The Prostate Cancer Company
Novel Medicines

Veru Corporate Presentation
June 2020
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, the following: 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 timing of and results from clinical trials and studies, including potential delays in the recruitment of patients and their ability to effectively participate in such trials and studies due to COVID-19, and the risk that such results will not support marketing approval and commercialization; potential delays in the timing of any submission to the FDA and regulatory approval of products under development and the risk that disruptions at the FDA caused by the COVID-19 pandemic may delay the review of submissions or approvals for new drugs; clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all; the Company’s pursuit of a COVID-19 treatment candidate is at an early stage and it may be unable to develop a drug that successfully treats the virus in a timely manner, if at all; risks related to the Company’s commitment of financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact its other development programs, despite uncertainty about the longevity and extent of COVID-19 as a global health concern; government entities may take actions that directly or indirectly have the effect of limiting opportunities for VERU-111 as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the risk that the Company’s products may not be commercially successful; risks related to the impact of the COVID-19 pandemic on our business, the nature and extent of which is highly uncertain and unpredictable; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; product demand and market acceptance; competition in the Company’s markets and therapeutic areas and the risk of new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; the risk that the Company’s will be affected by regulatory developments, including a reclassification of 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 extensive governmental regulation, and effects of healthcare insurance and regulation, including reductions in reimbursement and coverage or reclassification of products; 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 or the Company’s prescription business 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 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 or award; penalties and/or debarment for failure to satisfy tender awards; the Company’s reliance on its international partners and on the level of spending by country governments, global donors and other public health organizations in the global public sector; risks related to concentration of accounts receivable with our largest customers and the collection of those receivables; the economic and business environment and the impact of government pressures; risks involved in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers; the Company’s production capacity, efficiency and supply constraints and interruptions, including 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, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions; risks related to the costs and other effects of litigation, including product liability claims; the Company’s ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company’s ability to successfully integrate acquired businesses, technologies or products; and other risks detailed in the Company’s press releases, shareholder communications and Securities and Exchange Commission filings, including the Company’s Form 10-K for the year ended September 30, 2019 and Form 10-Q for each of the quarters ended December 31, 2019 and March 31, 2020. 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.
Veru, the prostate cancer company, has revenues from Urology Specialty Pharmaceuticals and legacy product divisions.

- **Veru**
  - The Prostate Cancer Company

- **Urology Specialty Pharmaceuticals Division**
  - TADFIN™ – Targeting NDA submission late 2020 / early 2021
  - PREBOOST®/Roman Swipes

- **The Female Health Company Division**
  - FC2® Female/internal condom (legacy product)
## Pipeline of proprietary product candidates

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<th>PRODUCT</th>
<th>TARGET</th>
<th>INDICATION</th>
<th>PRECLINICAL</th>
<th>PHASE 1</th>
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<tr>
<td>PROSTATE CANCER NOVEL MEDICINES</td>
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<tr>
<td><strong>VERU-111</strong></td>
<td>Oral, targeted α &amp; β tubulin inhibitor</td>
<td>Metastatic castration and androgen blocking agent resistant prostate cancer</td>
<td>Phase 1b</td>
<td></td>
<td>Phase 2</td>
<td>Planned for Phase 3</td>
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<td></td>
<td>“Cytoskeleton disruptor”</td>
<td>Nonmetastatic castration and androgen blocking agent resistant prostate cancer</td>
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<td>Planned for Phase 3</td>
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<td>SARS-CoV-2 infection</td>
<td>Phase 2</td>
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<td><strong>VERU-100</strong></td>
<td>Three-month depot injection GnRH peptide antagonist</td>
<td>Advanced prostate cancer</td>
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<td></td>
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<td>Planned for Phase 2</td>
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<td><strong>Zuclomiphene citrate</strong></td>
<td>Nonsteroidal estrogen receptor agonist</td>
<td>Hot flashes caused by prostate cancer hormone therapy</td>
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<td></td>
<td>Phase 2</td>
</tr>
</tbody>
</table>

- **VERU-111**: Phase 1b portion completed and Phase 2 enrolling
- **VERU-100**: Phase 3 FDA meeting planned 2021
- **Zuclomiphene citrate**: Completed positive Phase 2 FDA meeting planned 2020
Experienced in clinical practice, drug development and commercialization

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

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Prostate Cancer - Novel Medicines
Advanced prostate cancer is a chronic disease requiring active management of the disease and side effects from existing treatments

