

About Pivot Pharmaceuticals Inc.

Pivot Pharmaceuticals Inc. (OTCMKTS:PVOTF) is an emerging biotechnology company engaged in the development of novel therapeutics to treat unmet medical needs in women's health. It has developed a pipeline of drug candidates for the treatment of women's cancers by acquiring a novel portfolio of anticancer drugs targeting a novel mechanism to treat gynecological and triple-negative breast cancers. The Company will treat gynecological disturbances by repurposing approved drugs with proprietary technologies to create a pipeline of novel therapeutics. The company has developed an accelerated time to market strategy to enable commercializing the first of many new therapies by 2019.

Pivot Pharmaceuticals at a Glance

Symbol: PVOTF
Last Trade: \$0.550
52-Week Range: \$0.00 - \$1.25
Avg. Daily Volume: 3,961
Outstanding Shares: 74.722 million
Total Shares: 80.722 million
Market Cap: \$41.1 million
Cash on Hand: \$144,000

Opportunity Overview

The global market for women's health therapeutics was worth nearly \$18.3 billion in 2012 and the market is expected to increase to nearly \$22.5 billion in 2018, a compound annual growth rate (CAGR) of 3.5% for the 5-year period of 2013-2018. The worldwide sales for oncology products in 2012 were \$68 billion and are estimated to increase to \$114.4 billion in 2018, at a compound annual growth rate of 9.0%.

Pivot Pharmaceuticals entry into these markets will leverage its pyrrolbenzodiazepine dimers biotechnologies.

Pyrrolbenzodiazepine dimers (or PBDs) provide a novel 'synthetic lethal' approach for the treatment of resistant cancers such as metastatic endometrial, triple-negative breast, and/or metastatic colorectal cancers.

Pivot has identified several 'synthetic lethal' (SL) relationships in tumor suppressor gene functions, and its proprietary and novel small molecule anticancer drug candidates from the pyrrolbenzodiazepine dimer (PBD) class of drug candidates, that create synthetic lethality in tumor cells that have loss of function in tumor suppressor genes by inhibition of DNA replication in such impaired cells. Thus, these novel PBDs are poised to treat genetically and/or epigenetically-resistant cancers that result from a loss of function in tumor suppressor genes and/or DNA mismatch repair gene func-

tions in cancers such as refractory/relapsed metastatic endometrial, triple negative breast and/or metastatic colorectal cancers.

Leveraging Regulatory Pathways for Faster Time to Market

Pivot's oncology candidates will qualify for Orphan Drug Designation, thus providing the company the opportunity to benefit from accelerated regulatory initiatives and longer term exclusivity for its approved drug(s). The urogynecological program aims to seek approval by leveraging the 505(b)(2) pathway outlined by the United States Food and Drug Administration (FDA), which allows the company an accelerated time to market through the use of novel drug delivery technologies for existing drugs.

Revenue Opportunity

The degree of revenue anticipated by Pivot's pipeline depends on the drug in question. Its treatment for metastatic endometrial cancer (with recurrent metastatic disease) -- PVT-005 -- could be worth more than \$250 million per year, while the triple-negative breast cancer therapy PVT-006 -- for patients with DNA repair deficiencies -- is worth more than \$200 million per year. Meanwhile, its drugs for the treatment of dysmenorrhea and LUTS could be worth more than \$460 million and \$300 million per year, respectively, as new delivery technologies breathe new life into existing therapies that don't need to work their way through a new trial.

Opportunity Overview



Pivot Pharmaceuticals Inc. endeavors to bring new products to market to address women's health needs through a two-pronged approach of leveraging drug delivery technologies

for targeted delivery of drugs and it is also developing novel drugs for orphan indications in women's cancers. The use of novel drug delivery technologies will allow the Company to advance existing drugs for treating urogynecological disorders with a faster time-to-market. In addition, the Company's novel anticancer portfolio will

focus on new treatment options for resistant gynecological and triple-negative breast cancer needs, which have smaller numbers of patients and avail the opportunity of longer exclusivity period due to orphan disease nature of such patient populations.

