

Study on the potential of Antipsychotic drugs (Schizophrenia Disease) and identify launch opportunity in US market.

Dissertation Submitted to



The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Hospital and Health Management

by

Dr. Surabhi Singh

Under the Supervision and Guidance of

Dr. Susmit Jain

2023

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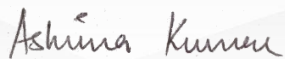
2023

Date: 06/06/2023

TO WHOMSOEVER IT MAY CONCERN

This is to certify that, **Surabhi Singh**, student of IIHMR University, Jaipur has completed her internship with **PharmaACE Analytics LLP** during the period of **March 01, 2023 to May 31, 2023**. During her internship she worked with the Competitive Intelligence department and has successfully worked on the project; **Study on the potential of Antipsychotic drugs (Schizophrenia Disease) and identify launch opportunity in US market**.

We wish her every success in life.



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DECLARATION

I hereby declare that this dissertation titled “Study on the potential of Antipsychotic drugs (Schizophrenia Disease) and identify launch opportunity for US market” is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)

Name of Student: Dr. Surabhi Singh

Date: 06/05/2023

Certificate by Faculty Guide

CERTIFICATE This is to certify that dissertation titled “Study on the potential of Antipsychotic drugs (Schizophrenia Disease) and identify launch opportunity for US market” is a record of the research work undertaken by Dr. Surabhi Singh in partial fulfilment of the requirements for the award of the degree of MBA (Hospital and Health Management from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide IIHMR University, Jaipur

School Dean IIHMR University, Jaipur

Date:

Acknowledgement

Any successful project is a teamwork that reflects the contribution of many people. I would like to thank everyone who has contributed to this effort by sharing their time and taking interest in my project and encouraging me all the way through.

I would also like to extend my gratitude to my Faculty Guide, **Dr. Susmit Jain, Associate Professor**, IIHMR University, Jaipur, for his constant guidance. My sincere gratitude to **Mrs. Pratima Chaudhary** (Practice head at PharmaAce, Innovations LLP) for her encouragement and aproval. I would also like to extend my heartiest gratitude to my organisation mentor **Dr. Sonali Singla** (Senior consultant at PharmaAce, Innovations LLP) who have constantly supported and guided me through my project. I would also like to extend my appreciation towards my family and friends who have contributed to this research project in their own special way.

Surabhi Singh

Date: 06/05/2023

ABSTRACT

Submitted by: Dr. Surabhi Singh

Guided by: Dr. Susmit Jain

Roll No. 1424

Title: Study on the potential of Antipsychotic drugs (Schizophrenia Disease) and identify launch opportunity in US market

Antipsychotics are the drugs primarily used to treat schizophrenia and has other therapeutic applications. The global antipsychotic drugs market size was valued at \$12.42 billion in 2020, and is estimated to reach \$26.81 million by 2030, growing at a CAGR of 8.0% from 2021 to 2030. It is anticipated to witness positive growth trends, owing to strong increase in prevalence of psychotic disorders. Increase in prevalence of mental disorders, rise in geriatric population, and growth in awareness program regarding mental health drive the market growth.

Schizophrenia affects about 1% of the population and is predicted to become more common in the future as the world becomes crowded and people live longer. The prevalence is extremely high among people in late adolescence and the twenties. Treatment of schizophrenia is done by typical and atypical antipsychotics but apart from other therapeutic applications in schizophrenic patients there are unmet needs such as low patient adherence/high discontinuation rate, treatment for positive symptoms only leaving negative and cognitive symptoms untreated.

The research is an observational study in which Secondary data was collected from various clinical studies, research articles, websites and journals to understand about the anticoagulant therapy. The study was conducted between Mar 1, 2023 to May 31, 2023

The competitive intelligence report was developed covering disease overview including epidemiology, treatment options, drugs in pipeline for schizophrenia in US market and forecasting was done on evenamide out of the drugs in pipeline based on the analyst report available to estimate the potential revenue of the drug.

Key words: Competitive intelligence, Antipsychotic drugs, Schizophrenia, Drugs, Inline drugs, Pipeline drugs, Forecasting.

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Abbreviations

1. FDA- Food and Drug Administration- Federal Agency
2. SEE- Southeastern Europe
3. CI- Competitive Intelligence
4. US- United States
5. CAGR- Compound Annual Growth Rate
6. R&D- Research and Development
7. MRI- Magnetic Resonance Imaging
8. CT- Computed Tomography
9. CSV- Comma Separated Values

Chapter 1 – Introduction

Competitive intelligence: Competitive intelligence for business development refers to the process of gathering, analyzing, and utilizing information about competitors and the overall market to gain a competitive advantage and drive business growth. It involves monitoring and researching competitors' strategies, products or services, pricing, marketing tactics, customer base, and strengths and weaknesses. The goal is to obtain valuable insights that can inform decision-making, identify opportunities for differentiation, and develop effective strategies to outperform competitors in the marketplace.

Competitive intelligence helps businesses understand their position relative to competitors, anticipate market trends and customer needs, and identify potential threats and opportunities. It involves gathering information from various sources, including competitor websites, industry reports, market research, social media, customer feedback, and internal data analysis. By analyzing and interpreting this information, businesses can make informed decisions regarding product development, marketing campaigns, pricing strategies, partnerships, and expansion plans.

The process of competitive intelligence involves not only collecting data but also analyzing and interpreting it to generate actionable insights. These insights can help businesses identify their unique selling propositions, understand market gaps, and develop strategies to differentiate themselves from competitors. It also enables businesses to proactively respond to changes in the market, seize emerging opportunities, and mitigate potential risks.

Overall, competitive intelligence for business development is a strategic approach to gathering and analyzing information about competitors and the market, enabling businesses to make informed decisions, stay ahead of the competition, and drive growth and success.

1.1 Therapeutics Applications

- **Schizophrenia**

It is a chronic, severe mental health condition that usually appears in late adolescence or early adulthood. Its impact on speech, thinking, emotions, and other areas of life can affect a person's social interactions and everyday activities.

- **Parkinson's Disease**

It is a brain disorder that causes unintended or uncontrollable movements, such as shaking, stiffness, and difficulty with balance and coordination.

- **Bipolar disorder**

It is a chronic mood disorder that causes intense shifts in mood, energy levels and behaviour. Manic and hypomanic episodes are the main sign of the condition, and most people with bipolar disorder also have depressive episodes. The condition is manageable with medications, talk therapy, lifestyle changes and other treatments.

