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**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 8, 2016

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**THE FEMALE HEALTH COMPANY**

(Exact name of registrant as specified in its charter)

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Wisconsin

(State or other jurisdiction of incorporation)

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1-13602

(Commission File Number)

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39-1144397

(I.R.S. Employer I.D. Number)

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4400 Biscayne Boulevard  
Suite 888  
Miami, Florida

(Address of Principal Executive Offices)

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33137

(Zip Code)

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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 7 – Regulation FD

### Item 7.01 Regulation FD Disclosure

The Female Health Company (the "Company") is furnishing the investor presentation, included as Exhibit 99.1 to this report, which will be used, in whole or in part, from time to time by executives of the Company at investor conferences or meetings with investors and analysts.

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 – The Female Health Company/Veru Healthcare Investor Presentation.

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 8, 2016

THE FEMALE HEALTH COMPANY

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



The Female Health Company/ Veru Healthcare  
NASDAQ: FHCO  
Headquarters: Miami, Florida  
Offices: Chicago, London, and Malaysia

December 2016

## Forward Looking Statements

This communication contains forward-looking statements. These statements are subject to known and unknown risks, uncertainties and assumptions, and if any such risks or uncertainties materialize or if any of the assumptions prove incorrect, our actual results could differ materially from those expressed or implied by such statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to: risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and Company operations; product demand and market acceptance; competition in the Company's markets and the risk of new competitors and new competitive product introductions. Some of the Company's products are in 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 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 Company's Annual Report on Form 10-K for the year ended September 30, 2015. This document is available on the "SEC Filings" section of our website at [www.veruhealthcare.com/investors](http://www.veruhealthcare.com/investors). All forward-looking statements are based on information available to us as of the date hereof, and Company does not assume any obligation and does not intend to update any forward-looking statements, except as required by law.



**Combined Capitalization**

- Approximately 53M<sup>1</sup> common shares outstanding on fully diluted/converted basis
- 29M FHCO diluted shares outstanding prior to merger
- 2M Common and 547,756 40-to-1 Convertible Preferred Shares issued upon merger
- \$10M available line of credit

**Combined Financial Highlights**

As of and for the Six Months Ended March 31, 2016  
(in millions)

Net Revenues	\$13.0
Operating Income	\$1.8
Net Income	\$0.8
Cash & Accounts Receivable	\$22.9

<sup>1</sup> See the Amended and Restated Agreement and Plan of Merger filed via Form 8-K on November 2, 2016 for detail on noted capitalization. Note that additional restricted shares, options, and warrants were issued in connection with the merger and are, or could potentially be, additionally dilutive in excess of the 53 million common share estimate noted above.

Public health sector product with \$33 million of revenue in fiscal year 2015

- **FC2 Female Condom is primarily a public health sector product**
  - Sold in US and 144 countries
  - Over 500 million units sold to date
  - 62 million units sold in 2015
  - Public sector represents approx. 90% of revenue (customers include UNFPA, USAID, Brazil, and South Africa)
- **Manufacturing plant in Malaysia and logistics and compliance in London, UK**
  - Current capacity of 100 million units annually
  - Ability to double production with minimal investment



Men's health product portfolio

Product	Indication	Key Differentiation	Intellectual Property	Expected NDA filing	Current US Market Size
PREBOOST	Premature Ejaculation	OTC convenient individual medicated wipes	Patent pending, expiry 2036	FDA OTC preapproved	\$500 million
Tamsulosin DRS	Benign Prostatic Hyperplasia	Delayed release sachet (DRS); a new oral powder formulation for elderly with swallowing disorders	Patent pending, expiry 2036, Licensed to Veru by Arina Therapeutics	2017	\$4.5 billion
MSS-722	Male infertility Orphan drug	Only oral agent that restores fertility by increasing GnRH, LH & FSH secretion to increase sperm production	Dose patent pending, expiry 2036 will be amended with actual dose to include infertility	2019	\$700 million
APP-944	Hot flashes in men on prostate cancer hormone therapies	Potentially the first approved oral drug for this indication	Patent pending, expiry 2036	2020	\$600 million
APP-111	3 <sup>rd</sup> line hormonal therapy advanced prostate cancer & oncology	Oral dosage; novel first-in-class anti-tubulin targeting chemotherapy	Licensed IP incl. 5 issued US patents, expiry 2029 possible ext. to 2034, and 63 foreign filings	2022	\$5 billion
APP-111/112	Gout and Familial Mediterranean Fever	Oral dosage; binds to same target as colchicine with potentially better safety profile	Licensed IP incl. 5 issued US patents, expiry 2029 possible ext. to 2034, and 63 foreign filings	2022	\$725 million



