



Veru Inc.
Nasdaq:VERU

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

October 25, 2018

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, including the Company's recent South Africa female condom 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 timing of orders under the Company's recent South Africa female condom tender award is uncertain, and any delay in orders under the award could result in lower revenue than anticipated in the earlier part of the three-year period covered by the tender; the Company's recent South Africa female condom tender award could be subject in the future to reallocation for potential local manufacturing initiatives, which could reduce the size of the award to the Company; 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 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; 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/investor. 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 supplement 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. 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	
PROSTATE CANCER NOVEL MEDICINES								
Zuclomiphene capsules	Hot flashes caused by prostate cancer hormone treatment	Nonsteroidal estrogen agonist	[Progress bar: Preclinical to Phase 2]					
VERU-111 (bisindole) capsules	Metastatic prostate cancer	Oral, targeted $\alpha + \beta$ tubulin inhibitor	[Progress bar: Preclinical to Phase 1]					
UROLOGY SPECIALTY PHARMACEUTICALS								
Tamsulosin DR5 granules & XR capsules (tamsulosin HCl)	BPH (no food effect)	Super selective α_1 -receptor blocker with no food effect	[Progress bar: Preclinical to Phase 3, labeled Bioequivalence study]					
Tadalafil-finasteride combo tablets (5mg tadalafil /5mg finasteride)	BPH & erectile dysfunction	PDE5 + 5 α reductase inhibitors	[Progress bar: Preclinical to Phase 3, labeled Bioequivalence study]					
Solifenacin DRG (solifenacin granules oral suspension)	Overactive bladder	Selective M3 muscarinic antagonist	[Progress bar: Preclinical to Phase 3, labeled Bioequivalence study]					

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

UPDATED

Prostate Cancer -
Novel Medicines



Zuclomiphene: potential to be the first FDA approved drug for hot flashes caused by prostate cancer hormone therapy



Hot flashes are one of the most common and debilitating side effect of androgen deprivation therapy (ADT) for advanced prostate cancer^{1,2}

- ◆ Occurs in up to 80% of men treated with ADT (leuprolide or degarelix) with 30-40% having moderate to severe hot flashes¹⁻³
- ◆ Symptoms do not subside over time
 - ◆ 48% of men at 5 years and 40% of men at 8 years still suffer from hot flashes²
- ◆ Concern over hot flashes make patients less likely to begin ADT and can lead to early discontinuation^{2A}

Zuclomiphene (aka *cis*-clomiphene) is an oral estrogenic agent^{4,5}

- ◆ 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^{6,7}
- ◆ FDA database and scientific literature show *cis*-clomiphene component of CLOMID is well tolerated with over 88,000 men/year⁸ using CLOMID off label for infertility or hypogonadism

¹ Gomella LG et al BJU Int 51:25-29 2007 | ² Karling P et al. J Urol 152:1170-1173 1994 | ^{2A} Gonzalez BD et al J Urol 194:690-695 2015 | ³ Dadd S et al J Support Oncol 4:315-320 2006 | ⁴ Turner RT et al Endocrinology 139:7712-20 1998 | ⁵ Fontenat GK et al BJU Int 117:344-50, 2016 | ⁶ Jones JM et al Asian J Androl 14:193-197 2012 | ⁷ Speltz AC et al J Support Oncol 4:263-273 2003 | ⁸ Camargo Pharma Clinical Report 3/17 and FDA Briefing Document BRUDAC Advisory meeting 12/16

Zuclomiphene clinical development plan: Phase 2 trial design

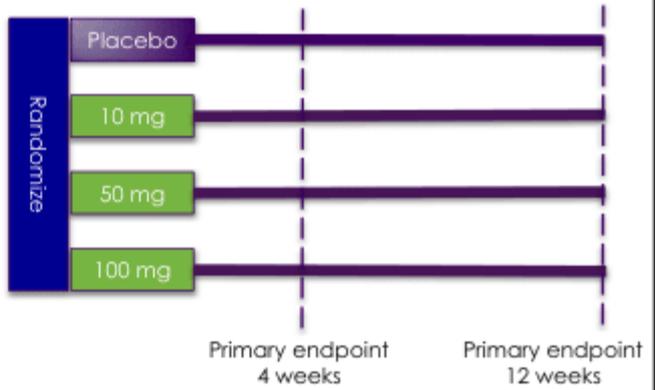


IND accepted 7/18

Phase 2 placebo controlled dose finding study
First subject expected in 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%¹
- ◆ Secondary endpoints- bone turnover markers



