Executive Summary

Schizophrenia: Key Metrics in the Seven Major Pharmaceutical Markets, 2012–2022

<table>
<thead>
<tr>
<th>2012 Epidemiology</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Prevalent population</td>
<td>2.5 million</td>
</tr>
<tr>
<td>Treated population</td>
<td>2.0 million</td>
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<table>
<thead>
<tr>
<th>2012 Market Sales</th>
<th></th>
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<tbody>
<tr>
<td>US</td>
<td>$5.2bn</td>
</tr>
<tr>
<td>5EU</td>
<td>$0.4bn</td>
</tr>
<tr>
<td>Japan</td>
<td>$0.7bn</td>
</tr>
<tr>
<td>Total</td>
<td>$6.3bn</td>
</tr>
</tbody>
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Pipeline Assessment

| Number of drugs in Phase II–III | 11 |
| Number of first-in-class drugs  | 2  |

Promising Pipeline Candidates

<table>
<thead>
<tr>
<th>Peak-Year Sales</th>
<th></th>
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<tr>
<td>Brexpiprazole (Otsuka/Lundbeck)</td>
<td>$1.8bn</td>
</tr>
<tr>
<td>Cariprazine (Forest/Gedeon Richter)</td>
<td>$0.9bn</td>
</tr>
<tr>
<td>EVP-6124 (EnVivo/Mitsubishi Tanabe)</td>
<td>$0.8bn</td>
</tr>
<tr>
<td>Aripiprazole lauroxil (Alkermes)</td>
<td>$0.7bn</td>
</tr>
<tr>
<td>Invega Sustenna (Three-Month)</td>
<td>$0.6bn</td>
</tr>
</tbody>
</table>

Key Events (2012–2022)

<table>
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<tr>
<th>Level of Impact</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Zyprexa (olanzapine) patent expiry in the 5EU in 2012</td>
<td>↓↓</td>
</tr>
<tr>
<td>Seroquel (quetiapine) patent expiry in the US and 5EU in 2012</td>
<td>↓↓</td>
</tr>
<tr>
<td>Geodon (ziprasidone) patent expiry in the US in 2012</td>
<td>↓</td>
</tr>
<tr>
<td>Launch of Abilify Maintena (aripiprazole) in the US in 2013</td>
<td>↑↑↑</td>
</tr>
<tr>
<td>Abilify (aripiprazole) patent expiry in the US and 5EU in 2015</td>
<td>↓↓↓</td>
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<table>
<thead>
<tr>
<th>2022 Market Sales</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>$6.1bn</td>
</tr>
<tr>
<td>5EU</td>
<td>$0.4bn</td>
</tr>
<tr>
<td>Japan</td>
<td>$1.4bn</td>
</tr>
<tr>
<td>7MM</td>
<td>$7.9bn</td>
</tr>
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</table>

The table above provides a summary of the key metrics for schizophrenia in the seven major pharmaceutical markets during the forecast period from 2012–2022.

Schizophrenia Drug Sales by Region, 2012–2022

The combined sales of medications carrying an indication in schizophrenia were estimated at $6.3 billion in 2012. By 2022, GlobalData projects these sales to grow to $7.9 billion, with a compound annual growth rate (CAGR) of 2.40% over the course of the decade. These estimates cover the sales in the seven major markets (7MM) included in this report: the US, France, Germany, Italy, Spain, the UK, and Japan. We believe that the following parameters will drive expansion in these markets:

- Growing awareness of mental health
- Enhanced community-level mental health care
- New product launches
- Increasing utilization of long-acting injectable (LAI) antipsychotics

Source: GlobalData.

7MM = US, France, Germany, Italy, Spain, UK, Japan; 5EU = France, Germany, Italy, Spain, UK
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The figure below illustrates schizophrenia drug sales in the 7MM by region during the forecast period.

