Veru Inc.
Nasdaq:VERU

The Prostate Cancer Company
Novel Medicines

October 2nd, 2019
Cantor Healthcare Conference Presentation

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; the risk that delays in orders or shipments under government tenders could cause significant quarter-to-quarter variations in the Company's operating results and adversely affect its net revenues and gross profit; 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 potential disruption of production at the Company's manufacturing facilities and/or of the Company's ability to timely supply product due to labor unrest or strikes, labor shortages, raw material shortages, physical damage to the Company's facilities, product testing, transportation delays or regulatory actions; 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, 2018. This document is available on the "SEC Filings" section of our website at 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.

Experienced in clinical practice, drug development and commercialization

Mitchell Steiner, MD

FOUNDER, CHAIRMAN, PRESIDENT & CEO

CEO & President Aspen Park Pharmaceuticals, President of Urology at OPKO Health, Inc.; CEO & Founder GTx, Inc.; Hopkins' trained urologist; Former Professor & Chairman of Urology University of Tennessee

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

FOUNDER, CHIEF CORPORATE OFFICER & VICE CHAIRMAN

Chairman Aspen Park Pharmaceuticals and Millennium Sciences, Inc.; urologist; Professor of Urology New York Presbyterian/ Weill Cornell

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

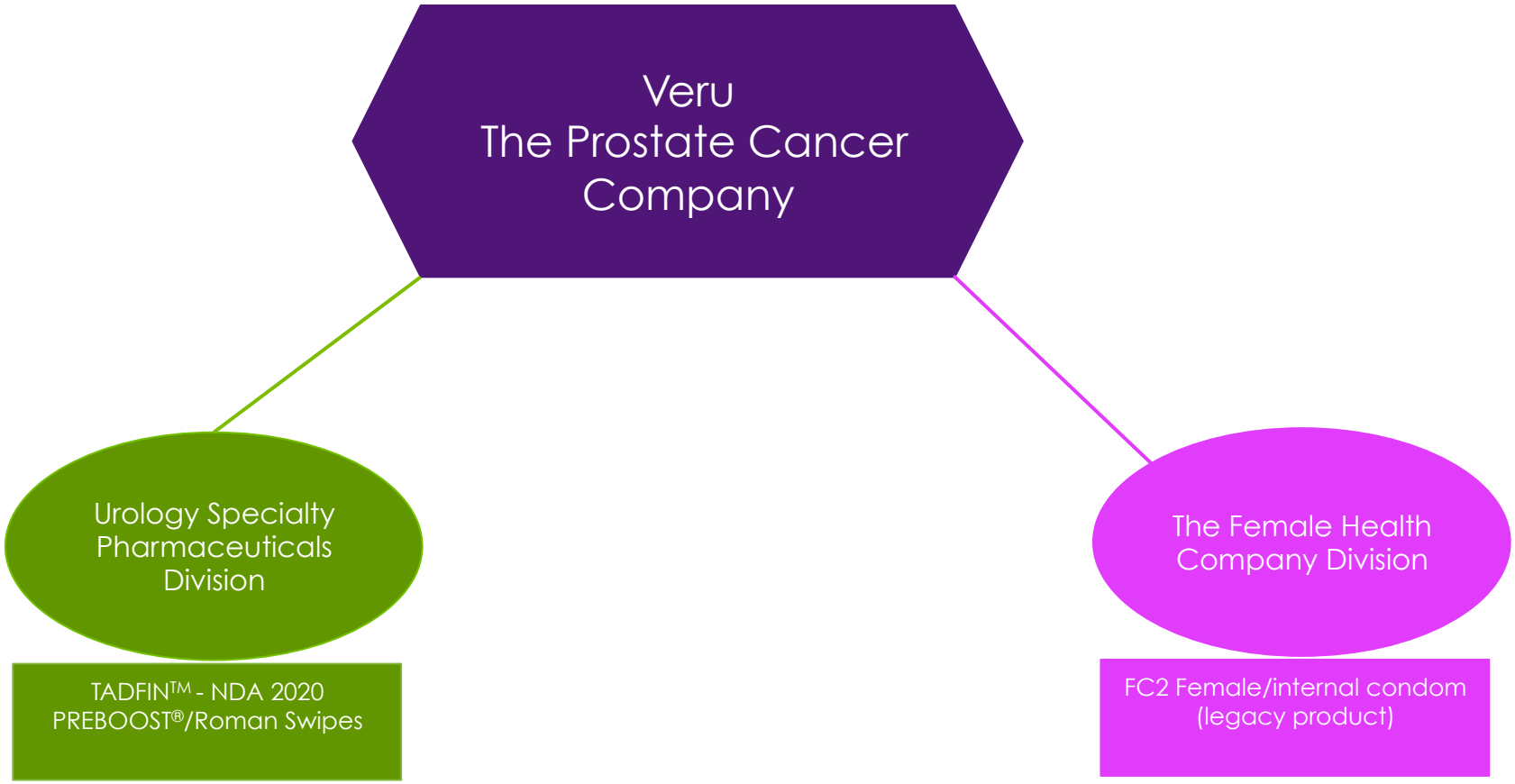
General Counsel Latin America Teva Pharmaceuticals with prior senior legal positions in international and North America divisions; Deputy General Counsel for IVAX Corporation

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

Veru, the leading prostate cancer company, has revenues from Urology Specialty Pharmaceuticals and legacy product divisions



Pipeline of proprietary product candidates and specialty pharmaceuticals

PRODUCT	INDICATION	TARGET	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	PHASE 4
PROSTATE CANCER NOVEL MEDICINES							
VERU-111	Castration resistant metastatic prostate cancer	Oral, targeted α & β tubulin inhibitor					
Zuclomiphene citrate	Hot flashes caused by prostate cancer hormone therapy	Nonsteroidal estrogen agonist					
VERU-100 3 month sc depot	Advanced hormone sensitive prostate cancer	GnRH antagonist					
UROLOGY SPECIALTY PHARMACEUTICALS							
Tadalafil-finasteride combo tablets (5mg tadalafil /5mg finasteride)	BPH & erectile dysfunction	PDE5 + 5α reductase inhibitors			Bioequivalence study		
Tamsulosin DRS granule & XR capsules (tamsulosin HCl)	BPH (no food effect)	Super selective α_1-receptor blocker with no food effect			Bioequivalence study		

Prostate Cancer - Novel Medicines

veru

Advanced prostate cancer has become a chronic disease requiring active management of the disease and side effects from existing treatments

Our Strategy

New prostate cancer treatments directed to cancer progression[1]

- Development of resistance to treatments
  - Progression to metastases
  - Skeletal related events with progression
- Inadequate androgen deprivation therapy
  - Testosterone surge during initial 2 weeks and repeated administration
  - Micro increases in testosterone above 50ng/dL
  - Testosterone not less than 20ng/dL

Prostate cancer supportive care- focuses on ameliorating side effects of cancer treatments[2]

- ADT induced estrogen deficiency related side effects
  - Hot flashes
  - Bone loss and fractures
  - Loss of libido
- Frailty- loss of muscle mass and strength because of testosterone deficiency
- Metabolic syndrome- cardiovascular events and liver disease (NASH)

[1] So A et al Can Urol Assoc J 6:465-470 2012 ; [2] Chen AC et al Current Urology Reports 6:210-216 2005

VERU-111,an oral selective antitubulin, may address largest growing unmet medical need in metastatic castration resistant prostate cancer

