
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): May 9, 2017

THE FEMALE HEALTH COMPANY

(Exact name of registrant as specified in its charter)

Wisconsin
(State or other jurisdiction of incorporation)

1-13602
(Commission File Number)

39-1144397
(I.R.S. Employer I.D. Number)

4400 Biscayne Boulevard
Suite 888
Miami, Florida
(Address of Principal Executive Offices)

33137
(Zip Code)

312-595-9123
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Section 2 – Financial Information

Item 2.02 Results of Operations and Financial Condition

On May 9, 2017, The Female Health Company issued a press release (the “Press Release”) announcing results for the quarter and six months ended March 31, 2017. A copy of the Press Release is attached as Exhibit 99.1 to this report. The attached Exhibit 99.1 is furnished pursuant to Item 2.02 of Form 8-K.

The information in this Form 8-K and the Exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in such filing.

Section 9 – Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

The following exhibit is furnished herewith:

Exhibit 99.1 – Press Release of The Female Health Company, issued May 9, 2017.

SIGNATURES

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

THE FEMALE HEALTH COMPANY

Date: May 9, 2017

BY /s/ Daniel Haines
Daniel Haines, Chief Financial Officer



Contact:
Kevin Gilbert: 312-366-2633

Veru Healthcare Reports Fiscal 2017 Second-Quarter Financial Results

MIAMI – May 9, 2017 –Veru Healthcare (NASDAQ:FHCO) (the Company) today reported its financial results for the second fiscal quarter ended March 31, 2017.

“We are excited about the great progress we have made in the past 5 months to execute our diversification plan by advancing our multiple drug candidates that address large markets as well as to find new sources of immediate revenue,” said Mitchell Steiner, MD, President and Chief Executive Officer of Veru Healthcare.

“We recently announced the successful completion of the first stage of our clinical trial for our proprietary slow releasing powder, Tamsulosin Delayed Release Sachet (DRS), for men with benign prostatic hyperplasia (enlarged prostate) that have difficulty swallowing tablets or capsules. Our bioequivalence (BE) trial results demonstrated that Tamsulosin DRS could have benefits over FLOMAX and tamsulosin generics as it does not have to be administered after a meal and may be taken on an empty stomach. The 2nd stage of the BE trial is set to commence soon. We remain on track for a New Drug Application submission in early 2018 with an expected approval sometime in the second half of 2018. This product utilizes a potentially lower cost, lower risk and expedited approval pathway.”

“In addition to this clinical development milestone, our commercial team is working hard. I am pleased to report that the infrastructure for FC2 prescription business is now in place. FC2 is being distributed by many of the largest US healthcare distributors, making FC2 immediately available by prescription through retail pharmacies. Our marketing and sales team is also in place, and we expect to recognize revenue from the prescription business starting in fiscal Q3 2017. This is a new revenue opportunity for us, and we believe it has significant potential to contribute meaningful gross profit in the near-term.”

“We anticipate submitting with FDA an Investigational New Drug application for our proprietary oral drug candidate MSS-722 for the treatment of male infertility. There are no FDA approved oral therapies for male infertility. In addition, we will be meeting with the FDA in May for a pre-IND meeting for APP-944 for the treatment of hot flashes in men with advanced prostate cancer who are receiving hormonal therapies. Hot flashes are the most common and most distressing side effect reported by these men. These drug candidates can also utilize a potentially lower cost, lower risk and expedited approval pathway.”

Commenting on the Company’s financial results, Dr. Steiner said: “Our financial performance continues to be impacted by significant fluctuations in public sector orders for FC2. Net revenues were lower, largely due to the global decline in budgets for public sector healthcare products and reduced donor contributions. The financial results are further skewed when compared to last year’s second quarter, as it included the larger than usual amount of FC2 shipments to the Brazilian Ministry of Health. These public sector dynamics further validate the wisdom of the Company’s Board of Directors in pushing for meaningful product diversification.”

Recent Highlights

- Unit sales of FC2 were 4.5 million in the fiscal 2017 second quarter. This compares with unit sales in the prior year second quarter of 9.2 million, which included a large tender of 2.4 million units to the Brazil Ministry of Health.
- On May 2, 2017, announced that the Company's PREBOOST product had been selected from among more than 3,000 abstracts for a podium presentation and press conference regarding its PREBOOST clinical trial results at the American Urological Association annual meeting.
- On April 12, 2017, announced the successful Stage 1 of a bioequivalence (BE) clinical trial which was designed to select formulation of the company's proprietary Tamsulosin DRS product to advance into Stage 2. Tamsulosin DRS is a new, slow release oral powder formulation that addresses the large patient population of men with benign prostatic hyperplasia (BPH) who have difficulty swallowing tablets or capsules.
- FC2 Female Condom is now available in the US as a prescription product making it reimbursable under most healthcare plans. FC2 is now included in the product distribution network of one of the largest US healthcare products distributor so it is available at all retail pharmacies.

