FEMALE HEALTH CO
Form 10QSB
February 14, 2005

U.S. SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-QSB

(MARK ONE)
[X] QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended December 31, 2004

[ ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT

For the transition period from _____ to _____

Commission File Number 1-13602

THE FEMALE HEALTH COMPANY
(Exact Name of Small Business Issuer as Specified in Its Charter)

| Wisconsin | 39-1144397 |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| 515 North State Street, Suite 2225, Chicago, IL | 60610 |
| (Address of Principal Executive Offices) | (Zip Code) |

312-595-9123
(Issuer's Telephone Number, Including Area Code)

Not applicable
(Former Name, Former Address and Former Fiscal Year, If Changed Since Last Report)

Check whether the issuer: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the issuer was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. YES [X] NO [ ]

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practical date:

Common Stock, $.01 Par Value - 23,322,838 shares outstanding
as of February 14, 2005

Transitional Small Business Disclosure Format (check one):
YES [ ] NO [X]

FORM 10-QSB

THE FEMALE HEALTH COMPANY AND SUBSIDIARIES

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PART I. FINANCIAL INFORMATION:

## CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

Certain statements included in this quarterly report on Form 10-QSB which are not statements of historical fact are intended to be, and are hereby identified as "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The Company cautions readers that forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievement expressed or implied by such forward-looking statements. Such factors include, among others, the following: the Company's inability to secure adequate capital to fund operating losses, working capital requirements, advertising and promotional expenditures and principal and interest payments on debt obligations; factors related to increased competition from existing and new competitors including new product introduction, price reduction and increased spending on marketing; limitations on the Company's opportunities to enter into and/or renew agreements with international partners, the failure of the Company or its partners to successfully market, sell and deliver its product in international markets, and risks inherent in doing business on an international level, such as laws governing medical devices that differ from those in the U.S., unexpected changes in the regulatory requirements, political risks, export restrictions, tariffs and other trade barriers and fluctuations in currency exchange rates; the disruption of production at the Company's manufacturing facility due to raw material shortages, labor shortages and/or physical damage to the Company's facilities; the Company's inability to manage its growth and to adapt its administrative, operational and financial control systems to the needs of the expanded entity and the failure of management to anticipate, respond to and manage changing business conditions; the loss of the services of executive officers and other key employees and the Company's continued ability to attract and retain highly-skilled and qualified personnel; the costs and other effects of litigation, governmental investigations, legal and administrative cases and proceedings, settlements and investigations; and developments or assertions by or against the Company relating to intellectual property rights.

THE FEMALE HEALTH COMPANY AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

| | December 31, 2004 | September 30, 2004 |
|---|---|---|
| ASSETS | | |
| Current Assets: | | |
| Cash | $ 1,503,863 | $ 755,482 |
| Accounts receivable, net | 1,429,209 | 1,450,756 |
| Inventories, net | 1,488,647 | 1,413,315 |
| Prepaid expenses and other current assets | 327,324 | 270,539 |
| TOTAL CURRENT ASSETS | 4,749,043 | 3,890,092 |
| | | |
| Certificate of deposit | 46,225 | 72,194 |
| Intellectual property rights, net | 154,002 | 178,940 |
| Other assets | 186,811 | 179,683 |
| | 387,038 | 430,817 |
| | | |
| PROPERTY, PLANT AND EQUIPMENT | 4,877,167 | 4,611,944 |
| Less accumulated depreciation and amortization | (4,692,519) | (4,437,583) |
| Net property, plant and equipment | 184,648 | 174,361 |
| | | |
| TOTAL ASSETS | $ 5,320,729 | $ 4,495,270 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | $ 327,156 | $ 398,672 |
| Accrued expenses and other current liabilities | 732,289 | 522,199 |
| Current maturities of obligations under capital leases | 17,119 | 21,552 |
| Preferred dividends payable | 7,306 | 11,464 |
| Note payable, bank, net of unamortized discount | - | 453,748 |
| TOTAL CURRENT LIABILITIES | 1,083,870 | 1,407,635 |
| | | |
| Deferred gain on sale of facility | 1,309,660 | 1,262,278 |
| | | |
| STOCKHOLDERS' EQUITY: | | |
| Convertible preferred stock, Class A Series 1 | 560 | 560 |
| Convertible preferred stock, Class A Series 3 | 4,734 | 4,734 |
| Convertible preferred stock, Class B | - | - |
| Common stock | 231,028 | 207,152 |
| Additional paid-in-capital | 62,247,861 | 59,700,265 |
| Unearned consulting compensation | (285,475) | (69,547) |
| Deferred compensation | (124,453) | - |
| Accumulated deficit | (59,650,630) | (58,427,365) |
| Accumulated other comprehensive income | 535,650 | 441,634 |
| Treasury stock, at cost | (32,076) | (32,076) |
| TOTAL STOCKHOLDERS' EQUITY | 2,927,199 | 1,825,357 |
| | | |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | $ 5,320,729 | $ 4,495,270 |

See notes to unaudited condensed consolidated financial statements.