¹ Lopinzi et al 2009, *Annals of Oncology* p1-8 [DOI:10.1093/annonc/mdn644 ;Table 2]

Zuclomiphene: greater than \$600 million/year expected market



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.¹
- ◆ Over a \$600 million/year expected market²

Intellectual property

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



¹ Scher et al. PLoS ONE 2015 10:1-12 (DOI:10.1371/journal.pone0139440) ² 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

VERU-111 may address key limitations of current prostate cancer treatments



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 challenges¹

- ◆ 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)



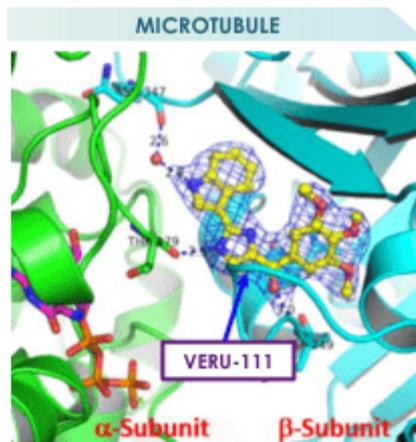
¹Diamond E et al Cur Treat Options Oncol 16:9 2015

VERU-111: novel, oral, next generation, tubulin inhibitor targeting α and β subunits of microtubules



Preclinical Product profile¹⁻³

- 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)⁴

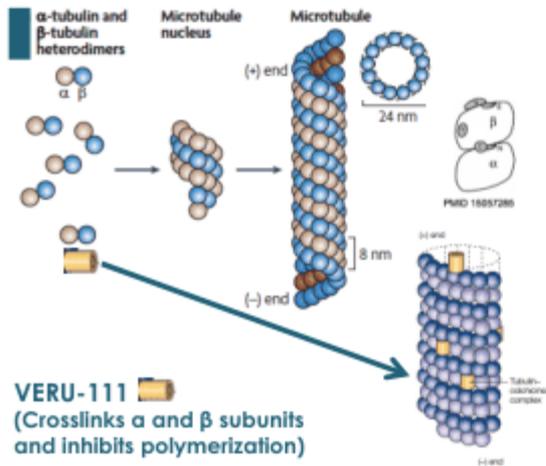


¹ Chen J et al. J Med Chem 55:7285-7289 2012 | ² Li CM et al. Pharm Res 29:3053-3063 2012 | ³ Lu Y et al. J Med Chem 57:7355-7366 2014 | ⁴ 28 day rat and dog toxicity studies on file at Veru, Inc.

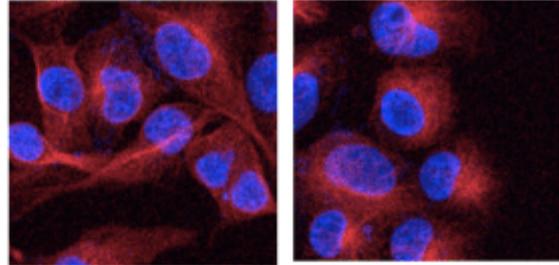
VERU-111 builds on a proven mechanism - inhibiting microtubule assembly



Microtubule assembly



Microtubules (red) disrupted from spindle to globular shape



control
"spindle shape"

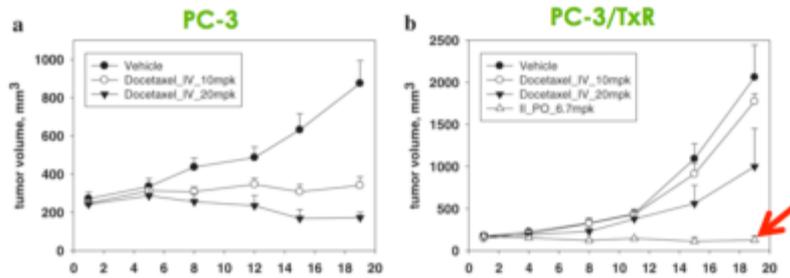
VERU-111
"globular shape"

