BROOKLINE CAPITAL MARKETS

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Equity Research

April 05, 2018

Healthcare

VERU

Buy
Initiation of Coverage

Current Price
$1.80

Target Price
$10.00

Market Capitalization
96.32M

Shares Outstanding
53.51M

Float
28.52M

Institutional Holdings
4.28%

12-month Low/High
$0.90/$3.00

Average 90-day Volume
129,981

Fiscal Year End
September 30

Revenues ($M)			
Period	2017A	2018E	2019E
Q1			
Q2			
Q3			
Q4			
	$13.7	16.1E	25.6E

EPS ($)			
Period	2017A	2018E	2019E
Q1			
Q2			
Q3			
Q4			
	($0.25)	($0.27)E	($0.26)E

Veru, Inc.

Potential to Create More Value Than Meets the Eye, Initiating Buy $10 TP

- **Conclusions** — We are initiating coverage with a Buy rating and $10 TP. In our view, Tamsulosin DRS, slow release granules, and Tamsulosin XR capsules have potential to be value drivers for the stock based on their differentiated profile including lack of food effect and use in patients with dysphagia. We model substantial revenues in benign prostatic hyperplasia (BPH) patients with dysphagia. We believe that the stock has significant upside potential with modest pipeline success, despite our conservative financial estimates. Our $10 TP is based on probability adjusted sum of parts valuation of Tamsulosin and 25% premium for rest of the pipeline.

- **Tamsulosin XR and DRS differentiated profile should drive uptake** — Tamsulosin XR and DRS would be addressing a well-defined indication with an established market and a medical need, and we conservatively model 33% probability of approval and expect launch in 2020. We model peak sales of $886M in 2036.

- **VERU-944 Phase 2 expected to begin in Q318** — Phase 2 trial to study another 505(b)(2) candidate VERU-944 (cis-clomiphene) to treat hot flashes in advanced prostate cancer patients on hormone therapy is expected to begin in Q318 with data in Q119.

- **VERU-111 significant potential in oncology** — Veru is also preparing to start a Phase 1/2 open label trial to study VERU-111, a novel, taxane-like oral therapy for metastatic castration resistant prostate cancer (MCRPC) that targets both alpha and beta tubulin. Investigational New Drug (IND) application for VERU-111 is expected to be filed in Q218 and the clinical trial, expected to be done in Johns Hopkins as the lead site is anticipated to have data in early 2019.

- **Multiple Catalysts in next 12 months** — We foresee multiple catalysts in next twelve months, including NDA filing for Tamsulosin, VERU-944 Phase 2 initiation and data, and VERU-111 IND filing and data. Solifenacin DRG and Tadalafil/Finasteride combo capsules NDA filing is expected in 2019.

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Portfolio Manager's Summary

Focus on Developing Urology and Oncology Products Leveraging 505(b)(2)

Veru is a biopharmaceutical company with a focus on developing products in Urology (including a female sexual health division) and Oncology. It has two products in the market generating revenues, a female condom and a male penile desensitizing wipe for premature ejaculation. These products have potentially large niche markets and would continue to generate revenues. Growth in established markets and entry into newer geographical markets in South America and Africa and increasing sales would ensure sustained revenue growth and a source of capital/expertise for portfolio products under development.

Veru is now focusing on development of differentiated products for urology and cancer indications and is advancing its efforts to have a pipeline of potential products that can be approved by 505(b)(2) regulatory pathway for commercializing successful products.

Figure 1. Pipeline focus on therapeutics targeting urology and oncology

Source: Veru

The most advanced products in its pipeline for 505(b)(2) approval are Tamsulosin DRS granules (soluble powder) and Tamsulosin XR (extended release capsules) for benign prostate hyperplasia (BPH) that the company is planning to file NDAs for in 2018. Solifenacin DRG granules are being developed for the indication of overactive bladder, and combination Tadalafil/Finasteride capsules for enlarged prostate and erectile dysfunction (ED), with NDA being

planned for these two products in 2019. All these products are well positioned for approval only after relatively straightforward pivotal bioequivalence (BE) studies.

Veru is also initiating a Phase 2 trial to study another 505(b)(2) candidate VERU-944 (cis-clomiphene) to treat hot flashes in advanced prostate cancer patients on hormone therapy with an eye for NDA in 2020.

In addition, Veru is also preparing to start a Phase 1/2 open label trial to study VERU-111, a novel, taxane-like oral therapy for metastatic castration resistant prostate cancer (MCRPC) that targets both alpha and beta tubulin. An Investigational New Drug (IND) application for VERU-111 is expected to be filed in Q218 and the clinical trial - expected to be done in Johns Hopkins as the lead site - is anticipated to have data in early 2019.

The company has interest in Urology products that can be approved by the 505 (b) (2) regulatory pathway. These drugs are already approved for other indications, and therefore are overall safe and efficacious with existing clinical data. These are good candidates for label expansion, with new formulations as approvals are potentially low risk and lower cost with faster path to pivotal trials.

Tamsulosin DRS formulations to overcome disadvantages of current SOC for BPH

Tamsulosin DRS (XR oral suspension) is 505(b)(2) candidate in an extended (slow) release soluble powder form for prostate gland enlargement (BPH) patients who have difficulties in swallowing pills due to dysphagia. BPH is a common old-age related condition affecting men. Based on census data there are ~42M men in U.S over that are age 55 and over. Based on a study published by Guess et. al in The Prostate Journal, the prevalence of histologically diagnosed BPH is 40 to 50 percent in men aged 51 to 60 and is over 80 percent in men older than age 80. Branded/generic Tamsulosin is approved (brand name as FLOMAX; available as Tamsulosin hydrochloride pills) and available for treatment of BPH. FLOMAX was developed by Astellas Pharma. However, many elderly patients, or those with neuropsychological disorders or those living with consequences of stroke often have dysphagia or swallowing difficulties. Up to 50% of more of those afflicted with Parkinson's disease, Alzheimer's disease, stroke, or those living in long term care centers suffer from dysphagia and cannot therefore be treated for BPH even when an approved treatment is available.

Tamsulosin is a selective alpha 1- adrenergic blocker for alpha 1 receptors in prostate gland. Enlarged prostate may push against the urinary bladder and affect the musculature around the bladder or urethra that passes urine for excretion, thus resulting in reduced capacity of the bladder, pinching/constriction of the urethra and other mechanical issues. Tamsulosin acts by relaxing the smooth musculature around the bladder/prostate neck area. This helps improving urine flow and reducing BPH symptoms.

