



Veru Inc.  
Nasdaq:VERU

*September 6, 2018*  
*HC Wainwright Healthcare Conference*

**Prostate Cancer  
Novel Medicines and  
Urology Specialty  
Pharmaceuticals**

# Forward looking statements



This communication contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 Veru Inc.'s (the "Company") product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; potential delays in the expected timing of and results from clinical trials and studies and in the timing of any submission to the regulatory authorities; the risk in obtaining any regulatory approval and the products being commercially successful; 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 or existing competitors with greater resources and capabilities and new competitive product introductions; the risk in sales being affected by regulatory developments, including a reclassification of the products; price erosion, both from competing products and increased government pricing pressures; manufacturing and quality control problems; compliance and regulatory matters including costs and delays resulting from the extensive governmental regulation, and effects of healthcare insurance and regulation, including reductions in reimbursement and coverage; 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 the uncertainty of obtaining patents, the effectiveness of the patents or other intellectual property protections and ability to enforce them against third parties, the uncertainty regarding patent coverages, the possibility of infringing a third party's patents or other intellectual property rights, and 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, restructuring or substantial delayed payments; 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; penalties and/or debarment for failure to satisfy tender awards; the Company's reliance on its international partners and on the level of spending by country governments, global donors and other public health organizations in the global public sector; risks related to concentration of accounts receivable with our largest customers and the collection of those receivables; 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 and interruptions, including due to labor unrest or strikes; risks related to the costs and other effects of litigation, including product liability claims; 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; the risk that the Company may not enter into definitive agreements to sell its FC2 Female Condom® business ("FC2 Business"); the risk that a sale of the FC2 Business may not be completed in a timely manner or at all; costs, fees and expenses related to any such transaction; 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, 2017. This document is available on the "SEC Filings" section of our website at [www.verupharma.com/investors](http://www.verupharma.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.

The Company has filed a registration statement on Form S-3 (including a prospectus) with the Securities and Exchange Commission ("SEC") that was declared effective on November 14, 2017. Before you invest in the offering to which this communication relates, you should read the prospectus in that registration statement, the preliminary prospectus related to the offering (when available) and the other documents the Company has filed and will file with the SEC for more complete information about the Company and the offering. You may get these documents for free by visiting EDGAR on the SEC website at [www.sec.gov](http://www.sec.gov). Alternatively, the Company, any underwriter or any dealer participating in the offering will arrange to send you the prospectus and the preliminary prospectus, when available, by calling Cantor Fitzgerald & Co., Attn: Capital Markets, 499 Park Avenue, 6th Floor, New York, NY 10022, by telephone at 212-829-7122.

# Pipeline of proprietary product candidates and specialty pharmaceuticals



PRODUCT	INDICATION	TARGET	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	PHASE 4
<b>PROSTATE CANCER NOVEL MEDICINES</b>							
Zuclomiphene capsules	Hot flashes caused by prostate cancer hormone treatment	Nonsteroidal estrogen agonist					
VERU-111 (bisindole) capsules	Metastatic prostate cancer	Oral, targeted $\alpha + \beta$ tubulin inhibitor					
<b>UROLOGY SPECIALTY PHARMACEUTICALS</b>							
Tamsulosin DRS granules & XR capsules (tamsulosin HCl)	BPH (no food effect)	Super selective $\alpha_1$ -receptor blocker with no food effect					
Tadalafil-finasteride combo tablets (5mg tadalafil /5mg finasteride)	"Male pill" BPH & erectile dysfunction	PDE5 + $5\alpha$ reductase inhibitors					
Solifenacin DRG (solifenacin granules oral suspension)	Overactive bladder	Selective M3 muscarinic antagonist					

# Experienced in clinical practice, drug development and commercialization



## **Mitchell Steiner, MD**

### **CHAIRMAN, PRESIDENT & CEO**

CEO & President Aspen Park Pharmaceuticals, President of Urology at OPKO Health, Inc.; CEO & Founder GTx, Inc.; urologist

## **Michele Greco, CPA**

### **CHIEF FINANCIAL & ADMINISTRATIVE OFFICER**

CFO/EVP The Female Health Company, 28 years with Ernst & Young, 15 years as an Audit Partner

## **Gary Barnette, PhD**

### **CHIEF SCIENTIFIC OFFICER**

Sr. VP Scientific and Reg Affairs Camargo Pharm. Services, VP Clinical & Reg and Founder GTx, Inc., Director Reg Affairs Solvay Pharma, Clinical Pharmacology/ Biopharmaceutics Reviewer FDA, PhD Basic Pharmaceutical Sciences West Virginia University

## **Harry Fisch, MD**

### **CHIEF CORPORATE OFFICER**

Chairman Aspen Park Pharmaceuticals and Millennium Sciences, Inc.; urologist

## **Kevin Gilbert, JD, CPA**

### **EVP CORPORATE DEVELOPMENT**

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

## **Philip Greenberg, JD**

### **EVP LEGAL**

General Counsel Latin America Teva Pharmaceuticals with prior senior legal positions in international and North America divisions; Deputy General Counsel for IVAX Corporation