The main 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 and men who progress on these agents are being treated off-label with IV antitubulin chemotherapies

Current antitubulins have challenges[1]

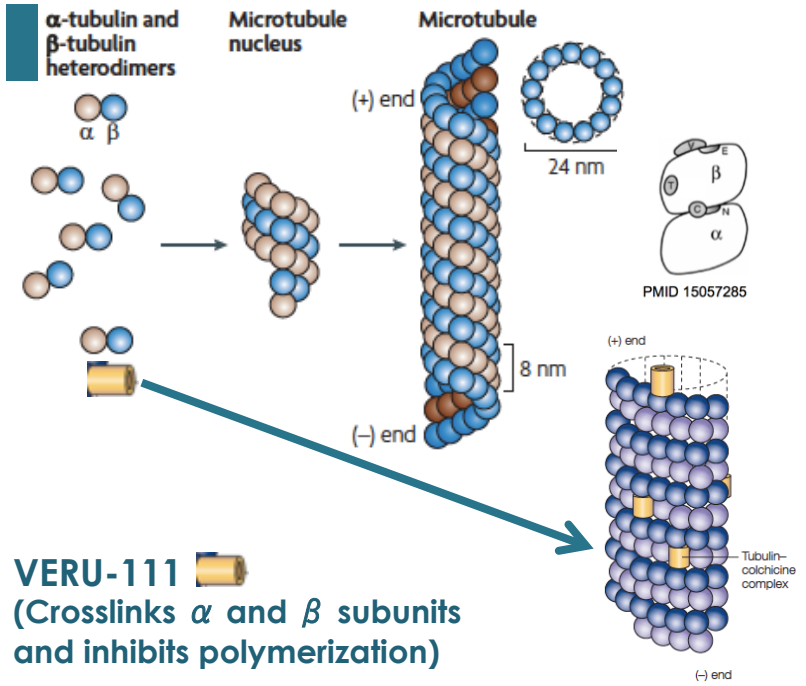
- Only available as intravenous administration
- Drug resistance is common- multidrug resistance proteins, tubulin mutations and overexpression
- Safety concerns- hypersensitivity reactions, neutropenia, and neurotoxicity (peripheral neuropathy & muscle weakness)

An oral selective antitubulin may be given by both urologists and medical oncologists

[1]Diamond E et al Curr Treat Options Oncol 16:9 2015

VERU-111 inhibits microtubule assembly by selective binding to α and β tubulin subunits of microtubules

Targets microtubule assembly



VERU-111
(Crosslinks α and β subunits and inhibits polymerization)

Preclinical Product profile[1-3]

- Low nanomolar inhibition of tubulin polymerization
- High oral bioavailability
- Not a substrate for MDRs (P-gp, MRPs, and BCRP)
- Not a substrate for CYP3A4
- Decreases production of βI, βIII and βIV tubulin isoforms
- Cleaves PARP protein
- Demonstrated activity against taxane, vinca alkaloid, doxorubicin, enzalutamide, and abiraterone resistant prostate cancers
- Favorable safety profile compared to taxanes (less neurotoxicity and no neutropenia or myelosuppression)[4]
- Has broad activity against other tumor types as well

[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 clinical development plan: PRECHEMO - castration and novel androgen blocking agent resistant metastatic prostate cancer

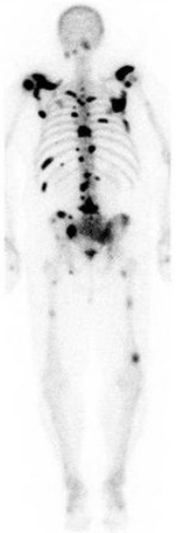
First in class, next generation, novel oral agent that targets α and β subunits of tubulin

***Indication 1- PRECHEMO- after patient becomes resistant to* novel AB agent mCRPC**

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

ADT

ADT +
novel AB agent:
enzalutamide or
abiraterone



VERU-111

This is now one of the fastest growing areas of unmet medical need in metastatic prostate cancer

Hormone sensitive metastatic prostate cancer

Castration resistant metastatic prostate cancer

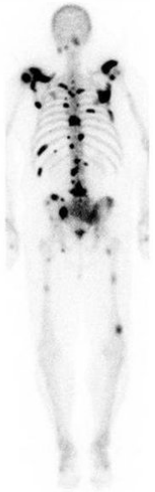
Castration and novel androgen blocking agent resistant metastatic prostate cancer

VERU-111 clinical development: we expect open label clinical data by year end 2019 and early 2020

Open label Phase 1b/2 initiated January 2019- Johns Hopkins Cancer Center and 4 other clinical centers; we have dosed 9 cohorts of 3 men (4.5mg-72 mg)

Open label Phase 1b 3+3 design

Anticipate completion by December 2019



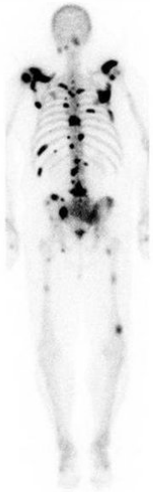
Early observations in 27 men (4.5-72mg)

- Oral bioavailability confirmed
- No dose limiting toxicity reached
  - No significant neutropenia, neurotoxicity, or LFT changes
- In some men,
  - PSA stabilizations and reductions
  - Stable bone/CT scans

N=27+ Metastatic castration and novel androgen blocking agent resistant prostate cancer ± 1 taxane

Open label Phase 2

Complete primary endpoint by year end/early 2020



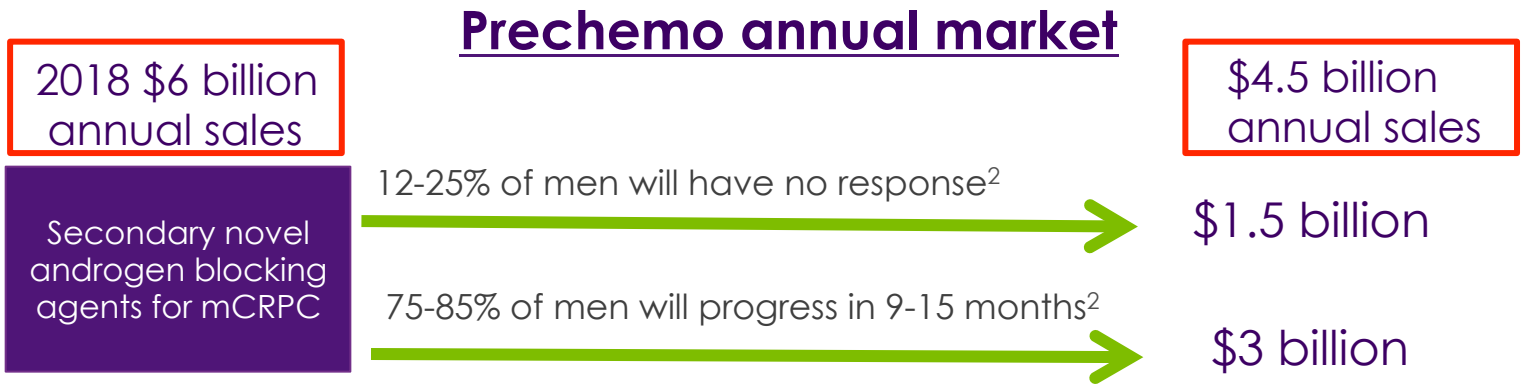
Primary endpoint- PSA reduction

N=26 Metastatic castration and novel androgen blocking agent resistant prostate cancer **PRECHEMO**

VERU-111 market opportunity

Current annual market for advanced prostate cancer drugs

- $6 billion market for secondary novel androgen blocking agents for prostate cancer in 2018[1]
  - Zytiga $3.5 billion
  - Xtandi $2.59 billion
- $1.5 billion market for taxanes for prostate cancer
  - Docetaxel $1 billion
  - Cabazitaxel $500 million in prostate cancer



[1]Pharma Intelligence 1/31/18 "How the prostate cancer market will change over next decade" by Kevin Grogan | [2] ES Antonarakis. *Clin Adv Hem Onc* 14:316-319 2016.