## Addressing large global markets

### Men

- Prostate cancer, including side effects of treatments, >\$6.4 billion<sup>1</sup>
- Benign prostatic hyperplasia (BPH) >\$5.2 billion<sup>2</sup>
- Sexual dysfunction >\$4 billion<sup>3</sup>
  - Premature ejaculation >\$500 million<sup>4</sup>
- Male infertility >\$700 million<sup>5</sup>
- Gout >\$1.5 billion<sup>6</sup>

### Women

- Breast cancer >\$3 billion<sup>7</sup>
- Ovarian cancer >\$1.5 billion<sup>8</sup>
- Protection against pregnancy and sexual transmission of HIV, Zika virus and STDs



**EXPERIENCED MANAGEMENT TEAM**

**Deep clinical and industry expertise**

**Mitchell Steiner, MD**

CEO and President. Urologist, Aspen Park Pharmaceuticals, OPKO Health, Inc. and GTx, Inc.

**Harry Fisch, MD**

Chief Corporate Officer. Urologist, Aspen Park Pharmaceuticals and Millennium Sciences, Inc.

**Kevin Gilbert**

SVP Corporate Development & Legal. JD & CPA, Legal & Corporate Development Consultant, Third Stream Bioscience, Attorney at McDermott, Will & Emery, Motorola, closed more than 100 transactions in 25 Countries.

**Daniel Haines, CPA**

Chief Financial Officer. Lennar Corp, Equity One, OPKO Health, Inc. and Ernst & Young.

**Shiao Zhu**

VP of Marketing. Watson Pharmaceuticals and Actavis, Novartis, extensive experience in pharmaceutical launches

**Denise Van Dijk**

President of The Female Health Company Global Public Health Sector Division. Consultant with Numerous Health Ministries & NGOs, Speaks 5 Languages, Has Worked in 34 Countries, MS Philosophy from Cambridge.



**STRATEGY**

**Utilize cash from operations to develop and commercialize pharmaceuticals for men's and women's health and oncology**





NOW

*A Leading Men's and Women's Health  
and Oncology Company*

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THE FEMALE HEALTH COMPANY

Public health sector product with \$33 million of revenue in fiscal year 2015 -  
Now a dedicated division of company

- Valuable form of dual pregnancy and STI protection
- Female Condom (FC2) primary focus will continue to be the global public health sector
- As global market leader, will intensify efforts to grow product for immediate revenue
- Appointed Denise van Dijk as President of Global Public Health Sector Division



**Create and grow prescription business in United States by converting public sector customer to prescription**

- **DCD (FC2) is the only female condom FDA approved for market (Class 3 Device)**
- **Non-hormonal birth control alternative**
  - Market as a disposable contraception device that also protects against STI
  - Many US women report dissatisfaction with the side effects of hormonal birth control
- **Public sector switch strategy**
  - 2015 public sector sales - 3.9M units to 1.3M women
    - Target is 30% conversion of public sector customers to prescription
  - DCD (FC2) reimbursed by prescription per the ACA, Medicaid, and private insurers
    - Pay up to \$3.50<sup>2</sup>/unit and 120 units per year
  - Prescription and fulfillment infrastructure in progress
- **Additional sales through customary channels**
  - DCD awareness program targeting physicians and pharmacists

PREBOOST® (4% benzocaine wipe)