## **Phil Kuhn, MBA**

### **EVP STRATEGY AND COMMERCIALIZATION**

Global Strategy and Commercial expertise in medical devices, diagnostics, and biologics; leadership roles at ISTO Biologics, Orthofix, Smith & Nephew, Boston Scientific, Johnson & Johnson, and Abbott

# Prostate Cancer - Novel Medicines



## Hot flashes are one of the most common and debilitating side effect of androgen deprivation therapy (ADT) for advanced prostate cancer<sup>1,2</sup>

- ◆ Occurs in up to 80% of men treated with ADT (leuprolide or degarelix) with 30-40% having moderate to severe hot flashes<sup>1-3</sup>
- ◆ Symptoms do not subside over time
  - ◆ 48% of men at 5 years and 40% of men at 8 years still suffer from hot flashes<sup>2</sup>
- ◆ Concern over hot flashes make patients less likely to begin ADT and can lead to early discontinuation<sup>2A</sup>

## Zuclomiphene (aka *cis*-clomiphene) is an oral estrogenic agent<sup>4,5</sup>

- ◆ Isolated *cis*-clomiphene from CLOMID (30% *cis*- and 70% *trans*-clomiphene; approved in 1967 for female infertility)
- ◆ Efficacy established for estrogens: off-label steroidal estrogens are effective but have safety concerns<sup>6,7</sup>
- ◆ FDA database and scientific literature show *cis*-clomiphene component of CLOMID is well tolerated with over 88,000 men/year<sup>8</sup> using CLOMID off label for infertility or hypogonadism

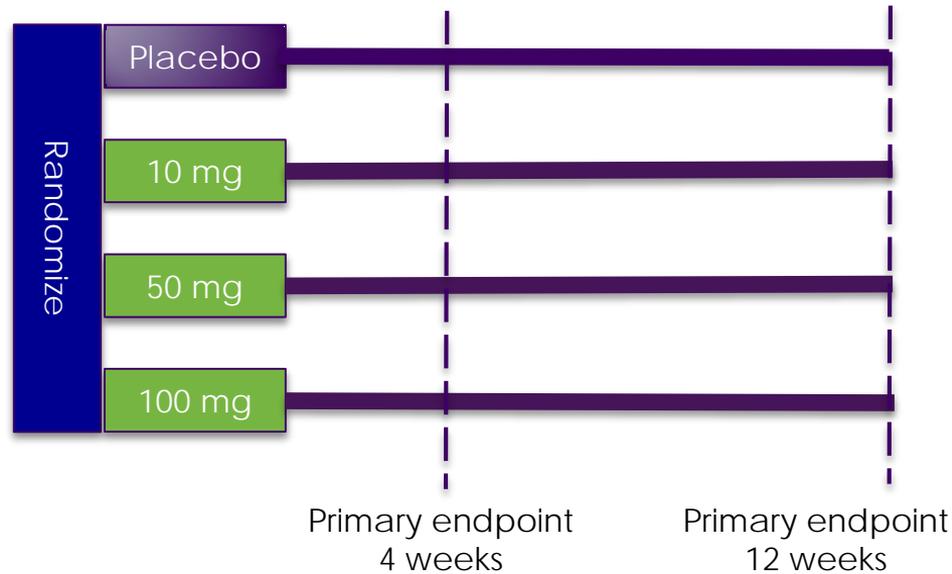
<sup>1</sup> Gomella LG et al *BJU Int* S1:25-29 2007 | <sup>2</sup> Karling P et al. *J Urol* 152:1170-1173 1994 | <sup>2A</sup> Gonzalez BD et al *J Urol* 194:690-695 2015 | <sup>3</sup> Dalal S et al *J Support Oncol* 4:315-320 2006 | <sup>4</sup> Turner RT et al *Endocrinology* 139:7712-20 1998 | <sup>5</sup> Fontenot GK et al *BJU Int* 117:344-50, 2016 | <sup>6</sup> Jones JM et al *Asian J Andrology* 14:193-197 2012 | <sup>7</sup> Spetz AC et al *J Support Oncol* 4:263-273 2003 | <sup>8</sup> Camargo Pharma Clinical Report 3/17 and FDA Briefing Document BRUDAC Advisory meeting 12/16

IND accepted 7/18

Phase 2 placebo controlled dose finding study  
FPI 9/18 & final data expected 1H 2019

Plan to enroll 120 men who have moderate & severe hot flashes on ADT in 10 US clinical sites

- ◆ Primary efficacy endpoint- mean change in frequency of moderate & severe hot flashes from baseline to week 4 and maintained until week 12
- ◆ Power 80%; 40% improvement compared to placebo
- ◆ Placebo effect from literature is 22%<sup>1</sup>
- ◆ Secondary endpoints- bone turnover markers