THE FEMALE HEALTH COMPANY AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | Three Months Ended December 31, | |
|---|---|---|
| | 2004 | 2003 |
| Net revenues | $ 1,545,657 | $ 2,328,748 |
| Cost of products sold | 1,016,502 | 1,454,517 |
| Gross profit | 529,155 | 874,231 |
| Advertising & promotion | 4,588 | 11,474 |
| Selling, general and administrative | 1,246,567 | 1,116,633 |
| Research & development | 17,686 | 34,271 |
| Stock compensation | 406,147 | 47,898 |
| Total operating expenses | 1,674,988 | 1,210,276 |
| Operating loss | (1,145,833) | (336,045) |
| | | |
| Interest, net and other expense | 52,925 | 316,199 |
| Foreign currency translation (gain)/loss | (16,320) | - |
| Net loss | (1,182,438) | (652,244) |
| | | |
| Preferred dividends, Class A, Series 1 | 3,048 | 3,048 |
| Preferred dividends, Class A, Series 3 | 37,779 | - |
| | | |
| Net loss attributable to common stockholders | $ (1,223,265) | $ (655,292) |
| | | |
| Net loss per common share outstanding | $ (0.06) | $ (0.03) |
| | | |
| Weighted average common shares outstanding | 22,156,056 | 19,599,988 |

See notes to unaudited condensed consolidated financial statements.

THE FEMALE HEALTH COMPANY AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Three Months Ended December 31, | |
|---|---|---|
| | 2004 | 2003 |
| OPERATING ACTIVITIES: | | |
| Net (loss) | $ (1,182,438) | $ (652,244) |
| Adjustment for noncash items: | | |
| Depreciation and amortization | 26,373 | 121,311 |
| Interest added to certificate of deposit | (1,093) | (972) |
| Amortization of discounts on notes payable | 46,252 | 240,246 |
| Amortization of unearned consulting fees | 84,071 | 47,898 |
| Common stock issued for bonuses | 56,672 | 44,063 |
| Stock compensation | 322,076 | - |
| Changes in operating assets and liabilities | (15,127) | (197,541) |
| Net cash (used in) operating activities | (663,214) | (387,239) |
| INVESTING ACTIVITIES: | | |
| Proceeds from maturity of certificate of deposit | 27,062 | 27,600 |
| Decrease in restricted cash | - | 119,664 |
| Capital expenditures | (20,371) | (12,441) |
| Net cash provided by investing activities | 6,691 | 134,823 |
| FINANCING ACTIVITIES: | | |
| Proceeds from exercise of common stock warrants | 1,945,000 | - |
| Proceeds from note payable, bank | - | 250,000 |
| Payments on note payable, bank | (500,000) | - |
| Dividends paid on preferred stock | (7,206) | (11,200) |
| Payments on capital lease obligations | (5,570) | (1,659) |
| Net cash provided by financing activities | 1,432,224 | 237,141 |
| Effect of exchange rate changes on cash | (27,320) | 24,609 |
| INCREASE IN CASH | 748,381 | 9,333 |
| Cash at beginning of period | 755,482 | 632,295 |
| CASH AT END OF PERIOD | $ 1,503,863 | $ 641,628 |
| Schedule of noncash financing and investing activities: | | |
| Common stock issued for payment of preferred stock dividends | $ 37,779 | - |
| Issuance of restricted stock to employees | 131,625 | 176,250 |
| Issuance of common stock and warrants provided as incentives for exercising warrants | 322,076 | - |
| Accrued expense incurred for restricted common stock granted to employees | 214,500 | - |

| | | |
|---|---|---|
| Preferred dividends declared | 40,827 | 3,048 |

See notes to unaudited condensed consolidated financial statements.

THE FEMALE HEALTH COMPANY AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - Basis of Presentation

The accompanying financial statements are unaudited but in the opinion of management contain all the adjustments (consisting of those of a normal recurring nature) considered necessary to present fairly the financial position and the results of operations and cash flow for the periods presented in conformity with generally accepted accounting principles for interim financial information and the instructions to Form 10-QSB and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

Operating results for the three months ended December 31, 2004 are not necessarily indicative of the results that may be expected for the fiscal year ending September 30, 2005. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's annual report on Form 10-KSB for the fiscal year ended September 30, 2004.

Principles of consolidation and nature of operations:

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, The Female Health Company - UK and The Female Health Company - UK, plc. All significant intercompany transactions and accounts have been eliminated in consolidation. The Female Health Company ("FHC" or the "Company") is currently engaged in the marketing, manufacture and distribution of a consumer health care product known as the female condom, "FC," in the U.S. and "femidom," "femy" and "the female condom" outside the U.S. The Female Health Company - UK, is the holding company of The Female Health Company - UK, plc, which operates a 40,000 sq. ft. leased manufacturing facility located in London, England.