Although FLOMAX is the choice alpha-blocker treatment for BPH in the elderly, there are several issues with the current state of treatment. FLOMAX is only available as a capsule and must be taken 30 minutes after meals to ensure optimal absorption. Fasting levels of absorption, or disintegration of the capsule can result from accident or nonconformance (chewing, crushing, opening of the capsule cover) in patients who have difficulties with instructions, and this results in very high absorption in a small amount of time which can have undesirable side effects. Since this relaxes musculature, reduction of blood flow could happen resulting in low blood pressure, dizziness, fainting. ~15% of patients with BPH may also suffer from dysphagia (often resulting from neurological damage in conditions like Parkinson's disease, stroke) as perhaps unrelated but associated conditions and such patients get precluded and cannot benefit fully from the standard of care regimen. In these patients that cannot take capsule form of Tamsulosin, BPH can lead to bladder infection, sepsis and may have to be treated with more invasive methods like catheterization to empty the bladder and/or surgery.

Tamsulosin-DRS can address a substantial market for BPH in dysphagic patients

Veru's Tamsulosin-DRS is its Tamsulosin-XR (extended release formulation) in an oral suspension form. XR slows the release of Tamsulosin, thus reducing the chances of overdose related side effects. Tamsulosin XR, made into dry granules in a powder form that can be suspended in water (DRS formulation) and taken orally would allow for the medication to be taken as a liquid instead of a capsule. This can therefore bring in the currently underserved population of BPH + dysphagia patients into the fold of pharmacological intervention. This leads to better conformance of the patients, is more comfortable and an affordable solution. This would be a long-awaited solution and Veru is well positioned to serve the space and take advantage of this substantial market opportunity.

Bioequivalence (BE) studies show DRS to be acceptable and safe

The XR version itself is the safer (no food effect) capsule version of Tamsulosin hydrochloride and should be able to gain traction in the existing BPH market that is served by FLOMAX capsules. Tamsulosin-DRS would extend the market for the first time to those who also have dysphagia. Two bioequivalence studies have been completed to show that the new DRS formulation (extended release as suspension granules) leads to similar exposure as FLOMAX.

In a stage 1 completed study on 12 patients, single dose FLOMAX (given after food) was compared with Tamsulosin DRS (after food and in fasting conditions) and the PK pharmacokinetics analysis showed that the absorbed amounts of Tamsulosin DRS given without food was equivalent to FLOMAX with food. This means that the DRS, even when administered as an oral suspension liquid (which provides with conformance benefits, but also should be slowly released, and therefore slowly absorbed) is able to achieve a slower, optimal absorption because of the XR formulation equivalent to FLOMAX with food, essentially showing that this formulation has no food effect.

Results of a stage 2 BE study on 36 patients for 21 days also reported bioequivalence between single dose Tamsulosin DRS (fed and fasted) and FLOMAX (fed) for measures of AUC (area under curve) but not for Cmax (maximum concentration in blood/plasma). AUC measures total drug exposure over time and is a function of absorption and elimination. Cmax is the maximum concentration of a drug in serum and depends on rate and extent of absorption. The ratio of these two measures gives a measure of absorption. The results here reiterate that, whereas the body gets the equivalent total amount of exposure to the Tamsulosin as DRS or capsule (FLOMAX), the maximum absorption (rate, extent) is lower for DRS suggesting a slower absorption rate or lower sustained exposure compared to FLOMAX capsules with food.

Another bioequivalence study, the final one, is ongoing now (1Q18) to confirm that Tamsulosin XR has no food effect with an *in vitro* dissolution study and validation of stability of GMP manufactured batches. The Cmax would also be tested to see if there is equivalence with FLOMAX. These bioequivalence studies are relatively straightforward and have shown acceptable profiles compared with FLOMAX. Added with the definite advantages of the XR/DRS formulation (removal/reduction of food requirement, ease of administration and lack of side

effects), this should lead to better acceptability and therefore better market potential than FLOMAX capsules. Veru anticipates filing an NDA application in 2018 based on these results. Veru has recently reported that it has received a waiver of $2.4M for NDA fees as a small business and it would free up resources for further development of pipeline programs

Major clinical and market need for BPH patients

FLOMAX and related generics of the alpha-blocker class enjoy a multibillion dollar market for BPH in US. The initial target for Tamsulosin DRS would be dysphagic men with BPH in long-term facilities. About 13% of FLOMAX and other generic markets are represented by long-term facilities. Around 3.6M new prescriptions are written annually for BPH patients with dysphagia. It is estimated that about 68% of men placed in long-term care facilities have dysphagia. In the US, three leading group purchasing organizations (GPOs) that manage FLOMAX purchasing supply for long-term facilities could be approached for Tamsulosin DRS to give access to this crucial patient population. Veru also plans to maintain pricing parity with FLOMAX, the wholesale acquisition cost (WAC) for which is about $730 (for 100 tablets) to gain acceptance by the medical community, payers and the patients.

That XR capsule (and therefore DRS powder) has no food effect is an attractive proposition for urologists to write prescriptions for Tamsulosin XR capsules over FLOMAX, the target prescriptions for which are over 22 million/year for men who do not have dysphagia and ~4M prescriptions a year for about ~15% patients who have dysphagia. This represents a market (for FLOMAX and Tamsulosin generics) of $3.5B in US alone (~$4.1B for all alpha-blockers), besides the ROW opportunity that could be even bigger. The IP exclusivity could potentially be enjoyed by Veru up to 2036 from the Tamsulosin franchise that it licensed from Ariana Therapeutics. Ariana (now Camargo) would receive $10M over three years after the drug has been in market for one year. Tamsulosin XR and DRS would be addressing a well-defined indication with an established market and a medical need, and we conservatively model 33% probability of approval and expect launch in 2020.

Solifenacin DRG granules for overactive bladder

Veru's urology pipeline for 505(b)(2) pathway includes solifenacin DRG granules for the treatment of overactive bladder (OAB). Overactive bladder is experienced by a sixth to a fifth of the adult US population and has a higher prevalence with

increasing age where the prevalence can be from a third of short-term care patients to over 70% of population in long-term care facilities. This causes an increase in the frequency of urination, lack of bladder control and urge incontinence or involuntary emptying of the bladder. OAB affects both men and women with a wide variety of causes ranging from medications, infections, tumors or stones. The musculature around the urinary bladder controls the urine flow and contracts when the bladder is full, resulting in an urge to urinate which is aided by the contraction of the muscles and controlled constriction of the bladder. In OAB, the muscles may be affected resulting in involuntary contraction of the muscles, thus leading to incontinence.