<sup>1</sup> Lopinzi et al 2009, Annals of Oncology p1-8 (DOI:10.1093/annonc/mdn644 ;Table 2)

## Market potential

- ◆ Indication: treatment of castration-induced hot flashes in men with advanced prostate cancer on ADT
- ◆ Estimated 600,000 men on hormonal therapies (androgen deprivation therapy as well as novel androgen blocking agents) in the U.S.<sup>1</sup>
- ◆ Over a \$600 million/year expected market<sup>2</sup>

## Intellectual property

- ◆ Patent (U.S. No. 9,913,815) issued March 2018, expiry 2035- method of use
- ◆ Polymorph identified- composition of matter patent



<sup>1</sup> Scher et al. PLoS ONE 2015 10:1-12 (DOI:10.1371/journal.pone0139440) | <sup>2</sup> Total market potential based on 30% of 600,000 men in US on ADT have moderate to severe hot flashes if the price was \$3,300 /year of treatment

The only effective agents against advanced and metastatic prostate cancer are hormonal and antitubulin cytotoxic drugs

Androgen blocking agents ZYTIGA (abiraterone) and XTANDI (enzalutamide) have significant cross resistance

Men who progress on these agents are being treated with antitubulin chemotherapies

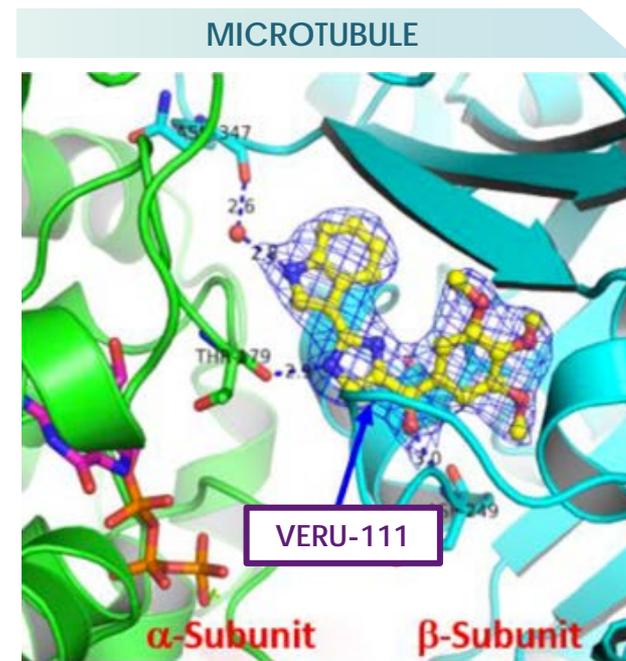
**Current antitubulins have challenges<sup>1</sup>**

- ◆ Only available as intravenous administration
- ◆ Drug resistance is common- multidrug resistance proteins, tubulin mutations and overexpression
- ◆ Safety concerns- hypersensitivity reactions, neutropenia, and neurotoxicity (peripheral neuropathy & muscle weakness)

