

VERU (Nasdaq/VERU)

June 25, 2018

BUY
Sales Rebound; R& D Progresses
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Veru is a marketer and developer of products for the urology, oncology and women's health markets
Investment Highlights

1) Veru is making solid progress on its R&D pipeline, most notably with the recent filing of an IND with the FDA for its VERU-944 (cis-clomiphene citrate) for a Phase 2 study for the treatment of hot flashes caused by androgen deprivation hormone therapy (ADT) in men with advanced prostate cancer. The Company expects to begin this study later this summer. Other near-term catalysts from Veru's pipeline include the start of an open-label Phase 1/2 clinical trial of VERU-111 (a novel oral α and β tubulin antagonist) against metastatic castration resistant prostate cancer, and the completion of a final bioequivalence (BE) study and filing of an NDA for Tamsulosin DRS in benign prostate hyperplasia (BPH), both expected by the end of this year.

2) The Company's product sales, primarily for its FC2 women's condom, also continue to grow. In the most recent Q2/18 ending March sales revenue grew 7% to \$2.6 million, fueled by higher sales in the US market following a push to increase availability for the product. Internationally, Veru is awaiting large unit contract awards as soon as this summer in Brazil and South Africa, historically two of the Company's largest markets, which could help this portion of Veru's product business rebound back to high levels last seen in 2015.

3) Finally, the Company is in solid financial shape following the March 2018 synthetic royalty financing deal on FC2 sales. Veru has already drawn down \$10 million as part of the arrangement, with another possible \$2 million available depending on international contract awards. Combined with nearly \$9 million in cash on hand (as of March 31), management is confident that the Company has adequate cash to fund operations for the next twelve months. A recent waiver by the FDA of a \$2.4 million new drug application filing fee for Tamsulosin DRS granules/Tamsulosin XR capsules will also help Veru fund the build-out of its R&D pipeline.

Current Price \$2.25
Price Target \$5.00

Estimates	F2016A	F2017A	F2018E
Revenues(\$000s)	\$22,127	\$13,656	\$13,159
1Q December	8,231	3,244	2,587 A
2Q March	4,773	2,406	2,573 A
3Q June	5,561	4,314	3,500 E
4Q September	3,563	3,692	4,500 E
EPS (diluted)	\$0.01	(\$0.25)	(\$0.33)
1Q December	0.05	(0.04)	(0.08) A
2Q March	0.00	(0.06)	(0.07) A
3Q June	0.02	(0.03)	(0.09) E
4Q September	(0.06)	(0.12)	(0.08) E

EBITDA/Share	\$0.14	(\$0.19)	(\$0.34)
EV/EBITDA (x)	0.9	N/A	N/A

Stock Data	
52-Week Range	\$0.90-\$4.78
Shares Outstanding (mil.)	53.4
Market Capitalization (mil.)	\$120.2
Enterprise Value (mil.)	\$120.8
Debt to Capital (3/18)	19.1%
Book Value/Share (3/18)	\$0.77
Price/Book	2.9 x
Average Trading Volume (10-day)	200,000
Insider Ownership	38.8%
Institutional Ownership	4.3%
Short interest (000s)	357.2
Dividend / Yield	\$0.00/0.0%


 Price target and ratings changes over the past 3 yrs:
 Initiated - June 25, 2018 - Buy - Price Target \$5.00

Conclusion

Although well known as a product marketer under the banner of The Female Health Company, last year's merger with Aspen Park Pharmaceuticals and name (and stock symbol) change to Veru have proven to be less familiar with investors, and Veru's share appreciation has lagged that of other specialty pharma stocks. However, with new experienced additions to the Company's management team and board of directors, a number of clinical programs showing progress so far this year, a strong balance sheet, and several currently marketed progress showing sales growth, we believe both long-term value-oriented and short-term event-focused investors will soon discover these undervalued shares, and thus, we are initiating coverage on VERU shares with a BUY rating and 12-18-month price target of \$5.00.

Company Business/History

Veru is a biopharmaceutical company focused on urology and oncology. The company is currently developing drug product candidates for benign prostatic hyperplasia (BPH or enlarged prostate), hot flashes associated with prostate cancer hormone treatment, male infertility and novel oral chemotherapy (alpha & beta tubulin inhibitor) for a variety of malignancies, including metastatic prostate, breast and ovarian cancers. To develop and commercialize drug candidates, Veru utilizes the FDA's 505(b)(2) regulatory approval pathway, designed to allow for potentially expedited regulatory approval based on a previously established safety and efficacy profile of the product. The Company is developing products under the 505(b)(1) pathway as well, which is the traditional new drug application (NDA) pathway.

Veru markets and sells the FC2 Female Condom and Preboost medicated individual wipe, which is a male genital desensitizing drug product for the prevention of premature ejaculation. The company's sales division, The Female Health Company, is focused on the global public health sector FC2 business. This division markets the company's Female Condom (FC2) to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world.

Veru Inc. is the successor to The Wisconsin Pharmacal Company, originally incorporated in 1971, which manufactured and marketed disparate specialty chemical and branded consumer products. The FDA approved the Company's first generation Female Condom, FC1, for distribution in the US in 1993. In 1996, the Company completed a series of actions which resulted in the Company's acquisition of worldwide rights to FC1, the divestiture of Wisconsin Pharmacal's other businesses and the change of the Company's name to "The Female Health Company." In 2005, the Company completed the development of its second generation Female Condom (FC2), which was first marketed internationally in March 2007 and has been marketed in the US since August 2009 following approval by the US FDA as a Class III medical device on March 10, 2009. On October 31, 2016, the Company completed the acquisition of Aspen Park Pharmaceuticals (APP) as part of the Company's strategy to diversify its product line to mitigate the risks of being a single product company, through the merger of a wholly owned subsidiary of the Company into APP. On July 31, 2017, the Company changed its corporate name from The Female Health Company to Veru, Inc. and began trading under the Nasdaq symbol VERU. The Company maintains its US headquarters in Miami, Florida and has sales offices in the United Kingdom and the US and manufacturing facilities in Malaysia.

Strategy

Veru's goal is to be a leading biopharmaceutical company focused on urology and oncology by developing a portfolio of pharmaceutical products that address significant health needs in large potential markets. Recently, the Company has combined the revenue and cash flows from the market leading FC2 female condom with

APP's pipeline of pharmaceutical and consumer health product candidates. Initially, Veru intends to focus on the three low-cost, near-term and potentially high-reward programs that are expected to qualify for the abbreviated 505(b)(2) FDA regulatory pathway: Tamsulosin DRS and Tamsulosin XR capsules for BPH and VERU-944 for hot flashes in men taking hormonal therapies for advanced prostate cancer. The Company is also developing new chemical entities such as VERU-111 for the treatment of metastatic prostate, breast, endometrial, ovarian, and other cancers and VERU-111/112 for the prevention and treatment of gout and Familial Mediterranean Fever (FMF) via the traditional 505(b)(1) regulatory development pathway.

The key elements of Veru's strategy are as follows:

- **Obtain regulatory approvals of products in North America, Europe and Asia** - Assuming the successful completion of clinical trials, the Company or a partner will file on their behalf for regulatory approval of pharmaceutical products in North America, Europe and Asia, including Tamsulosin DRS and Tamsulosin XR capsules for the treatment of BPH, Solifenacin DRG for the treatment of OAB, Tadalafil/Finasteride combination capsules for the initial treatment of BPH in men with enlarged prostate, VERU-722 for the treatment of male infertility, VERU-944 for the treatment of hot flashes in men on prostate cancer hormonal therapies, VERU-111 for the treatment of metastatic prostate, breast, endometrial, ovarian, and other cancers and VERU-111/112 for the prevention and treatment of gout and Familial Mediterranean Fever (FMF). antibodies than the currently licensed vaccine;
- **Develop a portfolio of urology and oncology pharmaceutical products** – Veru has developed or acquired development and marketing rights to a portfolio of urology and oncology pharmaceutical products and intends to continue to acquire, in-license and develop new pharmaceutical products that are believed to offer unique market opportunities and/or complement existing product lines. The Company has adopted a three-tier strategy with respect to licensing or acquiring new products and technologies designed to diversify the risks inherent in traditional new chemical entity pharmaceutical development: (1) license or acquire fully-developed, FDA-approved products that have development potential and offer certain market protection against competitors, such as patent rights, marketing exclusivity or orphan drug designation; (2) create differentiated products with potentially high commercial value by selecting a new indication for or modifying existing FDA-approved products utilizing the 505(b)(2) FDA approval pathway; and (3) identify and acquire products and technologies in late preclinical or early clinical stages of development to minimize the time and expense of development;
- **Focus on products with significant potential commercial opportunities in large, growth markets such as urology and oncology** - Veru intends to focus on developing drugs that have potential significant commercial opportunities, including core areas of interest such as BPH, overactive bladder, sexual dysfunction, erectile dysfunction, cancer treatments for prostate, breast, endometrial, ovarian and other cancers, amelioration of prostate cancer hormonal therapy side effects including hot flashes and bone loss, and male infertility;
- **Develop business and enhance research through strategic alliances** - A key component of the Company's business strategy is to leverage the resources gained from collaborations to expand its technology and operations base;
- **Develop opportunities in the consumer and prescription markets** - The Company believes that there are opportunities to develop the prescription market for FC2, and that such marketing of FC2 will complement the consumer launch of Preboost. The Company has appointed a Chief Commercial Officer for Veru to oversee the implementation of its marketing plan for both FC2 by prescription and PREBOOST, as well as the future prelaunch and launch activities for Tamsulosin DRS, Tamsulosin XR capsules, Solifenacin DRG, and Tadalafil/Finasteride combination capsules;