VERU-111 market opportunity beyond prostate cancer

VERU-111, like current antitubulins, may have efficacy against broad cancer types – Market > $5 billion

- 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

VERU-111 has applications in multiple areas of oncology; strong IP

Over 29 peer-reviewed publications

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

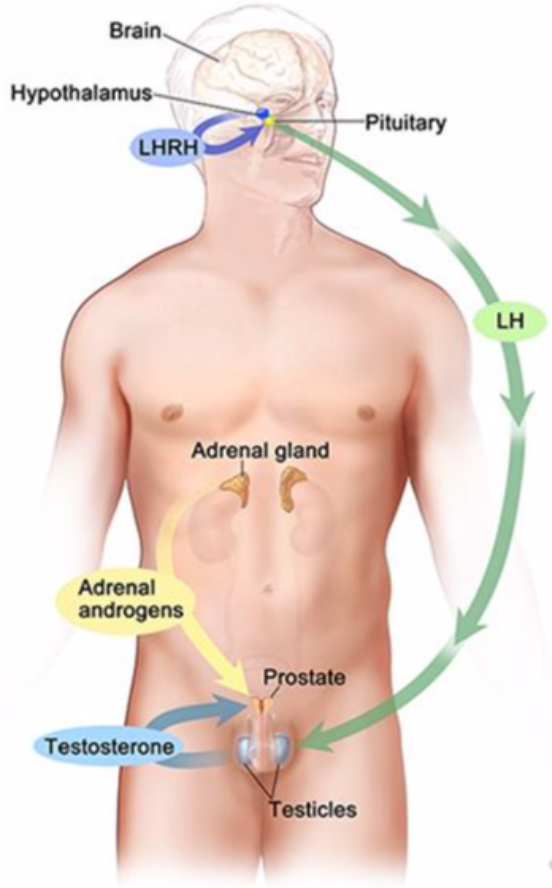
- U.S. patent expiry 2029 with possible extension to 2034 and 63 foreign granted or pending patents
- Polymorphs identified to extend time for composition of matter coverage

New commercial opportunity to become best in class androgen deprivation therapy for advanced prostate cancer

LHRH Agonist

Long-acting products: LUPRON® Depot (IM) and ELIGARD® (SC) are leuprolide products

- Concern over initial T "surge" and micro-increases
- Convenient 4 and 6 month slow release
- "Buy and bill" model attractive to community Urologists
- Most popular is 3 month depot



GnRH Antagonist

FIRMAGON® (degarelix)(SC)

- Loading Injection of 240mg in 6 mL (2 injections of 3mL each)
- Maintenance dose: 80mg (4mL) every 1 month
- Immediate castration with no initial testosterone surge
- No "black box" warning for cardiovascular adverse events

VERU-100: Long-acting 3 month depot GnRH antagonist can overtake current choices
Target product profile

- Novel proprietary GnRH antagonist decapeptide formulation[1]
- 3 month slow release subQ depot (<1 cc SQ injection) with no loading dose
- Immediate testosterone suppression no initial testosterone surge
- Suppression of testosterone to less than 20ng/dL
- Fewer testosterone escapes (micro-increases in testosterone)
- No black box warning for cardiovascular adverse effects
- Sustained suppression of FSH

[1]Developed in collaboration with Drug Delivery Experts, LLC (San Diego, California)

VERU-100 for the treatment of advanced prostate cancer
Clinical development program- now have FDA clarity

- Pre-IND meeting with FDA 4/22/19 reached agreement on an expedited regulatory pathway:
  - Single Phase 2 – Open label, multicenter dose finding study of three doses of VERU-100 in men with advanced prostate cancer (n=60-80)
  - Single Phase 3- Open label multicenter in men with advanced prostate cancer (n=100)- confirmed a single study with 100 men acceptable for pivotal study and NDA submission
- The Company plans to submit an Investigational New Drug application by no later than calendar Q1 2020 to support initiation of Phase 2 dose finding study

VERU-100 Market as ADT for advanced prostate cancer

Year	Zoladex (AZ)		Eligard (Astellas)		Gonax (Astellas)		Leuplin (Takeda)	Year	Lupron (Abbvie)		Decapeptyl (Ipsen)	
	US	Ex-US	US	Ex-US	US	Ex-US	Global		US	Ex-US	US	Ex-US
2016	$35M	$781M	-	$158M	-		$435M	**2016**	$663M	$158M	-	-
2017	$15M	$720M	-	$150M	-	$40M	$427M	**2017**	$669M	$160M	$75M	$233M
2018	$8M	$744M	$140M	$144M	-	$42M	$368M	**2018**	$726M	$166M	$87M	$228M

Year	Total	
	US	Ex-US
2018	$1,150M	$1,484 M

Total global sales of ADT drugs in 2018 was $2.6 billion

VERU-100 would have peak sales of $750 million with 28% global market share

Intellectual property

- Formulation patents owned by Veru pending expiry 2038

Androgen deprivation therapy for advanced prostate cancer
Side effects

Androgen deprivation therapy reduces both testosterone and estrogen to castrate levels

Low estrogen side effects

- Hot flashes
- Bone loss and fractures
- Loss of libido
- Memory loss
- Unfavorable lipid changes

Low testosterone side effects

- Muscle loss
- Frailty
- Muscle weakness
- Increase fat body composition

Adapted from: Freedland S et al. Prostate Cancer and Prostatic Diseases 12:333-338 2009

Hot flashes is one of the most common and debilitating side effect of androgen deprivation therapy and of novel androgen blocking agents[1,2]

Occurs in up to 80% of men treated with ADT (leuprolide or degarelix) with 30-40% having moderate to severe hot flashes[1-3]