- **PREBOOST – temporarily prolong time to ejaculation**
  - Only individual medicated wipe containing benzocaine
  - Temporarily desensitizes penis after topical application
  - Packaged as 10 wipes at \$29.99 per box
  - Planned launch of product Q4 2016
  - Compliant with FDA OTC monograph



- **Top line results of interim analysis from Phase 4 study<sup>1</sup> in 21 men**
  - After two months, men treated with PREBOOST® had significant improvement in their ability to control ejaculation, with a mean increase in duration of almost four minutes, which was significantly greater than placebo. After treatment, 80% no longer considered to have PE;
  - The interim study results met the primary endpoint of change in average intravaginal ejaculatory latency time (IELT) at two months, and secondary outcomes including change in questionnaire assessments, such as global rating of distress, medication assessment, and Index of Premature Ejaculation (IPE).

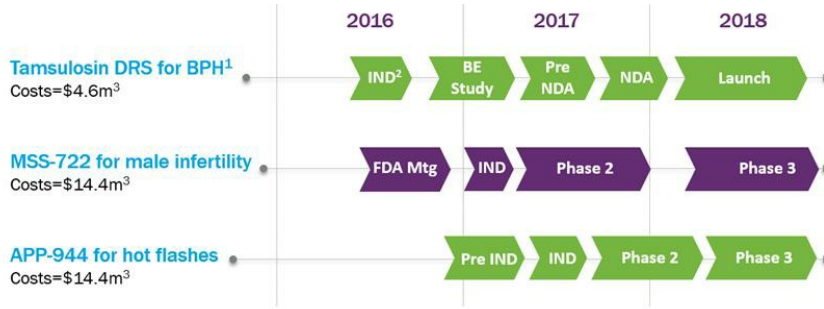
# SOON

*A Leading Men's and Women's Health  
and Oncology Company*



505(b)(2) PRESCRIPTION PRODUCTS

Plan is to prioritize and stagger programs to match resources.



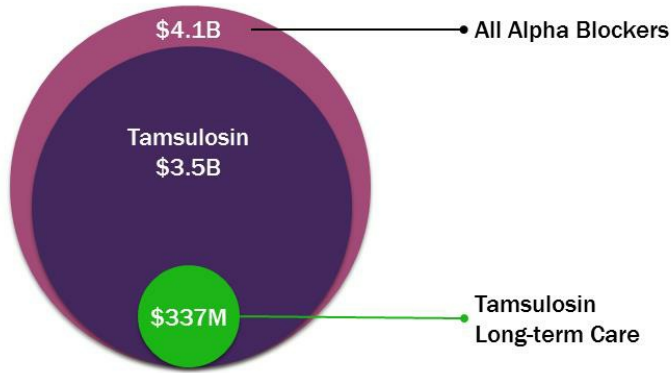
<sup>1</sup>Subject to installment payments upon certain milestones. | <sup>2</sup>8/12/16 PreIND meeting. FDA does not require new IND and single BE study would be acceptable as a 505(b)(2). | <sup>3</sup>Projected costs through 2018 milestones as noted assume each project immediately advanced.

## Alpha blockers most commonly prescribed drug class

- FLOMAX® (Tamsulosin HCl) is currently the number one prescribed alpha blocker treating the Medicare (long-term care) population<sup>1</sup>
- Difficulty swallowing (dysphagia) is a major problem with a 15% prevalence for the elderly, and 60% for those men living in long-term care facilities<sup>2</sup>
  - Solution and powder formulations are preferred in long-term care setting
  - Poor compliance with alpha blocker BPH drugs leads to increased risk of acute urinary retention, urosepsis and death
- Tamsulosin DRS (tamsulosin HCl for extended-release oral suspension) is a novel oral formulation for men with BPH and swallowing difficulties.

