



veru

HEALTHCARE

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

Veru Healthcare
NASDAQ: FHCO

June 2, 2017

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, 2016 and Report on Form 10-Q for the quarter ended March 31, 2017. This document is available on the "SEC Filings" section of our website at 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.

About us



- **Started as The Female Health Company (NASDAQ CM: FHCO)**
 - **Incorporated in 1971, focus on manufacturing and marketing of only 1 product: the female condom**
 - Received FDA approval for FC1 female condom in 1993 and for FC2 female condom in 2009 as a class 3 medical device. WHO cleared FC2 in 2006.
 - Sold over 550 million units, distributed to over 144 countries primarily to public sector
 - Profitable operating company for past 10 years
- **DBA Veru Healthcare (NASDAQ CM: FHCO)**
 - **Diversified** - Merger combined Female Health Company revenue-producing product with Aspen Park Pharma's men's health and oncology products – combined now d.b.a. Veru Healthcare
 - **Enterprise Value** - Pharmaceutical products that address significant markets
 - **Strategy** - Grow current commercial consumer health products and use available resources to fund a portfolio of men's health low cost, near term, and large market 505(b)(2) products as well as a novel NCE for oncology

EXPERIENCED MANAGEMENT TEAM

Mitchell Steiner, MD – CEO/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, JD, CPA – SVP Corp. Development & Legal

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

Robert Getzenberg, PhD – EVP Clinical Development

Therapeutic Area Lead, Prostate Cancer, GTx, Inc. 18 years as a faculty of the Johns Hopkins University School of Medicine and the University of Pittsburgh School of Medicine leading urological and oncology research.

Daniel Haines, CPA – Chief Financial Officer

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

Brian Groch – Chief Commercial Officer

Merck, Novartis, Phadia, Dendreon, Horizon Therapeutics, and Telesta Therapeutics. Extensive experience in pharmaceutical launches, market access, and marketing and sales.

Denise Van Dijk - President of The Female Health Co

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

Matthew Gosnell, PhD – SVP of Manufacturing

Preclinical and Pharmaceutical Development. GTx, Inc., Alkermes, Pharmacia, Johnson and Johnson, and Miles/Bayer.

Martin Tayler– EVP of Global Operations

Project and Operations Director at Reckitt Benckiser, Operations Director at SSL International, operating at various sites/countries for medicated products and medical device manufacture including Scholl and Durex Brands

PHARMACEUTICAL PIPELINE

Veru Healthcare

Product	Indication	Target	Preclinical	Phase 1	Phase 2	Phase 3	Filing	Marketed	
FC2 female condom (Class 3 medical device)	Barrier contraception	Protection STD and pregnancy	[Progress bar spanning Preclinical, Phase 1, Phase 2, Phase 3, Filing, and Marketed]						
PREBOOST (4% benzocaine)	Premature ejaculation	Desensitizer	[Progress bar spanning Preclinical, Phase 1, Phase 2, Phase 3, Filing, and Marketed]						
Tamsulosin DRS (Tamsulosin HCl for XR oral suspension)	BPH	Super Selective α_1 -receptor blocker	[Progress bar spanning Preclinical, Phase 1, Phase 2, and Phase 3]					BE study only 505(b)(2)	
MSS-722 (Fixed ratio isomer clomiphene)	Male infertility	Mixed Estrogen agonist/antagonist	[Progress bar spanning Preclinical, Phase 1, and Phase 2]				505(b)(2)		
APP-944 (Zuclomiphene)	Hot flashes from prostate cancer Tx	Nonsteroidal Estrogen agonist	[Progress bar spanning Preclinical, Phase 1, and Phase 2]				505(b)(2)		
APP-111	3 rd line oral chemo agent prostate cancer	Selective $\alpha\beta$ tubulin inhibitor	[Progress bar spanning Preclinical and Phase 1]						
APP-112	Gout	Colchicine mimic with no drug interactions	[Progress bar spanning Preclinical]						



