The Prostate Cancer Company
Novel Medicines

June 2019
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/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.
# Pipeline of proprietary product candidates and specialty pharmaceuticals

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>INDICATION</th>
<th>TARGET</th>
<th>PRECLINICAL</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>PHASE 4</th>
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<tbody>
<tr>
<td><strong>PROSTATE CANCER NOVEL MEDICINES</strong></td>
<td></td>
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<tr>
<td>VERU-111</td>
<td>Castration resistant metastatic prostate cancer</td>
<td>Oral, targeted α &amp; β tubulin inhibitor</td>
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<tr>
<td>Zuclomiphene citrate</td>
<td>Hot flashes caused by prostate cancer hormone therapy</td>
<td>Nonsteroidal estrogen agonist</td>
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<tr>
<td>VERU-100 3month depot</td>
<td>Advanced hormone sensitive prostate cancer</td>
<td>GnRH antagonist</td>
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<tr>
<td><strong>UROLOGY SPECIALTY PHARMACEUTICALS</strong></td>
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<tr>
<td>Tadalafil-finasteride combo tablets (5mg tadalafil/5mg finasteride)</td>
<td>BPH &amp; erectile dysfunction</td>
<td>PDE5 + 5α reductase inhibitors</td>
<td>Bioequivalence study</td>
<td>Completed</td>
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<td>Tamsulosin DRS granule &amp; XR capsules (tamsulosin HCl)</td>
<td>BPH (no food effect)</td>
<td>Super selective α₁-receptor blocker with no food effect</td>
<td>Bioequivalence study</td>
<td></td>
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</tr>
<tr>
<td>Name</td>
<td>Title</td>
<td>Background</td>
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<tr>
<td>Mitchell Steiner, MD</td>
<td>FOUNDER, CHAIRMAN, PRESIDENT &amp; CEO</td>
<td>CEO &amp; President Aspen Park Pharmaceuticals, President of Urology at OPKO Health, Inc.; CEO &amp; Founder GTx, Inc.; Hopkins’ trained urologist; Former Professor &amp; Chairman of Urology University of Tennessee</td>
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<tr>
<td>Michele Greco, CPA</td>
<td>CHIEF FINANCIAL &amp; ADMINISTRATIVE OFFICER</td>
<td>CFO/EVP The Female Health Company, 28 years with Ernst &amp; Young, 15 years as an Audit Partner</td>
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<tr>
<td>Gary Barnette, PhD</td>
<td>CHIEF SCIENTIFIC OFFICER</td>
<td>Sr. VP Scientific and Reg Affairs Camargo Pharm. Services, VP Clinical &amp; Reg and Founder GTx, Inc., Director Reg Affairs Solvay Pharma, Clinical Pharmacology/ Biopharmaceutics Reviewer FDA, PhD Basic Pharmaceutical Sciences West Virginia University</td>
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<tr>
<td>Harry Fisch, MD</td>
<td>FOUNDER, CHIEF CORPORATE OFFICER &amp; VICE CHAIRMAN</td>
<td>Chairman Aspen Park Pharmaceuticals and Millennium Sciences, Inc.; urologist; Professor of Urology New York Presbyterian/Weill Cornell</td>
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<tr>
<td>Kevin Gilbert, JD, CPA</td>
<td>EVP CORPORATE DEVELOPMENT</td>
<td>Corporate Development &amp; Legal, Third Stream Bioscience, Attorney at McDermott, Will &amp; Emery, Motorola, closed more than 100 transactions in 25 countries</td>
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<tr>
<td>Philip Greenberg, JD</td>
<td>EVP LEGAL</td>
<td>General Counsel Latin America Teva Pharmaceuticals with prior senior legal positions in international and North America divisions; Deputy General Counsel for IVAX Corporation</td>
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</tr>
<tr>
<td>Phil Kuhn, MBA</td>
<td>EVP STRATEGY AND COMMERCIALIZATION</td>
<td>Global Strategy and Commercial expertise in medical devices, diagnostics, and biologics; leadership roles at ISTO Biologics, Orthofix, Smith &amp; Nephew, Boston Scientific, Johnson &amp; Johnson, and Abbott</td>
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</table>
Veru is a leading prostate cancer company, but has revenues from Urology Specialty Pharmaceuticals and legacy product divisions.