- **Dementia**

It is a syndrome in which there is deterioration in cognitive function beyond what might be expected from the usual consequences of biological ageing.

- **Alzheimer's disease**

It is a progressive neurologic disorder that causes the brain to shrink (atrophy) and brain cells to die. It is the most common cause of dementia a continuous decline in thinking, behavioural and social skills that affects a person's ability to function independently.

- **Attention Deficit Hyperactivity Disorder (ADHD)**

It is a brain disorder that affects how you pay attention, sit still, and control your behaviour. It happens in children and teens and can continue into adulthood.

1. Antipsychotics Drugs

Antipsychotic drugs (also called neuroleptics or major tranquilizers) are used primarily to treat schizophrenia (biologic illness), but they are also effective in other psychotic states, including manic states with psychotic symptoms such as grandiosity, paranoia, and hallucinations, and delusions.

Antipsychotic drugs are not curative and do not eliminate the chronic thought disorder, but they often decrease the intensity of hallucinations and delusions and permit the person with schizophrenia to function in a supportive environment.

1.2 Classification of Antipsychotics

Antipsychotic agents have been categorized into two classes:

- **Typical Antipsychotics**

Typical antipsychotics were the first ones developed. They work by blocking dopamine receptors in the brain. Some examples of typical antipsychotics are Chlorpromazine (Thorazine), Haloperidol (Haldol), Fluphenazine (Prolixin), Perphenazine (Trilafon), and Thioridazine (Mellaril).

- **Atypical Antipsychotics**

Atypical antipsychotics are newer medications that have a broader way of working. They target multiple neurotransmitter systems, including dopamine and serotonin receptors. Atypical antipsychotics are generally associated with a lower risk of movement problems compared to typical ones. Examples of atypical antipsychotics include Risperidone (Risperdal), Olanzapine (Zyprexa), Quetiapine (Seroquel), Aripiprazole (Abilify), Ziprasidone (Geodon), Paliperidone (Invega), Lurasidone (Latuda), and Clozapine (Clozaril).

Table 01: Classification of Antipsychotics

Typical Antipsychotic Drugs	Atypical Antipsychotic Drugs
Haloperidol	Aripiprazole
<u>Loxapine</u>	Clozapine
Thioridazine	Ziprasidone
Molindone	Risperidone
Thiothixene	Quetiapine
Fluphenazine	Olanzapine
<u>Mesoridazine</u>	-
Trifluoperazine	-
Perphenazine	-
Chlorpromazine	-

Purpose of research- Client X wanted to review the antipsychotic drugs market in US in schizophrenia indication.

Aim- Study on the potential of Antipsychotic drugs (Schizophrenia Disease) and identify launch opportunity in US market

Objective of the report

- To assess the potential of Antipsychotics (Schizophrenia Disease) for US market
- To identify a launch opportunity in Antipsychotics for US market
- To assess the Antipsychotic drugs market in US.
- To assess in-line and pipeline drugs in US market.

Chapter 2- Review of Literature

By conducting a comprehensive literature review on the antipsychotic drugs market, one can gain a deeper understanding of the current landscape, identify gaps in knowledge, and highlight areas for further research or potential business opportunities.

2.1: Non-pharmacological interventions for schizophrenia-analysis of treatment guidelines and implementation in 12 Southeast European countries

Authors: Lidija Injac Stevović, Nikolina Jovanović

This study looked at the guidelines for treating schizophrenia in 12 countries in Southeastern Europe (SEE). The goal was to see which non-medication treatments were recommended, how much evidence supports these recommendations, and how often they are actually used. The researchers analyzed the guidelines and surveyed experts in each country. They found that most SEE countries have published guidelines for treating schizophrenia, but these guidelines mainly focus on using medication. However, nine countries did include recommendations for non-medication treatments. Three countries (Kosovo, Romania, and Slovenia) did not have published guidelines but still offered these treatments in their leading mental health institutions. On average, the guidelines included about seven recommended non-medication treatments, but the range varied from five to eleven. Family therapy and psychoeducation were commonly recommended. However, most of the recommended treatments had either negative or mixed evidence from randomized controlled trials. Only a small number of leading mental health institutions actually included these treatments in their official service price list. This suggests that the recommended treatments are not widely implemented within mental health services in the SEE countries.

2.2: The acute efficacy of antipsychotics in schizophrenia: a review of recent meta-analyses

Authors: Peter M. Haddad and Christoph U. Correll

Schizophrenia is a significant cause of disability, and before the 1950s, there were no effective medications for its treatment. This review focuses on the effectiveness of antipsychotic medications, including clozapine for treatment-resistant patients. Overall, antipsychotics were found to be more effective than placebo in reducing symptoms,

improving quality of life, and social functioning. First-episode patients had higher treatment response rates compared to multi-episode patients. Lack of response or worsening symptoms after 2 weeks of treatment predicted poor response at endpoint, suggesting the need for a change in treatment. Clozapine was found to be more effective than other antipsychotics for treatment-resistant schizophrenia. High doses and combinations of antipsychotics did not show superior efficacy. The effectiveness of antipsychotics varied depending on the targeted symptom domain and certain patient characteristics. However, there is still a need for new medications that target specific symptom domains and consider individual patient characteristics.

2.3: Exploratory analyses of efficacy data from schizophrenia trials in support of new drug applications submitted to the US Food and Drug Administration

Authors: Ni A Khin, Yeh-Fong Chen, Yang Yang, Peiling Yang, Thomas P Laughren

In conclusion, antipsychotic medications have demonstrated effectiveness in reducing symptoms and improving various aspects of functioning in schizophrenia patients. First-episode patients tend to have better treatment responses compared to those with multiple episodes. Lack of response or symptom worsening after 2 weeks of treatment indicates the need for treatment modification. Clozapine stands out as an effective option for treatment-resistant schizophrenia. However, individual response and symptom domains vary, highlighting the need for personalized approaches and the development of new medications that target specific symptoms and consider patient characteristics.

2.4: Schizophrenia | Primary Research (KOL's Insight) | Competitive Intelligence | Market Analytics & Forecast 2030

Author: Mellalta Meets LLP

The growth of the diagnosed prevalence of schizophrenia is expected to contribute to an increase in sales in the therapy market. The estimated annual growth rate of the diagnosed prevalence of schizophrenia across major pharmaceutical markets will drive sales growth in schizophrenia therapy. By 2030, the number of diagnosed cases is projected to exceed the current number due to population demographics and an increase in treatment-resistant cases.