Stock-Based compensation:

The Company accounts for its stock-based compensation plans under the recognition and measurement principles of APB Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of FASB Statement No. 123, Accounting for Stock-Based Compensation, to stock-based employee compensation.

| | Three Months Ended December 31, | |
|---|---|---|
| | 2004 | 2003 |
| Net loss, as reported | $ (1,223,265) | $ (655,292) |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (175,802) | (193,421) |
| Pro forma net loss | $ (1,399,067) | $ (848,713) |
| Loss per share: | | |
| As reported | $ (0.06) | $ (0.03) |
| Pro forma | $ (0.06) | $ (0.04) |

Reclassification:

Certain items in the financial statements for the three months ended December 31, 2003 have been reclassified to be consistent with the presentation shown for the three months ended December 31, 2004.

NOTE 2 - Earnings Per Share

Earnings per share (EPS): Basic EPS is computed by dividing income available to common stockholders by the weighted average number of common shares outstanding for the period. Diluted EPS is computed giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of the incremental common shares issuable upon conversion of convertible preferred stock or convertible debt and the exercise of stock options and warrants for all periods. Fully diluted (loss) per share is not presented since the effect would be anti-dilutive.

NOTE 3 - Comprehensive Loss

Total Comprehensive Loss was $(1,088,422) for the three months ended December 31, 2004 and $(477,022) for the three months ended December 31, 2003.

NOTE 4 - Inventories

The components of inventory consist of the following:

| | December 31, 2004 | September 30, 2004 |
|---|---|---|
| Raw material and work in process | $ 829,141 | $ 767,469 |
| Finished goods | 697,217 | 674,209 |
| Inventory, gross | 1,526,358 | 1,441,678 |
| Less: inventory reserves | (37,711) | (28,363) |
| Inventory, net | $ 1,488,647 | $ 1,413,315 |

Note 5. Acquired Intangible Asset

The Company follows SFAS 142, *Goodwill and Other Intangible Assets*. The following is a summary of acquired intangible assets at December 31, 2004 and September 30, 2004:

| | Gross Carrying Amount | Accumulated Amortization |
|---|---|---|
| Subject to amortization: | | |
| Patents as of December 31, 2004 | $ 1,123,214 | $ 969,212 |
| Patents as of September 30, 2004 | $ 1,123,214 | $ 944,274 |

Amortization expense recognized on all amortizable intangible assets totaled $34,668 and $31,729 for the three months ended December 31, 2004 and 2003, respectively.

Estimated aggregate amortization expense for each of the next following years is as follows:

| | |
|---|---|
| Years ending September 30: | |
| 2005 | $ 104,004 |
| 2006 | 49,998 |
| | $ 154,002 |

NOTE 6 - Preferred Stock

The Company has 56,000 outstanding shares of Series 1 Preferred Stock. Each share of Series 1 Preferred Stock is convertible into one share of the Company's common stock on or after August 1, 1998. Annual preferred stock dividends will be paid if and as declared by the Company's Board of Directors. No dividends or other distributions will be payable on the Company's common stock unless dividends are paid in full on the Series 1 Preferred Stock. The Series 1 Preferred Stock may be redeemed at the option of FHC, in whole or in part, on or after August 1, 2000, subject to certain conditions, at $2.50 per share plus accrued and unpaid dividends. In the event of a liquidation or dissolution of the Company, the Series 1 Preferred Stock would have priority over the Company's common stock.

The Company has 473,377 outstanding shares of Series 3 Preferred Stock. Each share of Series 3 Preferred Stock is convertible at any time into one share of the Company’s common stock. Holders of shares of the Series 3 Preferred Stock are entitled to cumulative dividends in preference to any dividend on the Company's common stock at the rate of 10% of the original issuance price ($3.17 per share) per annum, payable at the Company's option in cash or shares of the Company's common stock. If dividends are paid in shares of common stock, the dividend rate will be equal to 95% of the average of the closing sales prices of the common stock on the five trading days preceding the dividend reference date. The dividend reference date means January 1, April 1, July 1 and October 1 of each year. In the event of a liquidation or dissolution of the Company, the Series 3 Preferred Stock would have priority over the Company’s common stock and holders of any other series of preferred stock of the Company. The Company may redeem any share of Series 3 Preferred Stock at any time that is after the second anniversary of the date of issuance of the share, provided that the redemption may not occur until the first day on or after the second anniversary of the date of issuance of such share in which the market value of the Company’s common stock is at least 150% of the original issuance price of $3.17 per share. The liquidation preference on the Series 3 Preferred stock is $3.17 per share plus accrued and unpaid dividends.

NOTE 7 - Industry Segments And Financial Information About Foreign and Domestic Operations

The Company currently operates primarily in one industry segment which includes the development, manufacture and marketing of consumer health care products.