- Continue efforts in the global public sector** - The Company intends to continue to develop global markets for FC2 for both contraception and STI prevention, including HIV/AIDS and the Zika virus. The Company has developed contacts and relationships with global public health sector organizations such as WHO, UNFPA, USAID, and the United Nations Joint Programme on HIV/AIDS (UNAIDS), country-specific health ministries, NGOs and commercial partners in various countries. In November 2016, the Company appointed a President of its The Female Health Company Division. The Company also has representatives in various locations around the world to provide technical and marketing support as well as assist with its customers’ prevention and family planning education programs; and
- Capitalize on expertise and reputation of the management team and scientific advisors** – Veru’s management team has significant expertise and experience in urology and oncology as well as drug development, marketing and sales which will enable the Company to effectively manage preclinical studies and clinical trials of drug candidates and product commercialization. In addition, Veru intends to capitalize on the strong reputations of the members of its management and board of directors with academic institutions, hospitals, physicians, pharmacists and distributors to expand its customer base and to introduce new products.

The following table summarizes the current status of the Company’s product portfolio and clinical pipeline:

Product	Indication	Target	Preclinical	Phase 1	Phase 2	Phase 3	Filing	Marketed
FC2 female condom (Class III medical device)	Barrier contraception	Protection STD and pregnancy	[Progress bar spanning Preclinical, Phase 1, Phase 2, Phase 3, Filing, and Marketed]					
Tamsulosin DRS (tamsulosin HCl XR for oral suspension)	Prostate symptoms (BPH) & difficulty swallowing pills	Super Selective α_1 -receptor blocker with no food effect	[Progress bar spanning Preclinical, Phase 1, Phase 2, and Phase 3. BE study only]					
Tamsulosin XR Capsules (tamsulosin HCl)	Prostate symptoms (BPH)	Super Selective α_1 -receptor blocker with no food effect	[Progress bar spanning Preclinical, Phase 1, Phase 2, and Phase 3. Dissolution study only]					
Solifenacin DRG (solifenacin granules oral suspension)	Overactive bladder-urinating too often	Selective M3 muscarinic antagonist	[Progress bar spanning Preclinical, Phase 1, Phase 2, and Phase 3. BE study only]					
Tadalafil-Finasteride combo tablets (5mg tadalafil /5mg finasteride)	BPH & Erectile dysfunction	PDE5 + 5 α reductase inhibitors	[Progress bar spanning Preclinical, Phase 1, Phase 2, and Phase 3. BE study only]					
VERU-944 (cis-clomiphene)	Hot flashes from prostate cancer hormone Tx	Nonsteroidal Estrogen agonist	[Progress bar spanning Preclinical, Phase 1, and Phase 2]					
VERU-111	Metastatic prostate & other cancers	Selective oral $\alpha + \beta$ tubulin inhibitor	[Progress bar spanning Preclinical]					

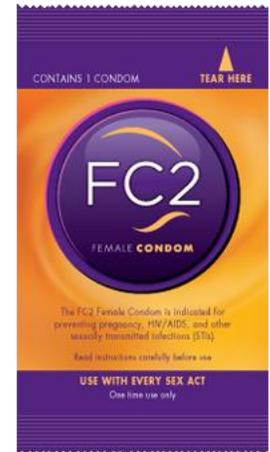
Source: VERU

Products

Veru markets and sells the FC2 Female Condom, now available by prescription in the US including through the virtual doctor smartphone app “HeyDoctor” and at www.fc2.us.com, and the Preboost medicated individual wipe, which is a male genital desensitizing drug product for the prevention of premature ejaculation. The company’s sales division, The Female Health Company, is focused on the global public health sector FC2 business. This division markets the company’s Female Condom (FC2) to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world.

FC2

The FC2 Female Condom is a thin, soft, loose-fitting sheath made from nitrile (non-latex) which is worn inside the vagina. It has flexible inner and outer rings that hold it in place during sex. It lines the walls of the vagina, allowing the penis to move freely inside the condom during sex, the silicone-based lubricant provides a natural sensation and the non-latex nitrile material heats up to your body temperature. Recent changes in the US market provided an opportunity for the promotion and expansion of FC2 to protect against sexually transmitted infections (STIs) and unwanted pregnancies. FC2 is the only device approved by the FDA (Class III medical device) for this use. As FC2 is non-hormonal, it is a viable alternative for many US women who have reported dissatisfaction with the side effects of hormonal birth control. Moreover, there are unique groups of women such as breast cancer survivors who desire contraception and cannot take hormonal birth control because of this underlying condition. FC2 is currently reimbursable by prescription under the Affordable Care Act. With necessary infrastructure to allow for broad access across the US now built out by the Company, FC2 is now available through multiple access channels including: 98% of retail pharmacies, community based organizations, by prescription, telemedicine, universities, direct purchase and 340B-qualified health care clinics, and directly to the public sector without distributors. Marketing and educational programs, both traditional and by digital and social media, are being developed and implemented to target health care providers (physicians, nurse practitioners, and physician assistants), pharmacies, and women to coordinate awareness and access to FC2 that is fully reimbursable. The graphic below outlines the Company’s commercial strategy for the sales of FC2 in the US, specifically the six ways that the product can be accessed:



↑ INCREASING ACCESS
6 Ways to Access FC2 Female Condom

The only FDA approved for market female condom, classified as a Class III medical device, proven safe and effective.

- 1 Dept. of Health/Community Organizations**
 Individual packets are available for direct purchase from Vera Inc. to 501(c)(3) and not-for-profit agencies for distribution through community outreach and awareness. Coming Soon: Search for organizations carrying FC2 on our website.
- 2 By Prescription**
 FC2 12-Packs are available with a prescription and are covered by most insurance companies with \$0 copay. The Rx can be filled at a local pharmacy or sent to a specialty pharmacy* who will deliver to the home at no additional cost.
*Certain states only, please visit our website for more information.
- 3 Telemedicine HeyDoctor app**
 Download the HeyDoctor app* and utilize this service to have an RX sent to a local pharmacy or shipped home via a specialty pharmacy* for just \$5 (free with code: FC2)
*Certain states only, please visit our website for more information.
- 4 340B Covered Entities**
 Contact your distributor to obtain 12-Packs of FC2 through the 340B Prime Vendor Program (PVP). We are committed to helping providers purchase FC2 at discounted pricing.
- 5 Uninsured or Underinsured**
 US residents or permanent US citizens are eligible to participate in the Vera Inc. FC2 Patient Assistance Program and to receive the FC2 Female Condom at a reduced cost. Visit fc2usa.com/patient/directpurchase
- 6 Colleges & Universities**
 Access to FC2 is available on campuses throughout the US at the Student Health Center, pharmacy, wellness center or clinic.
 For partnership opportunities, reach out to info@fc2usa.com.

Source: VERU

Internationally, The FC2 international team specializes in FC2 Female Condom programming and training in the US and around the world. They work in partnership with governments, donors and other agencies around the world to build successful reproductive and sexual health programs and policies that integrate FC2 Female Condom. The Company has a relatively small customer base for FC2, with a limited number of customers who



generally purchase in large quantities. Over the past few years, significant customers have included large global agencies, such as the United Nations Population Fund (UNFPA) and the United States Agency for International Development (USAID), Sekunjalo Investments Corporation (PTY) Ltd (Sekunjalo), the Company's distributor in the Republic of South Africa (RSA), and the Brazil Ministry of Health either through UNFPA or Semina Indústria e Comércio Ltda (Semina), the Company's distributor in Brazil. Other customers include ministries of health or other governmental agencies, which either purchase directly or via in-country distributors, and non-governmental organizations (NGOs).

