science and Technology to discuss the Cancer Moonshot initiative.

On June 20, 2024, we announced receipt of European Union Medical Device Regulation (EU MDR) and CE Mark certification for FemaSeed, FemVue, FemCerv and FemCath.

On August 29, 2024, we announced receipt of CE Mark certification and product approval from Health Canada, the Public Health Agency of Canada, for our compact, eco-friendly FemVue MINI for fallopian tube assessment.

On September 9, 2024, we announced receipt of 510(k) clearance from FDA for FemChec, an innovative diagnostic solution for fallopian tube check.

On September 11, 2024, we announced strategic distribution partnerships for CE-marked products, including FemaSeed and FemVue in Spain for over $1.3 million over the next year.

On September 18, 2024, we announced the onboarding of the first infertility medical clinic customers to offer FemaSeed infertility treatment to patients in California and Florida.

On October 2, 2024, we announced receipt of a second order from our Spain strategic distribution partners after successfully completing commercial FemaSeed infertility treatments .

On October 30, 2024, we announced a partnership with Boston IVF, a prominent network of fertility centers, to offer FemaSeed .

On November 1, 2024, we announced issuance of U.S. patent covering FemBloc device for female permanent birth control .

Clinical Update

FemaSeed – Our Intratubal Artificial Insemination Solution. In September 2023 we received 510(k) clearance from the FDA for FemaSeed intratubal insemination. The pivotal clinical trial was still ongoing at the time of receiving U.S. regulatory clearance from the FDA, as a result, the study was concluded with enrollment completed in November 2023. Topline results of the clinical trial were announced in March 2024. The trial demonstrated pregnancy rate was 26.3% by subject (n=38) and 17.5% by cycle (n=57) after FemaSeed. In contrast, a 6.7% pregnancy rate by cycle was described in the literature for intrauterine insemination (IUI) with male factor infertility (greater than 1 million total motile sperm count). 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=133 subjects, 222 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 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. Build-out of our initial commercial team in the United States was completed in June 2024. In June 2024, we received EU MDR and CE Mark certification for FemaSeed and in September 2024, we announced strategic distribution partnerships for CE-marked products, including FemaSeed and FemVue in Spain which are anticipated to generate over $1.3 million over the next year. Concurrently with direct commercial efforts in North America (U.S. and Canada), we are exploring other potential strategic partners for distribution in Europe and internationally.

FemBloc – Our Permanent Birth Control Solution. In June 2023 we received FDA approval of our IDE to conduct a pivotal trial to evaluate the safety and efficacy of FemBloc, our non-surgical, non-implant, in-office solution for permanent birth control. In August 2023 we 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 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. In September 2024, we announced receipt of 510(k) clearance from FDA for FemChec, an innovative diagnostic solution for fallopian tube check. FemChec is part of the confirmation test utilized to confirm FemBloc success. FemChec received CE Mark approval in September 2024 and previously received regulatory approval in Canada.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table shows our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,			
	2024	2023	Change	% Change
Sales	$ 554,908	244,361	310,547	127.1%
Cost of sales (excluding depreciation expense)	190,839	86,186	104,653	121.4%
Operating expenses:				
Research and development	2,303,241	2,072,830	230,411	11.1%
Sales and marketing	1,572,189	70,883	1,501,306	2118.0%
General and administrative	1,530,791	1,970,408	(439,617)	-22.3%
Depreciation and amortization	76,288	125,318	(49,030)	-39.1%
Total operating expenses	5,482,509	4,239,439	1,243,070	29.3%
Loss from operations	(5,118,440)	(4,081,264)	(1,037,176)	25.4%
Other income (expense):				
Interest income	124,028	92,392	31,636	34.2%
Interest expense	(413,290)	(8,033)	(405,257)	5044.9%
Other income (expense), net	(289,262)	84,359	(373,621)	-442.9%
Loss before income taxes	(5,407,702)	(3,996,905)	(1,410,797)	35.3%
Income tax expense	1,158	—	1,158	-100.0%
Net loss	$ (5,408,860)	(3,996,905)	(1,411,955)	35.3%

