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PharmaPoint

**POSTMENOPAUSAL VAGINAL ATROPHY -
GLOBAL DRUG FORECAST AND MARKET ANALYSIS
TO 2022**

Executive Summary

Postmenopausal Vaginal Atrophy: Key Metrics in the Seven Major Pharmaceutical Markets	
2012 Epidemiology	
Prevalent Population	31.6m
Treated Population	7.2m
2012 Market Sales	
US	\$975.9m
5EU	\$115.6m
Japan	\$16.1m
Total	\$1.108bn
Pipeline Assessment	
Number of drugs in Phase I–III	7
Number of first-in-class late stage drugs	2
Most Promising Pipeline Drugs	
Peak-Year Sales	
Osphena (ospemifene, Shionogi)	\$322.8m
Vaginorm (prasterone, Bayer)	\$318.4m
BZA/CE (bazedoxifene + conjugated estrogens, Pfizer)	\$25.16m
Key Events (2012–2022)	
Level of Impact	
Premarin (conjugated estrogens) cream patent expiry in the US in 2012	↓↓
Launch of Shionogi's Osphena in the US in 2013	↑↑↑
Launch of Pfizer's BZA/CE in the US and 5EU in 2013	↑
Bayer's Vaginorm launch in 2014	↑↑
Merck's Colpotrophine (promestriene) comes off patent in 2015	↓↓↓
2022 Market Sales	
US	\$1.9bn
5EU	\$149.6m
Japan	\$20.1m
Total	\$2.079bn
Source: GlobalData	
5EU = US, France, Germany, Italy, Spain, and UK	

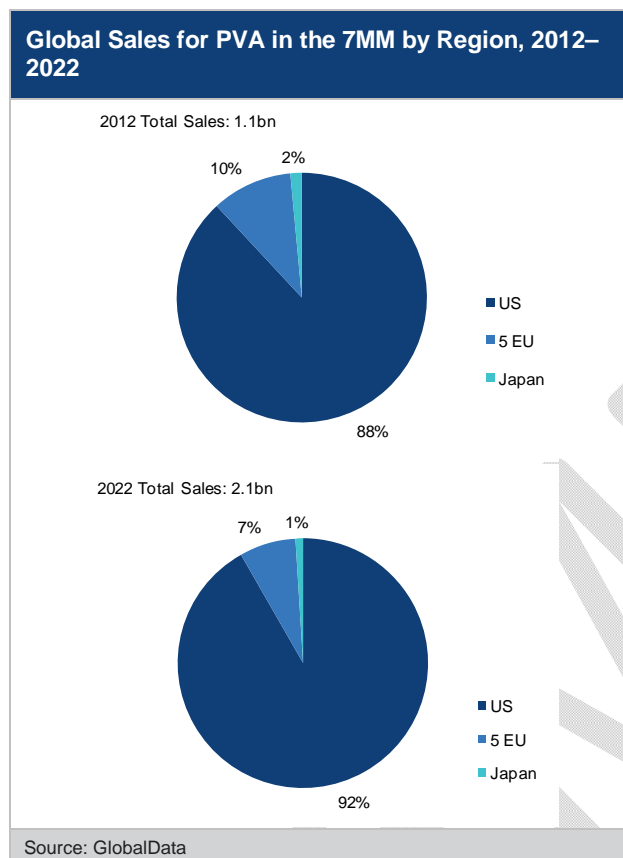
Above table provides a summary of the key metrics for postmenopausal vaginal atrophy (PVA) in the seven major pharmaceutical markets during the forecast period from 2012–2022.

Global Sales for Postmenopausal Vaginal Atrophy by Region, 2012–2022

The global PVA market, according to this report, includes the seven major markets (7MM) — namely, the US, France, Germany, Italy, Spain, the UK, and Japan. The global vaginal atrophy pharmaceutical market in 2012, the base year of the forecast period, was valued at \$1.108bn. With an 88% share of the overall vaginal atrophy market, the US is the dominant market, totalling approximately \$976m in branded pharmaceutical sales in 2012, primarily due to the much higher prices of pharmaceuticals in this country. In contrast, the 5EU countries made up only 10.5% of the global PVA market. Japan comprised 1.5% of the global PVA market. By 2022, the global PVA market will grow to approximately \$2.079bn at a Compound Annual Growth Rate (CAGR) of 6.5%.