To date, FC2 has been distributed in 144 countries. A significant number of countries with the highest demand potential are in the developing world. The incidence of HIV/AIDS, other STIs, and unwanted pregnancy in these countries represents a large potential for significant sales of a product that benefits some of the world's most underprivileged people. The Company has distribution agreements and other arrangements with commercial partners which market FC2 as a consumer health product through distributors and retailers in 16 countries, including Brazil, Spain, France, and the United Kingdom. These agreements are generally exclusive for a single country.

PREBOOST (4% benzocaine medicated individual wipes) for the prevention of premature ejaculation

Preboost is a proprietary OTC male genital desensitizer used for the treatment of premature ejaculation (PE). Currently, there are no prescription products for PE approved by the FDA, even though PE is the most common sexual dysfunction and even more frequent than erectile dysfunction, based on epidemiological studies. Premature ejaculation is a self-reported diagnosis. Preboost is the only individually packaged medicated wipe that contains a desensitizing agent (benzocaine 4.0%). The advantages of the product are:

- 1) Convenient individually wrapped wipes so it is easier to carry and to be discreet;
- 2) The correct dose is delivered each time;
- 3) The medicine is applied topically and dries quickly which prevents the potential for transference to partner; and
- 4) Benzocaine at 4.0% temporarily desensitizes, but does not completely numb the penis.



The Company has completed a Phase 4 clinical study of Preboost, which enrolled 26 men aged 18 years or older with PE in a heterosexual, monogamous relationship, and after treatment with Preboost, 82 percent of the men were no longer considered to have premature ejaculation. Results showed that treatment was well tolerated. PE is a large market worldwide, with an estimated prevalence of 50 million men in the US and 60 million in Europe, and currently the Company has entered into a co-promotion and distribution agreement for the product with Timm Medical Technologies (Private), of Fort Washington, Pennsylvania. In addition, The Company also plans to increase sales of Preboost by having a sampling program targeting urologists, introducing the product through additional internet outlets

including Walmart, CVS, Walgreens and other OTC distribution outlets, optimizing its internet ecommerce capabilities and digital marketing via www.preboost.com, as well as through out-licensing opportunities for markets outside the US.

R&D Pipeline

Central to the Company's business model is the conducting of research and development. Since the 2016 completion of the APP Acquisition, Veru has invested and expects to continue to invest significant time and capital in its research and development operations. Research and development expenses increased from \$0.1

million in fiscal 2016 to \$3.5 million for fiscal 2017, and the Company's expenses relating to research and development are also expected to increase in fiscal 2018 due to advancement of multiple drug candidates.

Tamsulosin Delayed Release Sachet (DRS) and Extended Release (XR) capsules

Tamsulosin DRS (Tamsulosin HCL extended release) is a new proprietary powder-like formulation containing the active pharmaceutical ingredient in Flomax (tamsulosin HCL) capsules which is a commonly used medicine for the treatment of BPH, also known as enlargement of the prostate. Flomax is indicated for the treatment of the signs and symptoms of BPH and was developed by Yamanouchi Pharmaceuticals (now part of Astellas Pharma) and was first marketed in 1996, but now can be purchased both in generic form and branded forms marketed by Boehringer Ingelheim and others, under license. Tamsulosin is a selective alpha1 adrenergic receptor blocking drug that is specific for the alpha1 adrenergic receptors located in the smooth muscle of the prostate and bladder neck. Symptoms associated with BPH typically occur as a result of increased smooth muscle tone of the prostate and bladder which leads to constriction of urinary flow, urinary retention, urinary infection, kidney damage and a life threatening blood infection called urosepsis. Blocking these alpha1 adrenergic receptors relaxes the smooth muscles of the prostate and bladder neck resulting in the improvement of urinary flow rate and reduction in the symptoms of BPH.

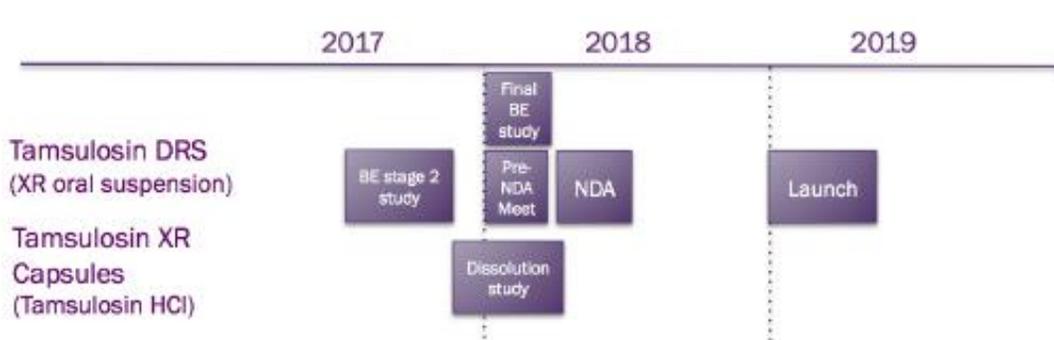
Flomax capsules should not be crushed, chewed or opened as is stated in the FDA package insert because men will have drug levels that are too high and are placed at higher risk for postural hypotension (sudden drop in blood pressure upon standing that can lead to fainting). Tablets and capsules are problematic for 15% of men over the age of 60 who have difficulty swallowing tablets and capsules and the up to 60% of men in long term facilities who have difficulty swallowing tablets and capsules because of certain medical conditions, including degenerative neurological diseases like Parkinson's or those that have suffered a stroke. Not being able to take alpha blocker drugs such as Flomax for BPH because of difficulty swallowing tablets and capsules may lead to the increased risk of acute urinary retention, urinary catheterization, urosepsis and death. Because Tamsulosin DRS is a new proprietary powder-like formulation containing the active pharmaceutical ingredient in Flomax, it would provide a more convenient and reliable way to deliver therapeutic levels of tamsulosin to men who have difficulty swallowing tablets and capsules.

Veru's initial marketing plan will target men in long term care facilities and men in the general community that have difficulty swallowing tablets and capsules. Initially, a sales force is not required for the marketing of this product as pharmacists and physicians have the ability to identify and to provide the appropriate formulation of tamsulosin for a patient who has BPH and difficulty swallowing tablets and capsules. Based on IMS data, the current Flomax and generic tamsulosin sales from March 2014 to March 2015 was \$3.48 billion in the US. The US market for all alpha blockers for BPH is estimated to be \$4.5 billion annually, per IMS. Men in long term care or nursing homes have up to a 60% prevalence of swallowing difficulties and account for about 13% of total tamsulosin sales, whereas over 15% of men over 60 years of age in the general population have difficulty swallowing tablets and capsules.

Veru's new formulation, called Tamsulosin DRS, contains the same tamsulosin active pharmaceutical ingredient that is found in Flomax (tamsulosin HCL) capsules and, as such, would be expected to have the same efficacy and safety as Flomax. The FDA has agreed that this formulation can be referenced under a 505(b)(2) NDA submission for Tamsulosin DRS. Veru to date has completed a pre-IND meeting with the FDA, completed a bioequivalence study, and plans to file an NDA in 2018.

The Company is also developing Tamsulosin XR (extended release) capsules, which contain the new formulated granules, for the urology and primary care markets. Tamsulosin XR capsules will be marketed to urology and primary care physicians, and the Company will either commercialize the product itself or seek

marketing and sales partnerships. The chart below depicts Veru's clinical and regulatory timeline for Tamsulosin DRS and Tamsulosin XR:



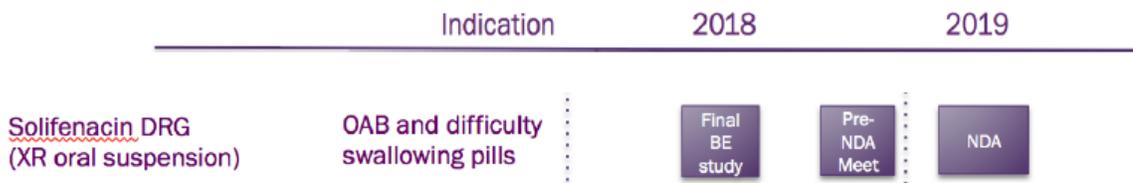
Source: Veru

Solifenacin Delayed Release Granules (DRG)

Solifenacin DRG (solifenacin succinate for extended release oral suspension) for the treatment of overactive bladder is a new proprietary granule formulation containing the active pharmaceutical ingredient in VESICare (Solifenacin 5mg or 10 mg tablets), also developed in the 1990's by Yamanouchi Pharmaceuticals (now part of Astellas Pharma). Solifenacin is a competitive selective M3 muscarinic receptor antagonist indicated for the treatment of overactive bladder (OAB) which include symptoms such as urge urinary incontinence, urgency, and urinary frequency in men and women. Muscarinic receptors play a major role in mediating contractions of the urinary bladder.