**New prostate cancer treatments directed to stopping cancer progression**¹

- 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
- Development of resistance to treatments
  - Progression to metastases
  - Skeletal related events with progression

**New therapies to ameliorate side effects of prostate cancer treatments**²

- Androgen Deprivation Therapy (ADT) - induced estrogen deficiency related side effects
  - Hot flashes
  - Bone loss and fractures
  - Loss of libido
  - Cognitive changes
  - Adverse lipid changes
- Frailty - loss of muscle mass and strength because of testosterone deficiency

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Growing unmet need
Metastatic castration and androgen blocking agent resistant prostate cancer

Androgen blocking agent
- 15-25% of men have no response\(^1\)
- 75-85% of men progress in 9-15 months\(^1\)


ADT + novel AB agent: enzalutamide or abiraterone

Metastatic hormone sensitive prostate cancer
Metastatic castration resistant prostate cancer
Metastatic castration and androgen blocking agent resistant prostate cancer

- Androgen Receptor (AR) targeted drug approaches have been exhausted
- Need for an oral drug with new mechanism of action

ADT = androgen deprivation therapy
AB agent= Androgen blocking agents: enzalutamide, abiraterone, and apalutamide
Current therapeutic limitations to address this growing unmet medical need in metastatic castration resistant prostate cancer

- AR targeted drugs have been exhausted in the treatment of advanced prostate cancer\(^1\)

- Men who progress on androgen blocking agents are being treated with IV chemotherapies which have challenges\(^2\)
  - 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)

- We believe that an oral drug that has a different mechanism of action with a well tolerated side effect profile is needed so that the drug may be prescribed by both urologists and medical oncologists

\(^2\)Diamond E et al Curr Treat Options Oncol 16:9 2015;
VERU-111 targets the cytoskeleton: “Railroad tracks disruptor”
Binds to α & β tubulin subunits of microtubules to disrupt intracellular receptor transport

Targets cytoskeleton and disrupts microtubule assembly

VERU-111 (Crosslinks α and β subunits to inhibit microtubule polymerization)

Preclinical Product profile

- Binds to “colchicine binding site” to crosslink α and β subunits to inhibit microtubule polymerization (low nM concentration)
- High oral bioavailability
- Not a substrate for multidrug resistance proteins (P-gp, MRPs, and BCRP)
- Not a substrate for CYP3A4
- Decreases production of βI, βIII and βIV tubulin isoforms
- Cleaves Poly (ADP-ribose) polymerase (PARP) protein
- Favorable toxicity profile no neurotoxicity and no neutropenia or myelosuppression
- Demonstrated activity against taxane, vinca alkaloid, doxorubicin, enzalutamide, and abiraterone resistant prostate cancers
- Has broad activity against other tumor types as well

References:
4. 28 day rat and dog toxicity studies on file at Veru, Inc.
VERU-111 clinical development:
Positive results reported in May 2020 for Phase 1b clinical trial conducted in 7 US centers

• Trial design is an open label standard 3X3 to determine Maximum Tolerated Dose (MTD) in men who have metastatic castration resistant prostate cancer and who have also become resistant to an androgen blocking agent
  
  • **7 day dose schedule** - increasing doses per cohort of 3 after 1 cycle of 7 days oral daily VERU-111 followed by 14 days off drug for a 21 day cycle
  
  • **Expanded dose schedule** - men who tolerated 7-day dosing cycle continued to 14 days on VERU-111 followed by 7 days off and then to continuous dosing for full 21-day cycle. No drug holiday between cycles

• **Patient characteristics**
  
  • Age – mean 75.6 years (range 61-92 yo)
  
  • 30 men were chemotherapy naive
  
  • 9 men had previous IV taxane
  
  • 30% had both abiraterone and enzalutamide

• **Safety results**
  
  • Dose escalated from 4.5mg to 81mg
  
  • MTD was determined to be 72mg; 3 of 11 men had reversible Grade 3 diarrhea
  
  • Recommended Phase 2 dose is 63mg for continuous 21-day cycle
    
    • No Grade 3 diarrhea reported at doses ≤ 63mg
    
    • No reports of neutropenia or neurotoxicity at doses ≤ 63mg
  
  • Most common adverse events (mostly Grade 1 & 2)
    