Symptoms do not subside over time

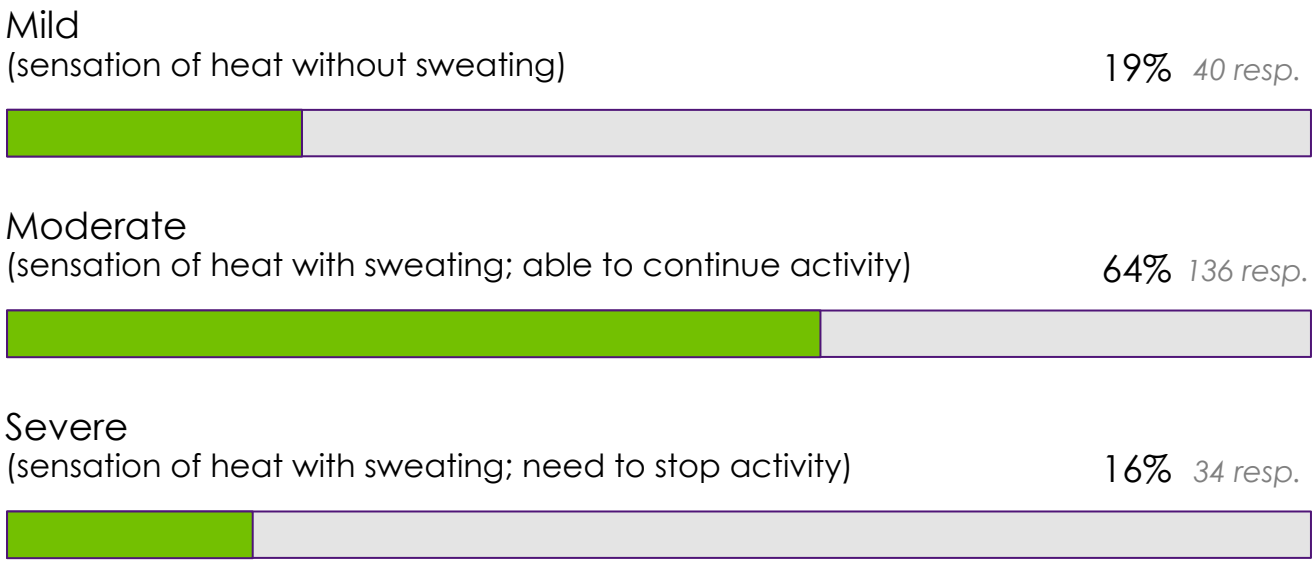
- 48% of men at 5 years and 40% of men at 8 years still suffer from hot flashes[2]

Concern over hot flashes make patients less likely to begin ADT and can lead to early discontinuation[3]

[1] Gomella LG et al *BJU Int* S1:25-29 2007 | [2] Karling P et al. *J Urol* 152:1170-1173 1994 | [3]Gonzalez BD et al J Urol 194:690-695 2015 |

Recent PCRI digital survey of 212 men on ADT September 2019
93% of survey responders suffer from hot flashes

What type of hot flashes do you suffer from on androgen deprivation therapy?

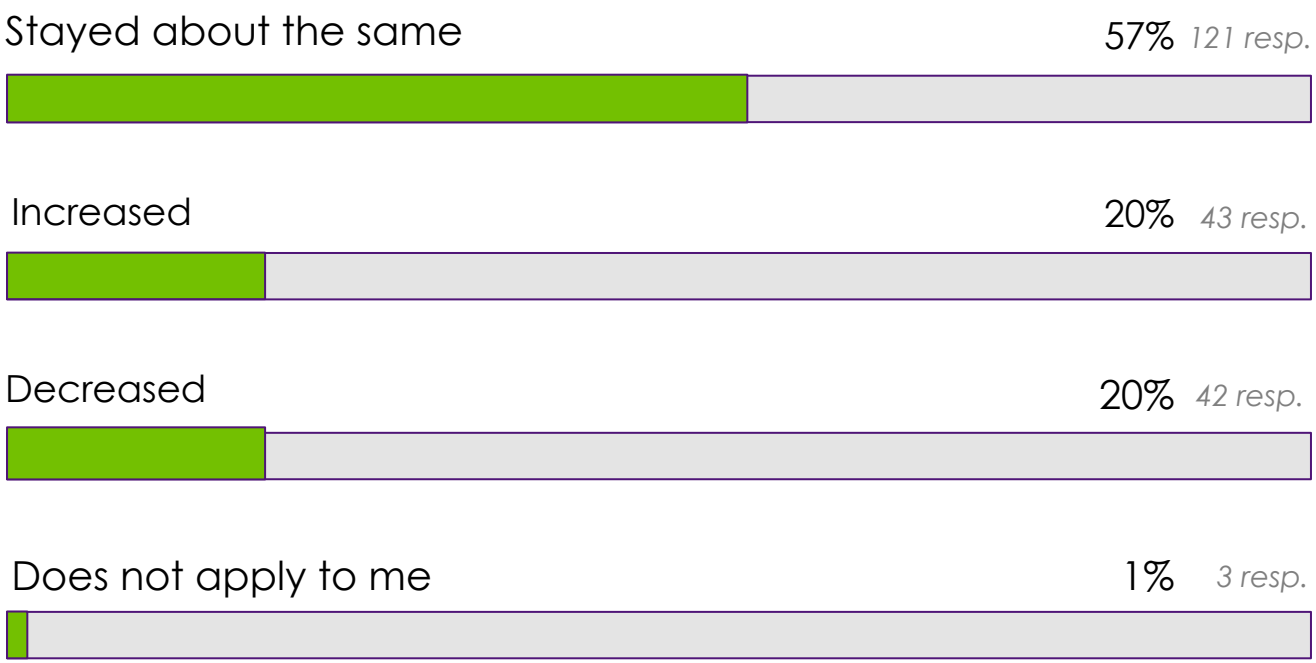


210 out of 212 answered

Prostate Cancer Research Institute (PCRI) Survey, September 2019, n=212

77% of patients report same or higher frequency of hot flashes while on ADT

Have the number of hot flashes increased or decreased over the course of your hormonal treatment?



209 out of 212 answered

PCRI Survey, September 2019, n=212

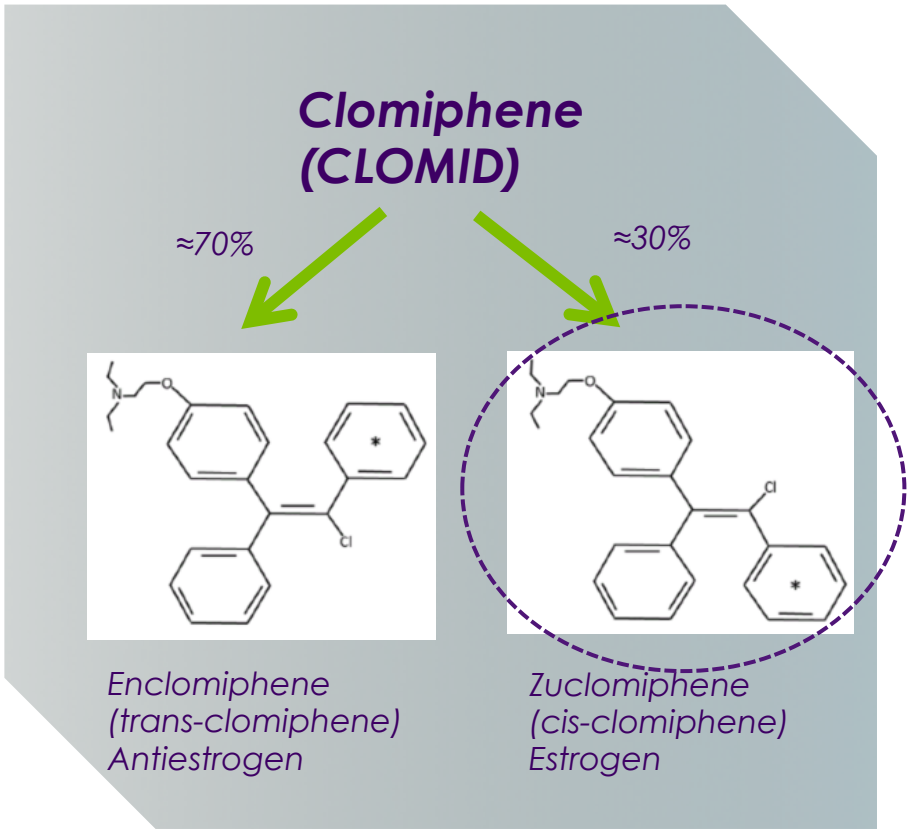
Off label treatment of hot flashes caused by ADT not adequate because of safety or efficacy concerns of current agents