The use of second-generation treatments for schizophrenia patients will contribute to overall market growth, and the adoption of emerging treatments will drive significant sales growth in the schizophrenia market by 2030. Schizophrenia is a chronic disorder that significantly impacts individuals' functioning and quality of life. Although there is no cure, treatment guidelines recommend a combination of medication and psychological interventions for managing the disease. Current antipsychotic medications primarily target positive symptoms, leaving many patients with residual negative and cognitive symptoms. Ongoing research and a better understanding of schizophrenia's causes and mechanisms are leading to the development of new treatments aimed at improving schizophrenia management. In high-income countries, studies based on DSM-5 diagnostic criteria provide more accurate data on the diagnosed prevalence and outcomes of schizophrenia. The diagnosis rate is estimated to range from 65% to 70%. While most individuals diagnosed with schizophrenia require medication treatment, a significant number may still not receive adequate healthcare, resulting in a treatment gap estimated at around one-third of patients.

2.5: Schizophrenia Drugs in Development by Stages, Target, MoA, RoA, Molecule Type and Key Players, 2022 Update

Authors: Global Markets Direct

Global Markets Direct has released a pipeline guide called "Schizophrenia - Drugs In Development, 2022," which provides comprehensive information on therapeutics being developed for Schizophrenia in the Central Nervous System (CNS). The guide analyzes the stage of development, drug targets, mechanisms of action, routes of administration, and molecule types of these therapeutics. It covers the pharmacological action, research and development history, and latest news and press releases related to the therapeutics. The guide also reviews key players involved in the development of therapies for Schizophrenia and includes information on dormant and discontinued projects. It presents the therapeutics under development by companies, universities, and institutes, highlighting the molecules in various stages of development, such as Pre-Registration, Filing rejected/Withdrawn, Phase III, Phase II, Phase I, IND/CTA Filed, Preclinical, Discovery, and Unknown. The universities' portfolio is also outlined in different stages of development. This pipeline guide aims to assist in identifying and tracking emerging players in the market, understanding their portfolios, making informed decisions, and developing effective strategies to gain a competitive advantage. The guide is compiled using data and information from Global Markets Direct's

proprietary databases, company/university websites, clinical trial registries, conferences, SEC filings, investor presentations, and featured press releases from company/university sites and industry-specific third-party sources. It is regularly updated to capture the most recent developments in real-time.

Chapter 3 - Methodology

3.1 Scope

The scope of this project is as under:

The study was carried out to understand the antipsychotics market for United States and identify the launch opportunity. Treatment of schizophrenia is done by typical and atypical antipsychotics but apart from other therapeutic applications in schizophrenic patients there are unmet needs such as low patient adherence/high discontinuation rate, treatment for positive symptoms only leaving negative and cognitive symptoms untreated hence the drugs for treatment of schizophrenia currently in pipeline address these unmet needs and have a great scope to positively impact the market in near future.

3.3 Methodology

Type of Research: Secondary Research

Setting: Organisation setting (PharmaAce Innovations LLP)

Duration of study: 3 Months

Data was collected by doing secondary research from clinical studies, research articles and websites.

Chapter 4 - Results

4.1 Antipsychotics Market Overview

In 2020, the total value of the global market for antipsychotic drugs was \$12.42 billion. It is predicted that by the year 2030, this market will grow and reach an estimated value of \$26.81 billion. The growth rate, known as the Compound Annual Growth Rate (CAGR), is expected to be 8.0% from the year 2021 to 2030. This indicated that the market for antipsychotic drugs is going to increase and get bigger every year in the next few years.^(1,2)

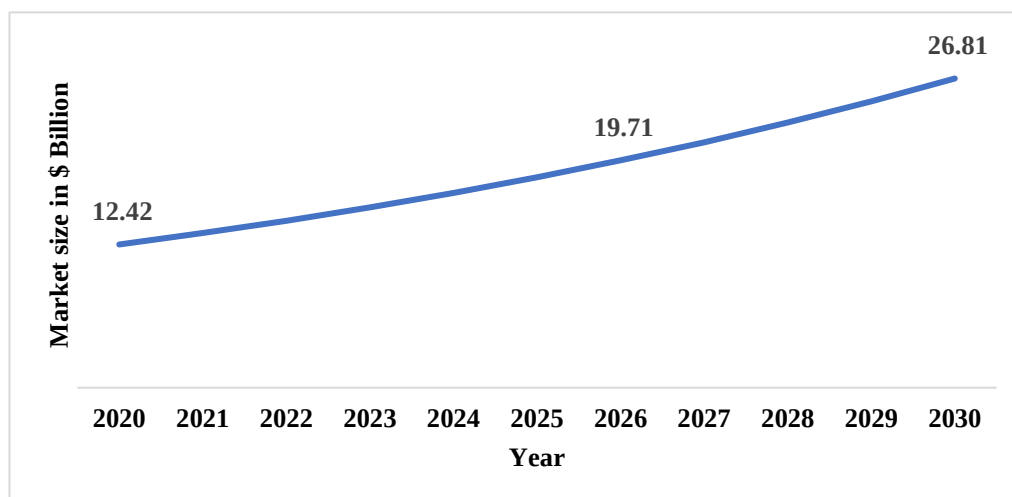


Fig. 1: Antipsychotic global market size 2020-2030 (\$Bn)

The global market for antipsychotic drugs is predicted to get bigger for a few reasons.

- It is because more and more people are facing mental disorders, so there is a greater need for these drugs/ medicines. ^(4,5,6)
- Also, as the world population ages, older people are more likely to have mental health problems, which is a driving factor for market growth.^(4,5,6)
- Another reason is that people are becoming more aware of mental health and learning about it in school and through advocacy. This helps reduce the shame and

embarrassment around mental disorders. As a result, more individuals are taking help and treatment, which increases the demand for antipsychotic drugs.^(4,5,6)

- However, there are some difficulties. The cost of mental health programs and treatment for substance abuse is going up, and this might slow down the market growth. Despite these challenges, overall, the global market for antipsychotic drugs is expected to grow because more people around the world are experiencing mental disorders and thus needing treatment. .^(4,5,6)

