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**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, DC 20549

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported): April 12, 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)

**1-13602**

(Commission File Number)

**39-1144397**

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

**515 North State Street  
Suite 2225**

**Chicago, Illinois**

(Address of Principal Executive Offices)

**60654**

(Zip Code)

**312-595-9123**

(Registrant's telephone number, including area code)

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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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**Item 8.01 Other Events.**

A copy of materials used in investor presentations by representatives of The Female Health Company (“FHC”) in connection with its proposed merger transaction with Aspen Park Pharmaceuticals, Inc. (“APP”) is attached to this report as Exhibit 99.1.

**Forward-Looking Statements**

This report and the attached Exhibit contain forward-looking statements, including those regarding the proposed merger transaction between FHC and APP and the integration of our two businesses. 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. These risks and uncertainties include but are not limited to: the risk that the proposed transaction may not be completed in a timely manner or at all; the satisfaction of conditions to completing the transaction, including the ability to secure approval by a two-thirds vote of FHC’s shareholders; risks that the proposed transaction could disrupt current plans and operations; costs, fees and expenses related to the proposed transaction; risks related to the development of APP’s product portfolio, including regulatory approvals and time and cost to bring to market; risks relating to the ability of the combined company to obtain sufficient financing on acceptable terms when needed to fund development and company operations; the risk that, even if it is completed, we may not realize the expected benefits from the transaction; and other risks described in FHC’s filings with the Securities and Exchange Commission (“SEC”), including our Annual Report on Form 10-K for the year ended September 30, 2015 and our Quarterly Report on Form 10-Q for the quarter ended December 31, 2015. These documents are available on the “SEC Filings” section of our website at <http://fhcinvestor.com>. All forward-looking statements are based on information available to us as of the date hereof, and FHC does not assume any obligation and does not intend to update any forward-looking statements, except as required by law.

**Additional Information about the Proposed Transaction and Where You Can Find It**

FHC plans to file a proxy statement with the SEC relating to a solicitation of proxies from its shareholders in connection with a special meeting of shareholders of FHC to be held for the purpose of voting on matters relating to the proposed transaction. BEFORE MAKING ANY VOTING DECISION WITH RESPECT TO THE PROPOSED TRANSACTION, FHC SECURITY HOLDERS ARE URGED TO READ THE PROXY STATEMENT AND OTHER RELEVANT MATERIALS WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION.

The proxy statement and other relevant materials, and any other documents filed by FHC with the SEC, may be obtained free of charge at the SEC’s website at [www.sec.gov](http://www.sec.gov). In addition, shareholders of FHC may obtain free copies of the documents filed with the SEC by contacting FHC’s Chief Financial Officer at (312) 595-9123, or by writing to Chief Financial Officer, The Female Health Company, 515 North State Street, Suite 2225, Chicago, Illinois 60654.

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**Interests of Certain Participants in the Solicitation**

FHC and its executive officers and directors may be deemed to be participants in the solicitation of proxies from the shareholders of FHC in favor of the proposed transaction. Other information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement and other relevant materials to be filed with the SEC when they become available.

**Item 9.01. Financial Statements and Exhibits.****(d) Exhibits.**

The following exhibit is filed herewith:

Exhibit 99.1 – Investor Presentation Material.

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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: April 12, 2016

THE FEMALE HEALTH COMPANY

BY /s/ Michele Greco

Michele Greco, Executive Vice President and  
Chief Financial Officer



**Proposed Merger of  
Aspen Park Pharmaceuticals  
and  
The Female Health Company**

*Transforming into A Leading Men's and Women's  
Health Care Company*

NASDAQ: FHCO

April 2016

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# The Proposed Merger of Aspen Park Pharmaceuticals (APP) and The Female Health Company (FHC)

- Merged company
  - New name will be selected to reflect new business
  - Reincorporate FHC as a Delaware corporation
  - Global headquarters, Miami, Florida
    - Women's Health Division Office, Chicago
      - FC2 compliance and international activities, London
      - FC2 manufacturing, Malaysia
  - Ownership will be approximately 45% APP stockholders and 55% FHC stockholder
    - Harry Fisch and Mitch Steiner, APP's two largest shareholders who collectively own about 85% of APP's stock, will be locked-up from selling 75% of the shares they receive in the merger for 18 months after closing
  - Definitive agreement signed April 5, 2016
  - Proxy, shareholder vote, closing expected third quarter of calendar 2016



# APP - FHC Merger Co.

## 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

1. MarketWatch 10/30/14 2. GlobalData 11/8/11 3. Transparency Market Research 10/21/13  
4. companiesandmarkets.com 6/30/11 5. www.alliedmarketresearch.com 6. GlobalData 4/29/2014 7. IMS 10/2/2014  
8. Visiongain 7/31/2015

## APP - FHC Merger Co. *Maximizes Both Short- and Long-Term Shareholder Value*

- Combined portfolio of products and expertise establishes the new company as a leader in men's and women's health care
  - Complementary diversification strategy with multiple shots on goal
  - Deep value, opportunistic, late stage development and near term products for large markets
  - Portfolio mostly less risky than other early-stage biopharmaceutical companies due to 505(b)(2) FDA pathway for a number of product candidates
  - Experienced, dedicated leadership
  - Women's Health Division: Expand existing, profitable business; begin development of newly acquired oncology pharmaceutical products for breast and ovarian cancer
  - Men's Health Division: Create a business unit focused on male health, especially in the areas of benign prostatic hyperplasia, male infertility, hot flashes in men on prostate cancer therapy, gout and advanced prostate cancer; augment with the commercialization of consumer health products for premature ejaculation and sexual health vitamin supplements
- 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 multi-product portfolio of promising potential products to provide near and future upside to shareholders

## Experienced Management Team for APP-FHC Merger Co. 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.
- Daniel Haines, CPA - Chief Financial Officer. E&Y, Equity One, Inc. (NYSE:EQY), OPKO Health (NYSE:OPK) and Lennar Corp (NYSE:LEN)
- Expected to join at closing:
  - Chief Medical Officer
  - VP Clinical Development
  - VP of Chemistry, Manufacturing, and Controls