Class	Drug	Efficacy hot flashes	Side effects from label and literature	Other potential benefits	FDA approved
Hormonal					
Estrogens	Estradiol DES	70-90%	Dose dependent increase in thromboembolic & CV events; breast pain (42%); increase in breast size (17%) Currently available doses are in mg (100-1000X too high); need microgram doses for hot flashes	Addresses other estrogen deficiency side effects including bone loss & fractures; loss of libido; cognitive impairment	No
Progesterone	Megestrol (Megace) Medroxyprogesterone Cyproterone acetate	70-90%	Thromboembolic & CV events (up to 30%); weight gain; bloating; fatigue; stimulates prostate cancer; weakness	None	No
Nonhormonal					
Antiseizure agents	Gabapentin Pregabalin	50-60%	Dizziness; fatigue; somnolence; cognitive difficulty; weight gain	None	No
Antidepressants	Venlafaxine Paroxetine	30-60%	Anorexia; dry mouth; insomnia; nausea &vomiting; dizziness; sexual dysfunction	None	No
NK3 antagonist	Fezolinetant	Unknown	?	None	No

Zuclomiphene is a weak oral estrogen receptor agonist

Zuclomiphene (aka *cis*-clomiphene)

- Isolated cis-clomiphene from CLOMID (30% *cis*- and 70% *trans*-clomiphene; approved in 1967 for female infertility)
- Zuclomiphene is an oral weak estrogenic agent[1] never approved as a pure isomer for any indication



[1] Fontenot G et al BJUI 117:344-350 2016

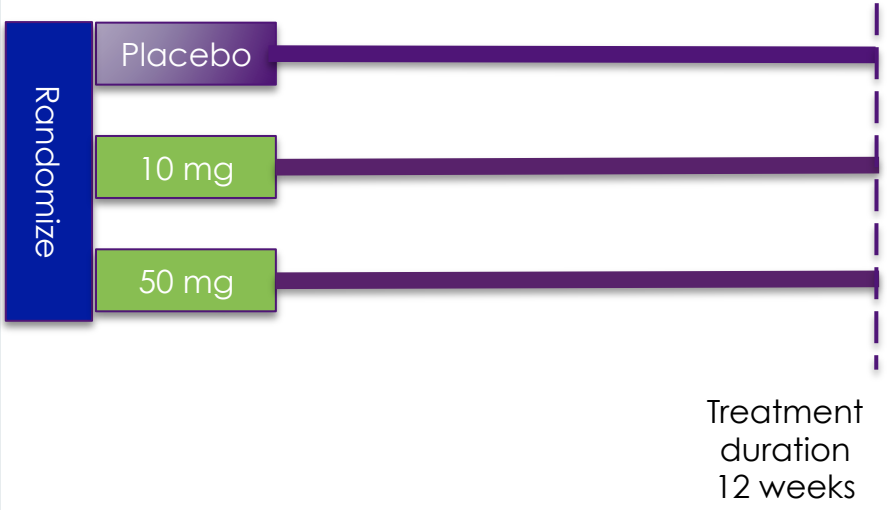
Zuclomiphene clinical development plan: Phase 2 trial design

Phase 2 placebo controlled dose finding study
Top line data expected Fall 2019

Announced 10/2/19 that enrollment goal of approximately 95 men has been achieved

Enrolled men who have moderate & severe hot flashes on ADT in ≈ 17 US clinical sites

- Primary efficacy endpoint- change in frequency of moderate & severe hot flashes
- Treatment duration is 12 weeks
- Power 80%
- Placebo effect from literature is 22%[1]
- Key secondary endpoints- bone turnover markers



Phase 3 trial is expected to have the same clinical design as this current Phase 2 trial

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

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

Market potential

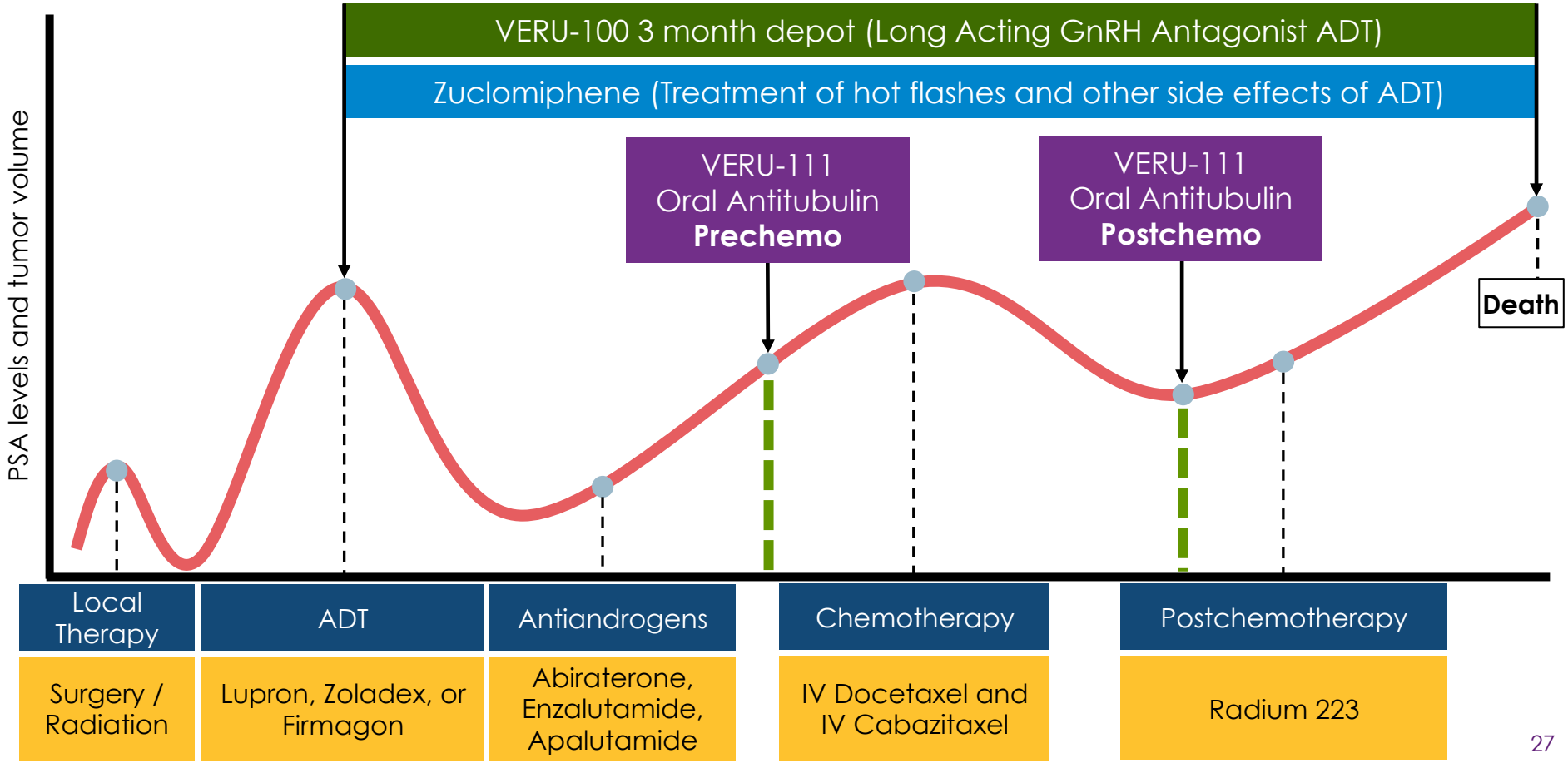
- Indication: treatment of castration-induced hot flashes in men with advanced prostate cancer on ADT
- Estimated 600,000 men on hormonal therapies (androgen deprivation therapy as well as novel androgen blocking agents) in the U.S.[1]
- Independent market research estimates $600-800 million/year expected sales for zuclomiphene in US [2]