Triple negative human breast cancer xenograft (MDA-MB-231)¹

¹ Published ASCO abstracts 2018

ct profile

VERU-111 inhibits growth of taxane-resistant prostate cancer¹



|| = VERU-111; PO- oral dosing; IV- intravenous dosing; mpk- mg per kg
 Treatment initiated when tumors reached 150-300 mm³

◆ 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)

¹ Li CM et al. Pharm Res 29:3053-3063 2012

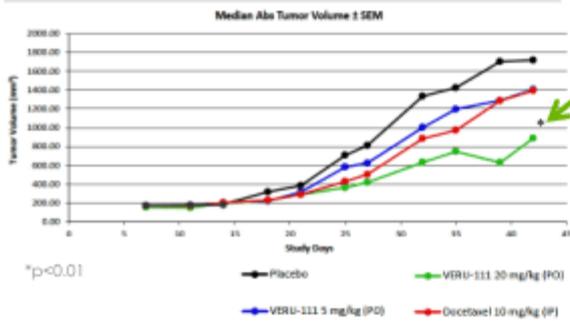
VERU-111 inhibits prostate cancer tumors resistant to novel androgen blocking (AB) agents with no effect on body weight (surrogate for toxicity)



22Rv1- human prostate cancer model¹

- ◆ 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)

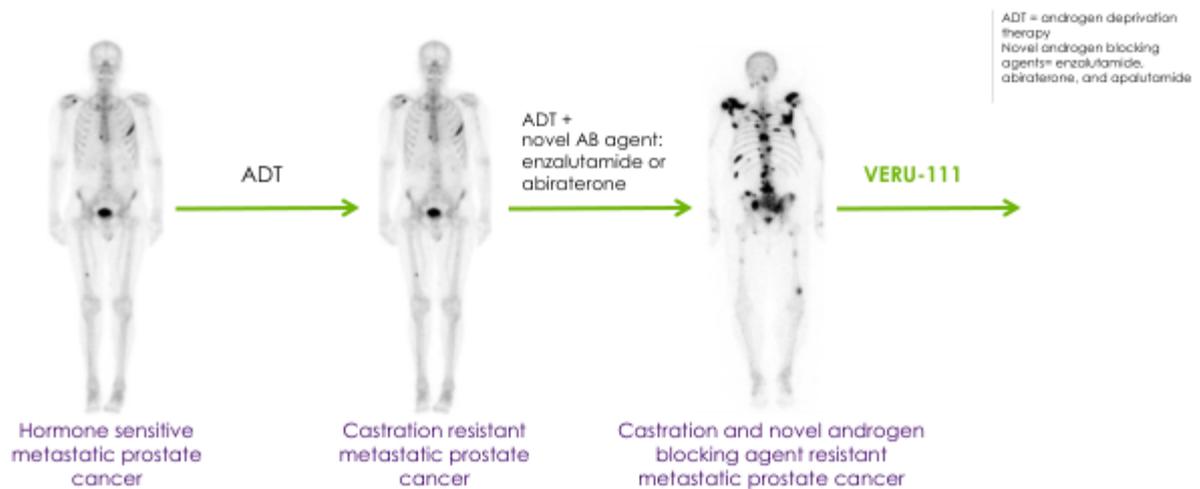
¹ASCO abstracts 2018

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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 α and β subunits of tubulin



VERU-111 clinical development: we expect open label clinical data Q1 2019



Successful pre-IND meeting with FDA 9/18

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

Men with metastatic castration resistant prostate cancer who have progressed on novel androgen blocking 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=26

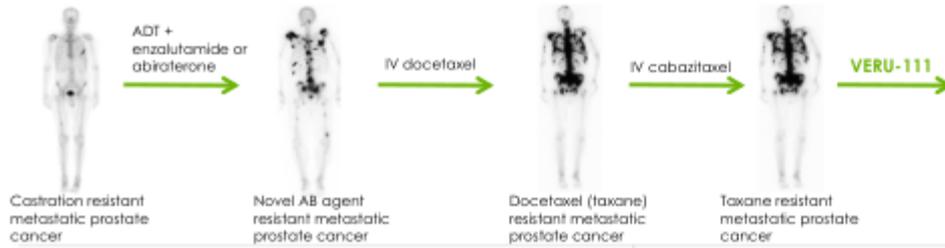
Castration and novel androgen blocking agent resistant metastatic prostate cancer