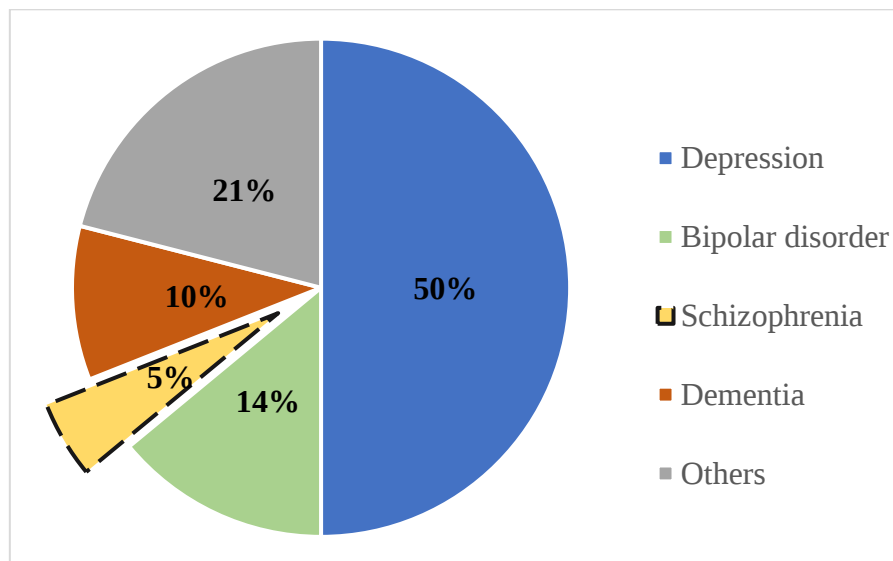


Fig 02: Antipsychotic therapy-wise usage split

- More and more people around the world are being diagnosed with schizophrenia, a mental condition. This has created a higher demand for effective treatments. .^(4,5,6)
- Pharmaceutical companies are investing in research to develop new and better antipsychotic drugs to meet this demand. The market for these medications primarily focused on treating of schizophrenia due to such an increasing number of diagnosed cases. .^(4,5,6)
- North American was the largest market for antipsychotic medications in 2020. The leading reason behind that was having good healthcare services and thus people were concerned about their mental health. The growth in mental illness and increasing

elderly population is another leading reason for increase in North America antipsychotic market.^(4,5,6)

We have seen a common trend of increasing schizophrenic patients in developing nations. People are now understanding the financial impact of mental illness and the need of a effective treatment to help with mental illness.

- Schizophrenia among other mental illness became the major largest sector of research and drug development because of it highest prevalence in other mental illness. Pharmaceutical industries are expanding their R&D section to develop new effective antipsychotic drugs.^(4,5,6)
- Due to high population density of Asia-Pacific, has highest Compound Annual Growth Rate (CAGR) during forecasted time period. Here the market is growing much faster than any other geographical area.^(4,5,6)

The reason behind the high growth in these areas can be considered due to increasing healthcare facilities and increase in people awareness towards mental health.^(4,5,6)

Bristol-Myers Squibb, AstraZeneca, Pfizer Inc, Eli Lilly and Company, Johnson & Johnson, Teva Pharmaceuticals, Dr. Reddy's Laboratories, AbbVie Inc., are few of the major companies that are producing or developing medications for mental health.^(8,9)

Table 02: Top Antipsychotics by 2026 Forecasted Worldwide Sales

Brand name	Generic Name	Company	Mechanism of action	2026 Sales
Invega	Paliperidone palmitate	Johnson & Johnson	5-HT2 antagonist, D2 antagonist	\$4856 m
Vraylar	Cariprazine hydrochloride	AbbVie	5-HT2A antagonist, 5-HT 1A partial agonist, D2 agonist, D3 agonist	\$1307 m
Abilify	Aripiprazole	Otsuka Holdings	5-HT2 antagonist, 5-HT1A partial agonist, D2 partial agonist	\$1,080 m
Rexulti	Brexipiprazole	Otsuka Holdings	5-HT2 antagonist, 5-HT1A partial agonist, D2 partial agonist	\$852 m
KarXT	Trospium chloride; xanomeline	Karuna Therapeutics	Selectively activate muscarinic acetylcholine receptors in the brain to improve the therapeutic potential of xanomeline	\$746 m
Caplyta	Lumateperone tosylate	Intra-Cellular Therapies	Unknown, but efficacy could be mediated through a combination of antagonist activity at central serotonin 5-HT2A receptors and post synaptic antagonist activity at central dopamine D2 receptors	\$705 m

4.2 Schizophrenia Disease Overview and Market Size

- Schizophrenia is a mental illness that has an impact on a person's thinking, perception of the world, emotional reactions, and social interactions. It can interfere with a person's ability to think clearly, lead them to perceive or hear things that are not there, struggle with their emotions, and make it difficult for them to socially interact with others. Schizophrenia is a serious and persistent mental condition that calls for ongoing care and assistance to help sufferers manage their symptoms and enhance their daily lives. ^(4,5,6)

4.2.1 Prevalence Rate:

The prevalence rate means the proportion of a population that is affected by a particular disease or condition at any given moment. ^(8,9,10)

Approximately 24 million people (or 1 in 300 or 0.32% of the population) worldwide suffer with schizophrenia. The rate is around 1 in 222 adults (0.45%). This demonstrates that although schizophrenia is rare, it has a big global impact on a lot of people. ^(8,9,10)

By the year 2020, about 2.8 million adults in the United States who are 18 or older will have schizophrenia, which is a serious brain condition. Sadly, 40% of those people won't receive any treatment in a year, which is concerning.

By 2025, the number of older people in the US with schizophrenia is expected to double to 1.1 million. This shows that more research and laws are needed to address the specific problems faced by this group. ^(8,9,10)

It's important to know that people with schizophrenia are 2 to 3 times more likely to die young compared to the general population. ^(8,9,10)

In simpler terms, schizophrenia is a severe brain condition that has a big impact on the world.

4.2.2 Unmet needs

Atypical antipsychotics are commonly used medicines for treating schizophrenia. They can help with hallucinations, delusions, and problems with speech. However, they don't work as well for the difficulties with thinking and negative symptoms of schizophrenia, and they don't always provide relief. ^(8,9,10)

One big problem in treating schizophrenia is that many patients don't take their medicines on time as instructed. When patients don't take their medicines as prescribed, they don't work as effectively, and there's a higher chance of having more episodes of psychosis.

These challenges show that we urgently need new medicines for schizophrenia that work in different ways. Doctors agree that untreated symptoms, especially problems with thinking and negative symptoms, greatly affect patients' quality of life. Even if the positive symptoms are controlled, these other symptoms often continue to cause trouble.⁽¹⁰⁾

New medicines with unique actions are being developed to meet these needs. These new treatments for schizophrenia aim to address the problems with thinking and negative symptoms that current medicines are not good at treating.

4.2.3 Symptoms:

Simply put, indications of schizophrenia typically appear in late adolescence or the beginning of adulthood, with some variances between men and women. The prodromal period is a time frame before the ailment fully manifests itself and can last for various amounts of time.