Solifenacin DRG (solifenacin succinate extended release for oral suspension) is a new proprietary oral extended release granule formulation being developed for men and women with overactive bladder and dysphagia, or difficulty or cannot swallow pills or capsules. In the US, the prevalence of OAB is similar in women and men, at 16.9% and 16.0%, respectively. According to the US Department of Health and Human Services (2014), up to 36.7% of short-term residents and 70.3% of long-term nursing home residents were not in complete control of their bladder. Annual sales in 2017 for VESICare tablets (5 mg and 10 mg) were approximately \$1.1 billion, according to IMS Health sales data and worldwide annual direct costs of OAB are expected to be greater than \$10 billion by 2018. Like OAB, dysphagia (swallowing difficulty) is also a growing health issue in our aging population. Up to 38% of the elderly who live independently and up to 68% of elderly nursing home residents have difficulty swallowing. Swallowing difficulties are particularly prevalent in people who have Parkinson's Disease (80%), Alzheimer's Disease (40%-70%) and Stroke (50%). These are the same conditions that are associated with OAB, and unfortunately, currently available selective M3 muscarinic receptor antagonists, including solifenacin, are only available as tablets. According to the FDA label, tablets should be swallowed whole and not chewed, crushed or broken. Currently, Solifenacin DRG oral suspension is not available, and if approved, would be the only oral suspension formulation of a M3 muscarinic antagonist that would be available on formularies in long term care pharmacies. A sales force is not required for this product as pharmacists and physicians in long term care facilities would identify patients that would benefit from this formulation.

In a November 2017 Pre-IND meeting with the US FDA, the agency confirmed that Solifenacin DRG qualifies for a 505(b)(2) regulatory pathway. The agency also agreed that a single bioequivalence study will be sufficient to support the approval of the Company's Solifenacin DRG product for the treatment of overactive bladder and no additional nonclinical, clinical efficacy and/or safety studies will be required. The Company plans to complete the Solifenacin DRG bioequivalence study in 2018 and to file an NDA in 2019. The chart below depicts Veru's clinical and regulatory timeline for Solifenacin DRG:



Source: Veru

Tadalafil-Finasteride combination capsules (tadalafil 5mg and finasteride 5mg)

Tadalafil-Finasteride combination capsule is a new, proprietary formulation that addresses men who have lower urinary tract symptoms and restricted urinary stream because of an enlarged prostate. Cialis (tadalafil 5mg) and Proscar (finasteride 5mg) co-administration is indicated for the initial treatment of benign prostate hyperplasia (BPH) for up to 26 weeks. Tadalafil 5mg daily has been previously approved for the treatment of erectile dysfunction and BPH, while Finasteride 5mg has been approved for the treatment of BPH, including to improve symptoms, to reduce risk of acute urinary retention and the need for prostate surgery, and to prevent progression of BPH.

The worldwide prevalence of BPH lower urinary symptoms is estimated to be 10%-25% of the male population and is estimated will rise to 1.1 billion men by 2018. Currently, co-administration of Cialis and Proscar is FDA approved for the initial treatment of signs and symptoms of BPH up to 26 weeks. However, a Tadalafil 5mg/ Finasteride 5mg combination capsule is not available at present, and it is the Company’s belief that a combination capsule would increase convenience and drug compliance. In a November 2017 Pre-IND meeting with the FDA, the agency confirmed that Tadalafil/Finasteride combination capsules qualify for a 505(b)(2) regulatory pathway. The FDA also agreed that a single bioequivalence study and no additional nonclinical, clinical efficacy and/or safety studies would be required to support the approval of Tadalafil/Finasteride combination capsules for the initial treatment of lower urinary tract symptoms in men with enlarged prostates. Thus, the Company plans to complete a Tadalafil/Finasteride combination capsule bioequivalence study in the second half of 2018 and to file an NDA in 2019. The chart below depicts Veru’s clinical and regulatory timeline for Tadalafil-Finasteride combination capsules:



Source: Veru

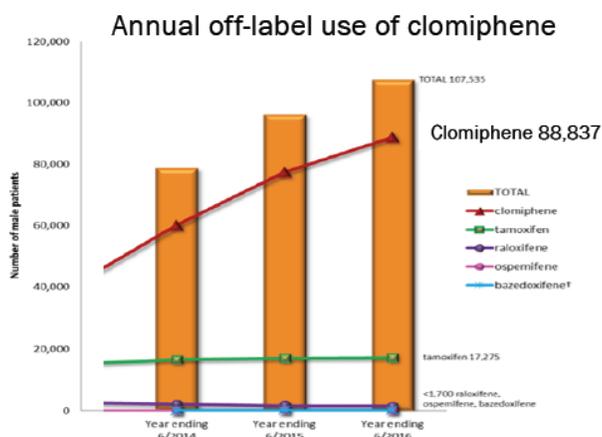
VERU-944

Prostate cancer is the most common non-cutaneous cancer diagnosed in men, with over 160,000 new cases expected in 2017 (American Cancer Society. Cancer Facts & Figures 2017). The estimated prevalence of prostate cancer is 2.35 million cases, for which over one-third will have received androgen deprivation therapy. Hot flashes, also known as vasomotor symptoms, are the most common and distressing side effect of hormonal

therapies for the treatment of advanced prostate cancer. Hormone therapies include androgen deprivation, like LUPRON (leuprolide) or ZOLADEX (goserelin), as well as newer agents approved to treat advanced prostate cancer such as ZYTIGA (abiraterone) and XTANDI (enzalutamide). In a 2010 study, up to 80% of men on androgen deprivation therapy complained of hot flashes. Hot flashes are defined as intense heat sensation, flushing and profuse sweating and chills as well as anxiety and palpitations. Although episodes of hot flashes occur repeatedly and often last only a few minutes, some may last up to 20 minutes. Hot flashes associated with prostate cancer hormonal therapies tend to persist over time with consistent frequency and intensity throughout therapy. Up to 50% of men continue to report hot flashes after five years on prostate cancer hormonal therapy, according to the 2010 study. Patients on prostate cancer hormonal therapy report significant negative effects on daily functioning and quality of life. Hot flashes are the main reason for patients to be noncompliant with their prostate cancer hormonal therapy. As prostate cancer patients with advanced and metastatic disease are living longer as a result of more effective hormonal therapies, hot flashes have become an even bigger concern and impact on quality of life.

Hormonal and non-hormonal therapies have been used off-label to treat hot flashes in men on prostate cancer hormonal therapies. In general, hormonal agents, especially estrogens are effective. However, estrogen treatment is complicated by lack of consistent dosing, dose dependent gynecomastia (breast enlargement), gynecodynia (painful breasts) and increase in thromboembolic events. Non-hormonal agents that have been used off-label include anti-seizure agents and antidepressants that have bothersome side effects. Moreover, non-hormonal agents tend to be less efficacious than hormonal therapies for the treatment of hot flashes. There are no FDA-approved therapies for hot flashes caused by prostate cancer hormonal therapy in men with advanced prostate cancer. VERU-944 active ingredient is cis-clomiphene (zuclomiphene), a potent nonsteroidal estrogen receptor agonist. Clomiphene, which contains 30%-50% zuclomiphene, appears to be well-tolerated in 39 published studies in over 2,200 men with doses as high as 400 mg/day and up to three years of use. A nonsteroidal hormone therapy such as VERU-944 may have the potential to be an effective and well-tolerated treatment for hot flashes resulting from the use of hormonal therapies in men with advanced prostate cancer.