There are no effective treatments available for tumors that have 'functional deficiencies' in genes like BRCA1 or BRCA2 (breast cancer); DNA mismatch repair (colon, endometrial, glioblastoma and bladder); PTEN (colon, endometrial, leukemia and breast) and ERCC1 (melanoma). Such tumors remain a highly unmet clinical need and

Opportunity Overview (cont.)

currently few drugs are under development that specifically target tumors with such 'loss of function' in tumor suppressor genes.

Pivot has a portfolio of novel and proprietary anticancer drugs that target a novel pathway in DNA damage response for the treatment of metastatic endometrial and triple-negative breast cancers that have mutations in the DNA repair pathways. Pivot has a strong patent estate with multiple issued patents and several patent applications that cover the composition of matter and methods of use for its anticancer drug portfolio. Pivot is also accessing novel drug delivery technologies and products through such technologies to buttress its portfolio of anticancer drugs, to provide short-term and long-term value drivers for the Company's growth through a diverse portfolio of novel therapeutics for improving women's health.

Pivot's novel PBDs are active in cancers associated with the loss of tumor suppression, DNA repair and/or homologous recombination gene function, which are responsible for some of the refractory nature of cancers such as metastatic endometrial, triple-negative breast and/or metastatic colorectal cancers through a novel DNA Damage Response (DDR) pathway. Furthermore, PBDs also exhibit 'synthetic lethality', which results in its ability to promote cytotoxicity and death of refractory cancers that have mutations in tumor suppressor functions.

Gynecological and Breast Cancer Programs

Pivot has a portfolio of novel anticancer drugs that have shown activity in resistant and refractory cancers affecting women. Specifically the Company will address cancers that are affected by changes such as loss of tumor suppression (p53), DNA mismatch repair and/or homologous recombination functions, that render cancers of the uterus, bladder, gastrointestinal tract, and triple-negative breast resistant to currently available therapies. Pivot's lead candidates PVT-005 and PVT-006 are poised to enter Investigational New Drug (IND)-enabling studies to support filing for the initiation of human clinical trials in cancers such as metastatic endometrial and/or triple negative breast cancer. Pivot plans to initiate clinical testing of at least one lead clinical candidate within a 12-month period from initiation of its pre-IND studies.

Urogynecological Disorders Program

Pivot is evaluating novel drug delivery systems to allow its development of treatments for urogynecological disorders such as lower urinary tract symptoms (LUTS) in women and other conditions such as dysmenorrhea. These possible drugs and delivery solutions include an off-the-shelf vaginal ring, an oral wafer/flash release mucoadhesive dermal patch, and foam drug delivery, just to name a few.

PVOTF Outlook & Analysis

While 2015 was a year of building and progress for Pivot Pharmaceuticals, 2016 is going to be a year of measurable advances, with milestones met all the way through 2022, when the company anticipates registration/licensing for PVT-005 and PVT-006. It will be able to drive revenue well before then, though, using 505b(2) rules - which circumvent three-phase R&D requirement - to launch new products in the areas of women health.

2016's path is already well defined too. In Q1 the company aims to secure new capital and start studies that will support its IND procedure. In Q2 Pivot will evaluate other developmental programs, and will likely select one for new development. Pivot will start a clinical trial for at least one product before the end of 2016. Between 2017 and 2019, the company anticipates pushing PVT-005 and PVT-006 into Phase 2 trials.

With all of that being said, while the next several years have several catalysts in the lineup, the strength of the opportunity lies in the fact that Pivot is addressing a sliver of the market that is underserved.

Gynecological and triple-negative-breast-cancers continue to present poor prognosis and treatment options for a smaller group of patients. Radical surgical interventions help address cancers that can be physically accessed, but these surgical interventions, followed by adjuvant chemotherapy, at best represent, partial treatment options for refractory and metastatic disease in gynecological and triple-negative breast cancers following initial treatments.