    • Nausea
    
    • Vomiting
    
    • Diarrhea
    
    • Fatigue
Efficacy (antitumor activity)

- 8 men have reached at least four 21-day cycles of continuous dosing
  - PSA responses
    - 6/8 had decrease in PSA
    - 4/8 had ≥ 30% decline in PSA
    - 2/8 had ≥ 50% decline in PSA
  - Objective tumor responses
    - 2 men had partial response (PR) (additional PR occurred in a subject who did not reach 4 cycles)
    - 6 men had stable disease (SD)
    - 7/8 men still on study with median duration of response 10 months (range 6-14 months)
- Total of 10 men still on study\(^1\)
  - 7 men ≥ 4 continuous dosing for 21-day cycles
  - 3 men ≤ 4 continuous dosing for 21-day cycles

\(^1\) As of May 05, 2020
VERU-111 Phase 1b clinical study case study

Subject with metastatic castration resistant node only disease dosed 3/19 after prostate cancer progression following treatment with leuprolide, bicalutamide, sipuleucel-T, enzalutamide, and abiraterone. VERU-111 for 11 months and -63% PSA from peak.

3/19 Screening CT scan: right anterior psoas muscle cancerous lymph node 1.7cm X 1.4cm

11/19 Screening CT scan: right anterior psoas muscle cancerous lymph node 1.1cm X 1.0cm
VERU-111 clinical development plan: Open label Phase 2 clinical trial initiated 2/26/20 is enrolling

First in class, novel oral antitubulin agent that disrupts the cytoskeleton

Indication: metastatic castration resistant prostate cancer that has also become resistant to androgen blocking agent and prior to IV chemotherapy

Androgen blocking agent

- 15-25% of men have no response\(^1\)
- 75-85% of men progress in 9-15 months\(^1\)

Phase 2 trial design

- VERU-111 63mg daily oral continuous dosing for 21-day cycles
- Efficacy endpoints
  - Imaging-based progression free survival
  - PSA responses (reductions)
- Monitor safety

VERU-111 clinical development plan:
VERU will meet with FDA next quarter to reach agreement on pivotal Phase 3 clinical trial

- First indication: chemotherapy naïve men who have metastatic castration resistant prostate cancer and have failed one androgen blocking agent (abiraterone or enzalutamide)
- No FDA approved drug currently for this indication
- Phase 3: Efficacy and safety of VERU-111 versus an alternative androgen blocking agent (abiraterone or enzalutamide) in men with metastatic castration resistant prostate cancer who have developed cancer progression while receiving an androgen blocking agent

Phase 3 trial design

- Open label
- VERU-111 63mg daily oral continuous dosing for 21-day cycles versus an alternative androgen blocking agent
- Efficacy endpoints
  - Primary endpoint
    - Imaging-based progression free survival
  - Secondary endpoints
    - PSA responses (reductions)
- Assumptions
  - Median iPFS- 9 months for VERU-111 vs 3.4 months for Alternative ABA
  - Sample size - 250 men
    - 90% power, alpha=0.05, 6 months recruitment time, 12 month follow up
VERU-111 Market Opportunity

- Estimated annual market for advanced prostate cancer drugs

  - $6 billion market for novel androgen blocking agents for prostate cancer in 2018
    - ZYTIGA® (abiraterone) $3.5 billion
    - XTANDI® (enzalutamide) $2.59 billion

Prechemotherapy estimated annual market for oral agents for prostate cancer

- 2018 - $6 billion global annual sales; $3.1 billion in the US
- 15-25% of men have no response
- 75-85% of men progress in 9-15 months
- $4.9 billion global annual sales in Japan, the Americas, EMEA, Asia and Oceania
- $1.5 billion
- $3.4 billion

VERU-111 has global intellectual patent protection

- Licensed from the Ohio State Innovation Foundation in 2015

- Composition of matter (molecule and polymorphs) issued or allowed patents
  - 2 US latest expiry 2031 (with possible patent extension for NCE expiry 2036)
  - 1 EU latest expiry 2029
  - 2 Japanese latest expiry 2031
  - 6 other countries (not counting EU jurisdictions)
  - 4 patents pending

- Method of use VERU-111 for the treatment of prostate and breast cancer issued or allowed patents
  - 3 US latest expiry 2031
  - 1 EU latest expiry 2029
  - 1 Japanese latest expiry 2029
  - 6 other countries (not counting EU jurisdictions)
  - 4 patents pending