Solifenacin for treating OAB

Solifenacin succinate (trade name Vesicare) tablets are given for managing OAB and represent the standard of care for overactive bladder. Vesicare is marketed by Astellas. Solifenacin is a small molecule urinary antispasmodic that helps by relaxing the musculature thereby reducing the urge to pass urine. Solifenacin is a selective M3 muscarinic receptor antagonist. These receptors are important for muscle contraction and solifenacin competes with acetylcholine to bind these receptors, thus resulting in reduced muscle tone in the bladder. This allows for reduction in the urge and better retention of urine in the bladder.

Available solifenacin formulations suffer from similar disadvantages as Tamsulosin in that they are available only as capsules or tablets that are to be taken in whole and cannot be chewed or crushed. Consequently, people who suffer from dysphagia (inability to swallow) remain underserved for treatment for OAB. In these patients, compliance is very low, and interventions include catheterization and wearing diapers, or surgery.

Solifenacin DRG oral solution to treat OAB in dysphagic patients

Veru is developing Solifenacin DRG, as a novel slow release granule formulation of solifenacin succinate that can be taken as an oral suspension in dysphagic patients with OAB. This will increase compliance in these patients who will be the first target population. Although solifenacin is one of the lowest cost drugs to treat OAB in US with an average cost of $6.8k for one successful treatment, solifenacin has a $1.1B market worldwide. We expect that Solifenacin-DRG can capture a substantial portion of the market because of its advantages over the solifenacin capsules. DRG formulation would not only bring in revenues from

treating the dysphagic OAB patients, it can be more attractive for urologists and patients because of improved compliance and ease of administration.

The FDA has already confirmed one bioequivalence study as valid and Veru is conducting another bioequivalence study in 2018 and will use the results for making an NDA filing planned for early 2019. We feel that since the safety, indication in question and the pharmacologic solution are very well defined, and the market potential is not in question, solifenacin DRG has a great shot at approval and should lead to successful commercialization in 2020. We also note that since the initial target population is the same, i.e., the elderly population at long-term care facilities, Veru can leverage the same salesforce and marketing infrastructure for both of its Tamsulosin and Solifenacin product lines.

Tadalafil/Finasteride for BPH.

Tadalafil/Finasteride is another asset that Veru is developing for treatment of BPH and would utilize 505(b)(2) pathway for approval. Tadalafil and Finasteride are both used for BPH besides several other disease/disorder conditions. Tadalafil manufactured by Eli Lilly is marketed as Cialis for treatment of erectile dysfunction (ED) and as Adcirca for pulmonary arterial hypertension (PAH). The FDA approved Cialis for treating BPH in 2011. Finasteride (brand names: Proscar, Propecia) marketed by Merck is approved for treatment of enlarged prostate (>30 cc volume) as well as hair loss. Tadalafil can be used in combination with Finasteride can be used for BPH as well as to treat symptoms of UTI, ED in BPH patients. Tadalafil is a small molecule inhibitor for phosphodiesterase type 5 (PDE5) which blocks degradation of cyclic GMP by the enzyme. PDE5 is present in smooth muscles and therefore could be targeted for treating musculature/vasculature disorders. Finasteride is a small molecule inhibitor of 5 alpha-reductase enzyme and exerts its action by decreasing the production of dihydrotestosterone (DHT). Reduction of DHT hormone may discourage prostatic dysplasia.

Tadalafil/finasteride combination approved for treating BPH

Eli Lilly completed a Phase 3 clinical trial in 2013 to study the combination of Tadalafil and Finasteride in patients with BPH and related clinical symptoms which showed that 5mg each of Tadalafil and Finasteride (once daily) showed a reduction in symptoms (scored by total international prostate symptom score, IPSS) from baseline by >5 units (at 12 weeks) whereas the placebo arm (placebo with 5mg Finasteride only) gave a IPSS reduction by 3.76 units. Combination

also showed a greater reduction on IPSS at other time frames (4,12, 26 weeks) as well as improvement in quality of life (IPSS-QOL) index scores and several international index of erectile function (IIEF) measures.

Co-administration of Tadalafil and finasteride is approved for treating initial symptoms of BPH for up to 26 weeks, but compliance is an issue which could lead to increased urological issues like urine retention, UTI and related toxinoses and even death. Veru's proposition is to formulate a combination capsule to target patients with enlarged prostate (>30cc volume) because of BPH to achieve increased convenience of taking 1 pill instead of two and achieve better compliance.

As discussed earlier, BPH is a very common condition and affects up to 25% of men and 1.1B men worldwide would suffer from BPH in 2018. FDA has reviewed and validated a BE study in 3Q17 and a final BE study is in the offing to support an NDA application that is anticipated for early 2019. Other than men with BPH (>30cc volume), those who experience partial or suboptimal response to finasteride alone or tamsulosin (alone or in combination with finasteride) can benefit from introduction of tadalafil in their treatment in form of a tadalafil + finasteride combination.

Veru seems well positioned to take advantage of this generic combination and the barriers to entry are very low or even non-existent. It might help Veru to establish itself as a leader in generic BPH medication market with this and other products that it plans to offer. Ensuring better compliance with an approved combination is an achievable goal and makes good business sense. However, we also note that this is not a great differentiator and the competitive space could get busy if this combination capsule achieves better compliance and ease over co-administration. It would be important on Veru's part to maintain a price parity with current co-administration standards.

VERU-944 for hot flashes.

Veru is developing VERU-944 or cis-clomiphene for treating hot flashes in men who are on prostate cancer hormonal therapy. There are no drugs that are currently approved for this indication but there is a huge number of patients who suffer nonetheless and represent a market ready for a new solution.

Prostate cancer is one of the most common cancers and androgen deprivation therapy (ADT) is an established treatment that reduces the increased male

hormone (testosterone/dihydrotestosterone) levels so that they do not stimulate growth in prostate cancer cells. These androgens are produced in testicles, and reduction in their levels involves surgical or chemical/medical castration. Surgical castration, also called orchiectomy is done to remove testicles, whereas chemical castration involves administration of female hormone analogs/agonists which eventually results in reduction in androgens. While the exact cause is unclear, reduction/fluctuation in hormone levels is associated with hot flashes, or sensation of sudden intense warmth/heat, flushing and sweating, and ~80% of ADT patients are affected by episodes of hot flashes (30-40% of them moderate to severe) that can be uncomfortable and disruptive to normal physical wellbeing. Hot flashes continue to affect men even years after ADT (48% at 5 years, 40% at 8 years) and as mentioned above, has no approved therapy to manage the condition.