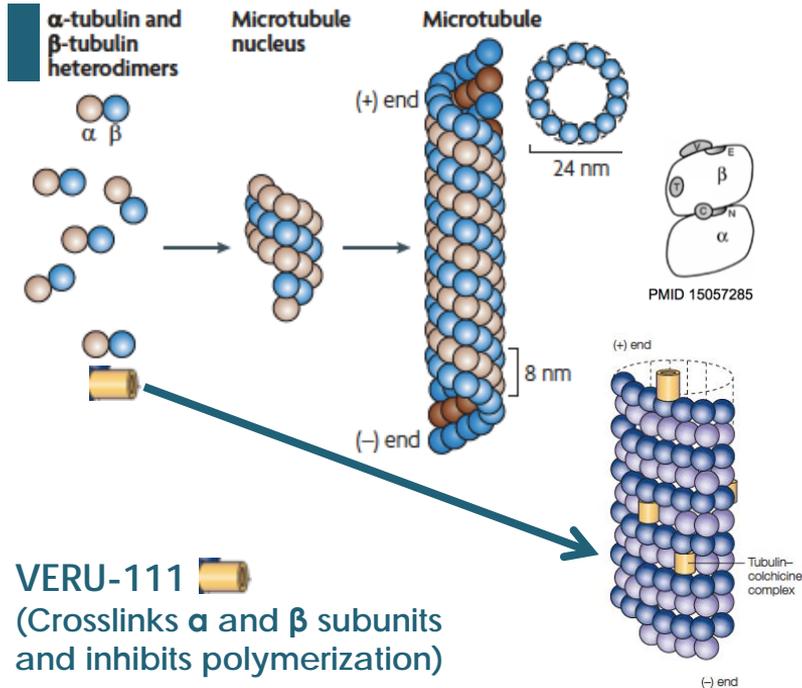


## Preclinical Product profile

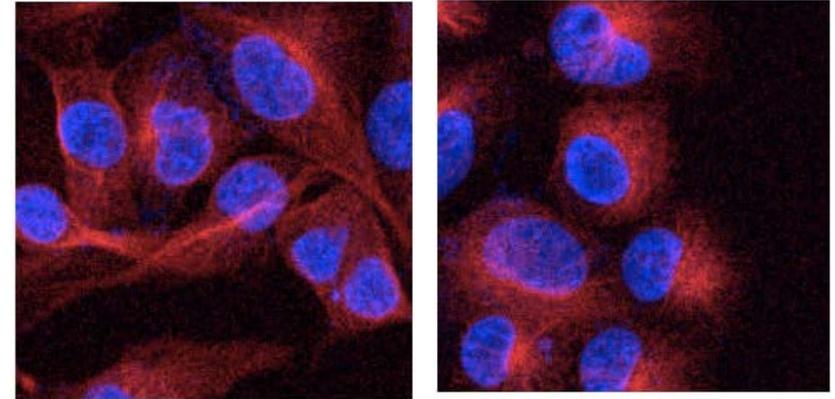
- ◆ Low nanomolar inhibition of tubulin polymerization
- ◆ High oral bioavailability
- ◆ High brain penetration
- ◆ Not a substrate for MDRs (P-gp, MRPs, and BCRP)
- ◆ Not a substrate for CYP3A4
- ◆ Efficacy against prostate and other cancers *in vitro* and *in vivo*
- ◆ Demonstrated activity against taxane, vinca alkaloid, doxorubicin, enzalutamide, and abiraterone resistant cancers
- ◆ Favorable safety profile (less neurotoxicity than docetaxel and unlike taxanes and vinca alkaloids –no neutropenia or myelosuppression)



## Microtubule assembly



## Microtubules (red) disrupted from spindle to globular shape

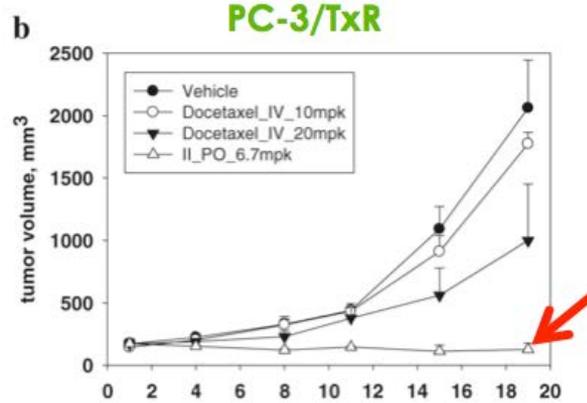
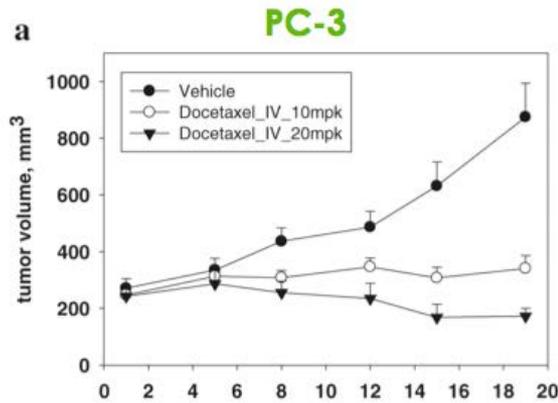


**control**  
"spindle shape"

**VERU-111**  
"globular shape"

Triple negative human breast cancer xenograft  
(MDA-MB-231)<sup>1</sup>

# VERU-111 inhibits growth of taxane-resistant prostate cancer<sup>1</sup>



II = VERU-111; PO- oral dosing; IV- intravenous dosing; mpk- mg per kg  
Treatment initiated when tumors reached 150-300 mm<sup>3</sup>

- ◆ PC-3 and taxane-resistant PC-3 (PC-3/TxR) human prostate cancer xenografts were grown in mice
  - ◆ Figure a- demonstrates that PC-3 cells are inhibited by a taxane (docetaxel)
  - ◆ Figure b- indicates PC-3/TxR are indeed resistant to a taxane (docetaxel)
- ◆ VERU-111 inhibited growth of taxane resistant human prostate cancer xenografts (3.3-6.7 mg/kg)