Veru
The Prostate Cancer Company

Urology Specialty Pharmaceuticals Division

TADFIN™ - NDA 2020
PREBOOST®/Roman Swipes

The Female Health Company Division

FC2 Female/internal condom (legacy product)
Prostate Cancer - Novel Medicines
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**

- 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**

- 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)

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VERU-111, an oral selective antitubulin, may address largest growing unmet medical need in refractory metastatic 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:
- 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.

1Diamond 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.

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

Destabilizes 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
VERU-111: novel, oral, next generation, selective tubulin inhibitor targeting \( \alpha \) and \( \beta \) subunits of microtubules

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 \( \beta \) I, \( \beta \) III and \( \beta \) IV tubulin isoforms and 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

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 $\alpha$ and $\beta$ subunits of tubulin

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

Hormone sensitive metastatic prostate cancer

Castration resistant metastatic prostate cancer

Castration and novel androgen blocking agent resistant metastatic prostate cancer

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

This is now one of the fastest growing areas of unmet medical need in metastatic prostate cancer
**VERU-111 clinical development: we expect open label clinical data by summer of 2019**

**Open label Phase 1b/2 initiated January 2019 - Johns Hopkins Cancer Center and 4 other clinical centers**

- **Open label Phase 1b, 3+3 design**
  - N=18
  - Metastatic castration and novel androgen blocking agent resistant prostate cancer ± 1 taxane

- **Phase 2, Open label**
  - Complete primary endpoint by year end
  - N=26
  - Metastatic castration and novel androgen blocking agent resistant prostate cancer
  - PRECHETO

- **Primary endpoint - PSA reduction**
  - Complete by summer 2019
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

**Prechemo annual market**

- 2018 $6 billion annual sales
- Secondary novel androgen blocking agents for mCRPC
- 12-25% of men will have no response\(^2\)
- 75-85% of men will progress in 9-15 months\(^2\)
- $4.5 billion annual sales
- $1.5 billion
- $3 billion

\(^1\)Pharma Intelligence 1/31/18 “How the prostate cancer market will change over next decade” by Kevin Grogan
VERU-111 strategy is to partner asset: Recent deals for metastatic castration resistant prostate cancer

<table>
<thead>
<tr>
<th>Date</th>
<th>Company/drug</th>
<th>Phase completed</th>
<th>Partner/ Purchaser</th>
<th>Deal terms/Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>Medivation</td>
<td>Phase 2</td>
<td>Astellas</td>
<td>$110 upfront Split US costs Astellas pays all exUS costs 50:50 US co-promote 20% royalty ROW</td>
</tr>
<tr>
<td></td>
<td>Xtandi</td>
<td></td>
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</tr>
<tr>
<td>2016</td>
<td>Medivation</td>
<td>Product launched</td>
<td>Pfizer</td>
<td>$14 billion</td>
</tr>
<tr>
<td></td>
<td>Xtandi</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>Cougar</td>
<td>Phase 2</td>
<td>J and J</td>
<td>$1 billion</td>
</tr>
<tr>
<td></td>
<td>Zytiga</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>Aragon</td>
<td>Phase 1</td>
<td>J and J</td>
<td>$1 billion</td>
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<td></td>
<td>ARN509</td>
<td></td>
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<tr>
<td>2018</td>
<td>Endocyte</td>
<td>Phase 2</td>
<td>Novartis</td>
<td>$2.1 billion</td>
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<td>177Lu-PSMA-617</td>
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</table>
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

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1 Pharma Intelligence 1/31/18 “How the prostate cancer market will change over next decade” by Kevin Grogan
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
Hot flashes is one of the most common and debilitating side effect of androgen deprivation therapy and of novel androgen blocking agents\textsuperscript{1,2}

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

Symptoms do not subside over time

\begin{itemize}
  \item 48\% of men at 5 years and 40\% of men at 8 years still suffer from hot flashes\textsuperscript{2}
\end{itemize}

Concern over hot flashes make patients less likely to begin ADT and can lead to early discontinuation\textsuperscript{3}

ADT reduces testosterone and estrogen to castration levels

- ADT lowers testosterone to castrate levels. As estrogen is derived from testosterone, ADT lowers estrogen levels too!

- Estrogen deficiency related side effects
  - Hot flashes - most common side effect
  - Bone loss and fractures
  - Loss of libido
  - Loss of memory and other cognitive impairments
  - Cardiovascular and lipid disturbances
How does low estrogen levels cause hot flashes?

ADT reduces testosterone which in turn drops estrogens to castrate levels.