Medications like Clomid, originally approved for female fertility in 1967 are often used off-label for hot flashes in men associated with ADT in prostate cancer. Clomid (cis-clomiphene) is an oral nonsteroidal estrogen agonist and has been used off label in men post ADT. This can raise testosterone levels and aid in hormonal imbalance and has been observed to help with hot flashes.

Clomid is a mixture of cis-and trans-isomers of clomiphene, out of which cis-clomiphene is a better estrogen agonist than trans-clomiphene and may result in reducing testosterone levels (compared with clomiphene which has trans-clomiphene in majority which might raise testosterone levels). Since ADT works by removal of androgens, cis-clomiphene might be better than a trans-clomiphene heavy mixture at keeping testosterone levels low while still maintaining hormonal balance (and therefore help in managing hot flashes). An established drug and one that has proven safety and tolerability, Clomiphene has seen increase in its off-label use in men with over 88,000 men taking clomiphene in 2016.

VERU-944 is a cis-clomiphene formulation that would be used to treat hot flashes. Clomid (Clomiphene) is a mixture of cis- and trans-clomiphene has already been in use for treating hot flashes in ADT men and VERU-944 should be better than Clomid because of its high estrogenic (because of cis-clomiphene content) lower androgenic (low amount of testosterone producing trans-clomiphene) potential. Besides, cis-clomiphene has a higher potency and slower clearance, making it the choice isomer for treating hot flashes. Consequently,

when commercially available, we believe that VERU-944 would be favored over Clomid by clinicians for its favorable properties.

VERU-944 can tap into a substantial market

We note that Clomid is one of the cheapest drugs in the market and is listed in WHO's List of Essential medicine list (as a female fertility drug) that gives it a credibility and a purposeful authority. The full treatment (for its intended use) runs to the tune of a few dollars. We believe that VERU-944 can benefit from the good name of Clomid and can establish a market in men with ADT from prostate cancer. On the other hand, we also feel that replacing Clomid, which has already been in off-label use, to become the new standard would take substantial efforts. Also, we feel that the differentiation from Clomid based on its isomer composition has not yet been proven without doubt to be of substantial advantage for the clinicians to take notice. The pricing would also have to be in line with Clomid to provide a worthy competition to it. Having said that, we are optimistic that VERU-944 would find its place in the market for treating hot flashes in men, and that these hurdles would be dealt with well, with data and good commercialization efforts.

This would be the first approved therapy for hot flashes in men on prostate cancer hormonal therapy. An IND is planned in 2018, followed by a Phase 2 trial dose finding study in 120 men. The planned 4 and 12-week endpoints to study efficacy should reveal dosing and clinical efficacy. We are hopeful that given the well-established background, VERU-944 would be successful in this regard. The market size for men with ADT is about 700,000 in US, and since hot flashes continue even after ADT for many years, VERU-944 would find chronic use. Even with a 30% penetration in the hormone-therapy related hot flashes, Veru estimates that VERU-944 could bring in ~$600M annual revenues. The intellectual property should ensure exclusivity in US up to 2035.

Other than hot flashes in prostate cancer related hormone therapy, VERU-944 can find use for other indications as well. Prostate cancer is associated with high bone metastases and results in bone loss and bone pain. Addition of estrogen or estrogen agonists like cis-clomiphene can stem/slow the loss, increase bone mineral density, and VERU-944 could potentially be used alone or with other therapies like bisphosphonate or radionuclide therapy. Bone metastases related bone pain occurs in over 40% of prostate cancer patients and is a significant market upwards of a billion dollars.

Analyzing conservatively, we expect the first indication to be most meaningful for Veru and it can possibly extract market value with its new cis-formulation. To be considered for other indications, Veru would need to conduct clinical trials, and the timelines could be significantly extended. We do not feel that there are any useful indicators as of now for the planned entry into the bone pain space. While bisphosphonate therapy is associated with ONJ (osteonecrosis of the jaw) and estrogen therapy might avoid causing such extreme side effects, VERU-944 is not differentiated well enough in terms of data sufficiently to stand alone. Without more conclusive studies, the hope for it in the bone indication is that it will be an effective product that would find use in conjunction with other therapies, which could be a significant market for VERU-944. We will keep a close eye on developments in this arena but realize that it could be some time before we see VERU-944 for bone remineralization.

VERU-111 is one of the most valuable assets in the pipeline

VERU-111 is a novel small molecule in preclinical development for treatment of MCRPC and other taxane resistant cancers. It is an orally available small molecule inhibitor that can target both alpha- and beta- subunits of tubulin and thus would be more effective to cytotoxic tubulin inhibiting drugs like colchicine, vinca alkaloids and taxanes.

Of the cytotoxic drugs used in chemotherapy, tubulin inhibitors differ from DNA-binding drugs in that they affect microtubule formation, an important step in cell division. Microtubules are needed for spindle formation that is an essential step in cell division and are therefore these molecules are also called spindle poisons. Microtubules are formed by structured organization of tubulin subunits, alpha and beta (recently discovered gamma subunit associates with MTOC and is not a microtubule component). While colchicine and vinca alkaloids affect formation or polymerization of the microtubules, drugs of the taxane family disrupt the depolymerization causing shortage of soluble tubulin subunits available and affects the dynamicity of further microtubule formation. Whereas all three families of tubulin disrupters bind the beta-subunit (colchicine bind alpha: beta interface), VERU-111 is unique in that it can bind both alpha as well as beta subunits at the colchicine binding site but more tightly.

Chemotherapy with microtubule disrupters like paclitaxel and taxotere is a major modality of treatment for prostate cancer and there are a few perceived advantages of VERU-111 to these other agents. VERU-111 is orally available

whereas the other microtubule disrupting therapies are available in IV form only. Secondly, VERU-111 binds to both alpha and beta subunits of tubulin and is likely to be more effective than the beta-binders. VERU-111 is not a substrate for multiple drug resistance mechanisms that plague the chemo therapy drugs like docetaxel (taxotere) which is an important first-line chemotherapy drug for Prostate cancer. Also, as a novel target, alpha-subunit targeting by this new class of inhibitors may reverse resistance against existing tubulin inhibitors and other chemotherapeutic agents in general. This is even more important since the established second line androgen-targeting drugs in use for Prostate cancer, the likes of Xtandi (enzalutamide) and Zytiga (abiraterone/prednisone) have a very high degree of cross resistance and cannot be used in sequence for a long-term management strategy for Prostate cancer. Xtandi (Astelllas/Pfizer), approved for treatment of metastatic castration-resistant prostate cancer (mCRPC) is a nonsteroidal antiandrogen and acts as an orally delivered antagonist of androgen receptor (AR, overexpressed in prostate cancer) and inhibits downstream signaling. However, resistance to the drug develops rather quickly through a variety of mechanisms including mutations in androgen receptor. Besides, Enzalutamide induces cytochrome P450 enzymes (enzymes 34A, 2C9, 2C19 and 1A2; and metabolized by 2C8) leading to reduction of its active concentrations. Zytiga (abiraterone; Janssen) with prednisone is another approved orally administered therapy for metastatic Prostate cancer. It is delivered as a prodrug (abiraterone acetate) that is metabolized into the abiraterone (the active compound) and inhibits androgen production by inhibiting Cytochrome P450-17A enzyme. Again, resistance develops almost as a rule, and unfortunately, most patients who receive one of these therapies do not respond to the other drug as well.