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Below mentioned figure illustrates the sales global for PVA in the 7MM by region during the forecast period.



In the Wake of the WHI, Current and Future Players Shift from Estrogen Replacement Drugs to SERMs and TSECs

The publication of the Women's Health Initiative (WHI) study in 2002 led to a dramatic fall in the use of hormone replacement therapy (HRT) and a revision of the package inserts for all hormone therapy preparations. This large-scale trial randomized over 16,000 women ages 50–79 years to 0.625mg Premarin and 2.5mg medroxyprogesterone acetate or placebo. The study was stopped early because analysis did not find the expected benefit in preventing coronary heart disease. In addition, the global index score — which measures the balance between benefit and harm — showed that the benefits were outweighed by the increased risk of breast cancer, stroke, and deep vein thrombosis (DVT). (Roberts, 2007) Although the hormone therapy market saw a drastic decline in the wake of widespread negative publicity associated with this trial, the market is reviving slowly.

All the currently marketed products for PVA are a form of estrogen replacement therapy (ERT), with the key differentiator being the route of administration. Vaginal creams, vaginal tablets, oral pills, vaginal rings, and patches are the major formulations prescribed for PVA. These drugs have comparable efficacy and are prescribed according to patient preference and the severity of the symptoms. Local estrogen therapy (LET) in the form of vaginal creams and vaginal tablets, has

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dominated the PVA market, with an average of 53% patient share for mild, moderate, and severe PVA patients across the 7MM. GlobalData expects LET to remain successful over the forecast period, although the class will likely lose share as Shionogi and Pfizer drive patients to the oral drugs Osphena and BZA/CE, respectively. This shift will be offset by the launch of the vaginal suppository, Vaginorm, in 2014. In addition, by 2022, according to doctors interviewed for this report, systemic therapies, such as topical gels and patches, will have fallen out of favor for treating patients in whom vaginal atrophy is the sole menopausal complaint.

Safety is a paramount unmet need for the vaginal atrophy market. One strategy companies have adopted is the development of efficacious ultra-low-dose LET formulations. However, despite the increased safety of low-dose LET, lingering concerns about the adverse effects of exogenous estrogens have prompted increased investment in alternative therapies. This fundamental paradigm shift away from estrogen therapy (ET) has pushed research investment towards selective estrogen receptor modulators (SERMs), tissue-selective estrogen complexes (TSECs), and hormone precursors. SERMs exhibit estrogen receptor agonist/antagonist activity, depending on the target tissue. TSECs are a newer approach to menopausal therapy that pair an SERM with one or more estrogens, with the goal of maintaining the benefits of estrogen without its stimulatory effects on the breast and uterus (Komm and Mirkin, 2013).

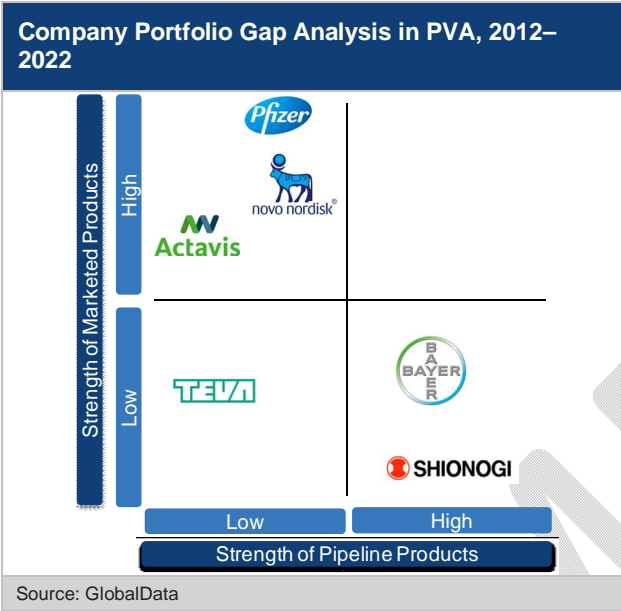
Both approaches are meant to be safer alternatives to estrogen-alone therapy.