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5. FDA Guidance for Industry Estrogen...to Treat Vasomotor Symptoms January 2003
### Off label treatment of hot flashes caused by ADT not adequate because of safety or efficacy concerns of current agents

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

Zuclomiphene (aka cis-clomiphene)

- FDA database and scientific literature show zuclomiphene component of CLOMID is well tolerated with over 88,000 men/year using CLOMID off label for infertility or hypogonadism\(^1\)

### Number of Prescriptions

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

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

\(^1\) Camargo Pharma Clinical Report 3/17 and FDA Briefing Document BRUDAC Advisory meeting 12/16
Phase 2 placebo controlled dose finding study
Top line data expected summer 2019

Plan to enroll ≈100 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 from baseline to weeks 4-12
- Power 80%; 40% improvement compared to placebo
- Placebo effect from literature is 22%<sup>1</sup>
- Key secondary endpoints- bone turnover markers

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<sup>1</sup> Lapinzi 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 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

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Zuclomiphene Revenue Potential

<table>
<thead>
<tr>
<th>Market Segments</th>
<th>Estimates</th>
<th>Sources</th>
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<tbody>
<tr>
<td>Prostate cancer prevalence</td>
<td>3,120,176</td>
<td>National Cancer Institute</td>
</tr>
<tr>
<td>Prostate cancer patients on ADT</td>
<td>39%</td>
<td>National Collaborating Centre for Cancer (UK); 2014 Jan.</td>
</tr>
<tr>
<td>% pts on ADT with moderate to severe hot flashes</td>
<td>50%</td>
<td>Cancer.net - up to 75% of ADT patients have hot flashes</td>
</tr>
<tr>
<td># pts on ADT with moderate to severe hot flashes</td>
<td>608,434</td>
<td>MME qual research - ~50% mild, ~35% moderate and ~15% severe</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monthly Price</th>
<th>$250</th>
<th>$350</th>
<th>$450</th>
<th>$600</th>
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<tbody>
<tr>
<td>Annual Price</td>
<td>$3,000</td>
<td>$4,200</td>
<td>$5,400</td>
<td>$7,200</td>
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<tr>
<td>ADT Hot Flash Patient Share</td>
<td>$183</td>
<td>$256</td>
<td>$329</td>
<td>$438</td>
</tr>
<tr>
<td>25%</td>
<td>$456</td>
<td>$639</td>
<td>$821</td>
<td>$1,095</td>
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<tr>
<td>33%</td>
<td>$602</td>
<td>$843</td>
<td>$1,084</td>
<td>$1,446</td>
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<tr>
<td>50%</td>
<td>$913</td>
<td>$1,278</td>
<td>$1,643</td>
<td>$2,190</td>
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</tbody>
</table>

US Revenue ($million)

1 Medical Marketing Economics, Inc. Independent company sponsored market research (data on file)
### Androgen deprivation therapy - current situation

<table>
<thead>
<tr>
<th><strong>GnRH Antagonist</strong></th>
<th><strong>LHRH Agonist</strong></th>
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<tbody>
<tr>
<td><strong>FIRMAGON® (degarelix)(SC)</strong></td>
<td>Long-acting products: LUPRON® Depot (IM) and ELIGARD® (SC) are leuprolide products</td>
</tr>
<tr>
<td>• Loading Injection of 240mg in 6 mL (2 injections of 3mL each)</td>
<td>• Concern over initial T “surge” and micro-increases</td>
</tr>
<tr>
<td>• Maintenance dose: 80mg (4mL) every 1 month</td>
<td>• Convenient 4 and 6 month slow release</td>
</tr>
<tr>
<td>• Immediate castration with no initial testosterone surge</td>
<td>• “Buy and bill” model attractive to community Urologists</td>
</tr>
<tr>
<td>• No “black box” warning for cardiovascular adverse events</td>
<td>• Most popular is 3 month depot</td>
</tr>
</tbody>
</table>

- **Common protocol in real-world clinical practice:**
  - Start patient off with degarelix injection (rapid T suppression)
  - Continue maintenance with leuprolide

- **Opportunity:** Long-acting 3 month depot form of GnRH antagonist can overtake current market leaders
VERU-100 a biologic for the treatment of advanced prostate cancer
Target product profile

- Novel proprietary GnRH antagonist decapeptide formulation
- 3 month slow release subQ depot (<1 cc SQ injection) and 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

1Developed 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

• PreIND 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

• Scaling up GMP clinical and commercial drug product using contract manufacturer

• The Company plans to submit an Investigational New Drug application by no later than calendar Q1 2020
## VERU-100 Market as ADT for advanced prostate cancer