- Other methods of use VERU-111
  - 2 US latest expiry 2034
  - 2 ex-US latest expiry 2034
  - 15 patents pending
Veru’s strategy is to focus on prostate cancer
VERU-111 clinical development plan summary

First in class, novel oral antitubulin agent that disrupts the cytoskeleton

**Phase 1b**
Metastatic castration and novel androgen blocking agent resistant prostate cancer ± 1 taxane (n=39)

12/18 FPI
Fully enrolled
10 men still on study

**Phase 2**
Chemotherapy-naïve Metastatic castration and novel androgen blocking agent resistant prostate cancer (n=26)

2/20 FPI
Study enrolling
15 men on study

**Planned Phase 3s**

Indication 1: Chemotherapy naïve metastatic castration and novel androgen blocking agent resistant prostate cancer

**Plan to meet with FDA Q3 2020**

Indication 2: Nonmetastatic castration and novel androgen blocking agent resistant prostate cancer

**Plan to meet with FDA 2021**
VERU-111 has shown antitumor activity in preclinical models of other tumor types:

- Triple negative breast cancer (taxane resistant)\(^1\)
- Cervical cancer (taxane resistant)\(^2\)
- Lung cancer (taxane resistant)\(^3\)
- Ovarian cancer (taxane resistant)\(^4\)
- Uterine cancer\(^5\)
- Pancreatic cancer\(^6\)
- Melanoma\(^7\)
- Human promyelocytic leukemia (vincristine resistant)\(^8\)

\(^1\) Deng S et al Mol Cancer Ther 19:348-63, 2020 |
\(^2\) Kashyap VK et al Cancer Lett 470:64-74, 2020 |
\(^3\) Foyez M et al Data on file Veru, Inc. 2020 |
\(^4,5\) Data on file Veru, Inc. 2020 |
\(^6\) Kashyap V et al J Experimental and Clinical Can Res 38:29, 2019 |
\(^8\) Data on file Veru, Inc. 2014 |
Quest for a better androgen deprivation therapy
Current commercial limitations

**LHRH agonist**

- Concerns over initial surge in T levels - “T surge”
- Escapes from castration T levels – periodic increases in T levels
- Up to 17% of men do not achieve castration
- Does not suppress FSH
- Generic

**GnRH antagonist**

- Painful injection as degarelix requires large loading and maintenance dose injected subQ
  - Loading 6mL (2X 3mL)
  - Maintenance 4 mL every month
- No long acting depot available; must be given every month

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New potential product to address limitations of current ADT
Long-acting 3 month depot GnRH antagonist may provide better alternative

**VERU-100 target product profile**

- Novel proprietary GnRH antagonist decapeptide formulation

- 3 month slow release subQ depot (1cc 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); 2 Veru Inc. VERU-100 Target Prescribing Information
VERU-100 for the treatment of advanced prostate cancer
Clinical development program has been discussed with FDA

- Pre-IND meeting with FDA on April 19, 2019 reached agreement on an expedited regulatory pathway:
  - Clinical supply GMP manufacturing in progress
  - Single Phase 2 – Open label, multicenter dose finding study of three doses of VERU-100 in men with advanced prostate cancer (n=35)
  - 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
- Veru plans to submit an Investigational New Drug application 3Q 2020 to support initiation of Phase 2 dose finding study
ADT market for advanced prostate cancer is well established

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

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Total</th>
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<tr>
<td></td>
<td>US</td>
<td>Ex-US</td>
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<tr>
<td>2018</td>
<td>$1,150M\textsuperscript{1}</td>
<td>$1,484M\textsuperscript{1}</td>
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Intellectual property
Formulation patents expire in 2038

\textsuperscript{1}MME LLC, VERU-100 Market as ADT for Advanced Prostate Cancer (2018)
Androgen deprivation therapy for advanced prostate cancer
Estrogen deficiency related side effects

- Androgen deprivation therapy reduces testosterone and estrogen to castrate levels resulting in estrogen deficiency