Several advantages of VERU-111, potential for market and indication expansion

Preclinical studies presented by Veru, showed a few advantages compared to Docetaxel. Oral administration of VERU-111 shows comparable tumor inhibition with IV administered Docetaxel in PC3 prostate cancer cell xenograft model. In a xenograft model with Taxol-resistant PC3 cells, more than 6x inhibition was seen with VERU-111 with better safety profile in animals. While *in vitro* inhibition was in PC3 cells was seen at 5.2 nM of VERU-111, comparable inhibition with Docetaxel was better at 1.2 nM, however, much better *in vitro* tumor inhibition was seen when taxol-resistant PC3 cells were tested with comparable inhibition

seen at 2.1 nM of VERU-111 and 18 nM of Docetaxel. This suggests that VERU-111 could potentially be used for tumors resistant to other chemotherapy interventions, and its binding to alpha-tubulin in addition to beta could be the key to breakdown resistance. Adding to its value proposition are its high oral bioavailability, availability across the blood brain barrier (can potentially be used for primary tumors or metastases in brain), a good safety profile and that it is not a substrate for CYP34A (metabolizes docetaxel/paclitaxel) or MDR (multiple drug resistance) proteins, factors that would drive VERU-111's entry and success in the huge Prostate cancer-treatment chemotherapy market where Docetaxel alone earned ~$2.2B in 2012.with generics market growing ever since. It can potentially be used with or in lieu of vinca alkaloids as well, and in different indications, and Veru would seek these indication expansions in time. Xtandi and Zytiga both have multibillion dollar markets.

We believe that VERU-111 could easily achieve indication expansion and can be used in other indications and can possibly be used singly and/or in combination. While it is still in preclinical studies, VERU-111, in our view has a very promising path ahead if it shows safety and efficacy in the Phase 1/2 trials that are in the offing. IND submission is planned for mid-2018. We assume the application would be successful in leading the company to the Phase 1/2 studies later in 2H18 where the company plans to enroll MCRPC patients who have progressed on Xtandi or Zytiga with or without taxane, as well as patients with taxane-resistant cancers of breast, endometrium and ovaries.

Several events in 2018 to raise interest

In the near term, we see several events in the near horizon that could boost Veru's profile and make a good case for early entry into sharing its business to reap benefits. For Tamsulosin DRS/XR, we could see completion of the final bioequivalence study, followed by an NDA for US and a Marketing Authorizing Application (for UK) submission, with launches planned for 2019.For Solifenacin DRG and Tadalafil-Finasteride, the bioequivalence studies could be completed giving supportive data for their respective NDAs and MAAs in 2019. We note that while we are enthusiastic about the success of the BE studies, and share the optimism with the company that FDA would accept and act on the BE data for approval, it is not outside of realm of possibility that FDA may require more data or ask Veru to conduct full-scale clinical studies which could push timelines for approval and commercialization. For VERU-944, we anticipate an IND approval

making way for a Phase 2 trial. For VERU-111, the road is a little longer, but we can see a start with an IND followed by initiation of Phase 1/2 trials in 2018.

Figure 2: Multiple catalysts in 2018 and 2019

	2018	2019
FC2	• Grow US business • Grow public sector- secure new Brazil and S. African tenders Q1 & Q2	• Explore strategic alternatives
Tamsulosin DRS & XR capsules- BPH	• Complete BE study Q1 • File NDA Q2 • Complete stability on manufactured batches Q2 (6 months) • Partner US and ROW • Meet EMA Q2 and file MAA Q4	• Launch in US 1H • Launch in EU 2H • Continue seeking partnership deals
Solifenacin DRG granules –OAB	• BE study Q3 • Partner US and ROW	• 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	• BE study Q2 • Partner US and ROW	• PreNDA meeting Q1 and NDA Q2 • Complete stability on manufactured batches (6months) • Meet EMA Q1 and MAA Q2 • Continue partnership deals
VERU-944- hot flashes in men on ADT	• IND Q1 • Initiate Phase 2 clinical trial Q2	• Complete Phase 2 Q1 • Initiate Phase 3 Q2 • Seek Partnerships
VERU-111	• IND Q2 • Initiate Phase 1/2 – prostate and other cancers Q2/3 at Hopkins	• Complete Phase 1/2 • Initiate Phase 2 Q3 • See large pharma partner

Source: Veru

Other pipeline programs

We note here that the other programs at Veru for VERU-722 [a 505(b)(2) candidate] for male infertility and VERU-112 for gout could see acceleration of their development with cash injunctions that could see decline in company value.

PREBOOST for premature ejaculation in market

On the other hand, female and male sexual health products have been bringing in valuable revenues for Veru and would continue to do so in the foreseeable future. Its product PREBOOST is a wipe with 4% benzocaine for topical application to prevent premature ejaculation by providing temporary desensitization of penis. While there are several pharmacological interventions available that address PE and associated problems like ED, PREBOOST has a couple of advantages in that it does not have to be taken orally and is available as a targeted topical application thus avoiding the potential side effects of the

oral drugs. This just causes a temporary desensitization given its anesthetic effects and acts closer to the problem without affecting the sensation of pleasure or the ability to attain orgasm, compared to other applications that are systemic and may have inhibitory effects on sex drive and libido besides other unpleasant side effects.

In a Phase 4 study in 21 men, PREBOOST has shown to significantly improve the control over ejaculation over placebo, with an over four-minute mean increase in duration in two months. 80% of men were considered treated for premature ejaculation and it met both primary (improvement in intravaginal ejaculatory latency time) as well as secondary (assessed by questionnaires on global rating of distress, medication assessment and index of premature ejaculation, IPE) outcomes.

Launched in 2017, this is an OTC product and should not be compared with other drugs in the space but drives revenues nonetheless. Veru shares distribution and promotion rights for PREBOOST in US with its partner, Timm's Medical Technologies.