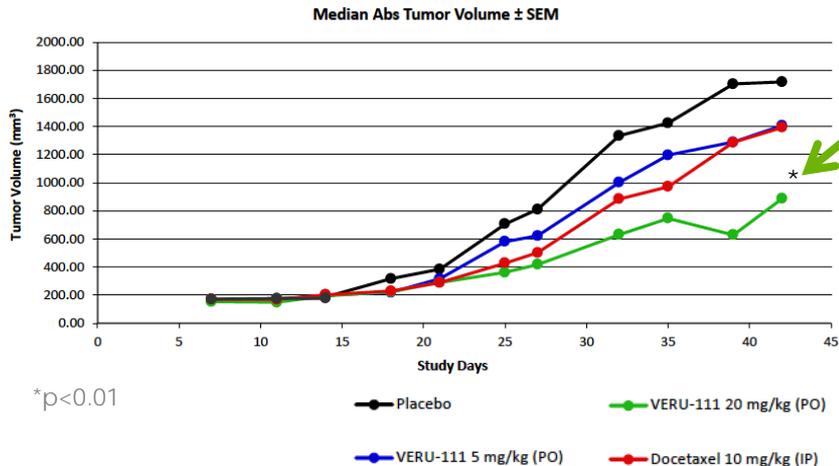
# VERU-111 inhibits prostate cancer tumors resistant to novel androgen blocking (AB) agents with no effect on body weight (surrogate for toxicity)



## 22Rv1- human prostate cancer model<sup>1</sup>

- ◆ Contains androgen receptor variants including AR-V7
- ◆ Resistant to novel AB agents: enzalutamide and abiraterone

### Efficacy (median tumor volume)



### Safety (% starting body weight rats)

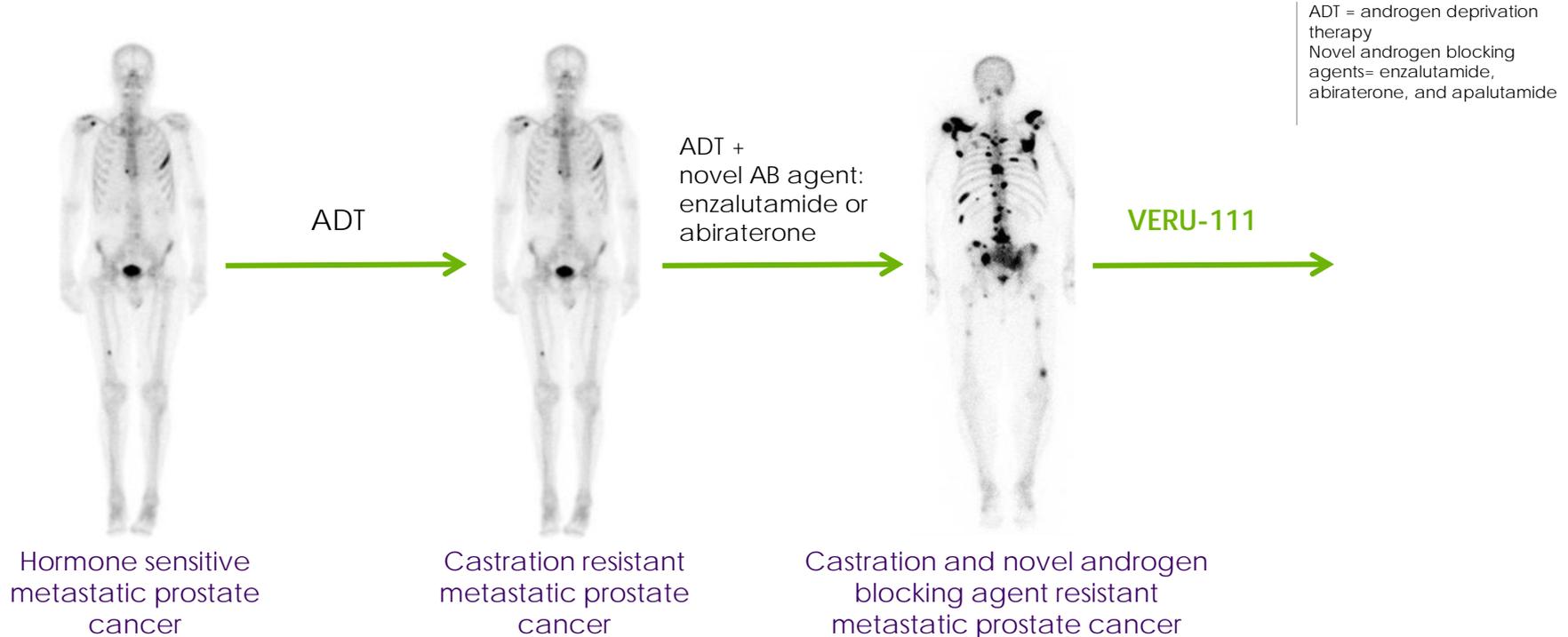
Treatment Group	Mean (%)	Median (%)	P-value
Placebo	122.26	122.81	
VERU-111 5 mg/kg (PO)	127.53	125.48	0.0370
VERU-111 20 mg/kg (PO)	124.52	124.30	0.2031
Docetaxel 10 mg/kg (IP)	118.35	118.00	0.0133

Difference between both VERU-111 treatment groups (5 and 20 mg/kg) and docetaxel treated animals (p=0.0135)