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] Independent market research – Medical Marketing Economics, LLC 2018

Disease focused: Prostate cancer continuum of care
Prostate cancer progression and therapies



Urology Specialty Pharmaceuticals

TADFIN™ tablet (tadalafil 5mg + finasteride 5mg combo) 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[1]

- Drug-drug interaction and co-administration studies are completed for combination indication[2]

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.***[3]
- PROPECIA (finasteride 1mg) daily- symptoms of ***male pattern hair loss***

The solution: proprietary TADFIN™ tablet formulation

- Increases convenience and compliance

[1] Cialis (tadalafil) FDA Package Insert | [2]Casabé A et al. J Urol 191:727-733 2014 | [3] Unger J et al. J Natl Cancer Inst 2018

Coadministration of Tadalafil and Finasteride for 6 months more effective than finasteride alone to treat men with lower urinary tract symptoms and BPH[1]

BPH symptom score

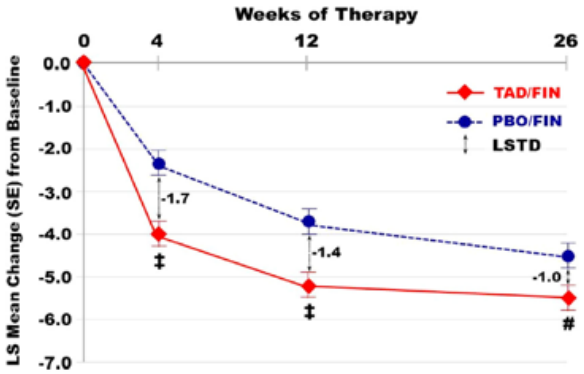


Figure 3. Time course of LS mean change (SE) from baseline in I-PSS total score. Double dagger indicates p ≤0.001 and number sign indicates p <0.05.

ED symptom score

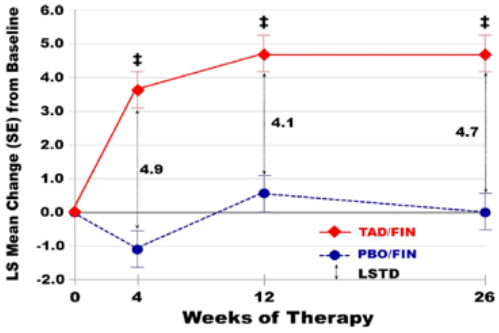


Figure 4. Time course of LS mean change (SE) from baseline in IIEF-EF score in men who were sexually active with ED at baseline (201 for PBO/FIN, 204 for TAD/FIN). Double dagger indicates p <0.001.

Safety

Table 3. *Summary of safety outcomes*

	No. PBO/FIN (%)	No. TAD/FIN (%)
At least 1 TEAE	95 (27.1)	108 (31.3)
At least 1 SAE	5 (1.4)*	9 (2.6)*
Discontinued due to AE	8 (2.3)	5 (1.4)
At least 1 treatment related AE	19 (5.4)	30 (8.7)
Frequently reported TEAEs (2% or more of pts treated with tadalafil):		
Back pain	6 (1.7)	16 (4.6)
Headache	12 (3.4)	12 (3.5)
Dyspepsia	2 (0.6)	8 (2.3)
Influenza	8 (2.3)	8 (2.3)
AEs related to sexual function:		
ED	5 (1.4)	1 (0.3)
Ejaculation delayed	0 (0.0)	1 (0.3)
Ejaculation failure	0 (0.0)	1 (0.3)
Libido decreased/lost	5 (1.4)	0 (0.0)
Peyronie disease	0 (0.0)	1 (0.3)
Semen vol decreased	0 (0.0)	1 (0.3)

* Includes 1 death in the treatment group.

- International, randomized, double-blind study in approximately 700 men
- 350 men treated with placebo + 5mg finasteride each day
- 345 men treated with 5mg tadalafil + 5mg finasteride each day

[1]Casabe A et al. J of Urol 2014; 191:717-733

Successful PreNDA meeting on Proprietary TADFIN™ capsule

- **Single dose randomized two period, crossover study in 33 healthy males over the age 45 years**
  - Successful BA/BE study
  - Tadalafil C_{max} in TADFIN is 25% less than Tadalafil alone
  - Process of getting12 month stability data on commercial batches
- **Pre-NDA meeting held May 2019**
  - NDA may be submitted after 12 months of stability data on manufactured/commercial drug batches
- **NDA expected to be submitted in Summer 2020**

TADFIN™ for benign prostatic hyperplasia - market

Market potential

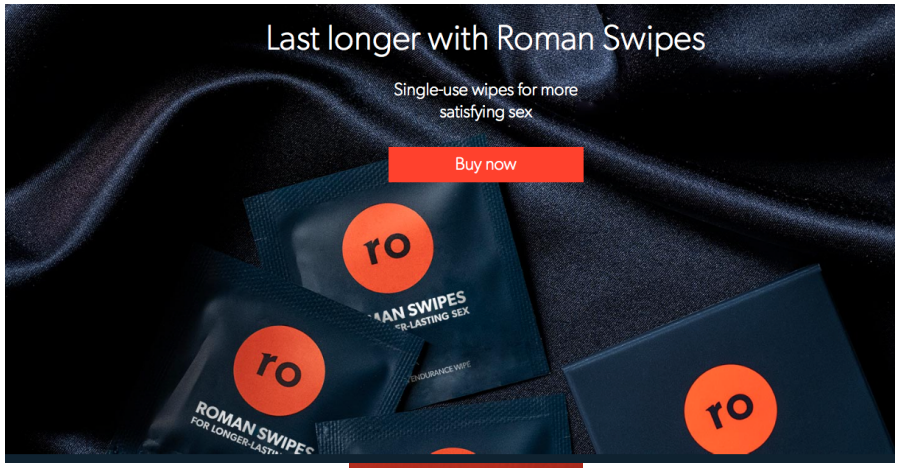
- BPH market is up to 25% of male population and estimated 1.1 billion males world wide in 2018[1]
    - Company estimates US and global markets to be >$200 million through telemedicine and salesforce channels
- Target men who have enlarged prostate >30cc as a cause for symptoms and signs of BPH and men with BPH and erectile dysfunction
- Plan to launch via telemedicine channels and license US and ex US for upfront and royalties to urology specialty pharmaceutical companies

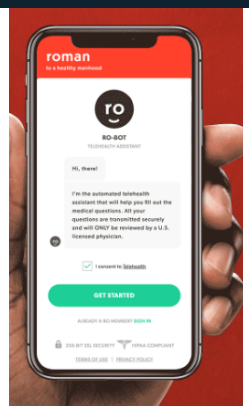
[11]Eikelany O et al. Therapeutics and Clinical Risk Management 11:507-513, 2015.