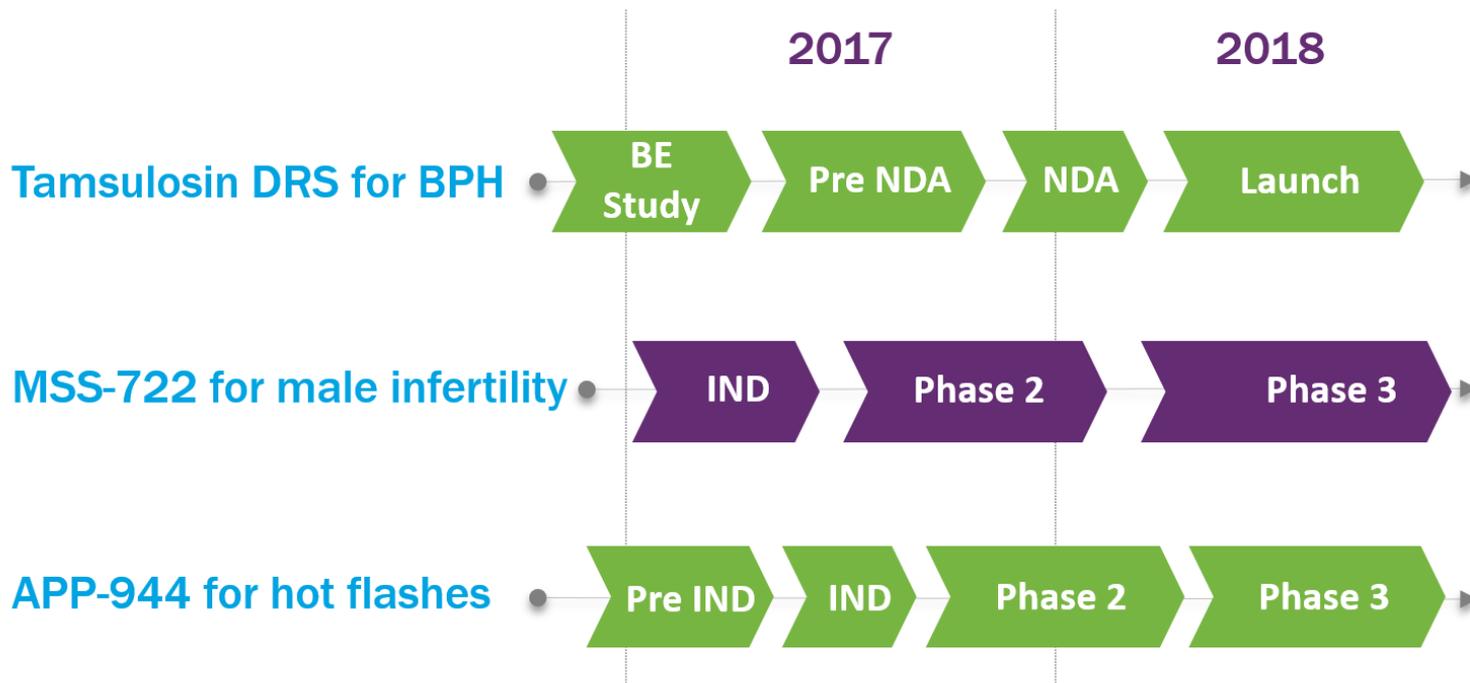
Men's Health

505(b)(2) products

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

505(b)(2) PRESCRIPTION MEN'S HEALTH PRODUCTS

Lower risk, shorter time, and less cost to access large markets



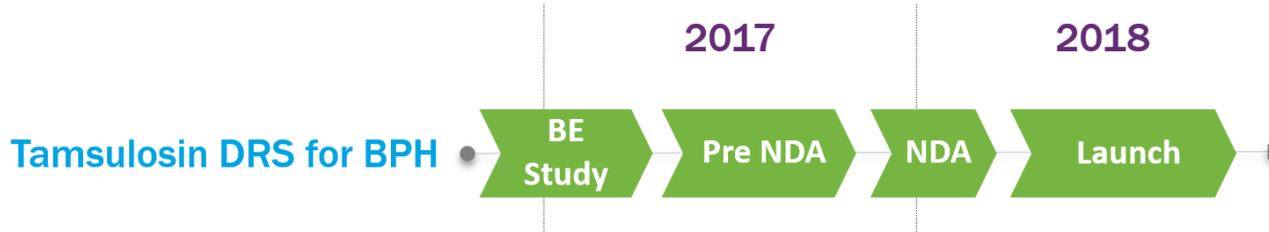
Alpha blockers most commonly prescribed drug class

- **FLOMAX® (tamsulosin HCl) is currently the number one prescribed alpha blocker treating the Medicare long-term care population¹**
- **Difficulty swallowing (dysphagia) is a major problem with a 15% prevalence for the elderly, and 60% for those men living in long-term care facilities²**
 - 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
- **FLOMAX absorption is affected by food resulting in 40-70% higher peak drug levels in the fasted versus the fed conditions. To avoid these higher drug levels, the FDA label states for safety reasons that FLOMAX should be taken 30 minutes after a meal and the capsule should not be crushed, chewed, or opened.**
- **Tamsulosin DRS (tamsulosin HCl for extended-release (XR) oral suspension) is a novel oral slow release granular formulation for men with BPH and swallowing difficulties that does not have to be administered after a meal.**

TAMSULOSIN DRS for BENIGN PROSTATIC HYPERPLASIA (BPH)

Anticipated clinical development plan 505(b)(2)