# VERU-111 clinical development plan: Target castration and novel androgen blocking agent resistant metastatic prostate cancer

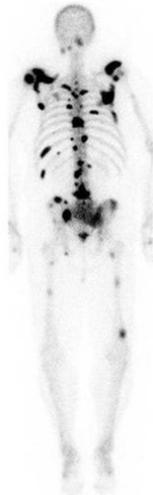


First in class, next generation, novel oral agent that targets  $\alpha$  and  $\beta$  subunits of tubulin



## IND and Phase 1/2 FPI expected calendar Q4 2018- Johns Hopkins Cancer Center- lead center

Men with metastatic castration resistant prostate cancer who have progressed on novel AB agent (either enzalutamide or abiraterone) and  $\pm$  1 taxane



Phase 1  
3+3 design

N=15

Phase 2 open label study  
Primary endpoint- PSA reduction



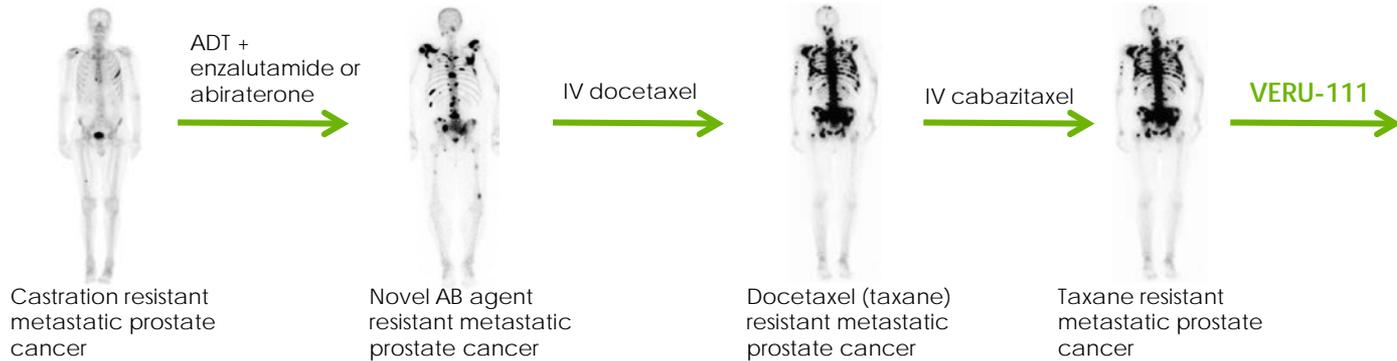
N=40

Castration and novel androgen  
blocking agent resistant  
metastatic prostate cancer

# VERU-111 has potential to treat multiple indications in prostate cancer

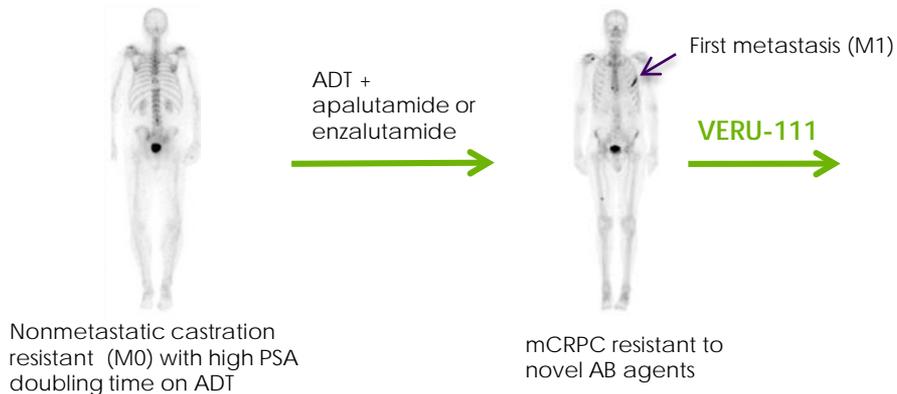


## Indication 2- novel AB agent and taxane chemotherapy resistant mCRPC

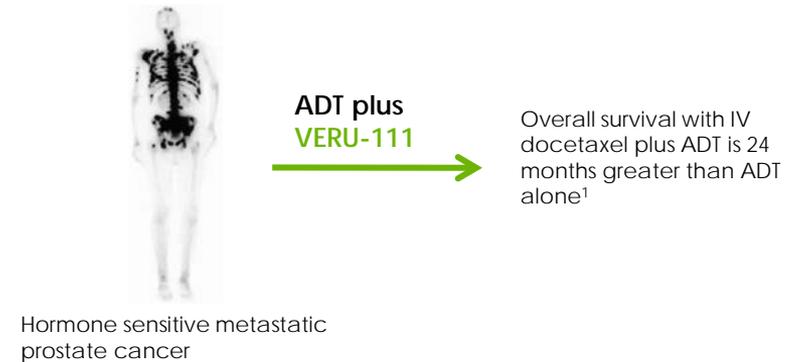


ADT = androgen deprivation therapy  
Novel AB agents= enzalutamide, abiraterone, and apalutamide