Sales

Sales increased by $310,547, or 127.1%, to $554,908 for the three months ended September 30, 2024 from $244,361 for the three months ended September 30, 2023, due to increased sales of FemaSeed and FemVue. FemVue U.S. and international units sold increased by 1.9% and 100%, respectively for the comparable periods, with pricing consistent across all markets. The Company recorded its first FemaSeed U.S. and international sales for the three months ended September 30, 2024, and additional sales are expected in the 4th quarter of 2024. Our Spanish distributors both placed orders in September 2024, each for approximately $210,000. One order was shipped in September. Due to hurricane Helene, the second order was unable to be shipped in September, and was recorded as revenue in October.

Cost of sales

Cost of sales increased by $104,653 or 121.4%, to $190,839 for the three months ended September 30, 2024 from $86,186 for the three months ended September 30, 2023. The increase is attributed to increased sales, specifically of FemaSeed.

Research and development

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

	Three Months Ended September 30,	
	2024	2023
Compensation and related personnel costs	$ 1,256,061	918,617
Clinical-related costs	437,163	534,789
Material and development costs	312,644	455,347
Professional and outside consultant costs	291,955	133,476
Other costs	5,418	30,601
Total research and development expenses	$ 2,303,241	2,072,830

R&D expenses increased by $230,411 or 11.1%, to $2,303,241 for the three months ended September 30, 2024 from $2,072,830 for the three months ended September 30, 2023. The increase relates primarily to increased compensation costs and professional and outside consultant costs.

Sales and marketing

Sales and marketing expenses increased by $1,501,306 or 2,118.0%, to $1,572,189 for the three months ended September 30, 2024 from $70,883 for the three months ended September 30, 2023. The increase is largely due to increased compensation costs and sales and marketing expenses as we recruited and hired commercial team members in connection with the initiation of commercialization of FemaSeed in the U.S.

General and administrative

General and administrative expenses decreased by $439,617, or 22.3%, to $1,530,791 for the three months ended September 30, 2024 from $1,970,408 for the three months ended September 30, 2023. The decrease is largely due to reduced compensation and professional fees.

Depreciation and amortization

Depreciation and amortization expenses decreased by $49,030, or 39.1%, to $76,288 for the three months ended September 30, 2024 from $125,318 for the three months ended September 30, 2023. The decrease is due to a reduction of depreciation expense associated with our fixed assets.

Other income (expense), net

Other income (expense), net decreased by $373,621, or 442.9%, to $289,262 of expense for the three months ended September 30, 2024 from $84,359 of income for the three months ended September 30, 2023. The decrease relates to an increase in interest expense and non-cash discount amortization related to the convertible notes payable, partially offset by an increase in interest income.

Results of Operations

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table shows our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,			
	2024	2023	Change	% Change
Sales	$ 1,047,532	858,859	188,673	22.0%
Cost of sales (excluding depreciation expense)	352,496	301,775	50,721	16.8%
Operating expenses:				
Research and development	6,049,847	5,137,441	912,406	17.8%
Sales and marketing	2,847,866	444,678	2,403,188	540.4%
General and administrative	4,645,412	4,642,182	3,230	0.1%
Depreciation and amortization	215,144	391,683	(176,539)	-45.1%
Total operating expenses	13,758,269	10,615,984	3,142,285	29.6%
Loss from operations	(13,063,233)	(10,058,900)	(3,004,333)	29.9%
Other income (expense):				
Interest income	532,850	232,133	300,717	129.5%
Interest expense	(1,163,153)	(9,903)	(1,153,250)	11645.5%
Other income (expense), net	(630,303)	222,230	(852,533)	-383.6%
Loss before income taxes	(13,693,536)	(9,836,670)	(3,856,866)	39.2%
Income tax benefit	(592)	—	(592)	-100.0%
Net loss	$ (13,692,944)	(9,836,670)	(3,856,274)	39.2%