### Table: Global Sales of ADT Drugs

<table>
<thead>
<tr>
<th>Year</th>
<th>Zoladex (AZ)</th>
<th>Eligard (Astellas)</th>
<th>Gonax (Astellas)</th>
<th>Leuplin (Takeda)</th>
<th>Year</th>
<th>Lupron (Abbvie)</th>
<th>Decapeptyl (Ipsen)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>$35M</td>
<td>$781M</td>
<td>-</td>
<td>$158M</td>
<td>-</td>
<td></td>
<td>$435M</td>
</tr>
<tr>
<td>2017</td>
<td>$15M</td>
<td>$720M</td>
<td>-</td>
<td>$150M</td>
<td>-</td>
<td>$40M</td>
<td>$427M</td>
</tr>
<tr>
<td>2018</td>
<td>$8M</td>
<td>$744M</td>
<td>$140M</td>
<td>$144M</td>
<td>-</td>
<td>$42M</td>
<td>$368M</td>
</tr>
</tbody>
</table>

### 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
Disease focused: Prostate cancer continuum of care
Prostate Cancer Progression and Therapy

VERU-100 3 month depot (Long Acting GnRH Antagonist ADT)
Zuclomiphene (Treatment of hot flashes and other side effects of ADT)

VERU-111 Oral Antitubulin

VERU-111 Oral Antitubulin

Death

PSA levels and tumor volume

Local Therapy
Surgery / Radiation

ADT
Lupron, Zoladex, or Firmagon

Antiandrogens
Abiraterone, Enzalutamide, Apalutamide

Chemotherapy
IV Docetaxel

Postchemotherapy
IV Cabazitaxel
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 weeks¹

- Drug-drug interaction and co-administration studies are completed for combination indication²

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

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

**BPH symptom score**

**ED symptom score**

**Safety**

![Graphs showing BPH and ED symptom scores over weeks of therapy](image)

- 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

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**Table 3. Summary of safety outcomes**

<table>
<thead>
<tr>
<th>Safety Parameter</th>
<th>No. PBO/FIN (%)</th>
<th>No. TAD/FIN (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least 1 TEAE</td>
<td>95 (27.1)</td>
<td>9 (2.6)*</td>
</tr>
<tr>
<td>At least 1 SAE</td>
<td>5 (2.3)</td>
<td>4 (1.4)</td>
</tr>
<tr>
<td>Discontinued due to AE</td>
<td>8 (2.3)</td>
<td>5 (1.4)</td>
</tr>
<tr>
<td>At least 1 treatment related AE</td>
<td>19 (5.4)</td>
<td>30 (8.7)</td>
</tr>
<tr>
<td>Frequently reported TEAEs 5% or more of pts treated with tadalafil:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back pain</td>
<td>12 (3.5)</td>
<td>16 (4.6)</td>
</tr>
<tr>
<td>Headache</td>
<td>2 (0.5)</td>
<td>8 (2.3)</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>2 (0.5)</td>
<td>8 (2.3)</td>
</tr>
<tr>
<td>Influenza</td>
<td>2 (0.5)</td>
<td>8 (2.3)</td>
</tr>
<tr>
<td>AEs related to sexual function:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ED</td>
<td>5 (1.4)</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Ejaculation delayed</td>
<td>0 (0.0)</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Ejaculation failure</td>
<td>0 (0.0)</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Libido decreased/hot</td>
<td>5 (1.4)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Peyronie disease</td>
<td>0 (0.0)</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Semen vol decreased</td>
<td>0 (0.0)</td>
<td>1 (0.3)</td>
</tr>
</tbody>
</table>

*Includes 1 death in the treatment group.

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1Casabe A et al. J of Urol 2014; 191:717-733
Coadministration of Tadalafil and Finasteride versus Finasteride for 6 months improves erectile function in men with or without erectile dysfunction\(^1\)

\(^1\) Glina S et al. J Sex Med 2015; 12:129-138 – Question 3 is vaginal penetrative ability and Question 4 is erection maintenance
Successful Proprietary TADFIN™ tablet BA/BE study

• Single dose randomized two period, crossover study in 33 healthy males over the age 45 years
  • Successful BA/BE study
  • Tadalafil $C_{\text{max}}$ in TADFIN is 25% less than Tadalafil alone
  • Process of getting 6 month stability data on commercial batches
• NDA expected to be submitted in late 2019 to early 2020 and approval expected 2020
• New formulation patent application filed with expected expiry 2040
Market potential