# Board of Directors

## Clinical and Industry Experience

- **Elgar Peerschke, MBA** - Chairman. President of Quintiles; Senior partner Global Health Care Practice of Bain and Company
- **Mitchell Steiner, MD** - Vice Chairman and CEO and President of the Company. Cofounder, CEO, President of Aspen Park Pharmaceuticals; President urology OPKO Health (NYSE:OPK); Cofounder, CEO, and Vice Chairman of public company GTx, Inc. Board certified Urologist; and Professor and Chairman of Urology, University of Tennessee
- **Harry Fisch, MD** - Director and Chief Corporate Officer of the Company. Cofounder and Chairman of Aspen Park Pharmaceuticals; Clinical Professor of Urology and Reproductive Medicine Cornell; Director of the Male Reproductive Center at Columbia University Medical Center; Professor of Urology Columbia University; CEO and President of Millennium Sciences; Board certified urologist; and author
- **O.B. Parrish** - Director. Co-founder, Chairman and CEO of The Female Health Company; President of Phoenix Health Care of Illinois; Chairman of Abiant, Inc.; Director of Algasol Renewables; President of Global Pharmaceutical Group Searle; and, Executive Vice President of Pfizer International division

# Board of Directors

## Clinical and Industry Experience (continued)

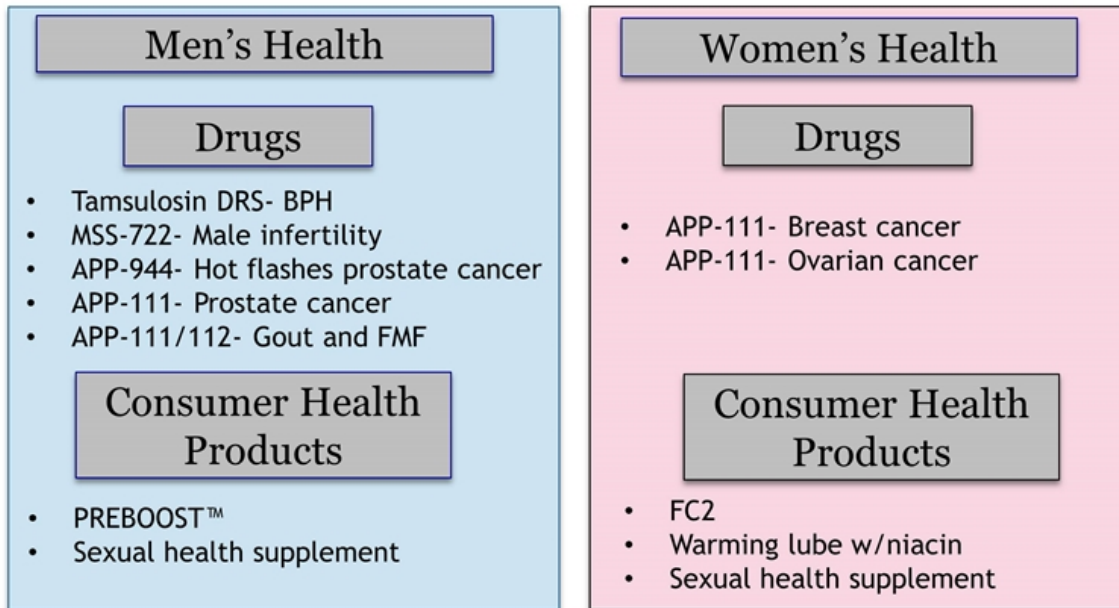
- **Georges Makhoul** - Director. CEO of Constellation Holdings; President Morgan Stanley Investment Banking Europe, Middle East, and North Africa; and led National Science Foundation Research Center at Columbia University
- **Mario Eisenberger, MD** - Director. Professor of Oncology Johns Hopkins University; head of Advanced Prostate Cancer Committee of Southwest Oncology Group; advisory boards Bristol Myers Squibb, Sanofi, Jansen, Ipsen, Medivation, Astellas, Ortho Biotech, Bayer and others; Ad Hoc member of the Oncologic Drugs Advisory Committee of FDA; and founded Oncology Insights, Inc. (clinical trials contract research organization)
- **Lucy Lu, MD, MBA** - Director. CEO of Avenue Therapeutics; Executive VP and CFO of Fortress Biotech; Senior biotechnology equity analyst Citigroup Investment Research; and Principal of First Albany Capital
- **Two additional board member from FHC to be determined later**

# APP-FHC Merger Co.

A Men's and Women's Health Care Company Focused on Pharmaceutical and Consumer Health Products

## APP - FHC Merger Co.

Separate men's and women's health divisions



# Men's Health Division

## Pharmaceuticals and Products Candidates in Development

- Benign prostate hyperplasia
  - Tamsulosin Delayed Release Sachet (DRS)
    - 505(b)(2) FDA pathway
    - Bioequivalence study planned Q4 2016 and file NDA 2017
    - U.S. patent on proprietary formulation applied for in 2015
- Male infertility
  - MSS-722, oral drug product candidate
    - 505(b)(2) FDA pathway & orphan drug eligible confirmed by FDA 5/28/15
    - Increases GnRH, LH & FSH and restores sperm production
    - Planned Phase 2 Q4 2016
    - 2 issued U.S. patents with expiration in 2021. Also seeking FDA orphan drug status exclusivity. Addition provisional application being enhanced.
- Hot flashes in men with prostate cancer on prostate cancer hormonal therapies
  - APP-944, oral drug product candidate
    - 505(b)(2) FDA pathway
    - PreIND meeting with FDA planned Q3 2016
    - PCT provisional application filed in 2015
- Anti-tubulin cytotoxic therapy prostate cancer
  - APP-111, oral tubulin targeting chemotherapy drug product candidate
    - New chemical entity
    - Preclinical toxicology study 2016
    - Phase 1a/1b planned 2017
    - Licensed IP includes 3 U.S. issued patents with expiration in 2029 with possible extension to 2034. Numerous foreign issuances and applications.
- Gout and Familial Mediterranean Fever (*MEFV* mutations)
  - APP-111/112, oral agent that binds tubulin with wide therapeutic index
    - New chemical entity
    - Preclinical toxicology 2016
    - Phase 1 planned 2017
    - Licensed IP includes 3 U.S. issued patents with expiration in 2029 with possible extension to 2034. Numerous foreign issuances and applications.