There may be imperceptibly modest behavioral changes at this time. These changes in teenagers may include a decline in academic performance, a decrease in social involvement, difficulty concentrating, an increase in irritability, and altered sleep patterns.

Positive Symptoms of Schizophrenia:

These are additional thoughts or actions that do not have a basis in reality. They include:

- **Delusions:** False beliefs that are difficult for the person to let go of and are not grounded in truth. Examples include believing they have supernatural abilities or that others can hear their thoughts.
- **Hallucinations:** Unreal sensations, such as perceiving voices that aren't there or seeing things that aren't there. The most frequent hallucination in schizophrenia is hearing voices.

- **Catatonia:** A situation in which a person may become immobile, unresponsive, or hold a stationary position for a protracted period of time.

Causes

It is unknown what specifically causes schizophrenia. The following circumstances, however, may make the disease more likely to develop:

- **Genetics (heredity):** Sometimes, schizophrenia can run in families. This suggests that there is a higher likelihood that someone will acquire schizophrenia if someone in their family does.
- **Brain chemistry and circuits:** A person with schizophrenia could also struggle to control certain neurotransmitters, which are brain chemicals. These substances play a part in regulating the nerve cell "circuits" or pathways that influence thought and behavior.
- **Brain abnormality:** Additionally, studies suggest that certain people with schizophrenia may have aberrant brain architecture. It's crucial to remember that not everyone who has schizophrenia exhibits these brain abnormalities. Similar to this, some people without schizophrenia may also have similar anomalies in their brain.
- **Environment:** When the body is undergoing hormonal and physical alterations, such as those that take place during the teen and young adult years, schizophrenia tends to manifest more frequently. In people whose genetics make them more likely to develop schizophrenia, conditions like viral infections, exposure to poisons like marijuana, or intensely stressful events may manifest the cause of disorder.

4.2.4 Prognosis

It is the outcome or course of a disease, the chance of recovery or recurrence.

The outlook for individuals with schizophrenia is unpredictable. The positive treatment outcome rate is only 20%, meaning they respond well to treatment and experience

improvement. The remaining patients face challenges such as recurring episodes of psychosis, ongoing symptoms, and limited response to antipsychotic medications. ⁽¹¹⁾

After ten years of being diagnosed with schizophrenia, about 50% of individuals either fully recover or improve enough to live independently. Another 25% show improvement but still require a strong support system, while 15% do not show significant improvement and often need to be hospitalized. Sadly, 10% of people with schizophrenia feel so overwhelmed that they resort to suicide as a way to escape their suffering. ^(8,9,10)

When looking at long-term statistics, thirty years after diagnosis shows similar trends to the ten-year mark. More individuals experience improvement and become independent, but there is also a rise in the number of suicides, reaching fifteen percent. Over time, women tend to have a better chance of maintaining recovery from symptoms compared to men.

4.2.5 Diagnosis

To diagnose schizophrenia, doctors first need to eliminate the possibility of other mental health disorders and confirm that the symptoms aren't caused by substance abuse, medication side effects, or a medical condition. In simpler terms, they want to make sure that the symptoms experienced by the individual are specifically related to schizophrenia and not caused by something else. This involves a process of considering different factors and ruling out alternative explanations before arriving at a diagnosis.

Determining a diagnosis of schizophrenia includes:

To determine a diagnosis of schizophrenia, several steps are involved:

- **Physical exam:** This is done to rule out other medical conditions that may be causing the symptoms and to check for any related complications.

- **Tests and screenings:** These comprise numerous examinations to rule out ailments with comparable symptoms. Additionally, testing for drug and alcohol use is done. To acquire a better understanding of the structure of the brain, imaging tests like an MRI or CT scan may be required.
- **Psychiatric evaluation:** A physician or mental health specialist evaluates the person's mental status by noting their demeanor, behavior, and mood. They enquire about any possibility for violence or suicide as well as thoughts, delusions, hallucinations, drug usage, and thoughts. Additionally mentioned are family and personal histories.
- **Diagnostic criteria for schizophrenia:** Referring to the criterias listed in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) issued by the American Psychiatric Association, the doctor or mental health specialist.

Specific tests used in the diagnosis of schizophrenia include:

- **Blood tests and imaging:** To monitor general health and solve other illnesses that could be causing the symptoms, a complete blood count (CBC) test may be carried out. Blood tests can also spot drug misuse symptoms, which might resemble schizophrenia symptoms. For the purpose of identifying any anomalies, imaging techniques like MRI scans provide precise views of the brain's structural makeup.
- **Psychological tests:** These assess the person's mental health, taking into account their look, demeanor, thought patterns, mood, and awareness. The potential for violence or suicide is assessed with particular care.
- **Positive and Negative Syndrome Scale (PANSS):** This test evaluates the potency of the treatment and the severity of the symptoms. Interviews with the patient, their family, or carers are conducted in order to evaluate their medical history, symptoms, and cognitive ability. The test has three sections and 30 items with scores ranging from absent to extremely high.
- **Scale for the Assessment of Negative Symptoms (SANS) and Scale for the Assessment of Positive Symptoms (SAPS):** These tests evaluate the consequences of schizophrenia's negative and positive symptoms, respectively. While SAPS assesses positive symptoms like hallucinations and delusions, SANS analyses negative symptoms including loss of

facial expression and social inattentiveness. On a scale of none to severe, symptoms are rated.

- **Brief Psychiatric Rating Scale (BPRS):** This common test evaluates how severe the symptoms of schizophrenia are. It rates the intensity of 18 symptoms or behaviors, including aggression, disorientation, and hallucinations, from not present to highly severe.

These examinations aid medical practitioners in assessing the signs of schizophrenia and making a precise diagnosis.

4.2.6 Population At Risk:

Compared to the general population, those with schizophrenia are more likely to pass away before their time. This frequently occurs because they are more prone to physical ailments such as infections, metabolic abnormalities, and cardiac difficulties.