The historic leaders in the PVA market include Pfizer, Novo Nordisk, Bayer, Teva, and Warner Chilcott. All of these companies have had market-leading drugs to treat menopausal conditions, including vasomotor symptoms and urogenital atrophy. However, this market is going to be hit with a flood of generics, as several top-branded products will lose patent exclusivity during the forecast period. In 2012, this was the case for Pfizer, which saw a large drop in patient share with the loss of market exclusivity of its blockbuster drug, Premarin. Teva will also be facing the patent expiry of its widely used promestriene-based drug, Colpotrophine, by 2015.

Future leaders in the PVA market during the forecast period will include Pfizer, Bayer, Shionogi, and Actavis. Shionogi's late-stage SERM, Osphena, will likely reshape the market once launched. Pfizer will remain a market leader due to its large overall HRT portfolio and pipeline TSEC, BZA/CE, which is set to launch late in 2013. Bayer, a historical leader in women's health, will remain prominent in this market, especially if its late-stage hormone precursor, Vaginorm, is approved across the 7MM. GlobalData also believes that Actavis will command a growing market position during the forecast period, fuelled by the acquisition of Warner Chilcott's HRT portfolio and the global shift towards generics in austere times.

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Below mentioned figure provides an analysis of the company portfolio gap in PVA during the forecast period.



Current Therapies Leave Significant Unmet Needs in the Vaginal Atrophy Market

The current postmenopausal atrophy therapeutics market comprises estrogen-based treatment options. However, significant unmet need remains. The safety of the existing therapies remains the primary physician concern, as all of the current products contain warnings about serious side effects, such as an increased risk for endometrial and breast cancers. Since PVA is not life-threatening, many women, finding the risk/benefit ratio unacceptable, opt for over-the-counter (OTC) remedies, exhibit low compliance behavior, or forego treatment altogether.

Below mentioned table lists the prominent unmet needs in the PVA market, along with a numerical value to depict the level of attainment of these needs in different markets (1 = low attainment, 5 = high attainment).

Overall Unmet Needs – Current Level of Attainment		
Unmet Need	Current Level of Attainment	Relative Importance
Safety	2	High
Disease Awareness	2	High
Patient Compliance	3	High
Efficacy	4	Low
Treatment Costs	4	Low

Source: GlobalData, based on primary research interviews with gynecologists in the G7 markets

Safety is the primary unmet need being targeted by the late-stage pipeline products for treating PVA. Three drugs — namely, Osphena, Vaginorm, and BZA/CE — aim to address this unmet need by being potentially safer alternatives to the mainstay estrogen-alone therapies. Shionogi’s Osphena is a novel non-hormonal product that has been shown to selectively target vaginal tissue while causing clinically insignificant effects on the endometrium. In this way, the drug treats vulvar and vaginal atrophy (VVA) symptoms without elevating the risk for endometrial cancer. In addition, preclinical studies have shown Osphena to have anti-estrogenic activity in models of breast cancer, making it a potential treatment option for women with breast cancer suffering from VVA, which is

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currently an untreated population. Bayer's Vaginorm works on the principle that restoring circulating levels of the hormone precursor, dehydroepiandrosterone (DHEA) to those found in young women may reverse vaginal atrophy, while having the additional benefit of improving sexual function. This product would also address the unmet need for safety. Pfizer's BZA/CE is a TSEC composed of the SERM bazedoxifene combined with conjugated estrogens. The ideal TSEC would provide the clinical benefits of each of its components, with improved tolerability. As such, the ideal drug profile would include relief of hot flashes, treatment of VVA, and prevention of bone loss, while providing safety for the endometrium and breast. (Tan et al., 2012) If approved, BZA/CE, will address the unmet need for safe treatment options with favorable risk/benefit profiles.