## Indication 3- 1<sup>st</sup> line mCRPC resistant to novel AB agents



## Indication 4- 1<sup>st</sup> line hormone sensitive metastatic prostate cancer



<sup>1</sup> Sweeney NEJM 2015 (DOI:10.1056/NEJMoa1503747)

## 4 abstracts at ASCO 2018

VERU-111 HAD EFFICACY AGAINST THE FOLLOWING HUMAN CANCER XENOGRAFT MODELS

- ◆ 22Rv1- human metastatic prostate cancer line resistant to enzalutamide and abiraterone
- ◆ Triple negative breast cancer
- ◆ Ovarian cancer
- ◆ Pancreatic cancer

## Over 29 peer-reviewed publications

## 7 issued composition of matter patents including U.S. 9029408, EU 2959900 and Japan 5507552

- ◆ U.S. patent expiry 2029 with possible extension to 2034 and 63 foreign granted or pending patents
- ◆ Polymorphs identified to extend time for composition of matter coverage

## Current market for advanced prostate cancer drugs

- ◆ \$5 billion market for secondary novel androgen blocking agents for prostate cancer<sup>1</sup>
- ◆ \$4.8 billion market for antitubulins such as vinca alkaloids & taxanes (docetaxel \$1 billion and cabazitaxel \$500 million in prostate cancer)
- ◆ VERU-111 potential global market greater than \$5 billion for prostate and other cancer types

## VERU-111, like current antitubulins, may have efficacy against broad cancer types

- ◆ **VINCA ALKALOIDS:** VELBAN (VINBLASTINE); ONCOVIN (VINCRISTINE); NAVELBINE (VINOURELBINE) Primarily used in combination chemotherapy (ABVD, Stanford-V, CHOP, MOPP) for hematologic malignancies (leukemia, lymphoma, and myeloma), and neuroblastoma, thyroid cancer, sarcoma and non small cell lung cancer
- ◆ **TAXANES:** TAXOL (PACLITAXEL); TAXOTERE (DOCETAXEL); JEVTANA (CABAZITAXEL); ABRAXANE (PROTEIN BOUND PACLITAXEL) Primarily used for solid tumors such as breast, ovarian, endometrial, cervical, lung, head and neck, esophageal, bladder, gastric, and prostate



# Urology Specialty Pharmaceuticals

**FLOMAX (tamsulosin HCl) is a super selective  $\alpha_1$ -receptor blocker for the treatment of BPH<sup>1</sup>**

**Food effect is a serious problem with current branded and generic formulations of tamsulosin:**

- ◆ FLOMAX has a food effect and must be taken 30 min after meals- absorption without food results in higher drug levels (Cmax increases up to 70%)
- ◆ Safety issues related to high drug levels include dizziness, fainting, and orthostatic hypotension
- ◆ Dose dependent increase in falls and fractures<sup>2</sup>

**Solution: proprietary new slow release formulation of tamsulosin DRS granules and XR capsules without a food effect**

**Patent filed, expiry 2037<sup>3</sup>**

## **FLOMAX Package Insert<sup>1</sup>**

**“Advise the patient that FLOMAX capsules should not be crushed, chewed, or opened”**

## Results from two bioequivalence (BE) studies show no food effect

- ◆ Stage 1 (completed) – 12 patients, single dose FLOMAX fed versus Tamsulosin DRS fed and fasted results reported successful BE study without food effect<sup>1</sup>
- ◆ Stage 2 (completed) – 36 patients, 21 day study, single dose of selected Tamsulosin DRS formulation vs. FLOMAX showed that Tamsulosin DRS fed and fasted met bioequivalence for FLOMAX fed AUC (no food effect) and not for C<sub>max</sub><sup>1</sup>

## Expected next steps:

**Final BE study by end of 2018 and stability validation GMP batches in progress**

**File NDA 2019**

**Post approval Phase 4 safety clinical trial- FLOMAX (food effect) versus tamsulosin XR capsules (no food effect) to assess dizziness, fainting, and orthostatic hypotension in a real world setting**

<sup>1</sup> Data on file Veru

# Tamsulosin DRS granules & XR capsules market strategy and commercialization

**Tamsulosin is the number one prescribed alpha blocker<sup>1</sup>**

## Urologists: initial target market

- ◆ Oral capsule branded product with no food effect for men
- ◆ Pricing strategy will be more comparable to FLOMAX (WAC=\$731.45/100 tablets Kinray Cardinal Health)

## Long term care is upside:

- ◆ Men with dysphagia in long term care facilities as no pharmacy formulary has a slow release granule formulation for any alpha blocker for BPH