## Benign Prostate Hyperplasia, Well-Established Market Alpha Blockers Most Commonly Prescribed Drug Class

- Alpha blocker benign prostatic hyperplasia (BPH) therapeutics class generated \$4.1 billion in U.S. pharmacy sales<sup>1</sup> (in 2014)
  - 12% is associated with long-term care facilities<sup>1</sup>
- Tamsulosin (FLOMAX®) is currently the number one prescribed alpha blocker treating the Medicare (long-term care) population<sup>1</sup>
- Swallowing disorders (dysphagia) are a major problem (15% prevalence) for the elderly, especially those living in long-term care facilities<sup>2</sup>
  - Solution 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
- APP's Tamsulosin DRS is a novel oral formulation for men with BPH and swallowing difficulties.

<sup>1</sup> Source: IMS Health Data March 2015

<sup>2</sup> Source: Clinical Interventions in Aging 2013;8 221-227



# BPH Alpha Blocker Sales

Tamsulosin (FLOMAX<sup>®</sup>) Has ~85% Market Share

ATC4	MAT Mar 2015 TRx	MAT Mar 2015 TRx Market Share	MAT Mar 2015 TRx Pharmacy \$	MAT Mar 2015 TRx Pharmacy \$ Market Share	MAT Mar 2015 EUTRx	\$/Unit
G04C2 BPH A-ADRENERG ANTAG PLN	29,233,610	100.00%	\$4,142,576,343	100.00%	1,478,295,890	2.80
TAMSULOSIN	23,317,951	79.76%	\$3,475,988,912	84.84%	1,150,429,482	3.02
COMBINED RETAIL	18,399,025	78.90%	\$2,606,030,239	88.56%	883,435,533	2.95
LONG-TERM CARE	3,131,953	13.43%	\$336,594,324	11.44%	86,185,219	3.91
MAIL SERVICE	1,759,171	7.54%	\$ 527,632,160	0.00%	178,865,537	2.95
SPECIALTY MAIL SERVICE	27,802	0.12%	\$ 5,732,189	0.00%	1,943,193	2.95
TERAZOSIN	3,747,430	12.82%	\$224,324,678	5.45%	225,105,689	1.00
COMBINED RETAIL	3,014,920	80.45%	\$173,334,504	91.73%	178,021,751	0.97
LONG-TERM CARE	377,636	10.08%	\$15,621,210	8.27%	10,758,540	1.45
MAIL SERVICE	348,340	9.30%	\$ 34,867,700	0.00%	35,810,579	0.97
SPECIALTY MAIL SERVICE	6,534	0.17%	\$ 501,264	0.00%	514,819	0.97
SILODOSIN	960,001	3.28%	\$243,925,303	5.53%	41,088,243	5.94
COMBINED RETAIL	797,089	83.03%	\$183,758,517	95.87%	30,994,595	5.93
LONG-TERM CARE	63,001	6.56%	\$7,921,218	4.13%	1,281,375	6.18
MAIL SERVICE	99,645	10.38%	\$ 52,160,242	0.00%	8,797,881	5.93
SPECIALTY MAIL SERVICE	266	0.03%	\$ 85,326	0.00%	14,392	5.93
ALFUZOSIN	1,208,228	4.13%	\$198,337,450	4.18%	61,672,476	3.22
COMBINED RETAIL	974,681	80.67%	\$140,176,755	96.58%	43,813,168	3.20
LONG-TERM CARE	48,917	4.05%	\$4,960,066	3.42%	1,231,101	4.03
MAIL SERVICE	182,833	15.13%	\$ 52,741,746	0.00%	16,484,780	3.20
SPECIALTY MAIL SERVICE	1,797	0.15%	\$ 458,883	0.00%	143,427	3.20

Source: IMS Health Data March 2015

# Tamsulosin DRS

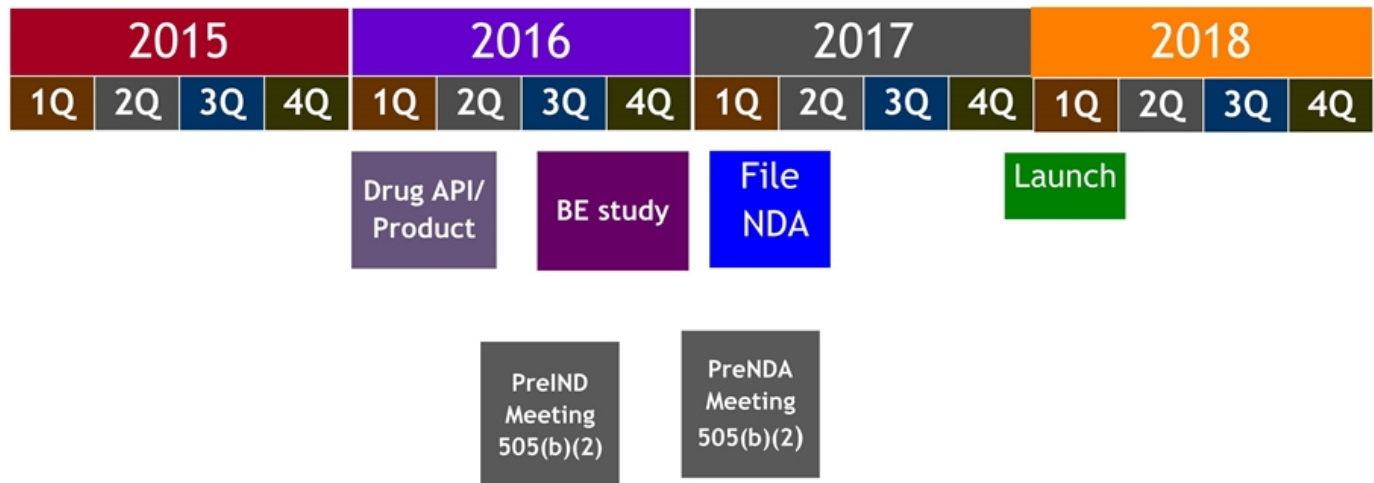
## No Sales Force Needed

- Initiate a focused contracting strategy (rebate/performance based) with specialty GPOs to provide immediate access to long term care population
  - 12% of market in long term care facilities
  - 2 Labs, Inc. has expertise in contracting with all third party logistics and providers
  - Tamsulosin DRS can be differentiated in pharmaceutical compendium
- Priced at 70% of branded tamsulosin (FLOMAX®) tablet, tamsulosin DRS could capture ~5% of the total alpha blocker BPH market in US:
  - Tamsulosin DRS ~\$300 million annually
  - Grow revenue by pharmacy switch and by expanding reach into geriatric PCPs & urologists
  - 15% of elderly patients who are not in long-term care suffer from dysphagia and could provide upside<sup>1</sup>
- Build awareness of a new formulation of gold standard product among geriatric and urology health care providers