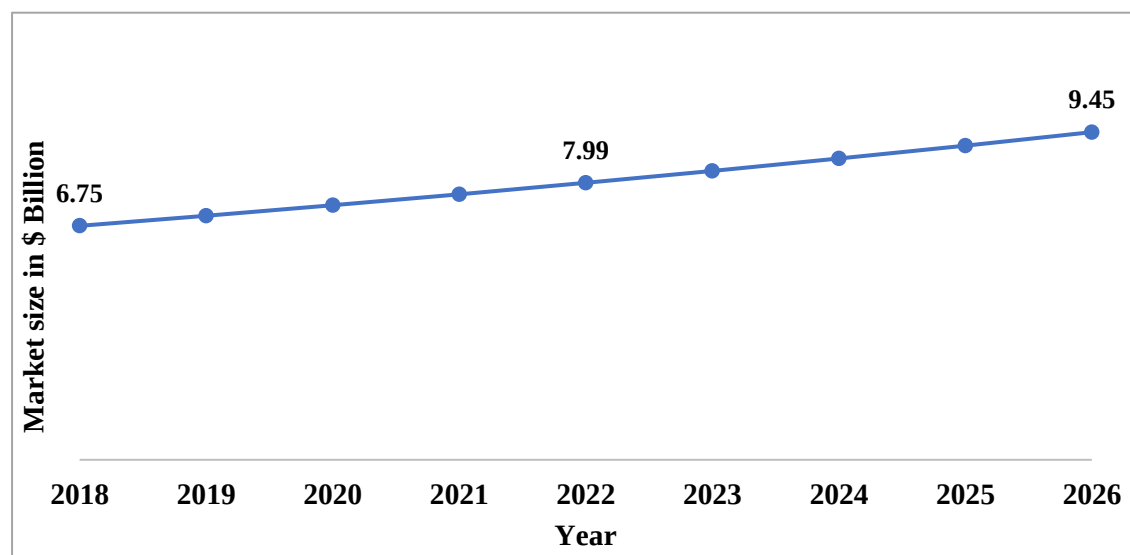
Oceania, the Middle East, and East Asia are among the regions with the highest prevalence of schizophrenia.

According to studies, men are more likely than women to have schizophrenia. Compared to women, men frequently start showing early symptoms in life. Men are more likely to have negative symptoms than women, and women are more likely to have affective symptoms. The specific symptoms that men and women feel differ. Schizophrenia symptoms usually appear in the late teens, early to mid-20s, or early to mid-30s. Men and women may differ in the timing of their initial psychotic episodes or symptoms.

As the world's population ages, adults 55 and older will account for a sizeable part (25% or more) of all schizophrenia sufferers globally. Schizophrenia is the third most common cause of disability-adjusted life years in those aged 60 and older with mental and substance use problems.

Schizophrenia- Market Size

The global market for medications for schizophrenia was \$6.75 billion in 2018 and is projected to rise at a compound annual growth rate (CAGR) of 4.3% to \$9.48 billion by 2026. Accordingly, the market is expanding gradually at a pace of 4.3% yearly.^(8,9,10)



Graph 03: Schizophrenia global market size 2020-2026 (\$Bn)

Market Drivers:

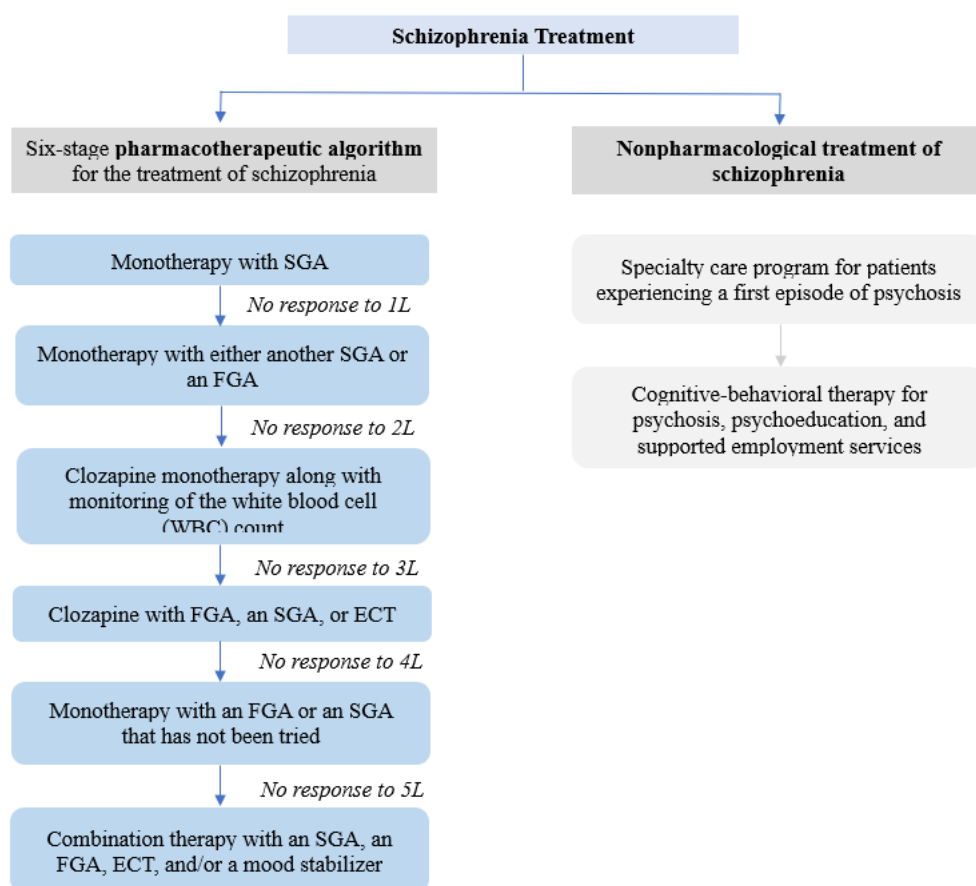
Multiple causes are driving up the demand for schizophrenia medications on the global market. The rising prevalence of mental illnesses like schizophrenia and a greater understanding of mental health are two major factors. Organisations, both public and private, are undertaking awareness campaigns to support mental health and offer care for mental health illnesses.⁽¹¹⁾

The market is also gaining from the ageing population because older people are more prone to mental illnesses. Increased awareness of mental diseases, improvements in mental therapies, a robust pipeline of novel medications, and the uptake of cutting-edge schizophrenia treatments in developing countries are just a few themes that have helped drive the market's expansion.

The market is also growing as a result of product launches, research and development initiatives, and the approval of new medications. Growth in the industry is also being fuelled by clinical studies for brand-new schizophrenia treatments and medication development partnerships.

Treatment adherence is being improved by developments in schizophrenia medicines, which is aiding market expansion. Additionally, as chronic anxiety and depression can result in the development of schizophrenia and its accompanying symptoms, such as delusions and hallucinations, they are fuelling the market's growth.