Significant quarter-to-quarter variations in the Company's results have historically resulted from the timing and shipment of large orders rather than from any fundamental changes in the business or the underlying demand for female condoms. Two of the largest customers for FC2 operate in markets where the government health ministries are either still under a multi-year tender or have had a multi-year tender recently expire, and as a result significant orders from these customers during the remainder of fiscal 2017 are unlikely. The Company is also currently seeing pressure on spending for FC2 by large global agencies and donor governments in the developed world.

About Veru Healthcare

Veru Healthcare is a pharmaceutical and medical device company, with a focus on the development and commercialization of pharmaceuticals that qualify for the FDA's 505(b)(2) accelerated regulatory approval pathway as well as the 505(b)(1) pathway. The Company does business both as "Veru Healthcare" and as "The Female Health Company" and is organized as follows:

- Veru Healthcare manages the Pharmaceuticals Division, which develops and commercializes pharmaceutical products for men's and women's health and oncology.
- Veru Healthcare manages the Consumer Health / Medical Devices Division, which is focused on commercializing sexual healthcare products and devices for the consumer market, including the Company's FC2 Female Condom® (now available by prescription) and PREBOOST® medicated individual wipe, which is a male genital desensitizing drug product that helps in the prevention of premature ejaculation.
- The Female Health Company division manages the Global Public Health Division, which is focused on the global public health sector FC2 business. This division markets the Company's Female Condom (FC2) to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world.

More information about the Company and its products can be found at www.PREBOOST.com and www.fc2femalecondom.com. For corporate and investor-related information about the Company, please visit <https://veruhealthcare.com/investors>.

“Safe Harbor” statement under the Private Securities Litigation Reform Act of 1995:

The statements in this release which are not historical fact are “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this release include statements relating to the regulatory pathway to secure FDA approval of the Company’s drug candidates, the impact of FHC’s strategies on operating results, and long-term demand for female condoms and the Company’s portfolio of drug products. These statements are based upon the Company’s current plans and strategies, and reflect the Company’s current assessment of the risks and uncertainties related to its business, and are made as of the date of this release. The Company assumes no obligation to update any forward-looking statements contained in this release as a result of new information or future events, developments or circumstances. Such forward-looking statements are inherently subject to known and unknown risks and uncertainties. The Company’s actual results and future developments could differ materially from the results or developments expressed in, or implied by, these forward-looking statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to, the following: product demand and market acceptance; competition in the Company’s markets and the risk of new competitors and new competitive product introductions; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; risks related to the development of the Company’s product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; many of the Company’s products are at an early stage of development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including licensing risks; government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay or restructuring; a governmental tender award indicates acceptance of the bidder’s price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount; the Company’s reliance on its international partners in the consumer sector and on the level of spending on the female condom by country governments, global donors and other public health organizations in the global public sector; the economic and business environment and the impact of government pressures; risks involved in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers; the Company’s production capacity, efficiency and supply constraints; risks related to the costs and other effects of litigation; the Company’s ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company’s ability to successfully integrate acquired businesses, technologies or products; and other risks detailed in the Company’s press releases, shareholder communications and Securities and Exchange Commission filings, including the Company’s Form 10-K for the year ended September 30, 2016. These documents are available on the “SEC Filings” section of our website at www.veruhealthcare.com/investors.

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FINANCIAL SCHEDULES FOLLOW

The Female Health Company
Unaudited Condensed Consolidated Balance Sheets

| | March 31, 2017 | September 30, 2016 |
|--|----------------------|-----------------------|
| Cash | \$ 1,241,593 | \$ 2,385,082 |
| Accounts receivable, net | 7,310,550 | 10,775,200 |
| Income tax receivable | 2,229 | 2,387 |
| Inventory, net | 2,538,266 | 2,492,644 |
| Prepaid expenses and other current assets | 607,962 | 634,588 |
| Total current assets | 11,700,600 | 16,289,901 |
| Other trade receivables | 7,837,500 | 7,837,500 |
| Other non-current assets | 179,028 | 189,219 |
| Plant and equipment, net | 735,893 | 825,087 |
| Deferred income taxes | 9,012,602 | 13,482,000 |
| Intangible assets, net | 20,833,178 | 0 |
| Goodwill | 6,878,932 | 0 |
| Total assets | <u>\$ 57,177,733</u> | <u>\$ 38,623,707</u> |
| Accounts payable | \$ 1,435,024 | \$ 701,035 |
| Accrued expenses and other current liabilities | 1,835,433 | 2,380,571 |
| Accrued compensation | 137,414 | 264,871 |
| Total current liabilities | 3,407,871 | 3,346,477 |
| Other liabilities | 1,233,750 | 1,233,750 |
| Deferred rent | 44,850 | 0 |
| Deferred income taxes | 975,771 | 110,069 |
| Total liabilities | 5,662,242 | 4,690,296 |
| Series 4 preferred stock | 17,981,883 | 0 |
| Total stockholders' equity | 33,533,608 | 33,933,411 |
| Total liabilities and stockholders' equity | <u>\$ 57,177,733</u> | <u>\$ 38,623,707</u> |