# Tamsulosin DRS

## Anticipated Clinical Development Plan 505(b)(2)

Indication: BPH



# Male Infertility

## 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 (LH-like activity) and FSH injections are only FDA approved therapies<sup>4,5</sup>
- Clomiphene (racemic mixture) 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 schedule are not known
- No FDA approved oral therapies<sup>5</sup>
- APP's MSS-722 is being developed as the first oral agent for the treatment of idiopathic male infertility

1.Roth LW et al. Semin Reprod Med 31:245-250 2013; 2.Chehab M et al Fertil Steril 103:595-604 2015; 3.Whitten SJ et al Fertil Steril 86:1664-1668 2006; 4. Nachtigall LB et al. N Engl J Med 336:410-415 1997. 5. <https://rarediseases.info.nih.gov/gard/diseases-with-medical-products/H> 6.Ko EY et al J Urol 187:973-978 2012

# MSS-722

## Male Infertility Efficacy Data from Literature

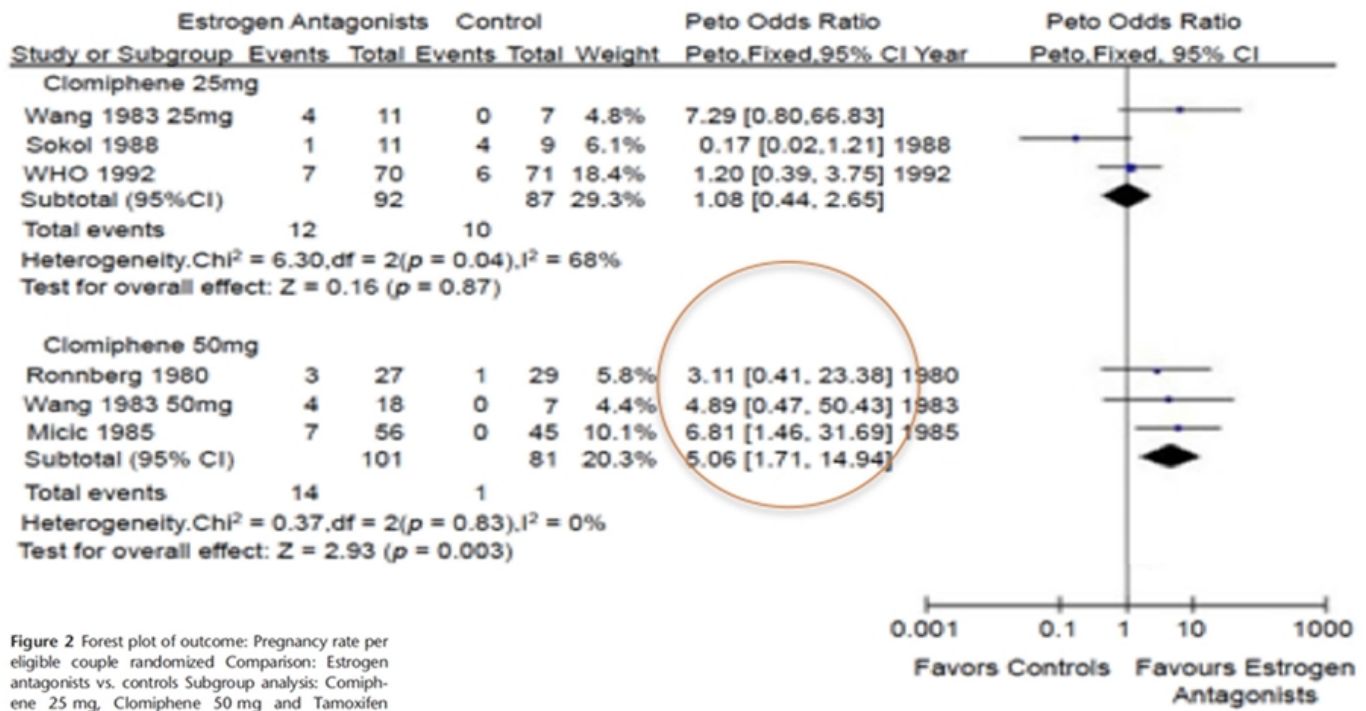


Figure 2 Forest plot of outcome: Pregnancy rate per eligible couple randomized Comparison: Estrogen antagonists vs. controls Subgroup analysis: Clomiphene 25 mg, Clomiphene 50 mg and Tamoxifen 20-30 mg.

# MSS-722

## Clomiphene Safety in Men & Women

- 39 published studies in men taking clomiphene
  - 2220 men, duration from 8 weeks to 3 years, and doses from 25mg-200mg/day
  - Reported adverse events included visual symptoms (blurring, spots, and flashes), gynecomastia, nipple tenderness, hot flashes, increased facial hair, increased facial acne, increased testicular volume, increased body weight, melena, dizziness, and headache"

**Table 11 Incidence of Adverse Events in Clinical Studies for the LD Clomid (Events Greater than 1%)**

<b>Adverse Event</b>	<b>% (N=8029<sup>a</sup>)</b>
Ovarian Enlargement	13.6
Vasomotor Flushes	10.4
Abdominal-Pelvic Discomfort/Distention/Bloating	5.5
Nausea and Vomiting	2.2
Breast Discomfort	2.1
Visual Symptoms – blurred vision, lights, floaters, waves, unspecified visual complaints, photophobia, diplopia, scotomata, phosphenes	1.5
Headache	1.3
Abnormal Uterine Bleeding – intermenstrual spotting, menorrhagia	1.3