Sales

Sales increased by $188,673, or 22.0%, to $1,047,532 for the nine months ended September 30, 2024 from $858,859 for the nine months ended September 30, 2023, attributable primarily to sales of FemaSeed. FemVue units sold decreased by 6.7% for the comparable periods, with pricing consistent across all markets. The Company recorded its first FemaSeed U.S. and international sales during the third quarter of 2024, and additional sales are expected in the 4th quarter of 2024. Our Spanish distributors both placed orders in September 2024, each for approximately $210,000. One order was shipped in September. Due to hurricane Helene, the second order was unable to be shipped in September, and was recorded as revenue in October.

Cost of sales

Cost of sales increased by $50,721 or 16.8%, to $352,496 for the nine months ended September 30, 2024 from $301,775 for the nine months ended September 30, 2023. The increase is primarily attributed to increased sales, specifically of FemaSeed.

Research and development

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

	Nine Months Ended September 30,	
	2024	2023
Compensation and related personnel costs	$ 3,219,997	2,659,411
Clinical-related costs	1,311,526	1,262,727
Material and development costs	845,473	827,603
Professional and outside consultant costs	578,614	345,938
Other costs	94,237	41,762
Total research and development expenses	$ 6,049,847	5,137,441

R&D expenses increased by $912,406 or 17.8%, to $6,049,847 for the nine months ended September 30, 2024 from $5,137,441 for the nine months ended September 30, 2023. The increase relates primarily to increased compensation costs, professional and outside consultant costs and clinical-related costs.

Sales and marketing

Sales and marketing expenses increased by $2,403,188 or 540.4%, to $2,847,866 for the nine months ended September 30, 2024 from $444,678 for the nine months ended September 30, 2023. The increase is largely due to increased compensation costs and sales and marketing expenses as we recruited and hired commercial team members in connection with the initiation of commercialization of FemaSeed in the U.S.

General and administrative

General and administrative expenses increased by $3,230, or 0.1%, to $4,645,412 for the nine months ended September 30, 2024 from $4,642,182 for the nine months ended September 30, 2023. The slight increase is attributed to increased facility costs, offset by decreased professional fees and compensation costs.

Depreciation and amortization

Depreciation and amortization expenses decreased by $176,539, or 45.1%, to $215,144 for the nine months ended September 30, 2024 from $391,683 for the nine months ended September 30, 2023. The decrease is due to a reduction of depreciation expense associated with our fixed assets.

Other income (expense), net

Other income (expense), net decreased by $852,533, or 383.6%, to $630,303 of expense for the nine months ended September 30, 2024 from $222,230 of income for the nine months ended September 30, 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 September 30, 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 September 30, 2024, we had $7,611,210 of cash and cash equivalents and an accumulated deficit of $122,074,573.

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 September 30, 2024, approximately 3.9 million shares of common stock have been sold for aggregate proceeds of approximately $8.7 million under the Equity Distribution Agreement pursuant to the prospectus. As of September 30, 2024, the amount we are authorized to sell is subject to baby-shelf limitations. In October 2024, the Company sold 665,669 shares under this facility, resulting in gross cash proceeds of $900,317.

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 September 30, 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 is sufficient into July 2025. However, it is not sufficient to fund our ongoing operations for twelve months from the date of these financial statements and we will need to obtain additional financing to fund our ongoing operations. 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. As a result of our current limited financial liquidity, we have concluded that substantial doubt exists about our ability to continue as a going concern.