Indication: BPH

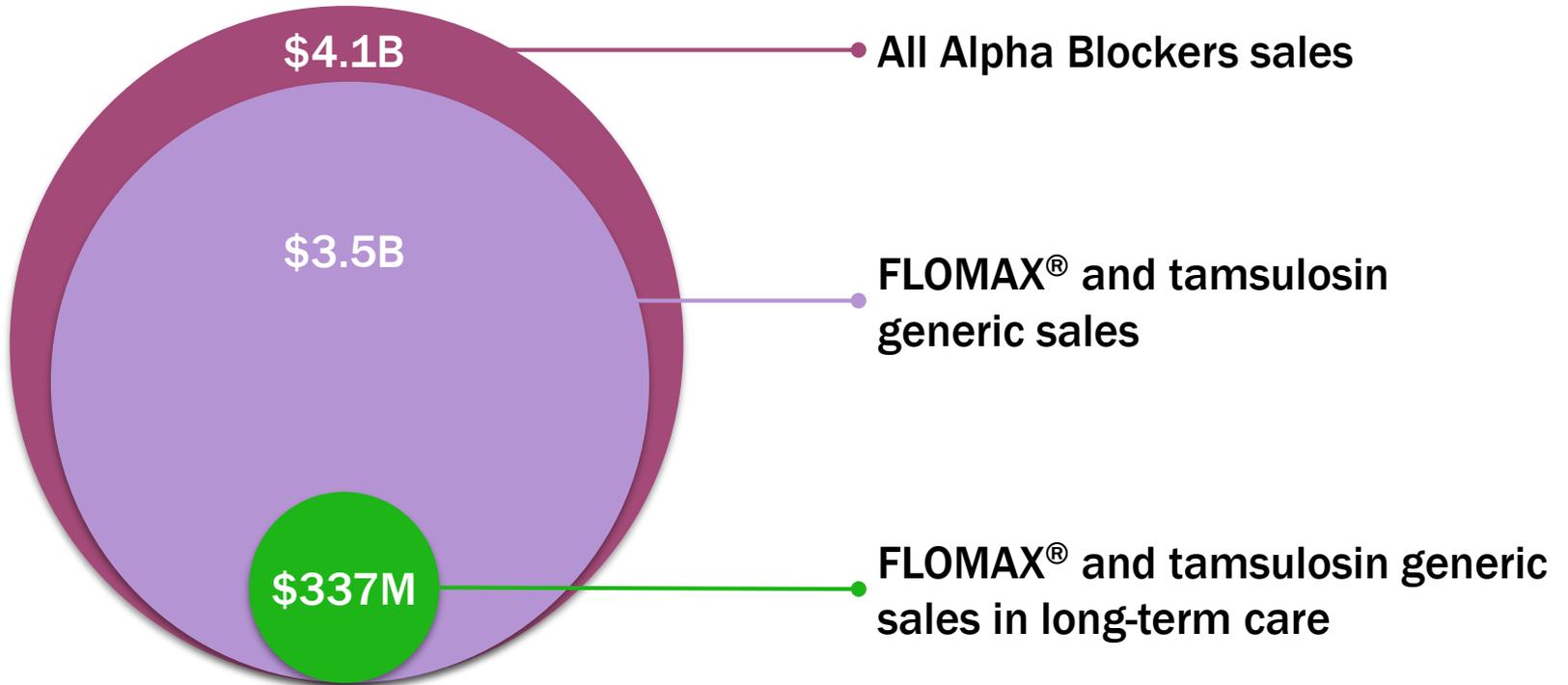


- **Bioequivalence (BE) Study Design**

- **Stage 1 (completed) – 12 patients, single dose FLOMAX fed versus Tamsulosin DRS fed and fasted results reported successful Stage 1 study :**
 - Tamsulosin DRS formulation given during fasted conditions matched FLOMAX given after a meal- potential safety and compliance benefits
- **Stage 2 – 36 patients, 21 day study, single doses of selected Tamsulosin DRS formulation vs. FLOMAX[®] fed and fasted expected data July 2017**
- **PreNDA and EMA meetings targeted for September 2017**

TAMSULOSIN DRS for BENIGN PROSTATIC HYPERPLASIA (BPH)

FLOMAX[®] and generic tamsulosin have ~80% US market share



TAMSULOSIN DRS for BENIGN PROSTATIC HYPERPLASIA (BPH)

Opportunity to introduce new branded BPH product

- Our product is **NOT** a generic and pricing strategy will be more comparable to FLOMAX® (AWP=\$828.06/100 tablets WAC=\$731.45/100 tablets as of 3/8/2016 Kinray Cardinal Health)
- **Advantages of new formulation over FLOMAX**
 - May be given under fasting conditions which provides safety and compliance benefits
 - Consider formulating a capsule version of Tamsulosin DRS and market directly against with FLOMAX and tamsulosin generics capsules
- **Initial focus will be on men in long term care facilities with Tamsulosin DRS**