Hot flashes are the most common side effect of prostate cancer hormone therapy. occurring in up to 80% of men, with about 30% having moderate to severe hot flashes. Approximately 700,000 men annually in the United States are on androgen deprivation therapy, abiraterone or enzalutamide for advanced prostate cancer. There are currently no FDA-approved therapies for hot flashes associated with prostate cancer hormonal therapies. The annual U.S. market for the treatment of hot flashes in men on prostate cancer hormonal therapies is estimated to be \$600 million, per IMS. The chart below depicts annual off-label use of clomiphene:

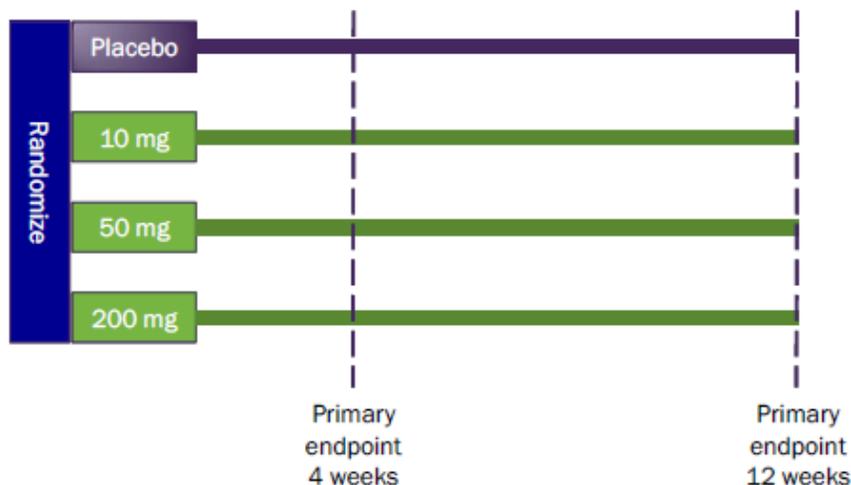


Source: Veru

Because VERU-944 (zuclomiphene) comprises 30-50% of CLOMID (clomiphene citrate) which is approved for the treatment of ovulatory dysfunction in women desiring pregnancy, Veru will be able to reference the

nonclinical and clinical safety information from both the listed drug labeling and the published literature under the 505(b)(2) regulatory pathway. Veru recently announced (June 2018) that following its earlier pre-IND meeting with the FDA, the Company has filed an IND for VERU-944 and plans to initiate a 120-patient Phase 2 multi-center, double-blind, placebo-controlled dose-finding clinical study in mid-2018.

The placebo controlled, randomized, blinded, dose finding Phase 2 clinical trial design for VERU-944 (ciscloimphene) is graphically depicted below:



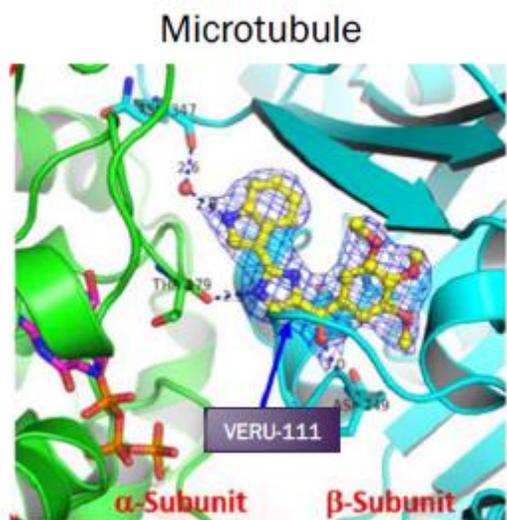
Source: Veru

VERU-111 for the treatment of metastatic prostate, breast, endometrial ovarian, and other cancers

In 2017 there were approximately 161,360 new cases of prostate cancer and about 25% will die from the disease, according to the American Cancer Society. In the US, 5% of men with prostate cancer will have metastatic cancer and up to 30% of men with high-risk, localized prostate cancer will develop metastatic cancer following initial therapy. The median survival of patients with metastatic prostate cancer ranges from 3.2-4.5 years. For these men, 1st line therapy is androgen deprivation therapy, or medical castration. Although most will initially respond, nearly all these patients will progress to metastatic castration resistant prostate cancer and have a poor prognosis with an average survival of 1.5 years. New 2nd line hormonal agents, such as XTANDI (enzalutamide) and ZYTIGA (abiraterone/prednisone), have resulted in an additional four to five months of average survival, but again, nearly all men on these agents will develop progressive metastatic prostate cancer.

Agents that target tubulin have been shown to be the most effective cytotoxic chemotherapy for the treatment of metastatic prostate cancer. Tubulin, a component of microtubules, is required for cancer cell replication and to shuttle the androgen receptor into the nucleus where the receptor stimulates genes for cancer cell proliferation. Docetaxel and cabazitaxel are examples of FDA-approved chemotherapy drugs that are given intravenously (IV) that target tubulin to treat metastatic prostate cancer. Although effective, the challenges for this class of chemotherapy agents, also known as taxanes, include that they must be given via IV (or intravenously) and that the cancer cells develop resistance to taxanes in a variety of ways: Cancer cells may (i) express multidrug resistance proteins which pump the taxane chemotherapy meant to kill the cancer cells out of the cancer cells; (ii) develop tubulin mutations so taxanes are no longer able to bind to the mutated tubulin; and/or (iii) over-express beta-tubulin so that there is plenty of tubulin present for cell replication even if some tubulin is bound by taxanes. There are also serious safety concerns with IV taxanes which include serious hypersensitivity reactions, myelosuppression and neurotoxicity such as peripheral neuropathy and muscle weakness.

Based on over 28 peer-reviewed scientific publications, VERU-111 is a novel small molecule and New Chemical Entity (NCE) that has been optimized to be an orally dosed tubulin targeting chemotherapy agent. VERU-111 binds to a different site from taxanes on tubulin called the “colchicine binding site.” VERU-111 has high oral bioavailability and does not interact with multiple drug resistance proteins so it cannot be pumped out of the cancer cell; minimal drug to drug interactions (especially not metabolized by CYP3A4); and has high activity against many tumor types including prostate, breast and ovarian cancers. Furthermore, it has activity against cancers that have become resistant to taxanes, vinca alkaloids and doxorubicin. In preclinical studies, VERU-111 has less neurotoxicity and leucopenia compared to other tubulin targeting agents. A graphic depiction of the mechanism of action of VERU-111 is shown below:



Source: Veru

In the US, there is a \$5 billion annual market for 2nd line hormone therapies for prostate cancer and a \$4.8 billion annual market for IV-given taxanes and vinca alkaloids (Docetaxel \$1 billion and cabazitaxel \$500 million in prostate cancer) per Decision Resources Group and Allied Market Research. Second line therapies like enzalutamide and abiraterone/prednisone have almost complete cross-resistance and should not be used in sequence for the treatment of metastatic prostate cancer. VERU-111, as an oral tubulin targeting chemotherapy agent, could replace docetaxel and cabazitaxel. VERU-111 could also be developed into a 1st line therapy given with androgen deprivation in men that have hormone sensitive, high volume prostate cancer where androgen deprivation therapy and docetaxel have been shown in several studies to increase survival in these men by 17-21 months. Another 1st line indication could be developed in men who have metastatic prostate cancer and a mutation of the androgen receptor known as AR-V7. Prostate cancer hormone therapies are not as effective in men who have AR-V7 mutations. However, this type of cancer appears to respond to docetaxel and may be potentially treated by an oral tubulin chemotherapy like VERU-111. VERU-111 could also be developed as an oral dosing alternative for the treatment of metastatic breast and ovarian cancers as these tumors also respond to IV taxanes.

Veru initially plans to develop VERU-111 as a 3rd line hormonal therapy after androgen deprivation (1st line) and enzalutamide or abiraterone (2nd line) have failed. Production of the active pharmaceutical ingredient and preclinical safety toxicology studies required for an IND are expected to be completed in 2018 and Phase 1a and Phase 1b studies are planned for the next year. Phase 1 studies of VERU-111 are planned in men who have metastatic prostate cancer that has progressed while taking androgen deprivation therapy and enzalutamide as well as in other solid tumors like breast and ovarian cancer. After the Phase 1s are completed, Veru plans to

conduct a Phase 2 study of VERU-111 in men as 3rd line hormonal therapy, as well as in other relevant indications.

VERU-111/112 for the treatment of gout and Familial Mediterranean Fever (FMF)

Colchicine is FDA-approved for prophylaxis and treatment of gout flares in adults and for FMF in adult and children four years and older. Gout is a type of arthritis characterized by sudden, severe attacks of burning joint pain, usually the big toe, because of the deposition of uric acid crystals in the joint. FMF is a hereditary inflammatory disorder caused by mutations in the MEFV gene that causes episodes of fever, pain and swelling in the abdomen (peritonitis), lungs (pleuritis), heart (pericarditis) and joints (arthritis) in adults and children. Colchicine has a narrow therapeutic index, which means that the doses required to treat the disease and the occurrences of serious safety issues are close, with common side effects such as abdominal cramping, nausea and diarrhea that have limited its use. More concerning, however, colchicine has "warning and precautions" in its label for drug-drug interactions and should not be taken in conjunction with other drugs that are P-glycoprotein (P-gp) or strong CYP3A4 inhibitors, for example certain antibiotics, antidepressants, lipid lowering drugs, tranquilizers, grapefruit juice and antihistamines.