Roman Swipes (PREBOOST®; 4% benzocaine wipes for premature ejaculation)

Veru signed supply and distribution agreement with Get Roman (Roman Health Ventures Inc.) Q2 FY 2019

- Telemedicine company
- Multi-year US supply and distribution agreement
- Minimum sales requirement obligates purchase of millions/year
- US only
- Marketed as "Roman Swipes"

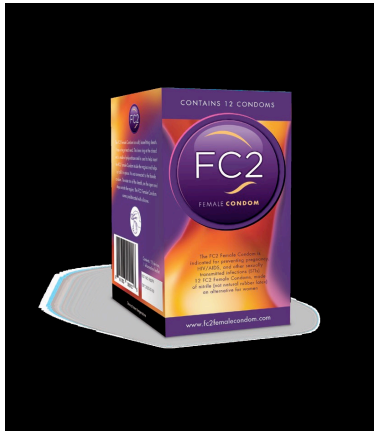




FC2 Female Condom® business revenues are growing

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

- Sold in U.S. and 150 countries
- Manufacturing plant with 100 million units annual capacity
- Public sector represents approx. 58 % of revenue (customers include UNFPA, USAID, Brazil, and South Africa) in Q3 FY 2019
- FC2 business profitable from FY 2006-present



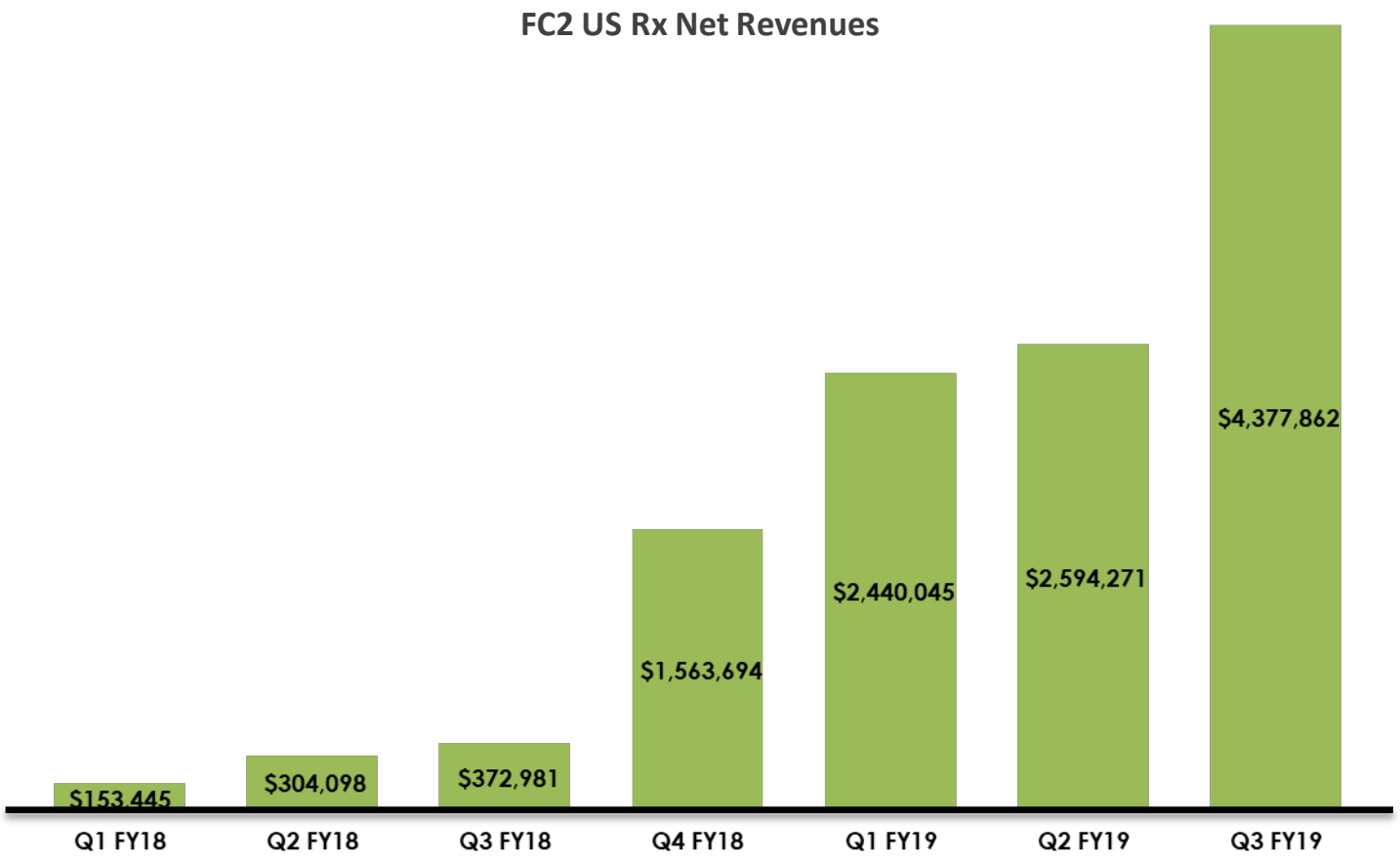
Global public sector revenues

- Base revenue $13.5 m in FY 2018
- Awarded South African tender 8/18 - should add $10.4 m in revenue/year for approx. $31 m over 3 years
- Awarded Brazil tender 12/18 up to 6 m units

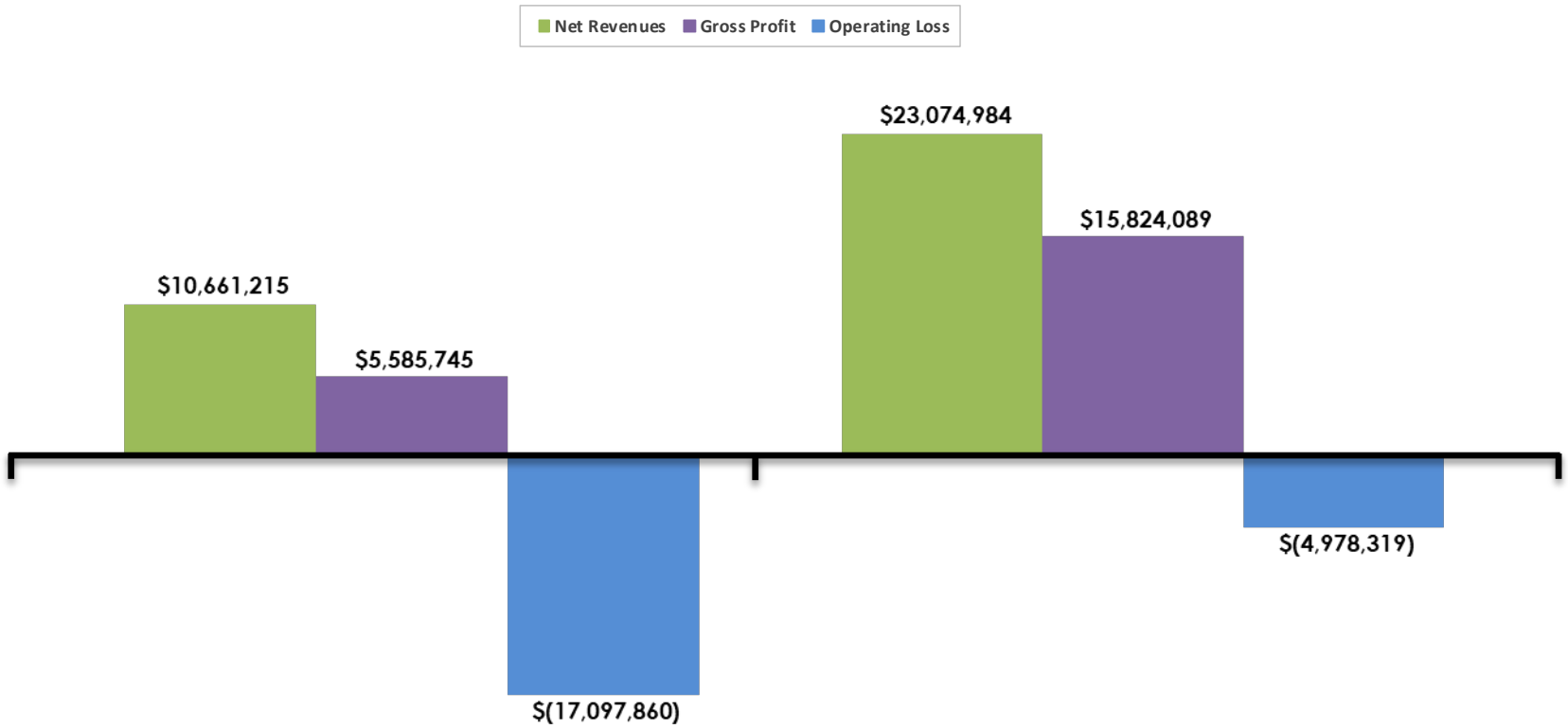
Building US prescription business for high margin revenues