 - 13% of FLOMAX® and tamsulosin current generic market is in long term care facilities
 - 3 specialty GPOs manage 90% of long term care facilities with early contracting which could provide immediate market access for the majority of long term care
- **Potential US and ROW partnering opportunities**
- **Patent pending , expiry 2036; Licensed from Arina Therapeutics**

MSS-722 FOR MALE INFERTILITY

A growing and underserved market

- **Infertility affects 6.1 million couples in US, which is 15% of all couples trying to conceive¹**
 - 50% of infertility is attributed to males who present with abnormal semen analysis^{1,2}
 - 2% of infertile men have adult onset form of hypogonadotropic hypogonadism (abnormal hypothalamic-pituitary-gonadal axis) ¹⁻⁴
- **hCG injection and FSH injections are expensive and only FDA approved therapies^{4,5}**
- **CLOMID (Clomiphene) is an inconsistent cis:trans racemic mixture which is used as first line empirical therapy in 90% of idiopathic infertile men⁶**
 - Off-label use
 - Most effective and safe dose as well as dosing schedule are not known
- **No FDA approved oral therapies⁵**
- **MSS-722 is being developed as a 505(b)(2) as the first oral agent for the treatment of male infertility so couples may avoid expensive *In vitro* fertilization (IVF) procedures**
- **Dose patent pending, expiry 2036**