Positive Symptom Therapies Dominate the Schizophrenia Drug Market

- The pharmaceutical market for schizophrenia is composed solely of symptomatic therapies that confer significant improvements in positive symptoms, but have little effect on negative and cognitive symptoms of the disease. Patients with schizophrenia have varying symptomatologies; negative-dominant schizophrenia or cases with pronounced cognitive impairments are generally untreated by the current market options. In recognition of the unmet therapeutic needs, current research and development (R&D) efforts are focused on developing drugs with novel mechanisms that target negative and cognitive symptom clusters. Several key players in the industry have concentrated on the two features of the disease that are currently without treatment options: cognitive and negative symptoms. However, several of these novel mechanisms in development are yet to be proven in clinical trials. Given the growing list of late-stage clinical trial failures, developing pharmacotherapies for negative and cognitive symptoms has proven to be challenging, but those agents that do emerge from the developmental landscape are poised to make a notable impact on the market and see substantial returns year-on-year.
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- The current schizophrenia drug armamentarium consists of first-generation and atypical antipsychotic medications. Due to the high competition in the schizophrenia drug market, new agents in the market have failed to meet the needs of psychiatrists and their patients with schizophrenia. However, during the forecast period, the schizophrenia drug market will encounter rapid changes as a result of patent expirations of key atypical products, and the companies that have led the market will be challenged to maintain their positions. By now, physicians have an established familiarity with these courses of therapy. Product-line extensions have helped to increase brand awareness as well as offering different dosage forms that may help clinicians achieve better treatment response. As LAIs are becoming increasingly utilized, product extensions, along with novel product launches, are poised to emerge during the forecast period and become significant players in the schizophrenia drug market.

- Adjunct therapies are being pursued by several companies. Add-on therapies may provide more complete symptomatic treatment by employing novel mechanisms. There is ample space within the schizophrenia drug market for therapies that can maintain efficacy more efficiently and with greater duration.

The figure below provides an analysis of the company portfolio gap in schizophrenia during the forecast period.

Unmet Needs

- The current schizophrenia market relies on first-generation antipsychotics (FGA) and atypical therapies that do not adequately satisfy the needs of patients with the disease. While these drugs can confer improvements in the patient’s positive symptoms like hallucinations and delusions, they do not improve a patient with a flat emotional affect or pronounced cognitive impairments, which can disrupt a patient’s response to their treatment. The pipeline consists of several candidates that target negative and cognitive symptoms.
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and several new LAI therapies. Given the fierce competition in the indication, however, they will have to demonstrate in clinical trials and in practice that their utility surpasses those of current market options.

- An additional challenge facing schizophrenia is the social stigma of mental health conditions in many areas of the world. The level of unmet need in schizophrenia and related mental health disorders is one of the highest in medicine today, but the pharmaceutical industry recognizes schizophrenia negative-symptom and cognitive-symptom therapeutics as “high-risk” investments. Consequently, government and academic institutions have stepped forward to become the key contributors to R&D. Their contributions may drive drug development by offering a better understanding of the disease’s molecular biology that provides the industry with novel targets for pharmacotherapy.

Ample Market Opportunity

- As drug development shifts from dopamine and serotonin receptor blockade to new mechanisms of action, the need for curative therapy will remain for patients with schizophrenia. However, it is not expected that a cure for schizophrenia will be developed by the current agents in the pipeline.

- Schizophrenia diagnosis remains a challenge, and first-episode psychosis is not usually met with a chronic antipsychotic treatment regimen. In addition, there are challenges in identifying persistent negative and cognitive symptoms in patients with schizophrenia. Supplementing diagnosis with objective lab variables or biomarkers may help to identify treatment-resistant, negative-predominant, cognitively impaired, or suicidal patients, allowing for treatments to be designed more specifically to meet their clinical needs.

- Improving the ease-of-use, efficacy, and duration of FGA and atypical therapies will increase the quality of life (QOL) and treatment response for patients with schizophrenia. However, oral administration of drugs can be difficult in acutely exacerbated patients. Offering patients therapy in dosage forms that require less-frequent dosing or providing drugs with easier routes of administration can directly affect their quality of care by improving medication compliance and relieving the demands on psychiatric healthcare services.

- The costs associated with novel LAI therapies are anticipated to be several-fold higher than those of the current oral medications, several of which are available as generics. Given that most patients with schizophrenia rely to some extent on government-funded insurance programs, it is especially important that cost-minimization measures be implemented and LAIs be prescribed appropriately to mitigate the costs associated with relapse.
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The Direction of Drug Development

- Alkermes’ aripiprazole lauroxil and Invega Sustenna (Three-Month) will introduce two new LAI treatment options, expanding market options by 33%. Aripiprazole lauroxil achieves a formulation advantage over Otsuka/Lundbeck’s Abilify Maintena, given that it does not require reconstitution with water before it is administered. A three-month version of J&J’s Invega Sustenna will provide patients with a reduced dosing burden. As novel products in an emerging part of the schizophrenia drug market, these agents could be met with high sales due to their higher costs of therapy and a growing popularity of LAIs in the space.

- Otsuka’s brexpiprazole is a follow-up product to the current market leader, Abilify (aripiprazole). With an improved tolerability profile and enhanced efficacy over Abilify, brexpiprazole’s introduction to the market could be met with rapid uptake from the high number of patients currently taking Abilify.