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

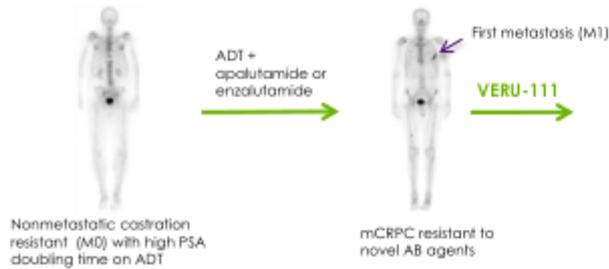


Indication 2- novel AB agent and taxane chemotherapy resistant mCRPC



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

Indication 3- 1st line mCRPC resistant to novel AB agents



Indication 4- 1st line hormone sensitive metastatic prostate cancer



¹ 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 cancer¹
- ◆ \$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 (VINOReLBINE) 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

¹Pharma Intelligence 1/31/18 "How the prostate cancer market will change over next decade" by Kevin Grogan



Urology Specialty Pharmaceuticals

**Urology specialty pharmaceuticals:
NDAs for 3 drug products to be submitted 2019**



Product	Indication	Formulation and advantages	Market	Status
Tamsulosin XR capsules and granules	BPH Branded- Flomax	0.4 mg Slow release granules with no food effect Sprinkles for dysphagia Compliance & safety	2017 US market- 28,341,404 scripts Long term care- 3,126,000 scripts	Final bioequivalence study will be completed 2018 NDA 2019
Tadalafil-finasteride combination tablet	BPH- enlarged prostate Erectile dysfunction Brand- Cialis/Proscar	Combination tablet containing 5 mg tadalafil and 5 mg finasteride Convenience and Compliance	Estimated US \$150	Bioequivalence study will be completed 2018 NDA 2019
Solifenacin DRG granules	Overactive bladder Brand- Vesicare	Sprinkles for dysphagia	Long term care Estimated US \$150	Bioequivalence study 2018/2019 NDA 2019/2020

Commercial
Product



FC2 Female Condom® business profitable from FY 2006- 2017¹



FC2 Female Condom only FDA approved female use product that protects against pregnancy & STDs

- ◆ Sold in U.S. and 149 countries
- ◆ Manufacturing plant with 100 million units annual capacity
- ◆ Public sector represents approx. 90% of revenue (customers include UNFPA, USAID, Brazil, and South Africa)
- ◆ FC2 business profitable from FY 2006-FY 2017¹

Global public sector revenues

- ◆ Base revenue \$14 million in FY 2017
- ◆ Awarded South African tender 8/18 - should add \$10.4 million in revenue/year for approx. \$31 million over 3 years

Building US prescription business for high margin revenue

- ◆ Working with Cardinal Distribution, Amerisource Bergen, McKesson, and Anda to support broad FC2 pharmacy availability
- ◆ Prescription business is growing

¹For fiscal year 2006 through fiscal year 2016, profitability is based on Veru's net income attributable to common stockholders. For fiscal year 2017, the first fiscal year which includes the financial results of Aspen Park Pharmaceuticals, Inc., profitability is based on operating income from our Commercial segment.

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Financial highlights (in millions)



Capitalization - approximately 54.7 million¹ 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	\$10.5

\$10 million received in March 2018 under SWK Holdings synthetic royalty financing on FC2 Female Condom® 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

¹Additional 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

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Veru projected development milestones



PRODUCT	INDICATION	2018	2019	2020	
PROSTATE CANCER NOVEL MEDICINES					
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	
UROLOGY SPECIALTY PHARMACEUTICALS					
Tamsulosin XR granules & capsules	BPH without food effect	BE3	NDA	Post approval safety study	US launch
Tadalafil-finasteride combo tablets	BPH and erectile dysfunction	BE	NDA		US launch
Solifenacin DRG granules	Overactive bladder in patients with dysphagia		BE	NDA	US launch

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