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

MSS-722 FOR MALE INFERTILITY CLINICAL DEVELOPMENT 505(b)(2)

Indication: men with low sperm count and low testosterone as a cause of their male infertility



• Clinical Trial Design

- Patient population: Men who have testicular dysfunction which oligozoospermia (impaired spermatogenesis) and hypogonadotropic hypogonadism as a cause for male factor infertility
- Short term study: 5 months of treatment in 105 men
- Efficacy endpoint may be semen analysis that qualifies for IUI and avoids IVF
- File IND and start Phase 2 in 2017

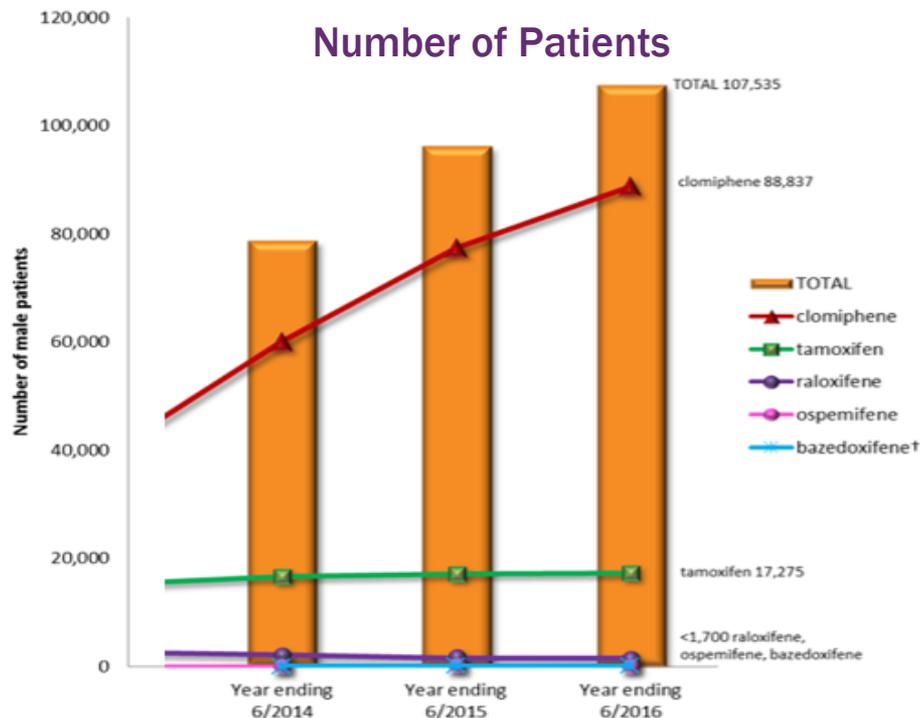
MSS-722 FOR MALE INFERTILITY

Off label market in men has been growing significantly year over year

Number of Prescriptions

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

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



Source: IMS Health, Total Patient Tracker™. July 2011-June 2016. Extracted August 2016 from FDA Briefing Document. Source File: TPT estrogen antagonists 2016-1232 8.5.2016.xlsx.

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
 - Currently, no FDA approved therapies to treat hot flashes in men on prostate cancer hormonal therapies
- **PreIND meeting with FDA May 18, 2017- FDA expressed enthusiasm for indication**
 - 505(b)(2) pathway for chronic dosing
 - Zuclophene (cis-isomer of clomiphene; this single isomer never approved before)
 - Once a week oral dosing
 - May file IND Phase 2 dose finding hot flash study in men on ADT
 - 12 weeks efficacy endpoint
 - Efficacy endpoint- will allow FDA Guidance for estrogen products to treat vasomotor symptoms 2003