TAMSULOSIN DRS for BENIGN PROSTATIC HYPERPLASIA (BPH)

FLOMAX® and generic tamsulosin have ~80% market share of \$4.1B Market



No sales force initially needed - pharmacy switch strategy

- **Tamsulosin DRS – Brand Name**
  - Not a generic and will have unique NDC code
  - Differentiate from generics by pricing at 70% of FLOMAX®
- **Focus on Long-term care populations**
  - 13% of market in long term care facilities
  - 3 specialty GPOs to provide immediate access the majority of long-term care
- **Upside potential**
  - Expand reach into geriatric PCPs & urologists

TAMSULOSIN DRS for BENIGN PROSTATIC HYPERPLASIA (BPH)

Anticipated clinical development plan 505(b)(2)

Indication: BPH



- BE Study Design

- Stage 1 – 18 patients, 18 day study, multiple formulations, single dose
- Stage 2 – 28 patients, 25 day study, selected formulation vs. FLOMAX®

## A growing and underserved market

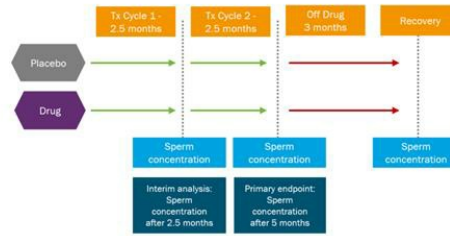
- Infertility affects 6.1 million couples in US, which is 15% of all couples trying to conceive<sup>1</sup>
  - 50% of infertility is attributed to males who present with abnormal semen analysis<sup>1,2</sup>
  - 2% of infertile men have adult onset form of idiopathic hypogonadotropic hypogonadism (abnormal hypothalamic-pituitary-gonadal axis)<sup>1-4</sup>
- hCG injection and FSH injections are expensive and only FDA approved therapies<sup>4,5</sup>
- CLOMID (Clomiphene) is an inconsistent cis:trans racemic mixture which is used as first line empirical therapy in 90% of idiopathic infertile men<sup>6</sup>
  - Off-label use
  - Most effective and safe dose as well as dosing schedule are not known
- No FDA approved oral therapies<sup>5</sup>
- MSS-722 is being developed as a 505(b)(2) as the first oral agent for the treatment of male infertility

## FDA advisory committee presentation

- FDA Advisory Committee Presentation - December 6, 2016
  - Agenda: discuss appropriate clinical trial design features, including acceptable endpoints for demonstrating clinical benefit, for drugs intended to treat secondary hypogonadism while preserving or improving testicular function, including spermatogenesis.

- Clinical Trial Design

- For men who have oligozoospermia (impaired spermatogenesis) and hypogonadotropic hypogonadism as a cause for male factor infertility.

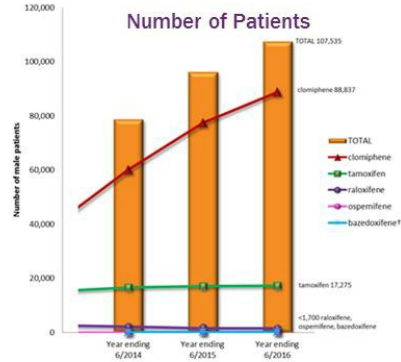


Off label use of clomiphene is growing significantly year over year

Number of Prescriptions

Product	MAT Apr 2013 TRx	MAT Apr 2014 TRx	MAT Apr 2015 TRx
<b>CLOMIPHENE CIT</b>	<b>869,286</b>	<b>902,370</b>	<b>915,851</b>
FEMALE	709,518	679,195	630,825
MALE	156,691	220,083	282,198
UNSPECIFIED	3,077	3,092	2,828

Source: IMS HealthData – Moving Annual Total TRx over the past 3 years (2013 to 2015)



Sources: IMS Health, Total Patient Tracker™, July 2011-June 2016. Extracted August 2016 from FDA Briefing Document. Source File: TPT estrogen antagonists 2016-12326\_5\_2016.xlsx





- Phase 2
  - 7.5 month duration
  - 2.5 month interim analysis
  - Approximately 120 patients

## Hot flashes in men on prostate cancer hormonal therapy



- **Hot flashes are the most common and distressing side effect of androgen deprivation therapy and other hormone therapies for prostate cancer**
  - Up to 80% of men treated with hormone therapies like Lupron and Zoladex experience hot flashes
  - Abiraterone and enzalutamide exacerbate hot flashes
  - Currently, no FDA approved therapies to treat hot flashes in men on prostate cancer hormonal therapies
- **Market for APP-944**
  - Oral agent to treat hot flashes in men on prostate cancer hormonal therapy
  - 700,000 men on androgen deprivation therapy in the US
  - 30% penetration = 255,000 men translates to \$600 million/year



# FUTURE

*A Leading Men's and Women's Health  
and Oncology Company*

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**PRESCRIPTION PRODUCTS**

Plan is to prioritize and stagger programs to match resources.