The Company operates in foreign and domestic regions. Information about the Company's operations by geographic area is as follows:

(Amounts in Thousands)

| | Net Sales to External Customers For the Three Months Ended December 31, | | Long-Lived Assets As of | |
|---|---|---|---|---|
| | 2004 | 2003 | December 31, 2004 | September 30, 2004 |
| United States | $ 394 | $ 872 | $ 90 | $ 103 |
| Venezuela | 388(1) | * | - | - |
| Congo | * | 267 | - | - |
| France | 108 | 413(1) | - | - |
| Senegal | * | 143 | - | - |
| United Kingdom | * | * | 482 | 502 |
| Zimbabwe | * | 208 | - | - |
| Other | 656 | 426 | - | - |
| | $ 1,546 | $ 2,329 | $ 572 | $ 605 |

* Less than 5 percent of total net sales

(1) Comprised of a single customer considered to be a major customer (exceeds 10% of net sales).

NOTE 8 - Contingent Liabilities

The testing, manufacturing and marketing of consumer products by the Company entail an inherent risk that product liability claims will be asserted against the Company. The Company maintains product liability insurance coverage for claims arising from the use of its products. The coverage amount is currently $5,000,000 for FHC's consumer health care product.

THE FEMALE HEALTH COMPANY AND SUBSIDIARIES
MANAGEMENT'S DISCUSSION AND ANALYSIS

General

The Female Health Company ("FHC" or the "Company") manufactures, markets and sells the female condom, the only FDA-approved product under a woman's control which can prevent unintended pregnancy and sexually transmitted diseases ("STDs"), including HIV/AIDS.

The female condom has undergone extensive testing for efficacy, safety and acceptability, not only in the United States but also in many countries around the world. Certain of these studies show that having the female condom available allows women to have more options, resulting in an increase in protected sex acts and a decrease in STDs, including HIV/AIDS.

The product is currently sold or available in various venues. It is commercially marketed in 21 countries by various FHC country specific partners, including the United States, United Kingdom, Japan, Canada, Holland, France, and Brazil. Currently there are programs and/or pilot studies ongoing in 87 developing countries.

Product

The female condom is made of polyurethane, a thin but strong material which is resistant to rips and tears during use. The female condom consists of a soft, loose fitting sheath and two flexible O rings. One of the rings is used to insert the device and helps to hold it in place. The other ring remains outside the vagina after insertion. The female condom lines the vagina, preventing skin from touching skin during intercourse. The female condom is pre-lubricated and disposable and is intended for use during only one sex act.

Raw Materials

Polyurethane is the principal raw material the Company uses to produce the female condom. The Company has entered into a supply agreement with Deerfield Urethane, Inc. for the purchase of all of the Company's requirement of polyurethane. Under this agreement, the parties negotiate pricing on an annual basis. The term of the agreement expires on December 31, 2005 and automatically renews for additional one year periods unless either party gives at least 12 months prior written notice of termination.

Global Market Potential

It is more than twenty years since the first clinical evidence of AIDS was noted. HIV/AIDS is the most devastating pandemic that humankind has faced in recorded history. The Joint United Nations Programme on HIV/AIDS ("UNAIDS") reported that at the end of 2004, 40 million people globally are living with HIV. Women now comprise the majority of the new cases. UNAIDS estimates that if further action isn't taken up to 100 million people will have died of AIDS by 2020.

Currently there are only two products that prevent the transmission of HIV/AIDS through sexual intercourse--the latex male condom and the female condom.

The Condom Market

Estimates for the global annual market for male condoms are between 6-9 billion units. In addition, given the rapid spread of HIV/AIDS in India and China, UNAIDS estimates that the need for condoms, both male and female, may be as high as 29 billion units in the next 6 years.

The Female Condom and the Male Condom

The female condom is currently the only available barrier contraceptive method controlled by women which allows them to protect themselves from unintended pregnancy and STDs, including HIV/AIDS. The most important advantage is that using the female condom, a woman has a prevention method she controls as many men do not like to wear male condoms and may refuse to do so.

The polyurethane material that is used for the female condom offers a number of benefits over latex, the material that is most commonly used in male condoms. Polyurethane is much stronger than latex, reducing the probability that the female condom sheath will tear during use. Unlike latex, polyurethane quickly transfers heat, so the female condom immediately warms to body temperature when it is inserted, which may result in increased pleasure and sensation during use. The product offers an additional benefit to the 7% to 20% of the population that is allergic to latex and who, as a result, may be irritated by latex male condoms. To the Company's knowledge, there is no reported allergy to date to polyurethane. The female condom is also more convenient, providing the option of insertion hours before sexual arousal and as a result is less disruptive during sexual intimacy than the male condom which requires sexual arousal for application.

Numerous clinical and behavioral studies have been conducted regarding use of the female condom. Studies show that the female condom is found acceptable by women and their partners in many cultures. Importantly studies also show that when the female condom is made available with male condoms there is a significant increase in protected sex acts. The increase in protected sex acts varies by country and averages between 25% and 35%.

Cost Effectiveness

A study entitled "Cost-effectiveness of the female condom in preventing HIV and STDs in commercial sex workers in South Africa" was reported in the *Journal of Social Science and Medicine* in 2001. This study shows that making the female condom available is highly cost effective in reducing public health costs in developing countries as well as in the U.S.