Market: Hot flashes in men on prostate cancer hormonal therapy

- **Oral agent to treat hot flashes in men who have advanced prostate on hormonal therapy**
 - LHRH agonists and antagonists (androgen deprivation therapy)
 - Abiraterone
 - Enzalutamide
- **Added benefits: treatment of estrogen deficiency side effects**
 - Treatment of hormone therapy induced bone loss
- **Potential direct anticancer effects**
- **Market potential**
 - 700,000 men on androgen deprivation therapy in the US
 - 30% penetration = 255,000 men translates to \$600 million/year
- **Intellectual property**
 - Patent pending, expiry 2035



Oncology

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

ONCOLOGY PRODUCTS

Large premium market opportunities to increase enterprise value

New chemical entity



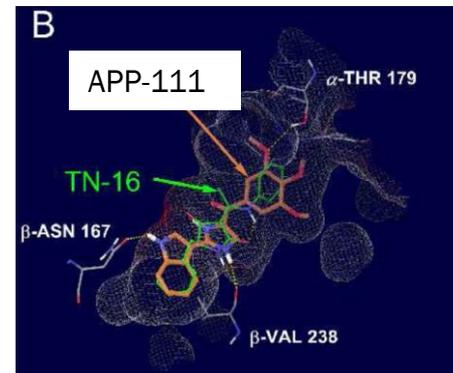
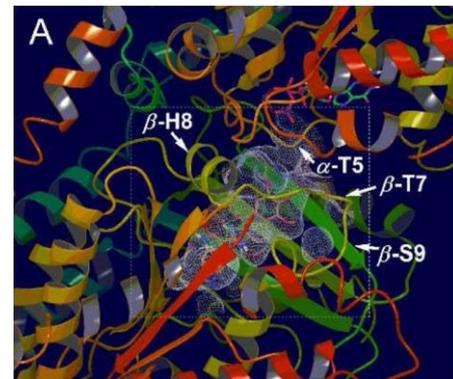
Oral novel agent that target α and β subunits of tubulin

- **Emerging Indications for anti-tubulins like $\alpha\beta$ tubulin inhibitor**
 - Second line: enzalutamide and abiraterone/prednisone have almost complete cross resistance and should not be used in sequence in advanced prostate cancer¹
 - First line: Androgen deprivation therapy and docetaxel increase survival in men with hormone sensitive prostate cancer and high volume disease²
- **Agents that target tubulin continue to be *the only effective* cytotoxic chemotherapy in advanced prostate cancer, but there are challenges³:**
 - 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)

APP-111 FOR ADVANCED PROSTATE CANCER

Oral novel agent that target α and β subunits of tubulin

- **Proof-of-concept preclinical studies were successful. We have a drug!!**
 - Low nanomolar tubulin inhibition
 - Binds to both α and β subunits 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-resistant cancers
 - High activity against prostate cancer *in vitro* and *in vivo*
 - Favorable safety profile (less neurotoxicity & leukopenia)
- **Over 28 peer-reviewed publications**
- **6 issued US and EU patents, expiry 2029 with possible extension to 2034, and 63 foreign granted or pending patents**



APP-111 FOR ADVANCED PROSTATE CANCER

Clinical development plan Indication: Advanced Prostate Cancer



- **Preclinical- Matt Gosnell PhD and Robert Getzenberg PhD**

- Manufacture drug substance
- 28 day animal study and safety pharmacology

- **Phase 1 - April 2018 IND**

- APP-111 for men with metastatic castration resistant prostate cancer who progressed on enzalutamide or abiraterone

MARKET: APP-111 FOR ONCOLOGY

APP-111 ($\alpha\beta$ TUBULIN INHIBITOR) Potential Platform Technology: FOCUS ON OTHER TUMORS THAT RESPOND TO IV ANTI-TUBULINS