<table>
<thead>
<tr>
<th>Low estrogen side effects</th>
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<tbody>
<tr>
<td>- Hot flashes</td>
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<tr>
<td>- Bone loss and fractures</td>
</tr>
<tr>
<td>- Loss of libido</td>
</tr>
<tr>
<td>- Memory loss</td>
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<tr>
<td>- Unfavorable lipid changes</td>
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<table>
<thead>
<tr>
<th>Low testosterone side effects</th>
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<tbody>
<tr>
<td>- Muscle loss</td>
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<tr>
<td>- Frailty</td>
</tr>
<tr>
<td>- Muscle weakness</td>
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<tr>
<td>- Increase fat body composition</td>
</tr>
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Adapted from: Freedland S et al. Prostate Cancer and Prostatic Diseases 12:333-338 2009
Hot flashes are one of the most common and debilitating side effects of androgen deprivation therapy\(^1,2\)

Occur 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\(^3\)

Zuclomiphene, an oral estrogen receptor agonist, is planning to advance into pivotal Phase 3 following report of positive interim topline results from Phase 2 placebo controlled dose finding study

- 93 men who have moderate & severe hot flashes on ADT randomized in 24 US clinical sites
  - Trial design - 12 week duration
    - Primary efficacy endpoint - change in frequency of moderate & severe hot flashes from baseline
  - Interim topline Day 42 results reported January 2020
    - Hot flashes reduction from baseline
      - 10mg group (p=0.15) - No effect
      - 50mg group (p<0.001)
    - Hot flashes at Day 42
      - 50mg group (41% reduction) vs No effect 10mg group (21% reduction) (p=0.03)
  - Estrogenic biomarkers - estrogenic activity of 50 mg versus 10mg and placebo (p<0.0001)
  - Safety data base - Zuclomiphene appears to be well tolerated with no reports of drug related SAEs and no reports of special interest side effects: gynecomastia, breast tenderness, or VTEs

Next steps:
- Plan to have end of Phase 2 meeting with FDA in 2020
Zuclomiphene: Potential to be the first FDA approved drug for ADT-induced hot flashes

Market potential

- Indication: treatment of ADT-induced moderate to severe hot flashes in men with advanced prostate cancer

- Estimated 600,000 men on ADT in the U.S.\(^1\)

- Number of men with hot flashes in 2020 expected to be 475,561 and 243,487 will have moderate to severe hot flashes\(^2\)

- Independent market research sponsored by Veru estimates $600-800 million/year expected sales for Zuclomiphene in US\(^3\)

Intellectual property


SARS-CoV-2
Global medical need for the treatment of coronavirus, also known as COVID-19 or SARS-CoV-2

SARS-CoV-2 Pandemic

• SARS-CoV-2 is an enveloped, nonsegmented, positive RNA virus that has club-like spikes on surface
• Global pandemic with over 4,308,357 cases and 290,165 deaths worldwide and rising¹
• Clinical presentation²
  • Mild disease (81%) - URI symptoms with dry cough, sore throat, headaches, and muscle pain
  • Severe disease (14%) - Dyspnea, blood oxygen saturation of <93% and lung infiltrates on imaging study with 24-48 hours
  • Critical disease (5%) - Respiratory failure, septic shock, and/or multiple organ failure as a result of a “cytokine storm”—inflammatory over reaction that leads to shock and extensive tissue damage
• Treatment - supportive care and oxygen with mechanical ventilation and hemodynamic support for septic shock
• Mortality rates appear to be around 3.4%³

¹ Worldometers.info 5/12/2020 | ² Chinese CDA and Cascella et al 2020 | ³WHO March 09, 2020
Virus’s most critical task is to hijack the host’s internal transportation system, the microtubules in the cytoskeleton\(^1\)

- Given the spatial distances between the point of virion entry at the plasma membrane to the different locations in the cell for viral replication and release of infectious virions out of the cell
- Viruses take control of their host’s cellular machinery to carry out viral replication, assembly and to exit from the cell to spread infectious virions
- The cytoskeleton has three major types of protein filaments: microfilaments (actin), microtubules (tubulin), and intermediate filaments. The principal ones involved in viral replication and trafficking (transport) are microtubules and actin which are involved in cellular transport
- Microtubules are dynamic network systems
- Target microtubule networks to disrupt intracellular trafficking to impair virus and host interactions may be an effective way to treat coronavirus infections.