Female Condom Reuse

Studies have shown that the female condom can be reused up to five times. The World Health Organization (the "WHO") has described on its website the procedure to use regarding the washing and preparation of the female condom if it is going to be reused. WHO, UNAIDS and FHC all make the statement that the female condom should only be reused when a new female condom is not available.

Worldwide Regulatory Approvals

The female condom received Pre-Market Approval ("PMA") as a Class III Medical Device from the U.S. Food and Drug Administration ("FDA") in 1993. The extensive clinical testing and scientific data required for FDA approval laid the foundation for approvals throughout the rest of the world, including receipt of a CE Mark in 1997 which allows the Company to market the female condom throughout the European Union ("EU") and in most countries of the world. In addition to the United States and the EU, several other countries have formally reviewed and approved the female condom for sale, including Canada, Australia, Japan and India.

The Company believes that the female condom's PMA and FDA classification as a Class III Medical Device create a significant barrier to entry. The Company estimates that it would take a minimum of four to six years to implement, execute and receive FDA approval of a PMA to market another type of female condom.

The Company believes there are no material issues or material costs associated with the Company's compliance with environmental laws related to the manufacture and distribution of the female condom.

Strategy

The Company's strategy is to act as a manufacturer, selling the female condom to the global public sector, United States public sector and commercial partners for country-specific marketing. The public sector and commercial partners assume the cost of shipping and marketing the product. As a result, as volume increases, the Company's operating expenses will not increase significantly.

The Company filed a patent on a second generation product (FC2) in 2003 and initiated a development program. Various regulatory approvals for FC2 are in process. It is expected that having FC2 available will result in a meaningful reduction in cost to manufacture the female condom, and thus ultimately reduce the cost to customers. It is the Company’s objective to use this opportunity to accelerate market penetration.

Commercial Markets

The Company markets the product directly in the United Kingdom. The Company has distribution agreements with commercial partners in 16 countries with major programs in 12 countries, including the United States, Canada, Brazil, Mexico, Spain, France and India. The agreements are generally exclusive for a single country. Under these agreements, each partner markets and distributes the female condom in a single country and the Company manufactures the female condom and sells the product to the partner for distribution in that country.

After terminating its relationship with its first partner, The Company entered into a non-binding Memorandum of Understanding with a large Japanese pharmaceutical company to distribute the female condom to public and private markets in Japan. In addition, the Company has signed an agreement with a second partner in Japan, Fuji Latex Inc. to manage the importation and quality control of the female condom under Japanese regulatory requirements.

Relationships and Agreements with Public Sector Organizations

The Company has an agreement with UNAIDS to supply the female condom to developing countries at a reduced price which is negotiated each year based on the Company's cost of production. The current price per unit is approximately £0.38 (pounds), or approximately $0.73. Under the agreement, UNAIDS and the Company cooperate in education efforts and marketing the female condom in developing countries. Sales of the female condom are made directly to public health authorities in each country at the price established by the agreement with UNAIDS. The term of the agreement currently expired on December 31, 2004, but automatically renewed for an additional one-year period. The female condom is available in 87 countries through public sector distribution.

In the United States, the product is marketed to city and state public health clinics, as well as not-for-profit organizations such as Planned Parenthood.

State-of-the-Art Manufacturing Facility

The Company manufactures the female condom in a 40,000 square-foot leased facility in London, England. The facility is currently capable of producing 60 million units per year.

Government Regulation

In the U.S., the female condom is regulated by the FDA. Pursuant to section 515(a)(3) of the Safe Medical Amendments Act of 1990 (the "SMA Act"), the FDA may temporarily suspend approval and initiate withdrawal of the PMA if the FDA finds that the female condom is unsafe or ineffective, or on the basis of new information with respect to the device, which, when evaluated together with information available at the time of approval, indicates a lack of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended or suggested in the labeling. Failure to comply with the conditions of FDA approval invalidates the approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the SMA Act.

Competition

The Company's female condom participates in the same market as male condoms but is not seen as directly competing with male condoms. Rather, the Company believes that providing the female condom is additive in terms of prevention and choice. Latex male condoms cost less and have brand names that are more widely recognized than the female condom. In addition, male condoms are generally manufactured and marketed by companies with significantly greater financial resources than the Company. It is also possible that other parties may develop a female condom. These competing products could be manufactured, marketed and sold by companies with significantly greater financial resources than those of the Company.

Patents and Trademarks

The Company currently holds product and technology patents in the United States, Japan, the United Kingdom, France, Italy, Germany, Spain, the European Patent Convention, Canada, the People's Republic of China, South Korea and Australia. These patents expire between 2005 and 2013. Additional patent applications are pending in the U.S. and in other countries around the world through the Patent Cooperation Treaty. The applications cover the key aspects of the second generation female condom, FC2, including its overall design and manufacturing process. The Company has the registered trademark “FC Female Condom” in the United States.

The Company has also secured, or applied for, 12 trademarks in 22 countries to protect the various names and symbols used in marketing the product around the world. These include "femidom" and "femy", “Reality” and others. In addition, the experience that has been gained through years of manufacturing the female condom has allowed the Company to develop trade secrets and know-how, including certain proprietary production technologies, that further secure its competitive position.