## MSS-722

### Treatment of Male Infertility- FDA Meeting May 28<sup>th</sup> 2015

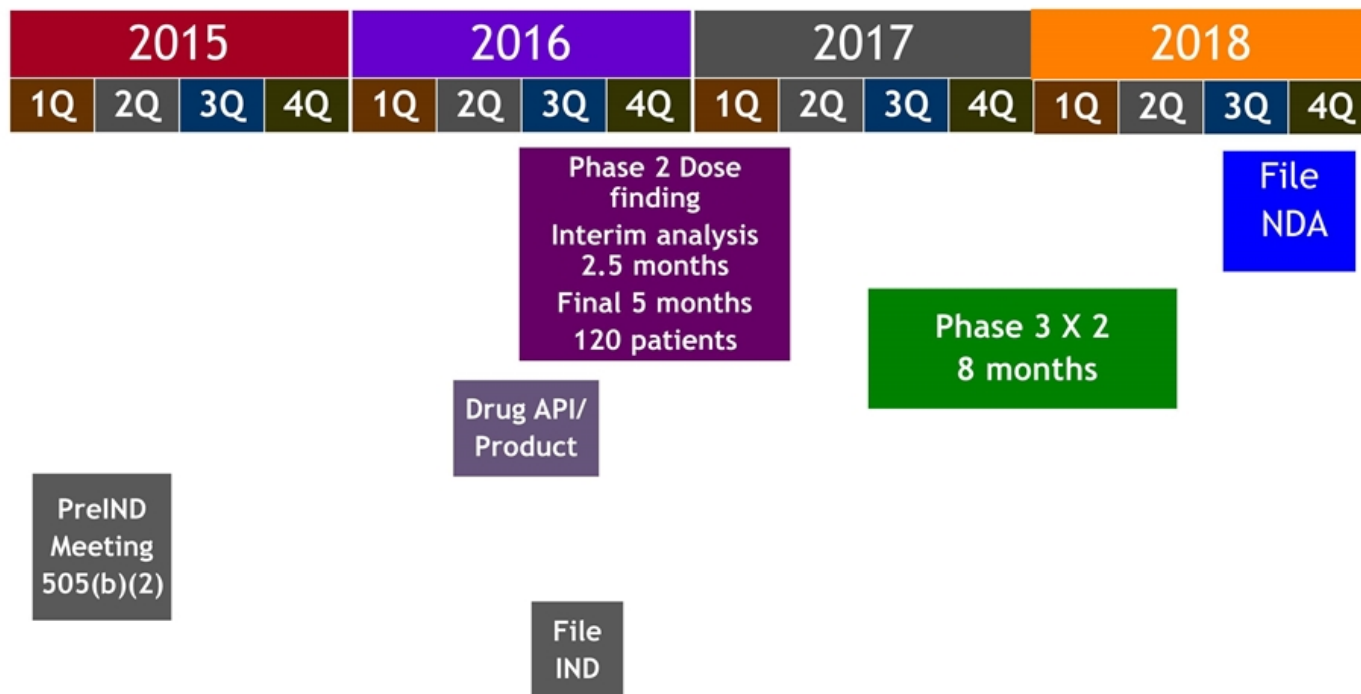
- FDA confirmed that MSS-722 qualifies for 505(b)(2) pathway
  - Utilize a fixed proprietary ratio of cis and trans isomers
- Indication of idiopathic male infertility with hypogonadotropic hypogonadism not due to primary testicular failure would be acceptable\*
  - Population - men with hypogonadotropic hypogonadism (low testosterone levels) and infertility (low sperm counts)
  - Acute therapy (5 months = 2 cycles)
    - No carcinogenicity studies or additional animal studies would be required in this setting
  - Primary endpoint that would represent clinical benefit may be the proportion of men who become fertile (improvement in sperm count into fertile range)
- Orphan drug request sent to FDA January 7<sup>th</sup> 2016

\* Rare Diseases with FDA approved products- <https://rarediseases.info.nih.gov/gard/diseases-with-medical-products/H>

# MSS-722

## Clinical Development Plan 505(b)(2)

Indication: Infertility in Men with Hypogonadism





## APP-944

### Oral Drug Product for the Treatment of 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 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
- 505(b)(2) pathway
- Market
  - 700,000 men on androgen deprivation therapy in the US
  - 30% penetration = 255,000 men translates to \$700 million/year

## APP-111

### Oral Novel Tubulin Targeting Chemotherapy for Advanced Prostate Cancer

- \$5 billion market for secondary hormone therapies for prostate cancer<sup>1</sup> and \$4.8B market for taxanes & vinca alkaloids (Docetaxel \$1B & cabazitaxel \$500 million in prostate cancer)<sup>2</sup>
- Emerging Indications:
  - Secondary hormone therapies like enzalutamide and abiraterone/prednisone have almost complete cross resistance and should not be used in sequence in advanced prostate cancer<sup>3</sup>
  - 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 have been **the only effective** cytotoxic chemotherapy in advanced prostate cancer, but there are challenges<sup>5</sup>:
  - Drug resistance is common - multidrug resistance proteins, tubulin mutations and overexpression
  - Safety concerns - hypersensitivity reactions, myelosuppression, and neurotoxicity (peripheral neuropathy & muscle weakness)
  - Route of administration-only available as IV dosing

1. MarketWatch 10/30/14; 2. Dimopoulos G Seeking Alpha 11/14/12; 3. Omlin A et al Therapeutic Advances in Urology 6:3-14 2014; 4. Sweeney C et al J Clin Oncol 32:5s 2014; 5. Diamond E et al Curr Treat Options Oncol 16:9 2015