Opportunities Remain for Therapies with Improved Safety and Compliance

After the launch of Ospheña, Vaginorm, and BZA/CE, opportunities will remain for product formulations that improve patient compliance and adherence. Since PVA is a non-life-threatening condition, the treatment frequency and duration often comes down to a matter of convenience. Since all the currently marketed and late-stage pipeline products are comparable in efficacy, a woman's choice of therapy will be based largely on her preference. In fact, studies have shown that women report a longer duration of therapy and greater compliance with vaginal tablets compared

with vaginal creams, despite vaginal tablets' higher out-of-pocket expense. Opportunities will remain for products that capitalize on drug delivery systems that maximize compliance. Lastly, Ospheña, Vaginorm, and BZA/CE each require once-daily dosing regimens. Considering the fact that LETs require application only two to three times a week, the opportunity will remain for products that combine the improved safety of these new products with less frequent dosing schedules.

Despite the fact that the soon-to-be-launched drugs present arguably better safety profiles compared with systemic estrogen therapies, these drugs are certainly not free of safety concerns. Improved safety profile will therefore remain an opportunity for drug developers, even after the launch of these new agents. Certain physicians interviewed for this report expressed concerns that systemic oral therapies, such as Ospheña and BZA/CE, may be overkill for treating vaginal atrophy. Their primary concern is that the elevated cardiovascular risk that accompanies SERMs and TSECs is a mark against these therapies, especially when local estrogen formulations that avoid systemic risks are already available. (Marshall and Iglesia, 2009)

In conclusion, opportunity will remain in the PVA market for products with improved safety profiles, whether these are achieved through local administration or as a result of a safer mode of action, as well as for products with more convenient dosing schedules.

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SERMs, DHEA, and TSECs Will Drive the Market by 2017

Despite the effects of generic erosion, the PVA market will grow, driven by the uptake of a new class of drugs with improved safety profiles and better convenience. Shionogi's first-in-class drug, Ospheña, is an orally-administered SERM that will be the first new agent to be launched in the VVA market. It will likely be positioned as a novel therapy for the treatment moderate/severe vaginal atrophy in postmenopausal women who list dyspareunia (pain during sexual intercourse) as their most bothersome complaint. Ospheña is projected to grow to achieve \$322.8m in global PVA-specific sales by 2020.

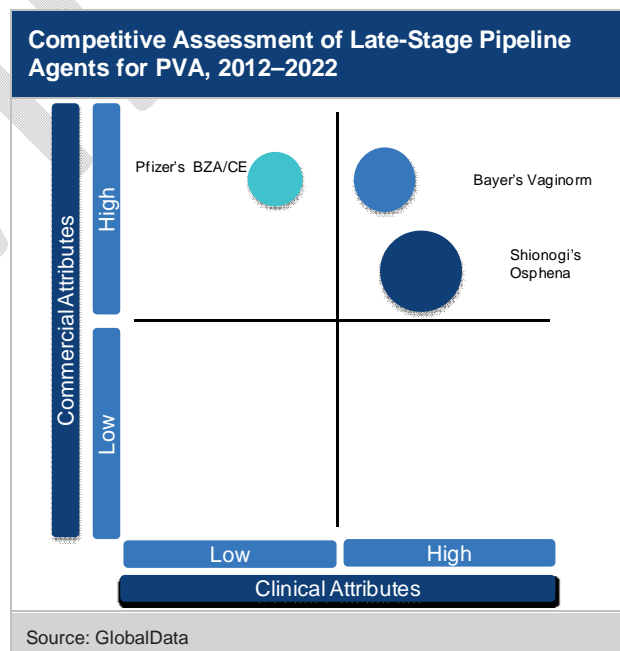
Vaginorm is a first-in-class intravaginal DHEA therapy that will likely be positioned as an alternative option to Vagifem (estradiol vaginal tablet) for women who prefer the convenience of vaginal tablets. This mode of administration will also constitute an incentive for women and prescribers who express concern about systemic therapies, which means that Vaginorm will also compete with Ospheña. Vaginorm is projected to reach \$318.4m in PVA-specific sales by 2020.