- **Current Market for prostate cancer**
 - \$5 billion market for secondary hormone therapies for prostate cancer¹
 - \$4.8B market for vinca alkaloids & taxanes (Docetaxel \$1B & Cabazitaxel \$500 million in prostate cancer)²
- **Other cancers types:**
 - **Vinca Alkaloids: Vinblastine (Velban®); Vincristine (Oncovin®); Vinorelbine (Navelbine®)**
 - Primarily used in combination chemotherapy (ABVD, Stanford-V, CHOP, MOPP) for hematologic malignancies (leukemia, lymphoma, myeloma, sarcoma), and some neuroblastoma, thyroid cancer, and NSCLC
 - **Taxanes : Paclitaxel (Taxol®); Docetaxel (Taxotere®); Cabazitaxel (Jevtana®)**
 - Primarily used for solid tumors such as breast, ovarian, endometrial, cervical, lung, head and neck, esophageal, bladder, gastric, and prostate



Commercial Products

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

THE FEMALE HEALTH COMPANY DIVISION for PUBLIC GLOBAL HEALTH SECTOR

FC2 Product had ~\$22 million of revenue in fiscal year 2016

- **FC2 Female Condom only product that protects against pregnancy and STD**
 - Sold in US and 144 countries
 - Over 550 million units sold to date
 - 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
- **As global market leader, will intensify efforts to grow product for immediate revenue**



PRESCRIPTION MARKET FEMALE CONDOM

FC2 prescription business in United States as new revenue launched April 2017

- **FC2 is the *only FDA approved female condom* as a Class III medical device**
- **Fully reimbursable by private and public insurance:**
 - Mandated by Affordable Care Act (ACA) 2010
 - Grandfathered plans active in 28 States prior to ACA

The 18 Contraception Categories

Under the Affordable Care Act, non-grandfathered plans must cover specified recommended preventive care services without cost-sharing, consistent with PHS Act section 2713.

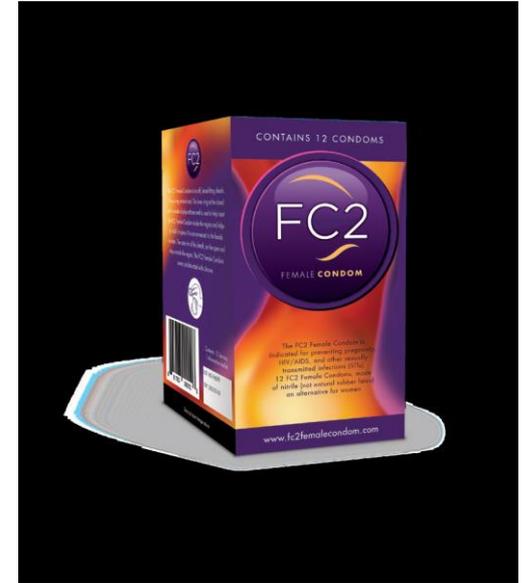
The [18 types of contraception](#) are:

- Sterilization surgery
- Surgical sterilization implant
- Implantable rod
- Copper intrauterine device
- IUDs with progestin (a hormone)
- Shot/injection
- Oral contraceptives (the pill), with estrogen and progestin
- Oral contraceptives with only progestin
- Oral contraceptives, known as extended or continuous use that delay menstruation
- The patch
- Vaginal contraceptive ring
- Diaphragm
- Sponge
- Cervical cap
- **Female condom**
- Spermicide
- Emergency contraception (Plan B/morning after pill)
- Emergency contraception (a different oral medication named Ella)

PRESCRIPTION MARKET FEMALE CONDOM

Commercial strategy for FC2 prescription business in United States

- Call to action against sexually transmitted disease epidemic including Zika virus, HPV, and HIV
 - \$16 billion US expense
- Established pricing, national distribution agreements, and fulfillment infrastructure to make product FC2 12 pack available through retail pharmacies nationally
- Launched in New York City and Miami in April 2017
 - Public sector: 1.3 M units to 333,000 women in 2016
 - Target STD clinics and GYN physicians that order tests for STDs
- Scale up commercialization efforts commensurate with sales into additional territories



CONSUMER HEALTH PRODUCTS

PREBOOST® (4% benzocaine wipe)