# APP-111

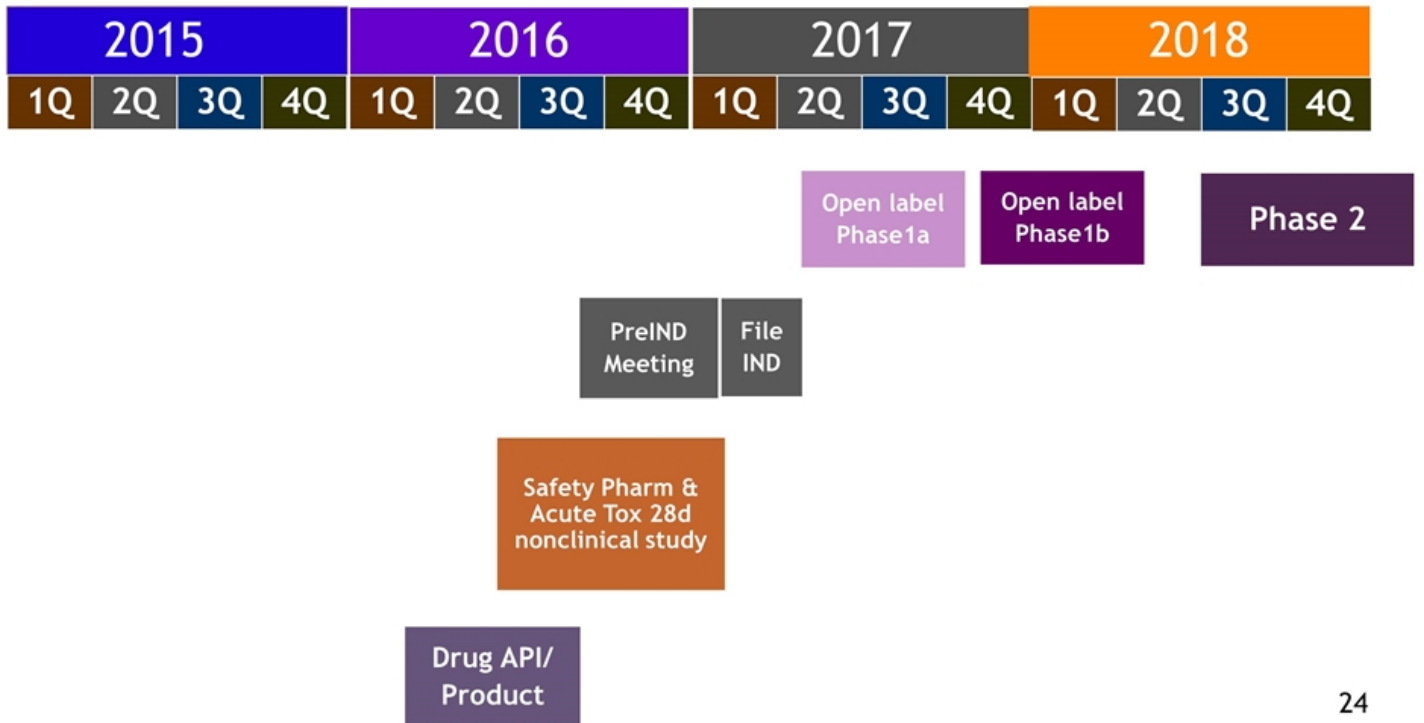
## Oral Novel Tubulin Targeting Chemotherapy

- 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 many cancer types including prostate cancer *in vitro* and *in vivo*
  - Favorable safety profile (less neurotoxicity & leukopenia)
- Over 28 peer-reviewed publications

# APP-111

## Anticipated Clinical Development Plan

Indication: Enzalutamide Resistant Prostate Cancer



## APP-111- Potential Platform Technology

### IV Anti-tubulins Have Demonstrated Activity Against a Broad Group of Tumor Types

- 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®)

## Gout is the Most Common Form of Inflammatory Arthritis in Men Over 40 Years of Age

- Gout is a type of arthritis characterized by sudden, severe attacks of joint pain because of the deposition of uric acid crystals in the joints
- Gout is 10x more common in men than women
- In the US, 8.3 million people with gout and the incidence is increasing
- Global market for gout drugs exceeds \$1.5 billion

## Current Gout Therapy Effective, But ...

- Colchicine is effective to treat and to prevent acute attacks, but has side effects such as abdominal cramping, nausea, and diarrhea
  - Low therapeutic index (low safety margin)
  - Drug-drug interactions are common
- APP-111/112 is an oral, novel small molecule that binds to same drug target site as colchicine, but potentially better safety profile
  - No drug-drug interactions, with potentially wide therapeutic index (wider safety margin)

## Men's Health Division

### Consumer Health Products

- Reducing the incidence of premature ejaculation
  - PREBOOST® OTC product
    - Desensitizing individual wipes FDA approved (compliant with FDA OTC monograph)
    - Phase 4 to be completed in 2016
    - Market launch Q3 2016
- Sexual health vitamin supplement
  - Special formulation to promote male sexual health