RESULTS OF OPERATIONS

THREE MONTHS ENDED DECEMBER 31, 2004 COMPARED TO THREE MONTHS ENDED DECEMBER 31, 2003

The Company had net revenues of $1,545,657 and a net loss attributable to common stockholders of $(1,223,265) or $(0.06) per share for the three months ended December 31, 2004 compared to net revenues of $2,328,748 and a net loss attributable to common stockholders of $(655,292) or $(0.03) per share for the three months ended December 31, 2003.

Gross profit decreased $345,076, or 39%, to $529,155 for the three months ended December 31, 2004 from $874,231 for the three months ended December 31, 2003. The decrease was a result of reduced net revenues coupled with a less than proportionate decrease in cost of products sold.

Net revenues decreased $783,091 in the current quarter, or 34%, compared with the same period last year. The lower net revenues occurred because of lower unit sales shipped to global and domestic public customers coupled with a reduction of the average selling price per unit due to sales mix. The lower net revenues is consistent with the Company's expectation that significant quarter to quarter variations will result from time to time due to the timing and shipment of large orders and not any fundamental change in the business. The Company routinely notes the potential for such variations in its press releases and SEC filings.

Cost of products sold decreased $438,015, or 30%, to $1,016,502 in the current quarter from $1,454,517 for the same period last year. The less than proportionate decline in cost of products sold is a result of higher direct material, direct labor and indirect production costs per unit for the current quarter compared to the same period last year offset by lower depreciation expenses. The higher costs were largely a result of adverse exchange rate fluctuations experienced during the current quarter combined with operating at lower, less efficient production levels. The lower depreciation costs were a result of a significant number of the Company’s fixed assets becoming fully depreciated during the first quarter of fiscal 2005.

Advertising and promotional expenditures decreased $6,886 to $4,588 in the current quarter from $11,474 for the same period in the prior year.

Selling, general and administrative expenses increased $129,934, or 12%, to $1,246,567 in the current quarter from $1,116,633 for the same period last year. The increase in the current quarter was a result of a rise in outside legal and consulting fees and an overall increase in UK operating expenses. The higher UK operating costs were largely a result of adverse exchange rate fluctuations experienced during the current quarter. The additional legal fees were due to non-recurring post-closing costs pertaining to credit agreements entered into in May 2004 while the higher consulting fees incurred represented services related to the initial planning and documentation stages necessary to design an internal control environment that complies with Section 404 of the Sarbanes-Oxley Act.

Research and development cost decreased $16,585 to $17,686 in the current quarter from $34,271 for the same period in the prior year. The Company filed a patent on a second generation product (FC2) in the latter part of the 2003 fiscal year. The Company initiated a development program related to FC2 in the 2004 fiscal year. The decrease in costs is due to the timing of services rendered during the first quarter of the 2005 fiscal year related to the safety and acceptability studies for the FC2 program.

Non-cash stock compensation costs increased $358,249 to $406,147 for the current quarter compared to $47,898 for the same period last year. The higher costs during the current fiscal year were a result of the Company recording charges related to shares of common stock and stock purchase warrants issued as an incentive for exercising existing stock warrants during the first quarter of fiscal 2005 as well as increased compensation for investor relation services. During the prior year first quarter the Company did not incur any charges related to issuance of incentive shares or warrants.

Net interest and other expenses decreased $263,274 to $52,925 for the current period from $316,199 for the same period last year. The current quarter decrease was due to the Company having a lower level of debt outstanding during the first quarter of fiscal year 2005 than the same period in fiscal year 2004. The result is a lower amount of both interest paid and non-cash expenses incurred from the amortization of discounts on notes payable during the current quarter than the same period in the prior year.

Preferred dividends increased $37,779 to $40,827 for the current quarter compared to $3,048 for the same period last year. The increase occurred as a result of the Company’s issuance of 473,377 shares of Series 3 Preferred Stock to eleven investors during February 2004 which thereby impacted the current quarter but not the prior year’s first quarter.

Factors That May Affect Operating Results and Financial Condition

The Company's future operating results and financial condition are dependent on the Company's ability to increase demand for and to cost-effectively manufacture sufficient quantities of the female condom. Inherent in this process is a number of factors that the Company must successfully manage in order to achieve favorable future results and improve its financial condition.

Reliance on a Single Product

The Company expects to derive the vast majority, if not all, of its future revenues from the female condom, its sole current product. While management believes the global potential for the female condom is significant, the product is in the early stages of commercialization and, as a result, the ultimate level of consumer demand around the world is not yet known. To date, sales of the female condom have not been sufficient to cover the Company's operating costs on an annual basis.