\(^1\) Ward B Virology 411:244-250, 2011 | \(^2\) Taken from Alsaadi et al Future Virology 14:275, 2019
Coronavirus’s spike (S) protein is the key structure that interacts with microtubules in the cytoskeleton during intracellular trafficking. The first stage of interaction with the microtubule cytoskeleton occurs when the spike (S) protein on the surface of coronavirus mediates attachment to the cell surface. Interactions between tubulin and the cytosolic domain of the S protein of human coronavirus-229E, human coronavirus-NL63, and TGEV are required for successful entry, assembly and release (egress) of viral particles. Rudiger et al. (2016) demonstrated the interaction of tubulin is the last 39 amino acids of the S protein cytoplasmic tail of alphacoronaviruses TGEV, human coronavirus NL63, and human coronavirus 229E and well as betacoronavirus human SARS-CoV.  

3 Taken and adapted from Simpson et al. Viruses 12:117, 2020  
4 Taken from Alsaadi et al Future Virology 14:275, 2019  

SARS-CoV-2 structure
Microtubule depolymerization agent, colchicine, has antiviral activity and has potent anti-inflammatory effects, but also has serious safety concerns.

Colchicine - broad spectrum activity against multiple types of viruses in vitro

- Active against:
  - Moloney Murine Leukemia virus
  - Porcine Reproductive and Respiratory Syndrome virus
  - Zika virus
  - Dengue
  - Respiratory Syncytial Virus

Colchicine\(^1\) is indicated for treatment of inflammation associated with:

- Gout
- Familial Mediterranean Fever (general polyserositis)

- Evidence that colchicine can reduce cytokine storm and septic shock\(^2,3\)

- However, clinically colchicine has low therapeutic index, drug-drug interactions (substrate for P-gp), and potential for serious safety issues\(^8\)

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VERU-111 is a more potent inhibitor of microtubule polymerization than colchicine in vitro¹

Tubulin (0.4 mg/assay) was exposed to 5, 10 μM of VERU-111 (6a) versus vehicle control, 5% DMSO

VERU-111, as a microtubule depolymerization agent, may have a two-pronged approach to the treatment of SARS-CoV-2: antiviral and anti-inflammatory agent

Based on VERU-111’s mechanistic similarities to other microtubule depolymerizing agents as well as its preclinical and clinical efficacy and safety experience:

- As an antiviral, it may have direct effects on S protein-microtubule trafficking with the potential to reduce the production of infectious virions particularly by affecting viral replication and assembly and virion egress.

- As an anti-inflammatory agent, it may reduce virally induced severe inflammation in the respiratory system and may reduce the incidence of cytokine storm and septic shock that can occur in patients that progress to severe acute respiratory pneumonia.
VERU-111 as a potential treatment for SARS-CoV-2: Clinical development plan

Double-Blind, Placebo-Controlled, Phase 2 Study of VERU-111 for the Treatment of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in Patients at High Risk for Acute Respiratory Distress Syndrome (ARDS)

• Approximately 40 subjects will be randomized 1:1 (20 18mg VERU-111 and 20 Placebo groups)

• Hospitalized subjects with documented evidence of COVID-19 infection with symptoms for less than 8 days and who are at high risk for ARDS will be enrolled.

• Subjects will receive study drug for up to 21 days.

• The primary efficacy endpoint of the study will be the proportion of patients that are alive and without respiratory failure at Day 29.

• Secondary endpoints include measured improvements on the WHO Disease Severity Scale (8 point ordinal scale)\(^1\)

• The total study duration for a patient from screening to follow up visit is planned to be 62 days.

VERU-111, a novel microtubule polymerization agent, as a potential treatment for SARS-CoV-2: Regulatory pathway

Regulatory update

• FDA program: Coronavirus Treatment Acceleration Program (CTAP)
• FDA granted IND permission on May 12, 2020
• Phase 2 expected to commence in May 2020
TADFIN™ capsule (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 or, for PROSCAR, used off label 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.
- PROPECIA (finasteride 1mg) daily - symptoms of male pattern hair loss

The solution: proprietary TADFIN™ tablet formulation

- Increases convenience and compliance

• Single dose randomized two period, crossover study in 33 healthy males over the age 45 years
  • Tadalafil $C_{\text{max}}$ in TADFIN is 25% less than Tadalafil alone
  • Process of getting 12 month stability data on commercial batches

• Pre-NDA meeting held May 23, 2019
  • NDA may be submitted after 12 months of stability data on manufactured/commercial drug batches

• NDA expected to be submitted in late 2020/early 2021
TADFIN™ for benign prostatic hyperplasia – market opportunity