Our cash and cash equivalents as of September 30, 2024 will not be sufficient to fund our product candidate FemBloc through regulatory approval, and we anticipate needing to raise additional capital to complete the development and commercialization of our product candidate. 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 candidate, 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 Nine months ended September 30, 2024 and 2023

The following table summarizes our cash flows for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,	
	2024	**2023**
Net cash used in operating activities	$ (14,369,440)	(8,244,566)
Net cash used in investing activities	(737,151)	(99,018)
Net cash provided by financing activities	1,001,724	4,074,083
Net change in cash and cash equivalents	$ (14,104,867)	(4,269,501)

Operating activities

For the nine months ended September 30, 2024, cash used in operating activities was $14,369,440, attributable to a net loss of $13,692,944 and a net change in our net operating assets and liabilities of $ 2,503,977, partially offset by non-cash charges of $1,827,481. Non-cash charges primarily consisted of $854,902 in amortization of the discount on convertible notes, $438,601 in right-of-use asset amortization, $310,004 in share-based compensation and $215,144 in depreciation and amortization. The change in our net operating assets and liabilities was primarily due to decreases in accounts payable and accrued expenses of $368,450, lease liabilities of $273,734 and increases in inventory of $1,273,382, prepaid and other assets of $266,518 and accounts receivable of $285,384.

For the nine months ended September 30, 2023, cash used in operating activities was $8,244,566, attributable to a net loss of $9,836,670, partially offset by non-cash charges of $1,341,880 and a net change in our net operating assets and liabilities of $250,224. Non-cash charges largely consisted of $626,529 in stock-based compensation, $391,683 in depreciation and amortization, $274,158 in right-of-use asset amortization and $44,538 for loss on disposal of assets. The change in our net operating assets and liabilities was primarily due to a decrease in prepaid and other assets of $313,154 and an increase in accounts payable and accrued expenses of $453,847, which were offset partially by increases in inventory of $170,917, accounts receivable of $26,086 and a decrease in lease and other liabilities of $319,774.

Investing activities

For the nine months ended September 30, 2024, cash used in investing activities for the purchase of property and equipment and acquisition of patents was $737,151.

For the nine months ended September 30, 2023, cash used in investing activities for the purchase of property and equipment was $99,018.

Financing activities

For the nine months ended September 30, 2024, cash provided by financing activities was $1,001,724, attributable to proceeds from sales under the at-the-market facility, net of issuance costs and proceeds from the issuance of shares under the ESPP plan.

For the nine months ended September 30, 2023, cash provided by financing activities was $4,074,083, primarily attributable to proceeds from the issuance of common stock and warrants of $4,965,046, offset by financing offering costs of $547,764, repayments on notes payable of $327,006 and payments under lease obligations of $16,193.

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 September 30, 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 September 30, 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 September 30, 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. As of September 30, 2024, we have not had a history of significant legal proceedings and there are no currently pending actions against us. We believe that any amount, or range, of reasonably possible losses in connection with any potential actions against us in excess of established reserves, in the aggregate, will not be 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 and the significance of any actions against us.

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 except as noted below.

There is substantial doubt about our ability to continue as a going concern

There is substantial doubt about our ability to continue as a going concern. If we are unable to raise sufficient capital in this offering or otherwise as and when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. Our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into critical contractual relations with third parties and otherwise execute our development strategy.

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
3.1	Eleventh Amended and Restated Certificate of Incorporation of Femasys Inc.	Form 8-K	001-40492	3.1	June 22, 2021
3.2	Amended and Restated Bylaws of Femasys Inc.	Form 8-K	001-40492	3.2	June 22, 2021
3.3	First Amendment to the Amended and Restated Bylaws of Femasys Inc.	Form 8-K	001-40492	3.1	March 30, 2023
31.1*	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				
31.2*	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				
32.1*	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				
32.2*	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 12th day of November 2024.

FEMASYS INC.

Dated: November 12, 2024

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

Dated: November 12, 2024

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

Exhibit 31.1

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: November 12, 2024

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

Exhibit 31.2

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.

Date: November 12, 2024

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

Exhibit 32.1

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 September 30, 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.

Date: November 12, 2024

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

Exhibit 32.2

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 September 30, 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.

Date: November 12, 2024

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