VERU-111, and its back up VERU-112, are NCEs, small molecules that have high oral bioavailability, and like colchicine, bind to the "colchicine binding site" of tubulin. Unlike colchicine, there should not be drug-drug interactions, as VERU-111 does not interact with P-gp or CYP3A4, which may potentially eliminate the possibility of serious and life-threatening side effects when given with other drugs that are P-gp or CYP3A4 inhibitors. VERU-111/112 could be used as a potentially safer alternative to colchicine, which remains the mainstay of therapy for both prevention and treatment of gout and FMF. The Phase 1 VERU-111 studies that are planned for 2019 in cancer patients are expected to provide the initial pharmacokinetics and safety information that can be used for dosing and safety considerations for filing the IND and conducting the Phase 2 studies for gout, expected in 2019 or later.

VERU-722

Up to 10% of infertile men have an endocrine cause and 2% of infertile men have an adult onset form of idiopathic hypogonadotropic hypogonadism. Current FDA-approved treatments for this indication include HCG and FSH injections. There are no FDA-approved oral therapies for male infertility. CLOMID (clomiphene citrate) 50 mg tablets are used off-label as first line empiric therapy in approximately two-thirds of idiopathic infertile men (2012). CLOMID is FDA-approved for the treatment of ovulatory dysfunction in women desiring pregnancy. CLOMID is a mixture of two geometric isomers cis-clomiphene (zuclomiphene) and trans-clomiphene (enclomiphene) containing between 30-50% of the cis-clomiphene isomer. Trans-clomiphene has antiestrogenic activity, while the cis-clomiphene has estrogenic activity. In men, clomiphene has the ability to interact with the hypothalamus and pituitary gland to cause the secretion of LH, and the higher levels of LH will stimulate Leydig cells in the testes to produce testosterone, to promote spermatogenesis, and to improve sperm count and quality.

Based on the scientific literature, clomiphene has demonstrated the ability to improve sperm quality and sperm counts in infertile men and result in higher pregnancy rates. Based on 39 published studies, clomiphene appears to be well tolerated in men with doses as high as 400 mg/day and up to three years of use. However, the efficacy results for an individual patient have been inconsistent from study to study for several reasons: the form of clomiphene used contained varying ratios of the trans- and cis-clomiphene isomers, different doses were given, various dosing schedules were followed and different patient populations were studied. Clomiphene has not been formally studied for regulatory approval for the indication of male infertility; therefore, there is no established dose or schedule for efficacy or safety in men. VERU-722 is a patented, proprietary daily oral tablet that has a specific fixed ratio of the combination of trans- and cis-clomiphene isomers.

If approved, VERU-722 would be indicated as the first oral treatment for male infertility. Infertility affects 6.1 million couples in the United States representing 15% of all couples trying to conceive. Up to 50% of infertility is attributed to males who are subsequently found to have abnormal semen analysis, of which 50% of these men are diagnosed with idiopathic, or unexplained, infertility. Two-thirds of men with idiopathic male infertility are empirically treated with off-label use of CLOMID. VERU-722 may be effective in treating cases of male factor infertility that arise from idiopathic infertility, including those with hypogonadotropic hypogonadism. The current US market size for idiopathic male infertility is estimated to be \$700 million annually per IMS.

VERU-722 is being developed as the first oral agent for the treatment of male infertility. VERU-722 has a fixed ratio of the combination of trans- and cis- clomiphene isomers. Using a fixed ratio approach will allow the determination of the correct dose and schedule for efficacy and safety for the treatment of male infertility. The patient population will be men who have hypogonadotropic hypogonadism and infertility. Veru met with the FDA for a pre-IND meeting where the FDA confirmed that VERU-722 qualifies for the 505(b)(2) regulatory pathway. The formulation, doses and dosing regimen for VERU-722 will differ from those of CLOMID. Despite the differences, the approval of VERU-722 will rely on nonclinical and clinical efficacy and safety information from the listed drug labeling and in the published literature.

Operations

Currently, the Company has approximately 175 full-time employees, including 27 located in the US, 11 in the United Kingdom, and 134 operating in leased production space in Selangor DE, Malaysia for the production of the Company's FC2 product. The Malaysian facility is comprised of production and warehouse space for a manufacturing capacity of approximately 100 million units annually with sufficient space to add manufacturing capacity for up to an additional 100 million units annually. The Company currently has an agreement with a third-party contract manufacturer to produce its Preboost medicated individual wipes and further expects to rely on third-party contract manufacturers and other third parties to produce, package and store sufficient quantities of any future drug candidates.

Intellectual Property

The Company currently owns or holds exclusive rights to 9 issued US patents, 6 pending US patent applications and additional patents and patent applications in other jurisdictions outside the United States. These include an international patent application relating to the Tamsulosin DRS product that is subject to deferred payment obligations and patents and patent applications relating to the VERU-111 and VERU-112 drug candidates that are licensed from a third party. Recently, Veru announced that the US Patent and Trademark Office issued Patent #9,913,815, which provides intellectual property protection for the use of VERU-944 in men with prostate cancer as a method of treating and preventing side effects caused by androgen deprivation hormone therapy (ADT) including hot flashes, bone loss and bone fractures, and expires in 2035.

Recent Results and Outlook

Veru reported financial results for their Q2/2018 quarter, ending March, including revenues of \$2.6 million, up 7% from \$2.4 million in the previous year period, and a net loss of \$3.8 million, or (\$0.07) per share, as compared with a net loss of \$1.8 million, or (\$0.06) per share in Q2/17. Revenue growth in the second quarter was led by a 7% increase in sales of the FC2 product, primarily from improved access for the US market, large unit orders in South Africa, and an initial order from the United Arab Emirates. Net loss increased during the

quarter, due to lower gross margins partially due to negative currency exchange factors, higher R&D expenses as Veru advanced additional pipeline programs this year, and higher overhead costs, including additional spending for marketing of FC2 in the US.

Cash burn from operations was approximately \$4.2 million for the first six months of the 2018E fiscal year for Veru, and at the end of March the Company held \$9.0 million in cash on hand, up from \$3.3 million at the start of the fiscal year (October 1), aided by \$9.9 million in proceeds from the March 2018 credit and residual royalty agreement with SWK Funding related to a FC2 sales.

The Company's balance sheets for the periods Q2/2018 (March) and Q4/2017 (September) are shown below:

	<u>Balance Sheets</u>	
	(\$000s)	
<i>Assets:</i>	<u>9/30/17</u>	<u>3/31/18</u>
<u>Current Assets</u>		
Cash and equivalents	\$3,278	\$8,972
Accounts receivable, net	3,555	2,969
Inventory, net	2,768	3,589
Prepaid expenses and other current assets	<u>697</u>	<u>630</u>
Total current	10,298	16,160
Plant and equipment, net	556	469
Other trade receivables	7,838	0
Goodwill and intangible assets	27,632	27,494
Deferred taxes and other long-term assets	<u>8,983</u>	<u>14,071</u>
TOTAL ASSETS	\$55,306	\$58,195
<i>Liabilities:</i>		
<u>Current liabilities</u>		
Accounts payable	\$2,686	\$3,540
Accrued expenses and other liabilities	1,441	1,940
Current portion of credit agreement	0	3,913
Other current liabilities	<u>1,361</u>	<u>1,195</u>
Total current	5,488	10,588
Long-term portion of credit agreement	0	5,823
Other non-current liabilities	<u>1,366</u>	<u>453</u>
Total liabilities	6,853	16,864
Stockholders' equity	<u>48,453</u>	<u>41,331</u>
TOTAL LIAB & EQ	\$55,306	\$58,195

Source: Veru

While Veru management has not provided specific revenue or earnings guidance going forward, they have discussed the outlook for sales of the FC2 product, the Company's main source of revenue, in light of recent quarterly sales, two large pending international orders for FC2 (Brazil and South Africa), and a recent transition to an independent contractor sales force. With these factors in mind, we are estimating that the Company will post revenues of \$3.5 million in Q3/2018 (June) and \$4.5 million in Q4/2018, making \$13.2 million in revenues for fiscal 2018E, with net losses of (\$0.09) and (\$0.08) per share for Q3/18 and Q4/18, respectively, and (\$0.33) per share for 2018E as a whole.