FC2 is the only FDA approved female condom. Strong revenues globally and rising.

Its subsidiary the Female Health Company markets the FC2, a female condom for prevention of pregnancy and STDs in US and 144 other countries. This is a very successful product that made ~$14M in revenues in 2017, with ~90% of coming from public sector buyers who are stakeholders in public and global healthcare like UNFPA, USAID and Governments of Brazil and South Africa. Manufactured in Kuala Lumpur, Malaysia with a capacity of 100M units/year, FC2 already has and anticipates large orders that would bring in revenues in the coming years. FC2 is the only FDA-approved female condom as of now was launched in US in April 2017 and is already experiencing stronger revenues in US in FY18 ($1.5M in first 4 months) and plans to keep up with demands and selling by hiring salesforce and medical representatives this year. This is a strong area of growth that Veru has already established leadership in, and we expect the demand and commercialization to trend higher in the near future. Currently classified as a Type 3 medical device by FDA with more stringent review requirements that discourages other brands/companies to enter this space, FC2 currently enjoys a unique place of being the only approved product in the market,

and one that is available only by prescription. Most insurance companies cover the use of FC2.

While this is beneficial for Veru at present as the exclusivity drives higher prices, it could change in future as there have been calls for reclassification to Type 2 as well as making this an OTC product. We feel that in the time to come, the FDA would come to reclassify the product category to Type 2, and broaden its use as an internal, rather than a female condom, thus rightfully acknowledging its use for anal sex and for sex between male partners. This would bring in more competition, but Veru would be well placed as an already established and recognized product. As a prescription-required object, it is enjoying exclusivity, premium pricing and insurance coverage, and even if FC2 is made into an OTC again because of market pressures, it could still benefit as a well-established product and bring revenues from serving a higher volume of demand.

Company Description

Veru (VERU) is a biopharmaceutical company with a focus on developing products in Urology (including a female sexual health division) and Oncology. It has two products in the market generating revenues, a female condom and a male penile desensitizing gel for premature ejaculation. Veru is now focusing on development of differentiated products for urology and cancer indications and is advancing its efforts to have a pipeline of potential products that can be approved by 505(b)(2) regulatory pathway for commercializing successful products. The most advanced products in its pipeline for 505(b)(2) approval are Tamsulosin DRS granules (soluble powder) and Tamsulosin XR (extended release capsules) for benign prostate hyperplasia (BPH) that the company is planning to file NDAs for in 2018. Solifenacin DRG granules are being developed for the indication of overactive bladder, and combination Tadalafil/Finasteride capsules for enlarged prostate and erectile dysfunction (ED), with NDA being planned for these two products in 2019. Veru is also initiating a Phase 2 trial to study another 505(b)(2) candidate VERU-944 (cis-clomiphene) to treat hot flashes in advanced prostate cancer patients on hormone therapy with an eye for NDA in 2020. In addition, Veru is also preparing to start a Phase 1/2 open label trial to study VERU-111, a novel, taxane-like oral therapy for metastatic castration resistant prostate cancer (MCRPC) that targets both alpha and beta tubulin. An Investigational New Drug (IND) application for VERU-111 is expected to be filed in Q218 and the clinical trial is anticipated to have data in early 2019.

We Value Veru Using a Sum of Parts Valuation

We value Veru based on a sum of parts valuation of the commercial potential of Tamsulosin DRS granules (soluble powder) and Tamsulosin XR in benign prostatic hyperplasia (BPH). We estimate revenues, COGS, R&D expenses and SG&A for the indication and calculate profit after tax until 2036 when Tamsulosin patents are expected to expire. We calculate NPV based on the profit after tax. We assume 33% probability of success for Tamsulosin in BPH. We assume 10% peak penetration and conservatively assume a price of $2,200 per year in 2020 when we expect Tamsulosin to be launched for BPH.

We apply a discount rate of 10% to our net present value calculations on top of the probability adjustments we apply to account for the development risks associated with these programs. We include a valuation of $107M based on 25% pipeline premium for the rest of the pipeline to reach our $10.00 target price.

Figure 3: Veru BioPharma Sum of Parts Valuation

	Expected Launch	Probability of Success	Peak Market Share	Peak Sales ($M)	Probability adjusted NPV
TAMSULOSIN DRS/XR	2020E	33%	10%	$886	$429
Pipeline premium 25%					$107
Sum of Parts Value ($M)					$536
NPV per share					$10

Source: Brookline Capital Markets Estimate

Risks

Veru is facing clinical, regulatory and reimbursement risks that are common in drug development. If these risks are greater than our expectations then the share price may not meet our target price.

Developmental Risk

Veru must complete bioequivalence and stability studies for some of the drugs being developed under the 505(b)(2) regulatory pathway. Some of these studies may not be successful or may be delayed. There is a possibility that some of the drugs under development may fail to meet efficacy and safety requirements in clinical trials. There is a lot of variability in patients being treated for various indications and, therefore predicting the outcome of clinical trials is inherently difficult.

Regulatory Risk

Veru is utilizing the 505(b)(2) regulatory pathway for getting its products approved by the FDA. While this pathway is comparatively shorter for approval as these drugs are already approved for other indications and therefore are overall safe and efficacious with existing clinical data, several risks remain including the inability to show bioequivalence, lack of long term stability of the drug product etc. These new formulations are potentially low risk and lower cost with a faster path to pivotal trials, but there is a possibility for regulatory authorities to require additional trials.

Commercial Risk

Veru shares distribution and promotion rights for PREBOOST in US with its partner, Timm's Medical Technologies. It is also marketing FC2 female condoms. It must participate in tender process and be successful to generate revenues

incremental for its FC2 female condoms. Veru will need to obtain pricing and reimbursement approvals following regulatory approval of it new products.

Intellectual Property Risk

Veru has filed patent applications covering Tamsulosin. Once granted, the patent protections are expected to last from the priority date to 2036. Veru does not have any issued patent for Tamsulosin. There are risks involved with patent prosecution and some of the patent applications may be rejected or limited claims may be allowed.