4.2.7 Treatment Algorithm



For most schizophrenia patients, effective rehabilitation programs often require the use of antipsychotic medications. It is crucial to start drug treatment promptly, particularly within the first five years after the initial acute episode, as this is when significant changes in the brain occur^(1,6). Poor prognosis can be predicted by illicit use of stimulant drugs like amphetamines,

alcohol and drug abuse. Additionally, substances like alcohol, caffeine, and nicotine can interact with medications.

Immediate drug therapy should be administered during an acute psychotic episode. The goal within the first seven days of treatment is hostility reduction and help the patient to resume normal functioning, including sleeping and eating. The appropriate dosage should be determined based on the patient's response.

Following the acute phase, maintenance therapy is necessary to increase socialization, improve self-care, and stabilize mood. Maintenance treatment helps prevent relapses, with relapse rates ranging from 18% to 32% for patients receiving maintenance therapy compared to 60% to 80% for those without it. Drug therapy should be continued for at least 12 months (1 year) after the initiation of the first psychotic episode.^(1,6)

According to the American Psychiatric Association (APA), the preferred choice of medication for first-line treatment of schizophrenia is second-generation (atypical) antipsychotics, excluding clozapine. This is because clozapine carries a risk of agranulocytosis. Second-generation antipsychotics are preferred over first-generation antipsychotics because they have fewer extrapyramidal symptoms. However, it's important to note that second-generation antipsychotics can have metabolic side effects, such as weight gain, high cholesterol levels, and diabetes. These side effects can increase the risk of cardiovascular problems in people with schizophrenia.^(1,6)

The Texas Medication Algorithm Project (TMAP) provides a six-stage treatment algorithm for schizophrenia. The first stage involves using a single second-generation antipsychotic as initial therapy. If there is limited or no response, the patient moves to stage two, which involves using another second-generation or first-generation antipsychotic as monotherapy. If there is still no response, stage three includes clozapine therapy with monitoring of the white blood cell count.^(1,6) If agranulocytosis occurs, clozapine should immediately be discontinued. If stage three treatment is unsuccessful, stage four combination therapy of clozapine with a first-generation or second-generation antipsychotic or electroconvulsive therapy is preferred. If there is no response to treatment, stage five involves trying a different first-generation or second-generation antipsychotic. In the end, if stage five treatment is unsuccessful, stage six

includes combination therapy with second-generation or first-generation antipsychotics, electroconvulsive therapy, and/or a mood stabilizer.^(1,6)

Combination therapy is usually recommended only in the later stages of the treatment.^(1,6) Due to the increased risk of drug interactions, nonadherence, and medication errors, the routine prescription of two or more antipsychotics is not recommended.

Before starting a new antipsychotic drugs, the patient's complete medication history should be noted^(1,6). Being aware of patient's previous response to antipsychotic treatment, helps the physician guide the selection of a new medication.^(1,6)

3.2.10 Non-pharmacological treatment of schizophrenia

Some of the recommended non-pharmacological interventions for schizophrenia, based on strong evidence, include:

- **Cognitive-behavioural therapy (CBT):** This type of therapy helps individuals identify and change negative and bad thought patterns and behaviours that contribute to their symptoms. It focuses on developing better coping strategies and improving problem-solving skills.
- **Cognitive remediation:** This intervention includes improving cognitive abilities such as attention, memory, and problem-solving, which can be affected in patients with schizophrenia. It involves exercises and training to enhance their cognitive functioning.
- **Psychoeducation:** This intervention involves providing education and information about schizophrenia, its symptoms, treatment options, and self-management strategies. It helps individuals and their families better understand the condition and actively participate in the treatment process.
- **Social and coping skills training:** This intervention focuses on enhancing social skills, communication, and problem-solving abilities. It helps individuals with

schizophrenia develop effective coping strategies to manage everyday challenges and improve their social interactions.

- **Family interventions:** These interventions include working with the family members of patients with schizophrenia to improve their communication, reduce stress, and enhance the family support. They aim to create a supportive environment and involve families in the treatment process.
- **Assertive community treatment (ACT) or case management:** These interventions involve providing comprehensive and coordinated support services to individuals with schizophrenia. They aim to ensure access to housing, employment, social support, and medical care, promoting stability and recovery in the community.

These evidence-based non-pharmacological interventions can complement medication treatments and help individuals with schizophrenia improve their overall well-being and reduce the risk of relapse.

- **Cognitive Behavioural Therapy (CBT)**

Cognitive-behavioural therapy (CBT) is a type of therapy that aims to help people with schizophrenia learn effective ways to cope with challenging situations. It is a short-term approach focused on specific problems and typically lasts for about 12 to 16 weeks with one-hour sessions each week. ^(13,14,5)

When using CBT to treat schizophrenia naturally, a mental health professional helps the patient change their negative thinking patterns. They work together to replace negative thoughts with more positive ones. Through consistent counselling, the patient becomes aware of harmful thoughts and learns to avoid triggers that can lead to negative thinking. ^(13,14,5)

CBT is a structured approach with clear goals. The therapist works systematically to achieve the best possible outcome. The main goal of CBT is to change the patterns of thinking in order to change behavioural patterns in the individual. ^(13,14,5)

- **Cognitive remediation**

Non-pharmacological interventions refer to approaches that do not involve medication and are aimed at helping individuals with mental disorders improve their daily life activities, such as social interactions and work. These interventions can play a significant role in reducing the risk of relapse in schizophrenia. ^(13,14,5)

Cognitive remediation is a proven non-medication treatment for the cognitive difficulties commonly observed in schizophrenia. It involves specific exercises or strategies aimed at improving cognitive functioning. In the context of psychiatric rehabilitation, cognitive remediation refers to a therapy that involves engaging the patient in learning activities focused on enhancing the specific cognitive skills relevant to their personal recovery goals. ^(13,14,5)

The goal is to help individuals with schizophrenia improve their cognitive abilities and enhance their overall functioning.

