
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): December 12, 2016

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))
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Section 2 – Financial Information

Item 2.02 Results of Operations and Financial Condition

On December 12, 2016, The Female Health Company issued a press release (the "Press Release") announcing results for the quarter and fiscal year ended September 30, 2016. 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 December 12, 2016.

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.

Date: December 12, 2016

THE FEMALE HEALTH COMPANY

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



Contact:
Kevin Gilbert 312-366-2633

The Female Health Company / Veru Healthcare Reports Fiscal 2016 Fourth-Quarter, Full-Year Financial Results

MIAMI – December 12, 2016 – The Female Health Company / Veru Healthcare (NASDAQ-CM: FHCO) (FHC or the Company) today reported its financial results for the fiscal 2016 fourth quarter and full year ended September 30, 2016. Subsequent to the fiscal year end, the Company completed a merger with Aspen Park Pharmaceuticals, Inc. (APP) on October 31, 2016. The combined company brings together FHC's existing FC2 Female Condom product with APP's extensive drug development portfolio of products that addresses multi-billion dollar industry segments.

"Our entire team is focused on generating immediate revenue by expanding the FC2 Female Condom® business in the global public health sector and as a disposable contraceptive device in the US prescription market, as well as launching the PREBOOST® product," said Mitchell Steiner, MD, recently named President and Chief Executive Officer of The Female Health Company / Veru Healthcare. "Over the last several weeks, we made excellent progress on advancing our deep pharmaceuticals product candidate pipeline for near-term revenue that includes a number of substantial opportunities including the Tamsulosin DRS for benign prostatic hyperplasia. The bioequivalence study and filing of the NDA are expected for 2017. We believe these actions will help lay the foundation for improved operating results."

Commenting on the Company's financial results, Dr. Steiner added, "Net revenues for the fiscal 2016 fourth quarter and full year reflect, in part both the longer sales cycles related to selling to public sector customers and the volatility associated with single-product companies. With our current product diversification and sales and marketing strategy, we are addressing this volatility by adding potential new and more consistent revenue streams. To do this, we are rebuilding and implementing a commercialization strategy for FC2 as a disposable contraceptive device, which when prescribed by a physician is fully reimbursable as mandated by the Affordable Care Act. In addition, we expect to generate revenue from the planned launch of PREBOOST® for men."

Quarter and Fiscal Year Highlights and Recent Activity

- On December 12, 2016, reported unit sales of FC2 were 42 million in fiscal 2016 compared with 61 million in fiscal 2015
 - On December 7, 2016, announced its plan for a Phase 2 clinical trial for MSS-722, the Company's proprietary oral drug candidate for the treatment of male infertility, following the Company's recent presentation at the U.S. Food and Drug Administration (FDA) meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee on December 6, 2016.
 - On December 6, 2016, presented an overview of its drug candidate for male infertility, MSS-722, including the design and primary endpoints of its planned Phase 2 clinical trial, at a meeting of the FDA's Bone, Reproductive and Urologic Drugs Advisory Committee.
 - In November, through its exclusive distributor in Brazil, Semina Industria e Comércio Ltda, it received a tender award for up to 1.2 million FC2 Female Condoms from the São Paulo Municipal Department of STDs and AIDS.
 - In November, completed an amendment to its existing \$10 million revolving credit facility with BMO Harris Bank N.A. The credit facility was approved and amended because of the merger with APP, and as a result of the amendment, the credit line is now available in accordance with its terms.
 - In November, completed an independent, double-blind, randomized, controlled clinical study of the Company's novel PREBOOST® product (topical 4% benzocaine wipes) for the management of premature ejaculation (PE). Top line results show that men treated with PREBOOST had significant improvement in their ability to control ejaculation compare to men treated with placebo. The scientific abstract that describes the full interim analysis results has been submitted to a major urological medical conference.
 - In November, strengthened its management team with the appointment of Shiao Zhu as Vice President of
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Marketing for Veru Healthcare, which manages both the Pharmaceuticals Division and Consumer Health/Medical Devices Division, and the promotion of Denise van Dijk to President of the Global Public Health Division.
On October 31, 2016, successfully completed the merger with Aspen Park Pharmaceuticals, Inc. under modified terms.