Financials

Figure 4: Veru Annual P&L ($)

Fiscal Year ending September 30	2017	2018E	2019E	2020E	2021E	2022E	2023E	2024E
Revenues:								
TAMSULOSIN DRS (Probability adjusted)			$0	$21,301,450	$32,591,219	$44,324,058	$56,513,174	$69,172,124
Revenues from The Female Health Company	$13,655,592	$16,119,772	$25,551,598	$26,829,178	$28,170,637	$29,579,168	$31,058,127	$32,611,033
Total revenues	**$13,655,592**	**$16,119,772**	**$25,551,598**	**$48,130,628**	**$60,761,856**	**$73,903,226**	**$87,571,301**	**$101,783,158**
Operating expenses:								
Cost of goods sold	$6,636,080	$7,497,827	$11,753,735	$13,406,494	$14,588,054	$15,822,620	$17,112,397	$18,459,682
Research and development	$3,504,482	$8,787,423	$10,544,907	$12,653,888	$15,184,666	$18,221,599	$21,865,919	$26,239,103
Advertising	$54,270	$2,947,697	$3,006,651	$3,066,784	$3,128,120	$3,190,682	$3,254,496	$3,319,586
Selling, general, and administrative	$11,019,091	$16,223,901	$17,846,291	$36,130,920	$39,744,012	$43,718,413	$48,090,255	$52,899,280
Business acquisition	$935,781							
Total operating expenses	**$22,149,704**	**$35,456,848**	**$43,151,584**	**$65,258,087**	**$72,644,852**	**$80,953,315**	**$90,323,067**	**$100,917,650**
Operating (loss) income	**($8,494,112)**	**($19,337,076)**	**($17,599,986)**	**($17,127,459)**	**($11,882,996)**	**($7,050,089)**	**($2,751,766)**	**$865,507**
Other income (expense)								
Interest and other (expense) income, net	($46,543)	($54,277)	($55,363)	($56,470)	($57,600)	($58,752)	($59,927)	($61,125)
Foreign currency transaction (loss) gain	($61,835)	($220,321)	($224,727)	($229,222)	($233,806)	($238,482)	($243,252)	($248,117)
Total other expenses	($108,378)	($274,598)	($280,090)	($285,692)	($291,406)	($297,234)	($303,178)	($309,242)
Net Loss/Income	**($8,602,490)**	**($19,611,674)**	**($17,880,076)**	**($17,413,151)**	**($12,174,402)**	**($7,347,323)**	**($3,054,945)**	**$556,265**
Income tax (benefit) expense	**($1,990,443)**	**($3,246,053)**						
Net income (loss)	**($6,612,047)**	**($16,365,621)**	**($17,880,076)**	**($17,413,151)**	**($12,174,402)**	**($7,347,323)**	**($3,054,945)**	**$556,265**
Net loss per share	($0.25)	($0.27)	($0.26)	($0.24)	($0.16)	($0.09)	($0.04)	$0.01
Shares outstanding, basic and diluted	34,640,308	61,515,637	67,472,723	71,846,359	75,438,677	79,210,611	83,171,141	87,329,698

Source: Company reports, Brookline Capital Markets Estimate

Figure 5: Veru Quarterly P&L ($)

Fiscal Year ending September 30		Dec 31	Mar 31	June 30	Sep 30	
	2017	Q1:18E	Q2:18E	Q3:18E	Q4:18E	2018E
Revenues:						
TAMSULOSIN DRS (Probability adjusted)						
Revenues from The Female Health Company	$13,655,592	$2,586,613	$3,103,936	$4,345,510	$6,083,714	$16,119,772
Total revenues	**$13,655,592**	**$2,586,613**	**$3,103,936**	**$4,345,510**	**$6,083,714**	**$16,119,772**
Operating expenses:						
Cost of goods sold	$6,636,080	$1,272,574	$1,427,810	$1,996,935	$2,796,508	$7,497,827
Research and development	$3,504,482	$2,038,786	$2,140,725	$2,247,762	$2,360,150	$8,787,423
Advertising	$54,270	$2,947,697				$2,947,697
Selling, general, and administrative	$11,019,091	$3,764,137	$3,952,344	$4,149,961	$4,357,459	$16,223,901
Business acquisition	$935,781					
Total operating expenses	**$22,149,704**	**$10,023,194**	**$7,520,880**	**$8,396,657**	**$9,516,117**	**$35,456,848**
Operating (loss) income	**($8,494,112)**	**($7,436,581)**	**($4,416,944)**	**($4,051,147)**	**($3,432,403)**	**($19,337,076)**
Other income (expense)						
Interest and other (expense) income, net	($46,543)	($13,169)	($13,432)	($13,701)	($13,975)	($54,277)
Foreign currency transaction (loss) gain	($61,835)	($53,455)	($54,524)	($55,615)	($56,727)	($220,321)
Total other expenses	($108,378)	($66,624)	($67,956)	($69,316)	($70,702)	($274,598)
Net Loss/Income	**($8,602,490)**	**($7,503,205)**	**($4,484,900)**	**($4,120,463)**	**($3,503,105)**	**($19,611,674)**
Income tax (benefit) expense	**($1,990,443)**	**($3,246,053)**				**($3,246,053)**
Net income (loss)	**($6,612,047)**	**($4,257,152)**	**($4,484,900)**	**($4,120,463)**	**($3,503,105)**	**($16,365,621)**
Net loss per share	($0.25)	($0.08)	($0.08)	($0.07)	($0.06)	($0.27)
Shares outstanding, basic and diluted	34,640,308	53,154,076	56,343,321	59,723,920	63,307,355	61,515,637