- Working with Cardinal Distribution, Amerisource Bergen, McKesson, and Anda to support broad FC2 pharmacy availability
- Prescription business is growing via existing and new contracts with multiple telemedicine partners

Financial highlights: FC2 US prescription business net revenues



Financial highlights: Veru Business June FYTD 2018 versus June FYTD 2019



Financial highlights (in millions)

Capitalization – approximately 64.8 million[1] common shares outstanding as of June 30, 2019

Revenue Estimate for FY 2019 between $29 and $32

Results of Operations for June FYTD 2019

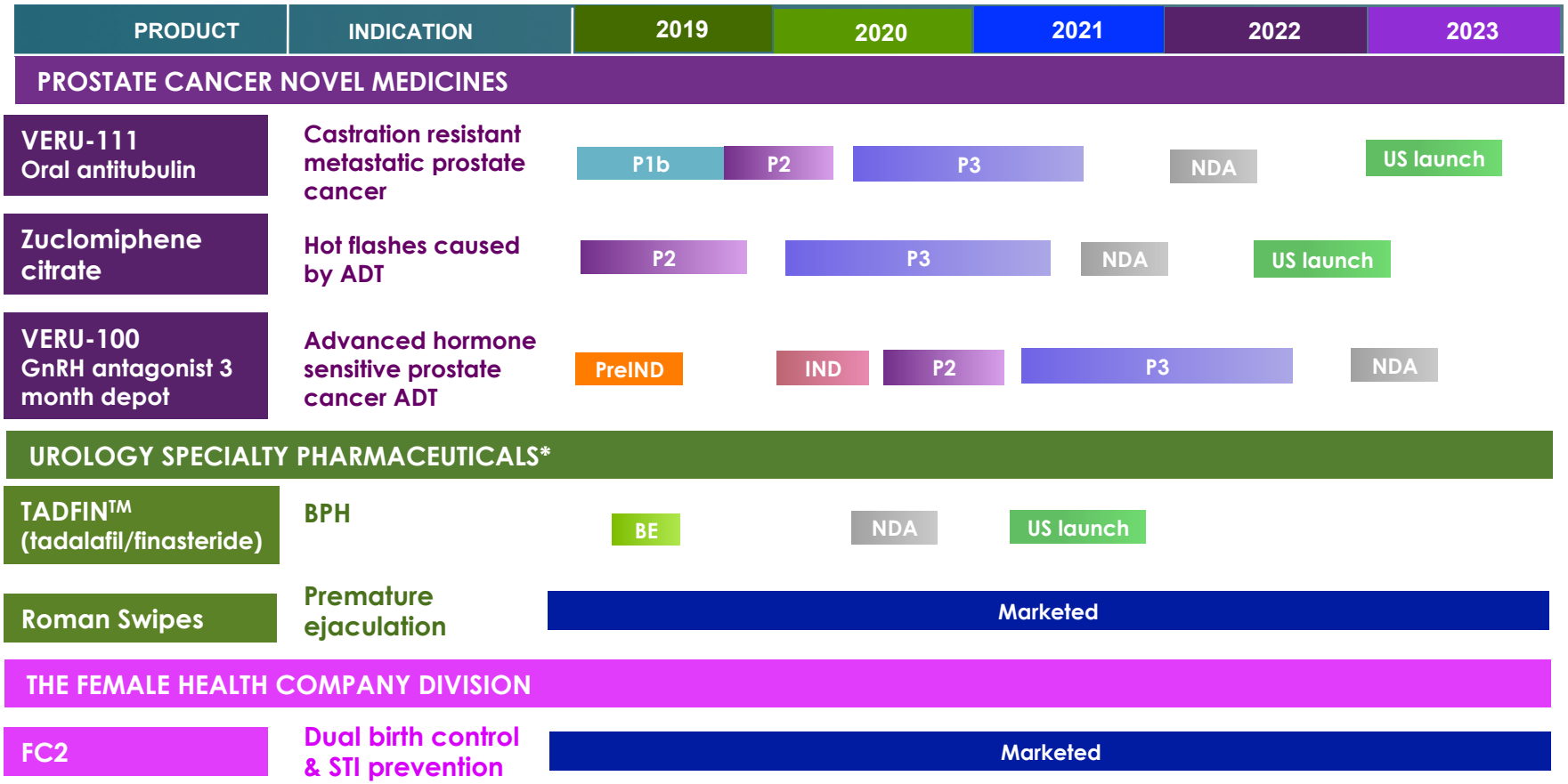
◆ Net revenues	$ 23.1
◆ Gross profit	$ 15.8
◆ Operating loss	$ 5.0

Balance sheet as of June 30, 2019

◆ **Cash & A/R**	**$12.8**
◆ Cash	$ 8.0
◆ Receivables	$ 4.8
◆ UK NOL carryforward	$ 62.3
◆ US NOL carryforward	$ 33.2

[1]An aggregate of 9.9 million stock options, stock appreciation rights, and warrants are outstanding and are, or could potentially be, dilutive in excess of the 64.8 million common shares above

Veru projected milestones



*Tamsulosin DRS granules and XR capsules and Solifenacin granules development programs are on hold for now

Key takeaways

- **Clinical stage assets in prostate cancer treatment and supportive care will have patient results in 2019 for VERU-111 and Zuclomiphene**
  - VERU-111 Phase 1b/2 for metastatic castration and androgen blocking agent resistant prostate cancer
  - Zuclomiphene Phase 2 for hot flashes in men on ADT
  - VERU-100 3 month depot planned Phase 2 after GMP scale up with expected IND early 2020; FDA confirmed VERU-100 qualifies for expedited regulatory pathway
- **Sales of urology specialty products and legacy product- FC2 will continue to deliver strong sales to invest in the development of clinical prostate cancer drugs**
  - PREBOOST/ROMAN SWIPES-growing sales via telemedicine
  - FC2 internal/female condom-growing sales global public sector and US prescription business
  - TADFIN™ for BPH and erectile dysfunction NDA Summer 2020 with launch early 2021
- **Based on current cash proceeds and expected cash from current sales forecasts along with existing sources of capital, the company does not anticipate the need for a new equity financing until at least 2021**

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