# PREBOOST™

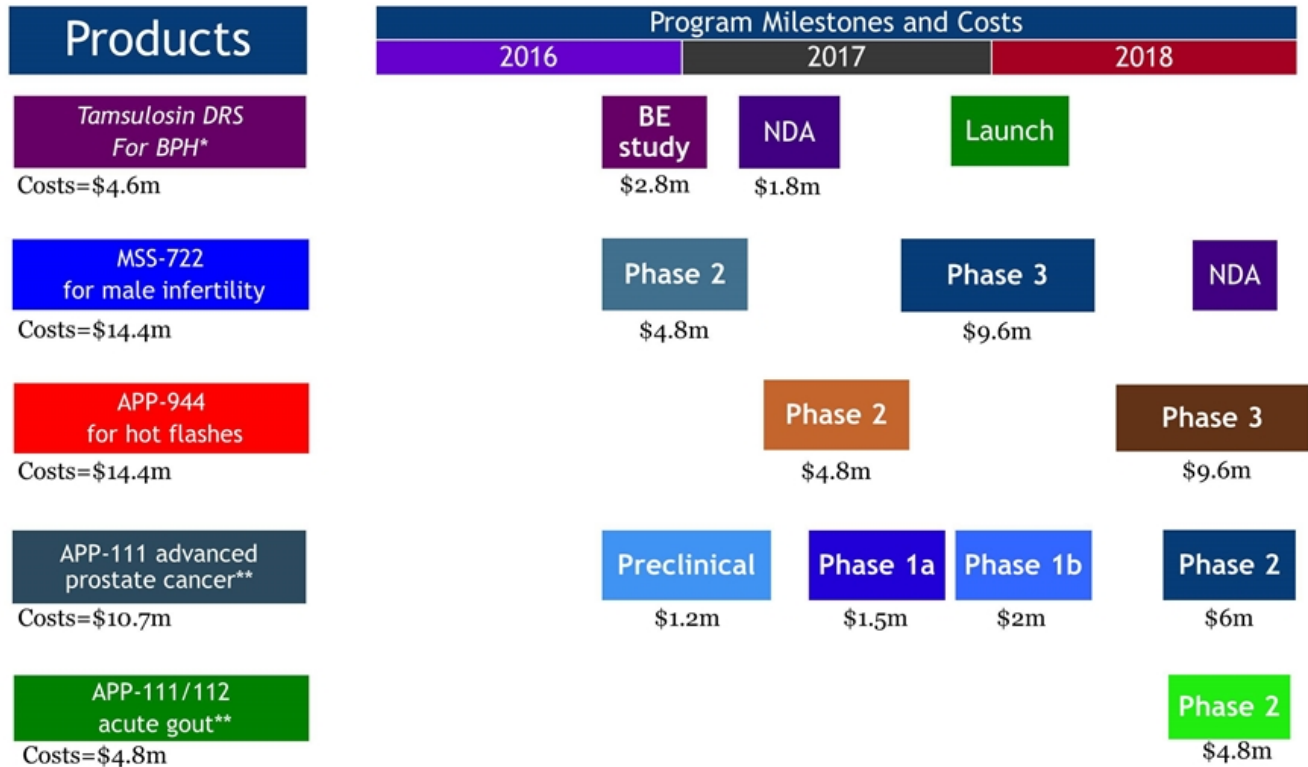
## Reducing the Incidence of Premature Ejaculation

- Compliant with FDA OTC monograph
- Only individual medicated wipes containing benzocaine that temporarily desensitizes penis after topical application
- Helps in temporarily prolonging time to ejaculation
- Each box contains 10 individually packaged medicated wipes priced at \$29.99 per box
- Planned launch of product Q3 2016



# Men's Health Division

Projected R&D costs for the first 3 years if all programs are advanced at once.  
Plan is to prioritize and stagger programs to match resources.



\*Subject to installment payments upon certain milestones.  
\*\*Subject to a 3% running royalty rate.

# Female Health Company

## \$33 Million of Revenue in Fiscal Year 2015

- Growing single consumer health product- FC2 Female Condom
  - Sold in US and 144 countries
  - Over 500 million units sold to date, 62 million units sold in 2015
  - Manufacturing capacity at 100 million units, can add another 100 million units in capacity
  - Almost all public sector customers, expanding into private sector (UNFPA, USAID, Semina, Sekunjalo)



- ~\$22 million (cash/AR) and \$10 million unused credit facility (lender consent required to proposed merger transaction)
- No debt and profitable since 2006
- \$62 million non-expiring NOL's in UK and \$13 million Federal and \$13 million State NOLs in USA

# Women's Health Division

Pharmaceutical Products Candidates and Consumer Health Products  
*Continue the Passion and Dedication to Grow Division*

- Anti-tubulin cytotoxic therapy
  - APP-111, oral tubulin targeting chemotherapy drug product candidate
    - New chemical entity
    - Preclinical toxicology study 2016
    - Phase 1a/1b planned 2018
  - Indications:
    - Breast cancer
    - Ovarian cancer
- FC2 Female Condom
  - Only FDA approved female condom
  - Commercialization in private and public sectors
- Niacin enhanced warming gel
  - File with FDA

# FC2 Female Condom: Demand Should Continue to Grow Globally

- Continued Global Focus on HIV
  - AIDS - leading cause of death women age 15-44
  - 35 million persons living with AIDS, 2.3 million newly infected in 2012
- Increasing incidence of STIs around the world
  - 20 million new cases every year in the US alone, half occurring in young people aged 15-24
- Zika virus - global health emergency for pregnant and non-pregnant women
  - Associated with severe birth defects like microcephaly & neurologic disease like Guillain-Barré syndrome



CDC website 2016

## Through sexual contact

- Zika virus can be spread by a man to his sex partners.
- In known cases of sexual transmission, the men developed Zika virus symptoms. From these cases, we know the virus can be spread when the man has symptoms, before symptoms start and after symptoms resolve.
- In one case, the virus was spread a few days before symptoms developed.
- The virus is present in semen longer than in blood.

## FC2 Female Condom: Demand Should Continue to Grow in United States

- Medical approach
  - Non-hormonal birth control alternative
    - Many US women report dissatisfaction with the side effects of hormonal birth control- diaphragm has been discontinued
  - Reimbursed with prescription by Affordable Care Act (ObamaCare) and private insurers
- Need a FC2 awareness campaign-physicians and pharmacists
  - Provide option for the growing concerns about Zika virus
  - TV/media, thought and social leaders
  - Tapping into direct-to-consumer (DTC) market, social media and online sales

# Anticipated Milestones

Flow of Clinical & Regulatory News Creates Opportunities to Influence Shareholder Value

Product	2016	2017	2018
PREBOOST	<ul style="list-style-type: none"> <li>• Launch</li> </ul>		
FC2	<ul style="list-style-type: none"> <li>• Expand into US and European private markets</li> </ul>		
MSS-722	<ul style="list-style-type: none"> <li>• Initiate Phase 2 fertility data</li> <li>• Get orphan drug status</li> </ul>	<ul style="list-style-type: none"> <li>• Phase 2 fertility data</li> <li>• Initiate Phase 3's studies</li> </ul>	<ul style="list-style-type: none"> <li>• Phase 3s fertility data</li> <li>• File NDA</li> </ul>
APP-944	<ul style="list-style-type: none"> <li>• Complete preIND meet</li> </ul>	<ul style="list-style-type: none"> <li>• Initiate Phase 2</li> </ul>	<ul style="list-style-type: none"> <li>• Phase 2 data</li> <li>• Initiate Phase 3's</li> </ul>
Tamsulosin DRS	<ul style="list-style-type: none"> <li>• Complete BE Study</li> </ul>	<ul style="list-style-type: none"> <li>• File NDA</li> </ul>	<ul style="list-style-type: none"> <li>• Launch</li> </ul>
APP-111	<ul style="list-style-type: none"> <li>• Complete preclinical studies -prostate</li> </ul>	<ul style="list-style-type: none"> <li>• Initiate Phase 1a - prostate</li> <li>• Complete Phase 1a - prostate</li> <li>• Initiate Phase 1b - prostate</li> </ul>	<ul style="list-style-type: none"> <li>• Complete Phase 1b - prostate</li> <li>• Initiate Phase 2 - prostate</li> <li>• Initiate Phase 1 - Breast and Ovarian cancers</li> </ul>