For next fiscal year, we anticipate higher product sales will help revenues rebound to \$22 million for the year, similar to recent highs from fiscal 2016. Combined with slightly improved gross margins, and R&D and other

overhead expenses at levels similar to those for fiscal 2018E, an improved net loss of (\$0.25) is forecast for Veru for fiscal 2019E.

In its recent Q2/18 10-Q, Veru asserted that the Company believes that it has adequate financial resources to cover the next twelve months, and our cash burn estimates of approximately \$2.0-\$2.5 million per quarter and current cash reserves of \$9.0 million on hand would corroborate that assertion.

Veru has a number of near- and long-term catalysts relating to both its products and R&D pipeline, as summed up in the following table:

	2018	2019
FC2	<ul style="list-style-type: none"> • Grow US business • Grow public sector- secure new Brazil and S. African tenders 	<ul style="list-style-type: none"> • Grow US business • Grow public sector- secure new Brazil and S. African tenders
Tamsulosin DRS & XR capsules- BPH	<ul style="list-style-type: none"> • Complete BE study Q3 • File NDA • Complete stability on manufactured batches (6 months) • Partner US and ROW 	<ul style="list-style-type: none"> • Meet EMA • Launch in US • Continue seeking partnership deals
Solifenacin DRG granules -OAB	<ul style="list-style-type: none"> • BE study • Partner US and ROW 	<ul style="list-style-type: none"> • PreNDA meeting Q1 and NDA Q3 • Complete stability on manufactured batches (6 months) • Meet EMA Q1 and MAA Q2 • Continue partnership deals
Tadalafil/Finasteride combo- prostate enlargement and ED	<ul style="list-style-type: none"> • BE study • Partner US and ROW 	<ul style="list-style-type: none"> • PreNDA meeting Q1 and NDA Q2 • Complete stability on manufactured batches(6 months) • Meet EMA • Continue partnership deals
VERU-944- hot flashes in men on ADT	<ul style="list-style-type: none"> • IND Q2 • Initiate Phase 2 clinical trial Q3 	<ul style="list-style-type: none"> • Complete Phase 2 Q1/2 • Initiate Phase 3 Q4 • Seek Partnerships
VERU-111	<ul style="list-style-type: none"> • IND Q2/Q3 • Initiate Phase 1/2 – prostate and other cancers Q3/4 at Hopkins 	<ul style="list-style-type: none"> • Complete Phase1/2 • Initiate Phase Phase 2 • Seek large pharma partner

Source: Veru

Management

Veru's management team and board of directors include:

Dr. Mitchell S. Steiner has served as President and Chief Executive Officer of the Company and as a director since October 2016, and previously was the co-founder of Aspen Park and served as its CEO. Previously, Dr. Steiner was President, Urology of OPKO Health (OPK, Not Ranked), and co-founder of GTx (GTXI, NR). Dr. Steiner is a Board Certified Urologist.

Dr. Harry Fisch is Chief Corporate Officer and has served as a director of the Company since October 2016. Dr. Fisch was the co-founder of Aspen Park and served as the Chairman of the Board and Chief Scientific Officer of Aspen Park from July 2014 to October 2016. Prior to joining the Company, Dr. Fisch served as the CEO and President of Millennium Sciences and Clinical Professor of Urology and Reproductive Medicine at Weill College of Medicine, Cornell University. Dr. Fisch is a Board Certified Urologist.

Dr. Robert H. Getzenberg is currently the Chief Scientific Officer at Veru. He previously served as the Therapeutic Area Lead, Prostate Cancer at GTx, Director of Research of the James Buchanan Brady Urological Institute and the Donald S. Coffey Professor of Urology and Professor of Pharmacology and Molecular

Sciences at the Johns Hopkins University School of Medicine, and as Co-Director of the Prostate Cancer Program at the Sidney Kimmel Comprehensive Cancer Center.

Michele Greco has served as Chief Financial Officer and Chief Administrative Officer of the Company since October 2016. Previously, Ms. Greco served as Executive Vice President and Chief Financial Officer of The Female Health Company, and as an audit partner for Ernst & Young LLP. Ms. Greco is a CPA.

Other key management at the Company includes: **Kevin Gilbert**, Senior Vice President Corporate Development and Legal who was previously with McDermott, Will & Emery, Motorola and Third Stream Bioscience; **Dr. Matthew Gosnell**, Senior Vice President of Manufacturing, Preclinical and Pharmaceutical Development and formerly with GTx, Alkermes, McNeil and Pharmacia; **Martin Tayler**, Executive Vice President of Global Operations of Veru since January 2017 and formerly with a subsidiary of Reckitt Benckiser Group plc; **Phillip Kuhn**, Executive Vice President – Strategy and previously with Abbott, Johnson & Johnson, Boston Scientific, Smith & Nephew, Orthofix, and most recently ISTO Biologic; and **Denise van Dijk**, President The Female Health Company, Global Public Sector Division, with over 10 years of experience in market development.

In addition to management team members Dr. Steiner and Dr. Fisch, Veru’s Board of Directors includes: **O.B. Parrish**, former CEO of The Female Health Company; **David R. Bethune**, a former executive with Zila, Ivax and Atrix Labs; **Dr. Mario Eisenberger**, currently Professor of Oncology at The Johns Hopkins University; **Dr. Lucy Lu**, currently Interim President and CEO of Avenue Therapeutics; **Jesus Socorro**, a CPA and Managing Principal of the Risk Advisory practice of Morrison, Brown, Argiz & Farra; and **Michael L. Rankowitz**, a former managing director at Morgan Stanley.

Stock Valuation/Comparables

We have compiled a comparable company group for VERU comprised primarily of smaller capitalization specialty pharmaceutical companies, including AcelRx Pharma (ACRX, Not Rated), BioDelivery Science (BDSI, NR), Cumberland Pharma (CPIX, NR), DURECT (DRRX, NR), Foamix Pharmaceuticals (FOMX, NR), Juniper Pharma (JNP, NR), KemPharm (KMPH, NR), Neos Therapeutics (NEOS, NR), ProQR Therapeutics (PRQR, NR), Recro Pharma (REPH, NR), Strongbridge Biopharma (SBBP, NR), TherapeuticsMD (TXMD, NR), Trevena (TRVN, NR), and Xenon Pharma (XENE, NR). On average, our comparable stock group shows market capitalization metrics of approximately \$270 million, representing a significant premium to Veru’s current market cap of approximately \$120 million, perhaps due to Veru’s relative lack of familiarity with investors following the recent merger of Aspen Park Pharmaceuticals into the former The Female Health Company. However, we believe as VERU continues to grow its product-oriented revenues and make progress on its substantial clinical pipeline, both short-term and long-term investors will discover these shares, and therefore we are initiating coverage on VERU shares with a Buy rating and 12-18 month price target of \$5.00 per share, based on the average market capitalization of our comparable stock group.

Risk Factors

In addition to normal economic and market risk factors that impact most equities and the common risks shared by Veru with other companies in the industry, we believe an investment in VERU involves the following risks:

- **Reliance on key management** – At present, VERU relies on several key members of its management team and board of directors who have been in these key positions or similar positions at predecessor companies for an extended period of time. Should one or more of these key executives leave the Company, VERU could find it difficult to replace their long-standing knowledge of operations and industry expertise.
- **Reliance on future collaborations and partnerships** – To date, VERU has not signed development contracts in its strategic areas of urology or oncology, but may do so in the future. Oftentimes in the case of development partnerships or joint ventures certain factors related to research and/or new product development may be determined by third parties and out of the control of Company management.
- **Limited stock liquidity** – Trading volume in VERU on the Nasdaq exchange is comparatively light as these shares have a relatively limited history of trading compared with other healthcare stocks. As such, news regarding VERU, its target market, partners and/or competitors could lead to significant volatility in the stock price.
- **Competitive markets** – The Company and its potential collaborative partners are expected to compete in its current and targeted women’s health, urology and oncology markets with a number of companies, many of which are considerably larger than the Company. There can be no assurance that the Company and its partners will be able to successfully compete and launch new products and services into these competitive markets in the future.
- **FDA and regulatory risks** – VERU is subject to regulatory review for current product offerings as well as for ongoing research and development efforts, including approval and review processes of the US Food and Drug Administration and other international regulatory agencies. In addition, the operation of the Company's facilities may be subject to ongoing oversight and regulation, and any negative correspondence from the FDA or other regulatory agencies in the future could have an adverse effect on the ongoing operations of the Company.
- **Lack of historic profitability** – VERU has not achieved operating profitability in several years, and according to our forecasts may not be expected to do so in the near future. Although the Company maintains adequate cash reserves at the present time, there can be no assurance the Company will not need to raise additional working capital in the future should operating losses continue.
- **Need to defend trade secrets and other intellectual property** – VERU currently holds a number of patents, exclusive patent licenses, and trademarks as well as has patent applications pending on a number of its key products and pipeline programs. The Company may be required to defend its patents or patent licenses in the US and overseas in the future, and there can be no assurance these defenses will be successful.