• BPH market is up to 25% of male population and estimated 1.1 billion males worldwide in 2018\(^1\)
  • Independent market research by MME and telemedicine estimates US and global markets to be >$200 million

• 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

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 is growing

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. 61% of revenue (customers include UNFPA, USAID, Brazil, and South Africa) in Q1 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 multiple telemedicine partners
Financial highlights: Veru Business Q2 FY 2018 versus Q2 FY 2019

<table>
<thead>
<tr>
<th></th>
<th>Q2 FY18</th>
<th>Q2 FY19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Revenues</td>
<td>$2,572,872</td>
<td>$6,976,115</td>
</tr>
<tr>
<td>Gross Profit</td>
<td>$(4,696,550)</td>
<td>$4,608,851</td>
</tr>
<tr>
<td>Operating Loss</td>
<td>$(2,124,590)</td>
<td></td>
</tr>
</tbody>
</table>
### Financial highlights: Veru Business Mar FYTD 2018 versus Mar FYTD 2019

<table>
<thead>
<tr>
<th>Mar FYTD18</th>
<th>Mar FYTD19</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Net Revenues</strong></td>
<td><strong>$13,347,924</strong></td>
</tr>
<tr>
<td><strong>Gross Profit</strong></td>
<td><strong>$9,252,931</strong></td>
</tr>
<tr>
<td><strong>Operating Loss</strong></td>
<td><strong>$(12,133,131)</strong></td>
</tr>
<tr>
<td><strong>Net Revenues</strong></td>
<td><strong>$5,159,485</strong></td>
</tr>
<tr>
<td><strong>Gross Profit</strong></td>
<td><strong>$2,511,557</strong></td>
</tr>
<tr>
<td><strong>Operating Loss</strong></td>
<td><strong>$(3,136,317)</strong></td>
</tr>
</tbody>
</table>

The chart above illustrates the comparison of net revenues, gross profit, and operating loss for Veru Business between March FYTD 2018 and March FYTD 2019.
Financial highlights: FC2 US prescription business net revenues

FC2 US Rx Net Revenues

- Q1 FY18: $153,445
- Q2 FY18: $304,098
- Q3 FY18: $372,981
- Q4 FY18: $1,563,694
- Q1 FY19: $2,440,045
- Q2 FY19: $2,594,271
Capitalization – approximately 62.8 million\(^1\) common shares outstanding as of March 31, 2019

Revenue Estimate for FY 2019 between $29 and $32

Results of Operations for Mar FYTD 2019

- Net revenues: $13.3
- Gross profit: $9.3
- Operating loss: $3.1

Balance sheet as of March 31, 2019

- Cash: $5.9
- Receivables: $4.0
- UK NOL carryforward: $62.3
- US NOL carryforward: $33.2

\(^1\)An aggregate of 8.8 million stock options, stock appreciation rights, and warrants are outstanding and are, or could potentially be, dilutive in excess of the 62.8 million common shares above
### Veru projected milestones

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>INDICATION</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PROTATE CANCER NOVEL MEDICINES</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>VERU-111 Oral antitubulin</td>
<td>Castration resistant metastatic prostate cancer</td>
<td>P1b</td>
<td>P2</td>
<td>P3</td>
<td>NDA</td>
<td>US launch</td>
</tr>
<tr>
<td>Zuclomiphene citrate</td>
<td>Hot flashes caused by ADT</td>
<td>P2</td>
<td>P3</td>
<td>NDA</td>
<td>US launch</td>
<td></td>
</tr>
<tr>
<td>VERU-100 GnRH antagonist 3 month depot</td>
<td>Advanced hormone sensitive prostate cancer ADT</td>
<td>PreIND</td>
<td>IND</td>
<td>P2</td>
<td>P3</td>
<td>NDA</td>
</tr>
<tr>
<td><strong>UROLOGY SPECIALTY PHARMACEUTICALS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TADFIN™ (tadalafil/finasteride)</td>
<td>BPH and erectile dysfunction</td>
<td>BE</td>
<td>NDA</td>
<td>US launch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roman Swipes</td>
<td>Premature ejaculation</td>
<td></td>
<td></td>
<td>Marketed</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>THE FEMALE HEALTH COMPANY DIVISION</strong></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>FC2</td>
<td>Dual birth control &amp; STI prevention</td>
<td></td>
<td></td>
<td>Marketed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

- Clinical stage assets in prostate cancer supportive care and treatment 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 late 2019 to early 2020 with launch 2020

- 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