# Men's Health Division

## Men's Health Product Portfolio

Product	Indication	Key Differentiation	Expected NDA filing	Current US Market Size
PREBOOST	Premature Ejaculation	OTC convenient individual medicated wipes	FDA preapproved OTC	\$500 million
Tamsulosin DRS	Benign Prostatic Hyperplasia	Delayed release sachet (DRS); a new oral powder formulation for elderly with swallowing disorders	2017	\$4.5 billion
MSS-722	Idiopathic male infertility  Orphan drug	Only oral agent Restores fertility by increasing GnRH, LH & FSH secretion to increase sperm production	2018	\$700 million
APP-944	Hot flashes in men on prostate cancer hormone therapies	Potentially the first approved oral drug for this indication	2019	\$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	2021	\$5 billion
APP-111/112	Gout and Familial Mediterranean Fever	Oral dosage; binds to same target as colchicine with potentially better safety profile	2020	\$725 million



# Women's Health Division

## Women's Health Product Portfolio

Product	Indication	Key Differentiation	Expected NDA filing	Current US Market Size
FC2	Prevention of sexually transmitted HIV and pregnancy	Only FDA approved female condom	FDA approved	US female condom market in early stages. US male condom market \$400- \$500M*
APP-111	3 <sup>rd</sup> line hormonal therapy advanced breast cancer	Oral dosage; novel first-in-class anti-tubulin targeting chemotherapy	2022	\$3 billion
APP-111	3 <sup>rd</sup> line hormonal therapy advanced ovarian	Oral dosage; novel first-in-class anti-tubulin targeting chemotherapy	2022	\$1 billion

\* Per Nielsen and Global Industry Analysts, Inc.

## Selected Unaudited Combined Financial Highlights

	As of and for the Year Ended September 30, 2015 (in millions)	As of and for the Three Months Ended December 31, 2015 (in millions)
Net Revenues	\$32.6	\$8.2
Operating Income	5.4	2.1
Net Income	\$3.1	\$1.3
Cash & Accounts Receivable	\$18.8	\$21.8

Note: FHC also has a \$10 million unused credit facility (lender consent required to proposed merger transaction)

We believe we will have the resources to fund our product development over the next 18-24 months based on cash balances and the assumed collection of accounts receivable balances.

## Why Vote For the Merger ?

- Seasoned management team with over 30 years average experience in the medical industry
- FHC brings a financially strong company with a successful track record, while APP brings a multi-product portfolio with significant upside potential
- Combined company will have successful existing products, together with an additional new product portfolio that offers investors upside potential for the near and long-terms
- 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

**ASPEN | PARK**  
PHARMACEUTICALS



**THANK YOU**

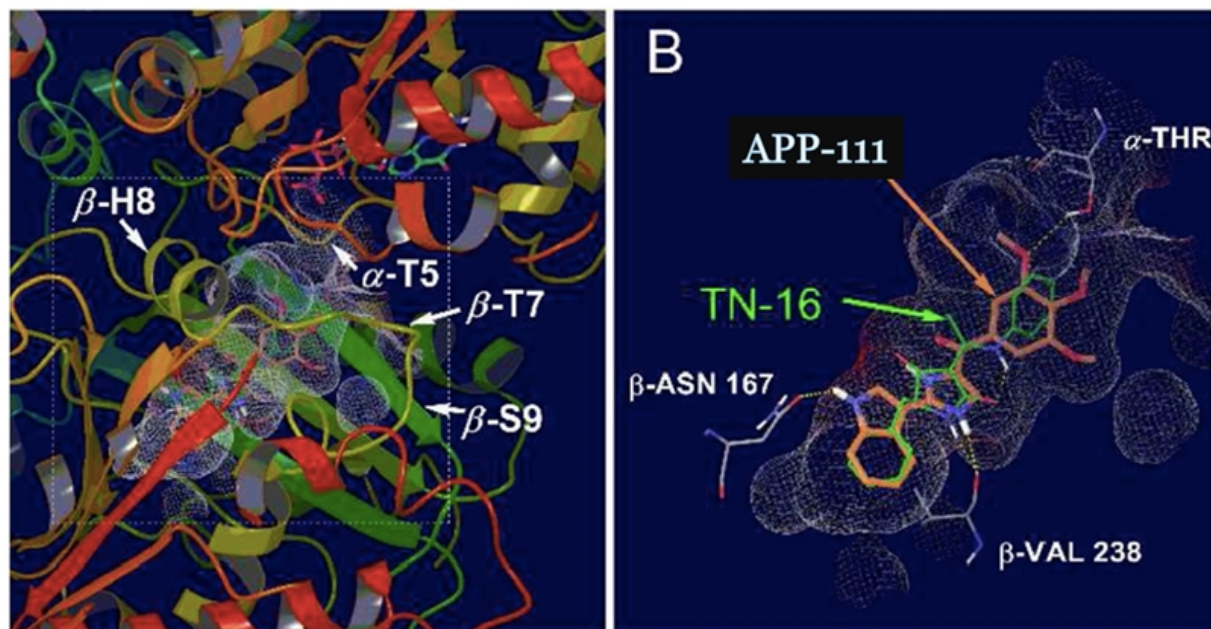
**ASPEN | PARK**  
PHARMACEUTICALS



# APPENDIX

# APP-111

Potential to be First-in-class Oral Anti-tubulin Drug to Target the Colchicine Binding Site



This binding pocket is located on the interface between  $\alpha$  and  $\beta$ -subunit of tubulin dimer and extended inside to the nucleoside-binding domain the  $\beta$ -subunit

Chen J et al J. Med Chem 55:7285-7289, 2012