The Female Health Company
Unaudited Condensed Consolidated Statements of Operations

| | Three Months Ended | |
|--|-----------------------|------------------|
| | March 31, | |
| | 2017 | 2016 |
| Net revenues | \$ 2,405,519 | \$ 4,772,801 |
| Cost of sales | <u>1,127,864</u> | <u>1,927,406</u> |
| Gross profit | 1,277,655 | 2,845,395 |
| Selling, general and administrative | 2,419,826 | 2,739,850 |
| Research and development | <u>1,437,062</u> | <u>35,120</u> |
| Total operating expenses | 3,856,888 | 2,774,970 |
| Operating (loss) income | (2,579,233) | 70,425 |
| Interest and other expense, net | (12,686) | (19,356) |
| Foreign currency transaction loss | <u>(8,756)</u> | <u>(43,848)</u> |
| (Loss) income before income taxes | (2,600,675) | 7,221 |
| Income tax benefit | <u>(824,033)</u> | <u>(27,824)</u> |
| Net (loss) income | <u>\$ (1,776,642)</u> | <u>\$ 35,045</u> |
| Net (loss) income per basic common share | \$ (0.06) | \$ 0.00 |
| Basic weighted average common shares outstanding | 30,982,497 | 28,652,635 |
| Net (loss) income per diluted common share | \$ (0.06) | \$ 0.00 |
| Diluted weighted average common shares | 30,982,497 | 29,059,296 |

The Female Health Company
Unaudited Condensed Consolidated Statements of Operations

| | Six Months Ended | |
|--|-----------------------|---------------------|
| | March 31, | |
| | 2017 | 2016 |
| Net revenues | \$ 5,649,118 | \$ 13,003,460 |
| Cost of sales | <u>2,719,179</u> | <u>4,755,728</u> |
| Gross profit | 2,929,939 | 8,247,732 |
| Selling, general and administrative | 5,775,700 | 5,711,337 |
| Research and development | <u>1,608,162</u> | <u>73,415</u> |
| Total operating expenses | 7,383,862 | 5,784,752 |
| Operating (loss) income | (4,453,923) | 2,462,980 |
| Interest and other expense, net | (22,307) | (47,152) |
| Foreign currency transaction loss | <u>(20,695)</u> | <u>(88,791)</u> |
| (Loss) income before income taxes | (4,496,925) | 2,327,037 |
| Income tax (benefit) expense | <u>(1,354,102)</u> | <u>801,629</u> |
| Net (loss) income | <u>\$ (3,142,823)</u> | <u>\$ 1,525,408</u> |
| Net (loss) income per basic common share | \$ (0.10) | \$ 0.05 |
| Basic weighted average common shares outstanding | 30,979,283 | 28,642,951 |
| Net (loss) income per diluted common share | \$ (0.10) | \$ 0.05 |
| Diluted weighted average common shares | 30,979,283 | 29,046,928 |

The Female Health Company
Unaudited Condensed Consolidated Statements of Cash Flows

| | Six Months Ended | |
|--|---------------------|---------------------|
| | March 31, | |
| | 2017 | 2016 |
| Net (loss) income | \$(3,142,823) | \$ 1,525,408 |
| Adjustments to reconcile net (loss) income to net cash used in operating activities: | | |
| Depreciation and amortization | 177,444 | 226,681 |
| Amortization of intangible assets | 66,822 | 0 |
| Share-based compensation | 422,469 | 254,116 |
| Warrants issued | 542,930 | 0 |
| Deferred income taxes | (1,464,900) | 673,252 |
| Loss on disposal of fixed assets | 4,469 | 278 |
| Changes in current assets and liabilities, net of effects of acquisition of a business | <u>2,333,592</u> | <u>(3,991,414)</u> |
| Net cash used in operating activities | (1,059,997) | (1,311,679) |
| Net cash used in investing activities | (83,492) | (2,739) |
| Net decrease in cash | (1,143,489) | (1,314,418) |
| Cash at beginning of period | <u>2,385,082</u> | <u>4,105,814</u> |
| Cash at end of period | <u>\$ 1,241,593</u> | <u>\$ 2,791,396</u> |