Fiscal Year Results: 2016 vs 2015

For fiscal 2016, net revenues were \$22.1 million compared with \$32.6 million for fiscal 2015. Net revenues in fiscal 2015 were among the highest in the Company's history, primarily due to the large number of FC2 units shipped under a Brazilian tender order received in fiscal 2014. Unit sales of FC2 were 42 million in fiscal 2016 compared with 61 million in fiscal 2015, the second highest annual sales volume ever recorded by the Company. The decrease primarily relates to units shipped under the Brazilian tender, which were 12 million in fiscal 2016 and 28 million in fiscal 2015. Gross profit was \$13.3 million, or 60% of net revenues, compared with \$19.0 million, or 58% of net revenues for fiscal 2015. Selling, general and administrative (SG&A) expenses significantly declined to \$8.7 million compared with \$12.1 million for the prior year, primarily due to reductions in payments to the Company's Brazilian distributor for marketing and management expenses for the 2014 tender and lower employee compensation expense. In fiscal 2016, the Company incurred business acquisition expenses of \$1.5 million compared to none in fiscal 2015. Operating income was \$3.0 million compared with \$6.6 million for fiscal 2015. Income tax expense was \$2.5 million compared with \$2.3 million for fiscal 2015. Due to net operating loss (NOL) carryforwards, the Company made cash payments for income taxes of \$353,000, or 14% of income tax expense, in fiscal 2016 resulting in cash savings of \$2.1 million. Net income was \$345,000, or \$0.01 per diluted share, compared with \$4.3 million, or \$0.15 per diluted share, for fiscal 2015.

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.

Fiscal Fourth Quarter Results: 2016 vs. 2015

For the fourth quarter of fiscal 2016, net revenues were \$3.6 million. This compares with the near record net revenues for the fourth quarter of fiscal 2015 of \$7.2 million, which included net revenues of \$1.8 million from Brazil. Gross profit was \$1.9 million, or 52% of net revenues, compared with \$4.1 million, or 58% of net revenues, for the fourth quarter of fiscal 2015. SG&A expenses declined to \$1.6 million compared with \$3.3 million for the prior year fourth quarter, for reasons similar to those discussed above. In the fiscal 2016 fourth quarter, business acquisition expenses were \$469,000. Operating loss was \$293,000 versus operating income of \$761,000 for the fourth quarter of fiscal 2015. Income tax expense was \$1.4 million compared with \$79,000 for the fourth quarter of fiscal 2015. Net loss was \$1.8 million, or \$0.06 per share, versus net income of \$703,000, or \$0.02 per diluted share, for the fourth quarter of fiscal 2015.

The Company will not be hosting an investor conference call related to its fiscal 2016 fourth quarter and full-year financial results. Shareholders and other interested parties with questions may contact Kevin Gilbert at 312-366-2633 or K.Gilbert@veruhealthcare.com.

About The Female Health Company / Veru Healthcare

The Female Health Company / Veru Healthcare is a medical therapeutics company, with a focus on the development and commercialization of pharmaceuticals that qualify for the FDA's 505(b)(2) accelerated regulatory approval pathways 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 Female Condom (FC2), which is referred to as the FC2 Female Condom® in the consumer health products sector and as the Female Disposable Contraceptive Device (FC2) in the U.S. prescription market, and

PREBOOST® medicated individual wipes which is a male genital desensitizing drug product that helps in the prevention of premature ejaculation.

The Female Health Company 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 Female Health Company and its products can be found at www.femalehealth.com, www.veruhealthcare.com and www.femalecondom.org. For corporate and investor-related information about the Company, please visit www.FHCinvestor.com.