## Oral novel tubulin targeting chemotherapy for advanced prostate cancer

- **Current Market**
  - \$5 billion market for secondary hormone therapies for prostate cancer<sup>1</sup>
  - \$4.8B market for taxanes & vinca alkaloids (Docetaxel \$1B & cabazitaxel \$500 million in prostate cancer)<sup>2</sup>
- **Emerging Indications for anti-tubulins**
  - Second line: enzalutamide and abiraterone/prednisone have almost complete cross resistance and should not be used in sequence in advanced prostate cancer<sup>3</sup>
  - First line: Androgen deprivation therapy and docetaxel increase survival in men with hormone sensitive prostate cancer and high volume disease<sup>4</sup>
- **Agents that target tubulin continue to be *the only effective* cytotoxic chemotherapy in advanced prostate cancer, but there are challenges<sup>5</sup>:**
  - Route of administration-only available as IV dosing (urology versus oncology use)
  - Drug resistance is common - multidrug resistance proteins, tubulin mutations and overexpression
  - Safety concerns - hypersensitivity reactions, myelosuppression, and neurotoxicity (peripheral neuropathy & muscle weakness)

## Oral novel tubulin targeting chemotherapy

- **Proof-of-concept preclinical studies were successful. We have a drug!!**
  - Low nanomolar tubulin inhibition
  - Binds to colchicine site of tubulin
  - High oral bioavailability
  - High brain penetration
  - Not substrate MDRs (P-gp, MRPs, and BCRP)
  - Not substrate for CYP3A4
  - Demonstrated activity against taxane-, vinca alkaloid- and doxorubicin-refractory cancers
  - High activity against prostate cancer in vitro and in vivo
  - Favorable safety profile (less neurotoxicity & leukopenia)
- **Over 28 peer-reviewed publications**

## Potential Platform Technology: IV anti-tubulins have established activity against many other tumors

- **Vinca Alkaloids**
  - Primarily used in combination chemotherapy (ABVD, Stanford-V, CHOP, MOPP) for hematologic malignancies (leukemia, lymphoma, myeloma, sarcoma), and some neuroblastoma, thyroid cancer, and NSCLC
  - Vinblastine (Velban®)
  - Vincristine (Oncovin®)
  - Vinorelbine (Navelbine®)
- **Taxanes**
  - Primarily used for solid tumors such as breast, ovarian, endometrial, cervical, lung, head and neck, esophageal, bladder, gastric, and prostate
  - Paclitaxel (Taxol®)
  - Docetaxel (Taxotere®)
  - Cabazitaxel (Jevtana®)

Clinical development plan Indication: Advanced Prostate Cancer



- **Preclinical**

- Manufacture of API
- 28 day animal study

- **Phase 1a**

- APP-111 combined with enzalutamide
- Patients with metastatic castration resistant prostate cancer who progressed on enzalutamide alone