Veru, Inc.
Consolidated Statements of Income
 (In 000s, except per share data)

FYE December	2014	2015	2016	1Q17	2Q17	3Q17	4Q17	2017	1Q18	2Q18	3Q18E	4Q18E	2018E	2019E
				December	March	June	September		December	March	June	September		
Net revenues	\$24,491	\$32,605	\$22,127	\$3,244	\$2,406	\$4,314	\$3,692	\$13,656	\$2,587	\$2,573	\$3,500	\$4,500	\$13,159	\$22,000
Cost of sales	11,370	13,635	8,778	1,591	1,128	2,019	1,898	6,636	1,273	1,373	1,840	2,360	6,846	9,900
Gross profit	13,121	18,970	13,349	1,652	1,278	2,295	1,795	7,020	1,314	1,199	1,660	2,140	6,313	12,100
Operating Expenses														
Research and development		220	99	171	1,208	427	1,699	3,504	2,039	2,077	2,100	2,150	8,366	8,000
Selling, General and administrative		12,132	8,749	2,530	2,541	3,134	2,868	11,073	2,948	3,819	4,000	4,100	14,867	15,000
Other, one-time	0	0	1,483	826	108	0	1	936	3,764	0	0	0	3,764	1,000
Total operating expenses	9,197	12,352	10,331	3,527	3,857	3,561	4,569	15,514	8,751	5,896	6,100	6,250	26,997	24,000
Income (loss) from operations	3,924	6,618	3,019	(1,875)	(2,579)	(1,266)	(2,774)	(8,494)	(7,437)	(4,697)	(4,440)	(4,110)	(20,683)	(11,900)
Other income (expense)														
Interest expense		10	(57)	(10)	0	(13)	(24)	(47)	(13)	(351)	(400)	(400)	(1,164)	(1,200)
Other income (expense)		58	(148)	(12)	(21)	(20)	(1,999)	(2,053)	(53)	(86)	(50)	(50)	(240)	(200)
Total other (expense)	33	69	(205)	(22)	(21)	(33)	(2,023)	(2,099)	(67)	(437)	(450)	(450)	(1,404)	(1,400)
Income (loss) before tax	3,957	6,687	2,814	(1,896)	(2,601)	(1,300)	(4,797)	(10,593)	(7,503)	(5,134)	(4,890)	(4,560)	(22,087)	(13,300)
Income tax (benefit)	1,524	2,341	2,469	(530)	(824)	(510)	(127)	(1,990)	(3,246)	(1,302)	0	0	(4,548)	0
Net income (loss)	2,433	4,346	345	(1,366)	(1,777)	(790)	(4,670)	(8,603)	(4,257)	(3,831)	(4,890)	(4,560)	(17,538)	(13,300)
Basic income per share	\$0.08	\$0.15	\$0.01	(\$0.04)	(\$0.06)	(\$0.03)	(\$0.12)	(\$0.25)	(\$0.08)	(\$0.07)	(\$0.09)	(\$0.08)	(\$0.33)	(\$0.25)
Diluted income per share	\$0.08	\$0.15	\$0.01	(\$0.04)	(\$0.06)	(\$0.03)	(\$0.12)	(\$0.25)	(\$0.08)	(\$0.07)	(\$0.09)	(\$0.08)	(\$0.33)	(\$0.25)
Basic shares outstanding	28,865	28,532	28,666	30,976	30,982	30,991	38,000	34,640	53,154	53,356	53,500	53,700	53,428	54,000
Diluted shares outstanding	28,865	28,532	28,927	30,976	30,982	30,991	38,000	34,640	53,154	53,356	53,500	53,700	53,428	54,000
Key ratios:														
Revenue growth	-22.1%	33.1%	-32.1%	-60.6%	-49.6%	-22.4%	3.6%	-38.3%	-20.3%	7.0%	-18.9%	21.9%	-3.6%	67.2%
Gross margins	53.6%	58.2%	60.3%	50.9%	53.1%	53.2%	48.6%	51.4%	50.8%	46.6%	47.5%	47.5%	48.0%	55.0%
R&D/revenue	0.0%	0.7%	0.4%	5.3%	50.2%	9.9%	46.0%	25.7%	78.8%	80.7%	60.0%	47.8%	63.6%	36.4%
S, G & A/revenue	0.0%	37.2%	39.5%	78.0%	105.6%	72.7%	77.7%	81.1%	114.0%	148.4%	114.3%	91.1%	113.0%	68.2%
Tax Rate	38.5%	35.0%	87.7%	-28.0%	-31.7%	-39.2%	2.6%	-18.8%	-43.3%	-25.4%	0.0%	0.0%	-20.6%	0.0%
Deprec, amort & non-cash comp.	1,000	1,000	922	980	230	240	330	1,780	320	880	600	700	2,500	2,500
Cash Flow/share	\$0.12	\$0.19	\$0.05	(\$0.01)	(\$0.05)	(\$0.02)	(\$0.06)	(\$0.14)	(\$0.07)	(\$0.05)	(\$0.08)	(\$0.07)	(\$0.28)	(\$0.20)
EBITDA/share	\$0.17	\$0.27	\$0.14	(\$0.03)	(\$0.08)	(\$0.03)	(\$0.06)	(\$0.19)	(\$0.13)	(\$0.07)	(\$0.07)	(\$0.06)	(\$0.34)	(\$0.17)

Balance Sheets

(\$000s)

Assets:

Current Assets

	9/30/17	3/31/18
Cash and equivalents	\$3,278	\$8,972
Accounts receivable, net	3,555	2,969
Inventory, net	2,768	3,589
Prepaid expenses and other current assets	697	630
Total current	10,298	16,160
Plant and equipment, net	556	469
Other trade receivables	7,838	0
Goodwill and intangible assets	27,632	27,494
Deferred taxes and other long-term assets	8,983	14,071
TOTAL ASSETS	\$55,306	\$58,195

Liabilities:

Current liabilities

Accounts payable	\$2,686	\$3,540
Accrued expenses and other liabilities	1,441	1,940
Current portion of credit agreement	0	3,913
Other current liabilities	1,361	1,195
Total current	5,488	10,588
Long-term portion of credit agreement	0	5,823
Other non-current liabilities	1,366	453
Total liabilities	6,853	16,864
Stockholders' equity	48,453	41,331
TOTAL LIAB & EQ	\$55,306	\$58,195

Quarterly Earnings Comparisons

	December	March	June	September	Total
Revenues (in \$Mill)					
2014					\$24,491
2015					32,605
2016	8,231	4,773	5,561	3,563	22,127
2017	3,244	2,406	4,314	3,692	13,656
2018E	2,587	2,573	3,500	4,500	13,159
Earnings per Share (diluted)					
2014					\$0.08
2015					0.15
2016	0.05	0.00	0.02	(0.06)	0.01
2017	(0.04)	(0.06)	(0.03)	(0.12)	(0.25)
2018E	(0.08)	(0.07)	(0.09)	(0.08)	(0.33)

Revenues by Country (\$000s)

	2015	2016	2017	2018E
United States	\$2,029	\$2,464	\$1,288	\$5,000
Zimbabwe	2,696	3,305	2,227	1,300
Mozambique	0	0	1,430	0
South Africa	2,331	1,117	951	2,500
Cameroon	0	0	891	0
Nigeria	0	0	846	0
Brazil	14,841	6,008	0	0
Other	10,708	9,233	6,022	4,400
Total	\$32,605	\$22,127	\$13,655	\$13,200

Significant Customers (by %)

USAID	16.0%	24.0%	44.0%	25.0%
UNFPA	18.0%	25.0%	25.0%	20.0%
Semina (Brazil)	47.0%	27.0%		
Total	81.0%	76.0%	69.0%	45.0%

Source: Dawson James Securities, Inc. estimates; Company documents

Important Disclosures:

Price Chart:



Price target and ratings changes over the past 3 years:

Initiated – Buy - June 25, 2018 – Price Target \$5

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Ratings Definitions:

- 1) **Buy:** the analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** the analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services in the last twelve months.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	88%	6	29%
Market Perform (Neutral)	3	13%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	24	100%	6	25%

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