Market potential

• BPH market is up to 25% of male population and estimated 1.1 billion males worldwide in 2018¹
  • Company estimates US and global markets to be >$200 million through telemedicine and salesforce channels²

• Target men who have enlarged prostate >30cc as a cause for symptoms and signs of BPH

• Plan to launch via telemedicine channels and license US and ex-US for upfront payments and royalties to urology specialty pharmaceutical companies

Veru entered into supply and distribution agreement with Get Roman (Roman Health Ventures Inc.) in February 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/internal Condom business revenues are growing

FC2 Female/Internal Condom is the only FDA approved female use product to prevent pregnancy and transmission of sexually transmitted infections

- Sold in U.S. and 149 other countries
- Manufacturing plant with annual capacity of 100 million units
- Public sector customers include UNFPA, USAID, Brazil, and South Africa
- FC2 business profitable from FY 2006-present

Rapidly growing US prescription business for high margin revenues

- Prescription business is rapidly growing via existing and new contracts with multiple telemedicine partners

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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.
Financial highlights: Veru Business Six Months Ended March 31, 2019 vs. 2020

Six Months Ended March 31, 2019
- Net Revenues: $13,347,924
- Gross Profit: $9,252,931
- Operating Loss: $(3,136,317)

Six Months Ended March 31, 2020
- Net Revenues: $20,521,120
- Gross Profit: $14,705,593
- Operating Loss: $(2,084,071)
Financial highlights: Veru Business Three Months Ended March 31, 2019 vs. 2020

Three Months Ended March 31, 2019
- Net Revenues: $6,976,115
- Gross Profit: $4,608,851
- Operating Loss: $(2,124,590)

Three Months Ended March 31, 2020
- Net Revenues: $9,943,104
- Gross Profit: $7,436,498
- Operating Loss: $(299,678)
Veru projected milestones

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>INDICATION</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
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<td>PROSTATE CANCER NOVEL MEDICINES</td>
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<tr>
<td>VERU-111 Oral antitubulin</td>
<td>Metastatic castration resistant &amp; androgen blocking agent resistant prostate cancer</td>
<td>P1b</td>
<td>P2</td>
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<td>VERU-100 GnRH agonist 3 month subcutaneous depot</td>
<td>Advanced hormone sensitive prostate cancer ADT</td>
<td>Pre-IND</td>
<td>IND</td>
<td>P2</td>
<td>P3</td>
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<td>SARS-CoV-2 infection</td>
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<tr>
<td>Zuclomiphene Estrogen receptor agonist</td>
<td>Hot flashes caused by ADT</td>
<td>P2</td>
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<td>P3 – 1</td>
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Represent Management’s current expectations and are not a guarantee of future results.
## Veru projected milestones

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<th>PRODUCT</th>
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<th>2020</th>
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<tr>
<td>TADFIN™ (tadalafil/finasteride)</td>
<td>BPH</td>
<td>BE</td>
<td>NDA</td>
<td>US launch</td>
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<td>Roman Swipes</td>
<td>Premature ejaculation</td>
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<td><strong>THE FEMALE HEALTH COMPANY DIVISION</strong></td>
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<tr>
<td>FC2</td>
<td>Dual birth control &amp; STI prevention</td>
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<td>Marketed</td>
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Represent Management’s current expectations and are not a guarantee of future results.

* Tamsulosin DRS granules and XR capsules and Solifenacin granules development programs are currently on hold
Next Steps for 2020

Clinical stage assets

• VERU-111 –
  • Complete enrollment of in June 2020 for Phase 2 clinical study – Metastatic castration & androgen blocking agent resistant prostate cancer prior to IV chemo
  • Meet with FDA and commence Planned pivotal Phase 3 clinical study – Metastatic castration & androgen blocking agent resistant prostate cancer prior to IV chemo
  • Initiate SARS-CoV-2 Phase 2 clinical trial
• VERU-100 – Aim to initiate Phase 2 clinical study in the 2nd half of 2020
• Zuclomiphene – Meet with FDA to reach agreement for planned Phase 3 clinical study

Sales of urology specialty products and legacy product – Believe that FC2 can continue to deliver strong sales revenue to support investment in the development of clinical prostate cancer drugs

• PREBOOST/Roman Swipes – Continue to grow sales via telemedicine
• FC2 female/internal condom – Increase sales in global public sector and US prescription business
• Target submission of TADFIN™ for BPH NDA by the end of 2020