BZA/CE consists of a combination of the SERM bazedoxifene and an estrogen, Premarin. Bazedoxifene was previously rejected by the US Food and Drug Administration (FDA) as a stand-alone therapy for osteoporosis due to safety concerns. Although Premarin achieved blockbuster status, its reputation remains marred by highly-

publicized clinical trials linking the drug to an increased cancer and stroke risk. If BZA/CE gains regulatory approval in the US, 5EU, and Japan, Pfizer's new product may face a slow uptake. BZA/CE is projected to grow to \$25.1m in PVA-specific sales over the forecast period.

Advertising and marketing efforts surrounding the launches of these three new therapies will bolster disease awareness, as companies strive to differentiate their newly-launched drugs from the existing products.

Below mentioned figure provides a competitive assessment of the late-stage pipeline agents for PVA during the forecast period.



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What Do the Physicians Think?

"If there was a product that could be used, for example, once a week, with no side effects, that would be ideal."

UK KOL, February 2013

"Certainly, the WHI study was a very large factor in terms of the heightened concerns about hormonal therapy."

US KOL, February 2013

"I think we have bottomed out; all the scares wrapped around the WHI study have now been put into perspective."

UK KOL, February 2013

"The percentage of patients who are treated will probably increase, based on the fact reassurances are being released by the North American Menopause Society and similar organizations."

US KOL, February 2013

"With any drug, the mode of delivery and what the potential advantage it may have over current formulations is what matters."

US KOL, February 2013

"There are all sorts of cultural reasons why women don't come forward to ask about the possibilities of relief from this problem. Worldwide, there is a tremendous variation in terms of how it is managed."

UK KOL, February 2013

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Introduction

2 Introduction

2.1 Catalyst

Although the postmenopausal vaginal atrophy (PVA) market has experienced anemic growth over the past decade, it is expected to undergo a considerable change between 2012 and 2022. Several market-leading therapies, including Pfizer's Premarin (conjugated estrogens) and Merck's Colpotrophine (promestriene), will lose patent protection between 2012 and 2015. In addition, a number of oral estrogens, vaginal patches, and vaginal creams will lose exclusivity, leading to a flood of cheaper generic options.

The launches of three novel drugs with improved safety profiles — Ospheña (ospemifene), Vaginorm (prasterone), and BZA/CE (bazedoxifene + conjugated estrogens) — will bolster treatment-seeking behavior during the forecast period. These non-estrogenic therapies will shift the PVA treatment paradigm away from systemic estrogen therapies (ETs), such as pills, patches, and gels. Furthermore, healthcare reform under the Affordable Care Act (ACA) will increase the number of insured elderly US women, thereby potentially boosting treatment-seeking behavior for menopausal conditions. These dynamics will be reflected in the moderate growth of the overall PVA market during the forecast period, which will increase from \$1.1108b in 2012 to \$2.079bn in 2022 at a Compound Annual Growth Rate (CAGR) of 6.5 %.

2.2 Related Reports

- GlobalData (2012). GlobalData Healthcare Policy Analysis 2012 – Regulatory, Pricing, and Reimbursement, July 2012, GDH001HPM
- GlobalData (2012). PharmaPoint: Osteoporosis – Global Drug Forecast and Market Analysis to 2022, January 2013, PHARMABIR31321

2.3 Upcoming Related Reports

- GlobalData (2013). Endometriosis – Opportunity Analyzer, September 2013

Appendix

11.7 About GlobalData

GlobalData is a leading global provider of business intelligence in the healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

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