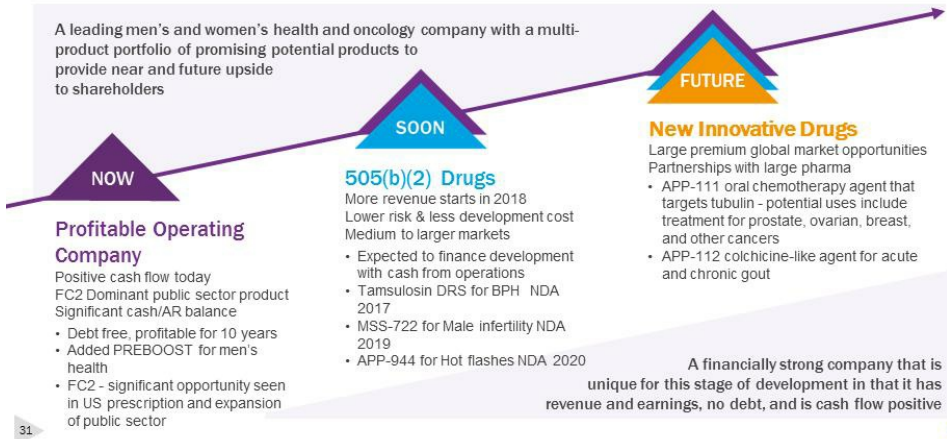
**ANTICIPATED MILESTONES**

**Flow of clinical & regulatory news creates opportunities to influence shareholder value**

	2016	2017	2018
<b>PREBOOST</b>	<ul style="list-style-type: none"> <li>• Launch</li> </ul>		
<b>FC2</b>	<ul style="list-style-type: none"> <li>• Expand into US prescription markets</li> </ul>	<ul style="list-style-type: none"> <li>• Expand into US prescription markets</li> </ul>	
<b>Tamsulosin DRS</b>	<ul style="list-style-type: none"> <li>• Complete PreIND meeting</li> <li>• IND</li> <li>• Initiate BE Study</li> </ul>	<ul style="list-style-type: none"> <li>• Complete BE study</li> <li>• preNDA meeting</li> <li>• File NDA for FDA</li> <li>• File MAA for EMA</li> </ul>	<ul style="list-style-type: none"> <li>• Launch</li> </ul>
<b>MSS-722</b>	<ul style="list-style-type: none"> <li>• FDA Advisory Meeting</li> </ul>	<ul style="list-style-type: none"> <li>• File IND</li> <li>• Initiate Phase 2 data</li> <li>• Orphan drug</li> </ul>	<ul style="list-style-type: none"> <li>• Initiate Phase 3</li> </ul>
<b>APP-944</b>		<ul style="list-style-type: none"> <li>• Complete preIND meet</li> <li>• File IND</li> <li>• Initiate Phase 2</li> </ul>	<ul style="list-style-type: none"> <li>• Complete Phase 2</li> </ul>
<b>APP-111</b>		<ul style="list-style-type: none"> <li>• Initiate preclinical studies</li> <li>• API</li> <li>• File IND</li> <li>• Initiate Phase 1a - prostate</li> </ul>	<ul style="list-style-type: none"> <li>• Complete Phase 1a – prostate</li> <li>• Initiate Phase 1b – prostate</li> <li>• Completed Phase 1b - prostate</li> </ul>

**Veru Healthcare/The Female Health Company maximizes both short- and long-term shareholder value (NASDAQ:FHCO)**

A leading men's and women's health and oncology company with a multi-product portfolio of promising potential products to provide near and future upside to shareholders



**NOW**

**Profitable Operating Company**

- Positive cash flow today
- FC2 Dominant public sector product
- Significant cash/AR balance
- Debt free, profitable for 10 years
- Added PREBOOST for men's health
- FC2 - significant opportunity seen in US prescription and expansion of public sector

**SOON**

**505(b)(2) Drugs**

- More revenue starts in 2018
- Lower risk & less development cost
- Medium to larger markets
- Expected to finance development with cash from operations
- Tamsulosin DRS for BPH NDA 2017
- MSS-722 for Male infertility NDA 2019
- APP-944 for Hot flashes NDA 2020

**FUTURE**

**New Innovative Drugs**

- Large premium global market opportunities
- Partnerships with large pharma
- APP-111 oral chemotherapy agent that targets tubulin - potential uses include treatment for prostate, ovarian, breast, and other cancers
- APP-112 colchicine-like agent for acute and chronic gout

A financially strong company that is unique for this stage of development in that it has revenue and earnings, no debt, and is cash flow positive



A Leading Men's and Women's  
Health and Oncology Company