Source: Company reports, Brookline Capital Markets Estimate

Figure 6: Tamsulosin Market Model

	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E
U.S men aged 55 and over (millions)	42	43	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	59	60
BPH Prevelance	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*
BPH Patients (millions)	19	19	20	20	20	21	21	22	22	22	23	23	24	24	25	25	26	26	27
% of patients with dysphagia	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*
Potential patients for TAMSULOSIN DRS (000's)	2,820	2,877	2,934	2,993	3,053	3,114	3,176	3,239	3,304	3,370	3,438	3,507	3,577	3,648	3,721	3,796	3,871	3,949	4,028
TAMSULOSIN DRS Penetration		*0.0%*	*1.0%*	*1.5%*	*2.0%*	*2.5%*	*3.0%*	*3.5%*	*4.5%*	*6.0%*	*7.0%*	*8.0%*	*9.0%*	*10.0%*	*10.0%*	*10.0%*	*10.0%*	*10.0%*	*10.0%*
TAMSULOSIN DRS treated patients		0	29,341	44,891	61,052	77,842	95,278	113,381	148,691	202,220	240,642	288,520	321,897	364,816	372,113	379,555	387,146	394,889	402,787
TAMSULOSIN DRS annual cost	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200	$2,200
TAMSULOSIN DRS revenues ($M)	$0	$0	$65	$99	$134	$171	$210	$249	$327	$445	$529	$617	$708	$803	$819	$835	$852	$869	$886
COGS ($M)	$0	$0	$3	$5	$7	$9	$10	$12	$16	$22	$26	$31	$35	$40	$41	$42	$43	$43	$44
R&D ($M)	$5	$5	$5	$5	$5	$5	$5	$5	$5	$5	$5	$5	$5	$5	$5	$5	$5	$5	$6
SG&A ($M)	$0	$0	$50	$53	$55	$58	$61	$64	$67	$70	$74	$78	$81	$86	$90	$94	$99	$104	$109
Total Expenses ($M)	$5	$5	$58	$62	$67	$71	$76	$81	$88	$98	$105	$113	$122	$131	$136	$141	$147	$152	$159
Net Profit ($M)	($5)	($5)	$6	$36	$67	$100	$133	$168	$239	$347	$424	$504	$586	$672	$683	$694	$705	$716	$727
Operating Margins			*10%*	*37%*	*50%*	*58%*	*64%*	*67%*	*73%*	*78%*	*80%*	*82%*	*83%*	*84%*	*83%*	*83%*	*83%*	*82%*	*82%*
Profit ($M)	**($5)**	**($5)**	**$6**	**$36**	**$67**	**$100**	**$133**	**$168**	**$239**	**$347**	**$424**	**$504**	**$586**	**$672**	**$683**	**$694**	**$705**	**$716**	**$727**
Tax Rate	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*130%*
Taxes ($M)				($10.9)	($20.2)	($29.9)	($40.0)	($50.4)	($71.6)	($104.2)	($127.2)	($151.1)	($175.9)	($201.6)	($204.9)	($208.2)	($211.5)	($214.9)	($218.0)
Profit after tax ($M)	**($5.0)**	**($5.0)**	**$6.3**	**$25.4**	**$47.2**	**$69.9**	**$93.3**	**$117.7**	**$167.1**	**$243.1**	**$296.8**	**$352.6**	**$410.4**	**$470.4**	**$478.0**	**$485.8**	**$493.6**	**$501.5**	**$508.7**
NPV of TAMSULOSIN ($M) (10% discount rate)	**$1,300**																		
Probability of success	33%																		
Probability adjusted NPV	**$429**																		
NPV per share	**$8.1**																		

Source: Company reports, Brookline Capital Markets Estimate

Figure 7: Veru Balance Sheet ($)

	2017	2018E	2019E	2020E	2021E	2022E	2023E	2024E
Current assets:								
Cash	$3,277,602	$24,516,939	$34,927,895	$45,852,782	$42,857,195	$48,581,248	$59,977,307	$76,654,144
Accounts receivable	$3,555,350							
Inventory, net	$2,767,924							
Prepaid expenses	$697,097	$731,952	$768,549	$806,977	$847,326	$889,692	$934,177	$980,885
Total current assets	**$10,297,973**	**$25,248,891**	**$35,696,444**	**$46,659,759**	**$43,704,520**	**$49,470,940**	**$60,911,484**	**$77,635,029**
Plant and equipment, net	$555,539	$583,316	$612,482	$643,106	$675,261	$709,024	$744,475	$781,699
Other trade receivables	$7,837,500	$8,229,375	$8,640,844	$9,072,886	$9,526,530	$10,002,857	$10,503,000	$11,028,150
Other assets	$156,431	$164,253	$172,465	$181,088	$190,143	$199,650	$209,633	$220,114
Deferred income taxes	$8,827,000							
Intangible assets, net	$20,752,991	$21,790,641	$22,880,173	$24,024,181	$25,225,390	$26,486,660	$27,810,993	$29,201,542
Goodwill	$6,878,932	$7,222,879	$7,584,023	$7,963,224	$8,361,385	$8,779,454	$9,218,427	$9,679,348
Total assets	**$55,306,366**	**$63,239,353**	**$75,586,430**	**$88,544,244**	**$87,683,230**	**$95,648,585**	**$109,398,011**	**$128,545,883**
Current liabilities:								
Accounts payable	$2,685,718	$2,820,004	$2,961,004	$3,109,054	$3,264,507	$3,427,732	$3,599,119	$3,779,075
Unearned revenue	$1,014,517	$1,065,243	$1,118,505	$1,174,430	$1,233,152	$1,294,809	$1,359,550	$1,427,527
Accrued expenses and other current liabilities	$1,441,359	$1,513,427	$1,589,098	$1,668,553	$1,751,981	$1,839,580	$1,931,559	$2,028,137
Accrued compensation	$345,987	$363,286	$381,451	$400,523	$420,549	$441,577	$463,656	$486,838
Total current liabilities	**$5,487,581**	**$5,761,960**	**$6,050,058**	**$6,352,561**	**$6,670,189**	**$7,003,698**	**$7,353,883**	**$7,721,578**
Other liabilities	$1,233,750	$1,295,438	$1,360,209	$1,428,220	$1,499,631	$1,574,612	$1,653,343	$1,736,010
Deferred rent	$131,830	$138,422	$145,343	$152,610	$160,240	$168,252	$176,665	$185,498
Total liabilities	**$6,853,161**	**$7,195,819**	**$7,555,610**	**$7,933,391**	**$8,330,060**	**$8,746,563**	**$9,183,891**	**$9,643,086**
Stockholders' equity								
Common shares	$553,922	$609,314	$670,246	$737,270	$810,997	$892,097	$981,307	$1,079,437
Additional paid-in capital	$90,550,669	$107,577,558	$136,917,063	$161,604,474	$167,620,386	$178,143,083	$190,809,706	$206,088,245
Accumulated other comprehensive loss	($581,519)							
Accumulated deficit	($34,263,262)	($52,143,338)	($69,556,489)	($81,730,891)	($89,078,213)	($92,133,158)	($91,576,892)	($88,264,886)
Treasury stock, at cost	($7,806,605)	($7,806,605)	($7,806,605)	($7,806,605)	($7,806,605)	($7,806,605)	($7,806,605)	($7,806,605)
Total stockholders' equity	$48,453,205	$56,043,534	$68,030,820	$80,610,854	$79,353,170	$86,902,022	$100,214,120	$118,902,797
Total liabilities and stockholders' equity	**$55,306,366**	**$63,239,353**	**$75,586,430**	**$88,544,244**	**$87,683,230**	**$95,648,585**	**$109,398,011**	**$128,545,883**

Source: Company reports, Brookline Capital Markets Estimate

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Public Companies Mentioned in this Report:

Astellas Pharma (ALPMY – NR - $15.00)

Eli Lilly (LLY – NR - $78.60)

Merck & Co (MRK -NR-$54.54)

Pfizer Inc. (PFE -NR-$36.13)

Johnson & Johnson. (JNJ -NR-$130.41)

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