Distribution Network

The Company's strategy is to act as a manufacturer and to develop a global distribution network for the product by completing partnership arrangements with companies with the necessary marketing and financial resources and local market expertise. To date, this strategy has resulted in numerous in-country distributions in the public sector, particularly in Africa, Latin America and recently in India. Several partnership agreements have been completed for the commercialization of the female condom in private sector markets around the world. However, the Company is dependent on country governments as well as city and state public health departments within the United States to continue their commitment to prevention of STDs, including AIDS, by including female condoms in their programs. The Company is also dependent on finding appropriate partners for the private sector markets around the world. Once an agreement is completed, the Company is reliant on the effectiveness of its partners to market and distribute the product. Failure by the Company's partners to successfully market and distribute the female condom or failure of country governments to implement prevention programs which include distribution of barrier methods against the AIDS crisis, or an inability of the Company to secure additional agreements for AIDS crisis, or an inability of the Company to secure additional agreements for new markets either in the public or private sectors could adversely affect the Company's financial condition and results of operations.

As part of this strategy, on September 30, 2003, the Company entered into an agreement with the U.S. Agency for International Development (USAID). Under this agreement, the Company may supply up to 25 million units of FC Female Condoms to USAID through December 31, 2006 principally for use in family planning programs supported by USAID in developing countries. USAID has ordered 3 million units of FC Female Condoms for delivery between September 30, 2003 and December 31, 2004. USAID also has the option to order up to 8 million units of FC Female Condoms for the 2005 and 2006 calendar years. USAID has the right to terminate the agreement at any time for its sole convenience, and no assurance can be given as to the amount of FC Female Condoms that USAID will purchase during the term of the agreement. As of February 14, 2005, USAID has purchased 3.0 million units.

On March 25, 2004, the Company appointed Global Protection Corporation ("Global") as the exclusive distributor of the female condom for public sector sales within a 9 state region in the eastern United States. Global is required to purchase 2.6 million units within a three year period to retain exclusive distribution rights. As of February 7, 2005, Global has purchased 251,000 units.

Inventory and Supply

All of the key components for the manufacture of the female condom are essentially available from either multiple sources or multiple locations within a source.

Global Market and Foreign Currency Risks

The Company manufactures the female condom in a leased facility located in London, England. Further, a material portion of the Company's future sales are likely to be in foreign markets. Manufacturing costs and sales to foreign markets are subject to normal currency risks associated with changes in the exchange rate of foreign currencies relative to the United States dollar. For the first quarter of fiscal 2005, 65% of the Company’s net revenues, 88% of the Company’s cost of products sold and 37% of the Company’s operating expenses were affected by changes in the exchange rate of foreign currencies relative to the United States dollar. Approximately 25% of net revenues in first quarter fiscal 2005 were to the Company’s customers in Venezuela. On an ongoing basis, management continues to evaluate its commercial transactions and is prepared to employ currency hedging strategies when it believes such strategies are appropriate. In addition, some of the Company's future international sales may be in developing nations where dramatic political or economic changes are possible. Such factors may adversely affect the Company's results of operations and financial condition. For the first quarter of fiscal 2005, the Company estimates that the net adverse impact of the unfavorable exchange rate fluctuations was approximately $81,000.

Government Regulation

The female condom is subject to regulation by the FDA, pursuant to the federal Food, Drug and Cosmetic Act (the "FDC Act"), and by other state and foreign regulatory agencies. Under the FDC Act, medical devices must receive FDA clearance before they can be sold. FDA regulations also require the Company to adhere to certain "Good Manufacturing Practices," which include testing, quality control and documentation procedures. The Company's compliance with applicable regulatory requirements is monitored through periodic inspections by the FDA. The failure to comply with applicable regulations may result in fines, delays or suspensions of clearances, seizures or recalls of products, operating restrictions, withdrawal of FDA approval and criminal prosecutions. The Company's operating results and financial condition could be materially adversely affected in the event of a withdrawal of approval from the FDA.

Liquidity and Sources of Capital

Historically, the Company has incurred cash operating losses relating to expenses to develop, manufacture, and promote the female condom. In fiscal 2003 the Company experienced a positive cash flow from operations of $0.3 million. Cash used in continuing operations was $0.2 million for 2004. Cash used in continuing operations was $0.7 million for the first quarter of the 2005 fiscal year.

In prior years, the Company has funded operating losses and capital requirements, in large part, through the sale of common stock or debt securities convertible into common stock.

At December 31, 2004, the Company had working capital of $3.7 million and stockholder’s equity of $2.9 million compared to working capital of $2.5 million and stockholder’s equity of $1.8 million as of September 30, 2004.

The Company currently has three revolving promissory notes with Heartland Bank that allow the Company to borrow up to $2,500,000 and expire in July 2006. The Company had a balance on one of the promissory notes of $500,000 at September 30, 2004 and this amount was paid off as part of the warrant exercise program discussed below on November 23, 2004.