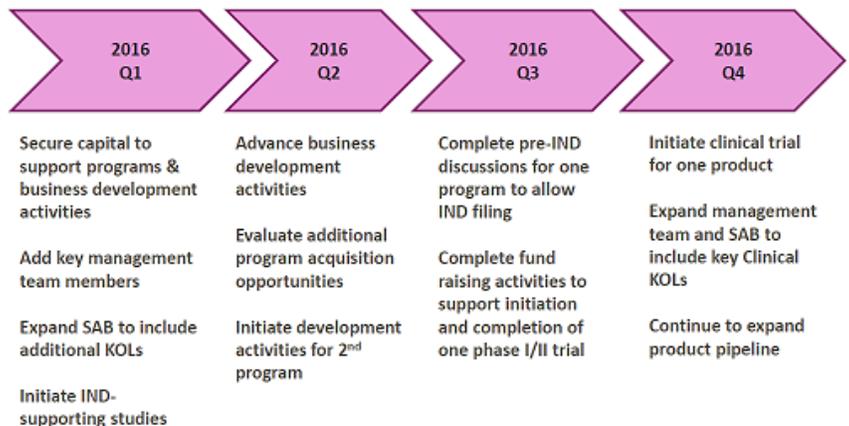
Triple-negative breast cancer - a small subset of the much larger breast cancer population affecting about 170,000 women in the US each year - remains an enigma for the patients and caregivers. Due to the lack of estrogen, progesterone and HER2 neu receptors,

many of the treatment options available to breast cancer patients provide minimal-to-poor treatment benefits.

Pivot's anticancer agents a unique opportunity to develop targeted/personalized medicine for such metastatic and/or refractory patients that have mutations in DNA repair. By targeting metastatic and subtype-selective treatments for smaller groups of patients, the Company can develop these drugs for "orphan" indications, thus allowing itself a longer exclusivity (7-year) period compared to the standard 5-year exclusivity in the U.S.

The kicker: Several members of the company's management team are responsible for bringing key drugs to the market.

Simultaneously, a severely depressed biotech market has pulled the price (but not the value) of PVOTF shares lower right before a key "high profile" phase for the company and its pipeline. Investors seeking an undervalued/underappreciated trading opportunity from the small cap biotech realm should consider taking on a stake in Pivot Pharmaceuticals sooner than later.



Company Management

Pivot has assembled a highly experienced management and advisory team that has clinical, commercial, product development and financial experience. Collectively the team has participated in the commercialization of more than 12 drugs representing total revenue in excess of several billion dollars.

Pravin Chaturvedi, PhD - Chief Executive Officer Director



25+ year veteran of the pharmaceutical and biotech industry. Founder and Chairman of IndUS Pharmaceuticals and co-founder of Oceanyx Pharmaceuticals. Formerly served as CEO of Scion Pharmaceuticals; CSO of Napo Pharmaceuticals; Head of Lead Evaluation at Vertex Pharmaceuticals; and in the Product Development group at Alkermes and Parke-Davis/Warner-Lambert

(now Pfizer). Chair of the Research Advisory Council for the Health Sciences Center of West Virginia University and adjunct faculty member at Georgetown Medical School.

Ahmad Doroudian, PhD - Chairman, Director

25 years of experience in management and development of private and publicly traded pharmaceutical companies. Founder, CEO and Director of MerusLabs Inc., a publicly listed specialty pharmaceutical company (MSL:TSX and MSLI:NASDAQ).

Wolfgang Renz, MD, PhD - Director

15 years of experience in medicine, pharmaceutical product and technology development. Leadership roles at Roche and Boehringer Ingelheim GmbH.

Patrick Frankham, PhD, MBA - Director

20 years of experience in biopharma and CRO industries across several therapeutic areas. Executive roles with BD & L, M & A, and startups. Formerly with ICON and Boehringer Ingelheim GmbH.

Moira Ong, CPA, CA, CFA - Chief Financial Officer

18 years of experience as a Chartered Professional Accountant. Previously with Grant Thornton LLP, Deloitte & Touche LLP and Merus Labs. CFO of TSX and NASDAQ listed companies.

Report Prepared by James Brumley

SmallCap Network Contributor

For questions and inquiries, please [contact](#) SmallCap Network.

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