- Roche/Chugai’s bitopertin will introduce a new class of medications to the schizophrenia drug market, and the first therapy for schizophrenia’s negative symptoms. As a first-in-class Glycine Transporter Type-1 (Glyt-1), bitopertin is expected to improve negative symptoms and suboptimally controlled positive symptoms by enhancing N-methyl-D-aspartate (NMDA) receptor activity via the regulation of glycine. However, several challenges stand in the way of pipeline agents for negative-symptom predominant schizophrenia, such as a lack of effective identification and monitoring of these symptoms.

- EnVivo’s EVP-6124 is a first-in-class α7 nicotinic acetylcholine receptor (nAChR) agonist in development for cognitive symptoms associated with schizophrenia. EVP-6124 sensitizes the α7 receptor, making it possible for smaller amounts of acetylcholine (ACh) to be effective in activating the α7 receptor. Unlike the current agents that target primarily dopaminergic and serotonergic receptor sites, EVP-6124 works on a new monoamine system and may potentiate the effects of FGA and atypical medications. We expect EVP-6124 to be used generally in combination with marketed antipsychotics. Given its effects on a current unmet therapeutic need, we project that EVP-6124 can yield solid sales that will peak after the forecast period closes.
The figure below provides a competitive assessment of the late-stage pipeline agents in schizophrenia during the forecast period.

What Do the Physicians Think?

“Unfortunately there is really nothing out there which would give me confidence that we will have something reasonably effective in the next several years. We are probably coming to one set of results very soon, probably sometime early next year or maybe the spring of next year, the glutamatergic compounds.”

[US] KOL, October 2013

“There isn’t that much coming out these days, so that’s a fact which many of us have actually agreed on is a major, major issue. We’ve had discussions with pharmaceutical companies as a group of pharmacologically oriented and research-oriented psychiatrists and say, ‘Please come back and reactivate your research and development sections and divisions. Don’t desert this group of patients, because we need better drugs.’ There’s no doubt about it.”

[US] KOL, September 2013

“If you look at the utilization patterns of antipsychotics you do see that once the atypicals were introduced, the usage of these medications went up significantly. And this is not at all because there are more schizophrenic patients around. In fact, schizophrenia has actually decreased slightly in terms of epidemiology. But they have increased in terms of rate of prescribing because the diagnosis has expanded to which these medications are directed to.”

[EU] KOL, November 2013
“[We] treat them according to the presenting syndrome. And even more specifically – in terms of the positive symptoms, depression, affective symptoms, or cognitive symptoms, negative symptoms – they will be cueing in much more on that rather than on the label of, ‘Is this schizoaffective, is it bipolar, is it a schizophrenic patient?’ I think once it gets down to medications, then it gets much simpler. These discussions do not reach into the medication decision-making process.”

[EU] KOL, December 2013

“Going systematically, you have the glutamatergic compounds, you have nicotinic acid agonists, you have the me-too drugs, which are the D₂/5-HT₂ antagonists, and of those we have plenty, we don’t need anything more, that mechanism of action is entirely taken care of, so to speak.”

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Introduction

2 Introduction

2.1 Catalyst

Schizophrenia is a chronic, severe, and disabling group of psychotic disorders characterized by fundamental disturbances of thinking such as hallucinations, delusions, disorganized communication and reduced motivation (NIMH, 2013; WHO, 2013). Globally, the condition is prevalent in approximately 7 persons per 1,000 of the adult population ages 15–35 years (WHO, 2013).

- This report provides an overview of the risk factors, comorbidities, and the global and historical trends for schizophrenia in the seven major markets (7MM: US, France, Germany, Italy, Spain, UK, and Japan). In addition, the report also includes a 10-year forecast of diagnosed prevalent cases of schizophrenia segmented by age and sex.

- To forecast the diagnosed prevalent cases of schizophrenia in the 7MM, GlobalData epidemiologists selected nationally representative studies that provided diagnosed prevalence of schizophrenia using uniform diagnostic criteria and classification defined by the World Health Organization's International Classification of Diseases 9th revision (ICD-9).

- GlobalData epidemiologists forecast an increase in the diagnosed prevalent cases of schizophrenia in the 7MM from 2,495,903 diagnosed prevalent cases in 2012 to 2,643,660 diagnosed prevalent cases in 2022, with an annual growth rate (AGR) of 0.59% in the forecast period.

- In 2022, the US will have the highest number of diagnosed prevalent cases of schizophrenia with 1,777,333 diagnosed prevalent cases, followed by Japan with 454,961 diagnosed prevalent cases, and Italy with 154,331 diagnosed prevalent cases.
2.3 Upcoming Reports

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.

GlobalData has offices in New York, Boston, London, India, and Singapore.

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