"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. 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, 2015 and the Company's proxy statement filed on August 8, 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

	September 30, 2016	September 30, 2015
Cash	\$2,385,082	\$4,105,814
Accounts receivable, net	10,775,200	14,088,390
Income tax receivable	2,387	21,251
Inventory, net	2,492,644	1,745,180
Prepaid expenses and other current assets	634,588	609,320
Deferred income taxes	2,025,000	1,016,000
Total current assets	18,314,901	21,585,955
Other trade receivables	7,837,500	0
Other non-current assets	189,219	136,766
Plant and equipment, net	825,087	1,239,990
Deferred income taxes	11,457,000	14,509,000
Total assets	\$38,623,707	\$37,471,711
Accounts payable	\$701,035	\$1,077,349
Accrued expenses and other current liabilities	2,380,571	2,555,231
Accrued compensation	264,871	592,428
Total current liabilities	3,346,477	4,225,008
Other liabilities	1,233,750	0
Deferred rent	0	15,389
Deferred income taxes	110,069	98,252
Total liabilities	4,690,296	4,338,649
Total stockholders' equity	33,933,411	33,133,062
Total liabilities and stockholders' equity	\$38,623,707	\$37,471,711

The Female Health Company
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended	
	September 30,	
	2016	2015
Net revenues	\$ 3,563,106	\$ 7,154,985
Cost of sales	<u>1,694,547</u>	<u>3,031,341</u>
Gross profit	1,868,559	4,123,644
Operating expenses	<u>2,161,546</u>	<u>3,362,327</u>
Operating (loss) income	(292,987)	761,317
Interest and other (expense) income, net	(2,505)	15,280
Foreign currency transaction (loss) gain	<u>(19,098)</u>	<u>5,203</u>
(Loss) income before income taxes	(314,590)	781,800
Income tax expense	<u>1,436,351</u>	<u>79,229</u>
Net (loss) income	<u>\$ (1,750,941)</u>	<u>\$ 702,571</u>
Net (loss) income per basic common share outstanding	\$ (0.06)	\$ 0.02
Basic weighted average common shares outstanding	28,723,666	28,566,021
Net (loss) income per diluted common share outstanding	\$ (0.06)	\$ 0.02
Diluted weighted average common shares outstanding	28,972,303	28,918,231

The Female Health Company
Unaudited Condensed Consolidated Statements of Income

	Year Ended	
	2016	2015
Net revenues	\$ 22,127,342	\$ 32,604,865
Cost of sales	<u>8,777,858</u>	<u>13,634,906</u>
Gross profit	13,349,484	18,969,959
Operating expenses	<u>10,330,972</u>	<u>12,351,552</u>
Operating income	3,018,512	6,618,407
Interest and other (expense) income, net	(57,056)	10,150
Foreign currency transaction (loss) gain	<u>(147,540)</u>	<u>58,483</u>
Income before income taxes	2,813,916	6,687,040
Income tax expense	<u>2,469,191</u>	<u>2,341,004</u>
Net income	<u>\$ 344,725</u>	<u>\$ 4,346,036</u>
Net income per basic common share outstanding	\$ 0.01	\$ 0.15
Basic weighted average common shares outstanding	28,666,477	28,532,327
Net income per diluted common share outstanding	\$ 0.01	\$ 0.15
Diluted weighted average common shares outstanding	28,926,557	28,917,048

The Female Health Company
Unaudited Condensed Consolidated Statements of Cash Flows

	Year Ended	
	September 30,	
	2016	
Net income	\$ 344,725	\$
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	423,572	
Provision for obsolete inventory	(8,630)	
Share-based compensation	499,873	
Deferred income taxes	2,054,817	
Changes in current assets and liabilities	(5,028,715)	
Net cash used in operating activities	(1,714,358)	
Net cash used in investing activities	(6,374)	
Net cash used in financing activities	0	
Net decrease in cash	(1,720,732)	
Cash at beginning of period	4,105,814	
Cash at end of period	\$ 2,385,082	\$