In an effort to generate funds for operating needs and to retire outstanding debt, between September 2004 and January 2005, the Company conducted a program to induce the holders of the Company's outstanding common stock purchase warrants to exercise their warrants. Pursuant to this program, the Company offered an incentive to such holders providing for issuance of (1) shares of the Company's common stock equal to 10% of the aggregate number of common stock purchase warrants exercised or (2) new common stock purchase warrants equal to 20% of the aggregate number of outstanding warrants exercised containing an exercise price per share equal to the closing price of the Company's common stock as reported on the OTC Bulletin Board on the date the holder committed to exercise the outstanding warrants. Under the incentive program, five investors exercised a total of 1,500,000 warrants and received 1,650,000 shares of the Company's common stock, including 150,000 incentive shares, and two investors exercised a total of 1,200,000 warrants and received 1,200,000 shares of the Company's common stock and 240,000 incentive warrants with an exercise price in each case of $1.50 per share and an expiration date of November 23, 2007. Among the six persons participating in this program include three of the Company's directors (Stephen M. Dearholt, Richard E. Wenninger and O.B. Parrish). The Company received aggregate proceeds of $2.5 million from the exercise of the outstanding warrants. With the proceeds, the Company paid off the remaining outstanding balance of its long-term debt.

The Company believes it’s current cash position and available borrowings are adequate to fund the operations of the Company for the year ended September 30, 2005; however, no assurances can be made.

If the Company is unable to raise adequate financing when needed, the Company may be required to sharply curtail the Company's efforts to promote the female condom, to attempt to sell certain of its assets and rights or to curtail certain of its operations and may ultimately be forced to cease operations. Currently, the Company is focused on growing its business and, therefore, the Company has made no plans to sell any assets nor has it identified any assets to be sold or potential buyers.

IMPACT OF INFLATION AND CHANGING PRICES

Although the Company cannot accurately determine the precise effect of inflation, the Company has experienced increased costs of product, supplies, salaries and benefits, and increased selling, general and administrative expenses. Historically, the Company has absorbed increased costs and expenses without increasing selling prices.

CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and the Company's Principal Accounting Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on this evaluation, the Company's Chief Executive Officer and Principal Accounting Officer concluded that the Company's disclosure controls and procedures were effective, except as discussed below, in timely alerting them to material information relating to the Company required to be included in the Company's periodic filings with the Securities and Exchange Commission. It should be noted that in designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The Company has designed its disclosure controls and procedures to reach a level of reasonable assurance of achieving desired control objectives and, based on the evaluation described above, the Company's Chief Executive Officer and Principal Accounting Officer concluded that the Company's disclosure controls and procedures were effective at reaching that level of reasonable assurance, except as discussed below.

For the year ended September 30, 2004, the Company has identified two material weaknesses within its internal control framework.

The first item relates to the timeliness of accounting for certain transactions. There have been non-cash transactions approved by senior management and not communicated timely to the Company's accounting/finance department for proper recording into the Company's accounts.

The second relates to the adequacy of supervisory reviews. There were several instances where items affecting the financial reporting of the Company were not reviewed by others for propriety. These lack of reviews resulted in adjustments being proposed by the Company's external auditors.

The Company is in the process of implementing Section 404 of Sarbanes-Oxley. In doing so the above material weaknesses will be addressed and remediated.

Changes in Internal Control over Financial Reporting

There was no change in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934, as amended) during the Company's most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

## PART II - OTHER INFORMATION

### ITEMS 1-5

Not applicable.

### ITEM 6. EXHIBITS

| Exhibit Number | Description |
|---|---|
| 3.1 | Amended and Restated Articles of Incorporation. (1) |
| 3.2 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 27,000,000 shares. (2) |
| 3.3 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 35,500,000 shares. (3) |
| 3.4 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 38,500,000 shares. (4) |
| 3.5 | Amended and Restated By-Laws. (5) |
| 4.1 | Amended and Restated Articles of Incorporation (same as Exhibit 3.1). |
| 4.2 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company (same as Exhibit 3.2). |
| 4.3 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 35,500,000 shares (same as Exhibit 3.3). |
| 4.4 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 38,500,000 shares (same as Exhibit 3.4). |
| 4.5 | Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.5). |
| 31.1 | Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | |

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|---|---|
| | Certification of Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002) (6) |

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| (1) | Incorporated herein by reference to the Company's Registration Statement on Form SB-2, filed with the Securities and Exchange Commission on October 19, 1999. |
| (2) | Incorporated by reference to the Company's Registration Statement on Form SB-2, filed with the Securities and Exchange Commission on September 21, 2000. |
| (3) | Incorporated by reference to the Company's Registration Statement on Form SB-2, filed with the Securities and Exchange Commission on September 6, 2002. |
| (4) | Incorporated by reference to the Company's Quarterly Report on Form 10-QSB for the quarter ended March 31, 2003. |
| (5) | Incorporated herein by reference to the Company's Registration Statement on Form S-18, as filed with the securities and Exchange Commission on May 25, 1990. |
| (6) | This certification is not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended. |

SIGNATURES

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

THE FEMALE HEALTH COMPANY

DATE: February 14, 2005 /s/ O.B. Parrish
O.B. Parrish, Chairman and
Chief Executive Officer

DATE: February 14, 2005 /s/ Robert R. Zic
Robert R. Zic, Principal
Accounting Officer (Principal
Financial Officer)

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