2017  
U.S. tamsulosin  
prescriptions  
28,341,404<sup>2</sup>

Long term care  
tamsulosin annual  
prescriptions  
3,136,000

POPULATION	% PREVALENCE DYSPHAGIA
Elderly (>60 yo) in community	15% <sup>2</sup>
Long term care facilities	60% <sup>2</sup>
Parkinson's disease	80% <sup>3</sup>
Alzheimer's disease	Up to 75% <sup>4</sup>
Stroke	50% <sup>5</sup>

# “Male pill”: combination tadalafil/finasteride to improve compliance & safety



Co-administration of CIALIS (tadalafil 5 mg) and PROSCAR (finasteride 5 mg) is currently approved for the initial treatment of symptoms of BPH for up to 26 weeks<sup>1</sup>

- ◆ Drug-drug interaction and co-administration studies are completed for combination indication<sup>2</sup>

The solution: proprietary tadalafil/finasteride combination tablet formulation

- ◆ Increases convenience and compliance

The “male pill”: each component is approved for

- ◆ CIALIS (tadalafil 5 mg) daily- symptoms of *BPH and erectile dysfunction*
- ◆ PROSCAR (finasteride 5 mg)- symptoms and signs of prostate enlargement to decrease prostate size, reduces risk of acute urinary retention and need for surgery and prevents growth. *Off label use prevents prostate cancer.*<sup>3</sup>

Bioequivalence study by year end 2018 and NDA filing expected in 2019

All current selective M3 muscarinic antagonists are only available as capsules/tablets

According to FDA label, these capsules/tablets should be swallowed whole and not crushed, or chewed.

Expected next steps:

- ◆ Bioequivalence study 1H 2019
- ◆ File NDA in late 2019

Solifenacin tablets represent a \$1 billion annual market<sup>1</sup>

Solifenacin DRG granules will target underserved population of men and women with OAB who have difficulty or cannot swallow tablets/capsules<sup>2-4</sup>

Patent filed, expiry 2037<sup>5</sup>



Commercial  
Product





**FC2 Female Condom only FDA approved female use product that protects against pregnancy and STD**

- ◆ Sold in U.S. and 149 countries
- ◆ Public sector represents approx. 90% of revenue (customers include UNFPA, USAID, Brazil, and South Africa)
- ◆ FC2 business profitable over past 11 years

**Manufacturing plant is in Kuala Lumpur, Malaysia**

- ◆ Current capacity of 100 million units annually

**Building US prescription business for immediate high margin revenue**

- ◆ FC2 now available by prescription in 98% of retail pharmacies
- ◆ Prescription business is growing

### The overall tender is for up to 120 million female condoms over 3 years

- ◆ Veru was awarded up to 29.8 million units of the 40 million total for the first year
- ◆ The anticipated total revenue of the South Africa tender awarded to Veru is \$31 million with the first year revenue expected to be USD \$10.4 million with up to another \$10.4 million of revenue for each of years two and three

## Revenue and positive operating margin from FC2 global business will help fund Veru's drug pipeline

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With the South African tender award, we expect global public sector unit volumes to return to three-year historical averages—significantly higher than the last fiscal year's volume.

In addition, we continue to see strong growth in our higher margin US FC2 Rx market

**Capitalization - approximately 54.7 million<sup>1</sup> common shares outstanding as of June 30, 2018**

### Balance sheet as of June 30, 2018

◆ Cash and receivables	\$9.2
◆ UK NOL carryforward	\$62.2
◆ US NOL carryforward	\$12.1

**\$10 million received in March 2018 under SWK Holdings synthetic royalty financing on FC2 Female Condom<sup>®</sup> product sales**

### Results of operations for the nine months ended June 30, 2018

◆ Net revenues	\$10.7
◆ Gross profit	\$ 5.6
◆ Operating loss	\$17.1

### Results of operations for the year ended September 30, 2017

◆ Net revenues	\$13.7
◆ Gross profit	\$7.0
◆ Operating loss	\$8.5

<sup>1</sup>Additional options, restricted stock units, and warrants are outstanding and are, or could potentially be, additionally dilutive in excess of the 54.7 million common shares above | See latest filed SEC documents for additional information

# Veru projected development milestones



PRODUCT	INDICATION	2018	2019	2020		
<b>PROSTATE CANCER NOVEL MEDICINES</b>						
Zuclomiphene capsules	Hot flashes caused by prostate cancer hormone therapy	IND	P2	P3	NDA	
VERU-111 (bisindole) capsules	Metastatic prostate cancer	IND	P1b/P2	P3		
<b>UROLOGY SPECIALTY PHARMACEUTICALS</b>						
Tamsulosin XR granules & capsules	BPH without food effect	BE3	NDA	Post approval safety study	US launch	
Tadalafil-finasteride combo tablets	"Male pill" for BPH and erectile dysfunction	BE	NDA		US launch	
Solifenacin DRG granules	Overactive bladder in patients with dysphagia		BE	NDA	US launch	