- **PREBOOST – prevention of premature ejaculation**

- Only individual medicated wipe containing benzocaine
- Temporarily desensitizes penis after topical application
- Launched Q1 2017
- Compliant with FDA OTC monograph
- Plan to find major OTC distribution partner



- **Top line results of interim analysis from Phase 4 study¹ in 21 men**

- After two months, men treated with PREBOOST® had significant improvement in their ability to control ejaculation:
 - Mean increase in duration of four minutes, which was significantly greater than placebo
 - 80% of men no longer considered to have PE
- Clinical trial presented at American Urological Association scientific meeting May 16, 2017
- American Urological Association held press conference on PREBOOST clinical data May 13 2017

CORPORATE COMMERCIAL STRATEGY

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

Profitable Operating Company

Positive cash flow today
FC2 dominant public sector product
Significant cash/AR balance

NOW

- Debt free, profitable 10 years
- Immediate revenue
 - Launched PREBOOST for men's health 1-17
 - Launched FC2 US prescription 4-17
 - Stabilized FC2 public sector sales

505(b)(2) Drugs

More revenue starts in 2018
Lower risk & less development cost
Medium to larger markets

SOON

- Expected to finance development with cash from operations
 - Tamsulosin DRS for BPH NDA/expected approval 2018
 - MSS-722 for Male infertility NDA 2019
 - APP-944 for Hot flashes NDA 2020

New Innovative Drugs

Large premium global market opportunities
Partnerships with large pharma

FUTURE

- Increase enterprise value
 - APP-111 oral chemotherapy agent $\alpha\beta$ tubulin inhibitor for prostate, ovarian, breast, and other cancers- Phase 1 initiation & results 2018
 - APP-112 colchicine-like agent for acute and chronic gout- preclinical

Financial highlights

Capitalization

- **Approximately 53.3M¹ common shares outstanding on fully diluted/converted basis**
 - 31.3M FHCO diluted shares outstanding prior to merger
 - 2M Common and 547,756 40-to-1 Convertible Preferred Shares issued upon merger

Financial Highlights

(in millions)

P&L - Year ended September 30, 2016³

Net Revenues	\$22.1
Gross Profit	\$13.3
Operating Income	\$3.0

Balance Sheet – As of December 31, 2016

Cash and Receivables ²	\$19.7
UK NOL Carryforward	\$60.9
US NOL Carryforward	\$11.7

¹ 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 53.3 million common share estimate noted above. | ² As of 12/31/16. Includes \$7.8M of long term receivables. | ³ Note that P&L only includes the operations of historical FHCO without including Aspen Park. See latest filed SEC documents for information regarding the combined results on a post-merger basis.

ANTICIPATED MILESTONES

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

	2017	2018
PREBOOST	<ul style="list-style-type: none"> • Launch Q1 • Partner 2H 	
FC2	<ul style="list-style-type: none"> • Launch US prescription business in NY and FL Q2 • Grow public sector- New Brazil and South African tenders Q4 	<ul style="list-style-type: none"> • Launch US prescription in other territories Q1 • Grow public sector Q1
Tamsulosin DRS	<ul style="list-style-type: none"> • Complete BE study Q3 • preNDA meeting and prepare NDA Q4 • Complete stability on manufactured batches Q4 • Meet with EMA Q4 	<ul style="list-style-type: none"> • Launch in Europe 2H • Launch in US 2H • Partner ROW 1H
MSS-722	<ul style="list-style-type: none"> • File IND Q2 • Initiate Phase 2 Q3 • Orphan drug Q3 	<ul style="list-style-type: none"> • Complete Phase 2 2H • Initiate Phase 3 2H
APP-944	<ul style="list-style-type: none"> • Complete preIND meet Q2 • File IND Q4 	<ul style="list-style-type: none"> • Initiate Phase 2 1H
APP-111	<ul style="list-style-type: none"> • Initiate preclinical studies Q3 • API Q2 	<ul style="list-style-type: none"> • File IND Q2 • Initiate Phase 1 - prostate cancer Q2



veru
HEALTHCARE

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