- **Assertive Community treatment (ACT)**

ACT (Assertive Community Treatment) is a team-based approach to intensive case management. In ACT, a team of professionals works together to provide comprehensive support and care to individuals with mental health needs. The team members share the responsibility of managing a group of patients and maintain frequent contact with them, usually meeting at least once a week. The team ensures that there are enough staff members available for each patient, allowing for personalized care. Additionally, the team actively reaches out to patients in the community, providing support and assistance where needed. ^(13,14,5)

Table 03: FDA approved Drugs

Brand name	Generic Name	Company	Mechanism of action	2026 Sales
Invega	Paliperidone palmitate	Johnson & Johnson	5-HT2 antagonist, D2 antagonist	\$4856 m

Brand name	Generic Name	Company	Mechanism of action	2026 Sales
Vraylar	Cariprazine hydrochloride	AbbVie	5-HT _{2A} antagonist, 5-HT _{1A} partial agonist, D ₂ agonist, D ₃ agonist	\$1307 m
Abilify	Aripiprazole	Otsuka Holdings	5-HT ₂ antagonist, 5-HT _{1A} partial agonist, D ₂ partial agonist	\$1,080 m
Rexulti	Brexipiprazole	Otsuka Holdings	5-HT ₂ antagonist, 5-HT _{1A} partial agonist, D ₂ partial agonist	\$852 m
KarXT	Trospium chloride; xanomeline	Karuna Therapeutics	Selectively activate muscarinic acetylcholine receptors in the brain to improve the therapeutic potential of xanomeline	\$746 m
Caplyta	Lumateperone tosylate	Intra-Cellular Therapies	Unknown, but efficacy could be mediated through a combination of antagonist activity at central serotonin 5-HT _{2A} receptors and post synaptic antagonist activity at central dopamine D ₂ receptors	\$705 m
Generic (Brand) Name	Indications	Formulations	Notable Side Effects	
Aripiprazole (Abilify)	Schizophrenia, acute agitation	Tablet, orally disintegrating tablet, short-acting intramuscular injection	Dizziness, insomnia, akathisia, nausea, vomiting, sedation	
Asenapine (Saphris)	Schizophrenia	Orally disintegrating tablet	May increase risk for Diabetes and Dyslipidemia, EPS (dosage dependent), hyperprolactinemia (dosage dependent), sedation, weight gain, akathisia, neuroleptic malignant syndrome, tardive dyskinesia.	

Brand name	Generic Name	Company	Mechanism of action	2026 Sales
Clozapine (Clozaril, Leponex)	Treatment - resistant schizophrenia, suicidal behavior associated with schizophrenia	Tablet, orally disintegrating tablet	Increases risk for diabetes and dyslipidemia, increased salivation (possibly severe), sweating, agranulocytosis, sedation, weight gain, constipation, hypotension, seizures	
Iloperidone (Fanapt)	Schizophrenia	Tablet	May increase risk for diabetes and dyslipidemia, EPS (dosage dependent), hyperprolactinemia (dosage dependent), sedation, weight gain, akathisia, neuroleptic malignant syndrome, tardive dyskinesia.	
Lurasidone (Latuda)	Schizophrenia	Tablet	May increase risk for diabetes and dyslipidemia, EPS (dosage dependent), hyperprolactinemia (dosage dependent), sedation, weight gain, akathisia, neuroleptic malignant syndrome, tardive dyskinesia.	
Olanzapine (Zyprexa) (Zyprexa Relprevv)	Schizophrenia, acute agitation Schizophrenia	Tablet, orally disintegrating tablet, short-acting intramuscular injection Long-acting intramuscular injection	Increases risk for diabetes mellitus and dyslipidemia, sedation, weight gain, hyperprolactinemia, constipation, hypotension, seizures	

Brand name	Generic Name	Company	Mechanism of action	2026 Sales
Paliperidone (Invega) (Invega Sustenna)	Schizophrenia, Schizoaffective disorder Schizophrenia	Tablet Long-acting intramuscular injection	May increase risk for diabetes and dyslipidemia, EPS (dosage dependent), hyperprolactinemia (dosage dependent), sedation, weight gain, tachycardia, headache	
Quetiapine (Seroquel, Seroquel XR)	Schizophrenia	Tablet	May increase risk for diabetes and dyslipidemia, dizziness, sedation, weight gain, constipation, hypotension	
Risperidone (Risperdal)	Schizophrenia	Tablet, orally disintegrating tablet, oral solution, long-acting intramuscular injection	May increase risk for diabetes and dyslipidemia, EPS (dosage dependent), hyperprolactinemia (dosage dependent), sedation, weight gain, akathisia, neuroleptic malignant syndrome, tardive dyskinesia.	
Ziprasidone (Geodon)	Schizophrenia, acute agitation	Capsule, short-acting intramuscular injection	Possible activating side effects at very low dosages, sedation, hypotension, akathisia	
Risperidone (Perseris) (Risperdal)	Schizophrenia	Extended-release abdominal subcutaneous injection Tablet, orally disintegrating tablet, oral solution, long-acting intramuscular injection	EPS (dosage dependent), hyperprolactinemia (dosage dependent), sedation, weight gain, akathisia, reddening and injection site pain EPS (dosage dependent), hyperprolactinemia (dosage dependent), sedation, weight gain, akathisia	

Brand name	Generic Name	Company	Mechanism of action	2026 Sales
(Risperdal Consta)		Long-acting intramuscular injection		
(Risperdal M-Tab)		Orally disintegrating tablet		
Chlorpromazine (Thorazine)	Schizophrenia, acute agitation	Tablet, capsule, oral solution, suppository, short-acting intramuscular injection	Akathisia, EPS, sedation, weight gain, hypotension, constipation, hyperprolactinemia, photosensitivity, prolongation of QTc interval	
Fluphenazine (Prolixin)	Schizophrenia	Tablet, oral concentrate, oral elixir, short-acting intramuscular injection, long-acting intramuscular injection	Sedation, weight gain, hyperprolactinemia, EPS, akathisia, dystonia	
Haloperidol (Haldol)	Schizophrenia, acute agitation	Tablet, oral concentrate, short-acting intramuscular injection, long-acting intramuscular injection	Akathisia, EPS, dystonia, sedation, hypotension, constipation, hyperprolactinemia, prolongation of QTc interval	
Loxapine (Loxitane)	Schizophrenia	Capsule, oral concentrate, short-acting intramuscular injection Inhalation powder	Akathisia, EPS, sedation, hypotension, constipation, hyperprolactinemia, dystonia	

Brand name	Generic Name	Company	Mechanism of action	2026 Sales
(Adasuve)	Schizophrenia, acute agitation			Altered taste, sedation
Molindone (Moban)	Schizophrenia	Tablet		Akathisia, EPS, sedation, constipation, hyperprolactinemia, dystonia
Perphenazine (Trilafon)	Schizophrenia	Tablet, oral concentrate, short-acting intramuscular injection		Akathisia, EPS, sedation, weight gain, hypotension, constipation, hyperprolactinemia, dystonia
Pimozide (Orap)	Schizophrenia	Tablet		Sedation, constipation, hypotension, hyperprolactinemia, EPS, akathisia, dystonia
Prochlorperazine (Compazine)	Schizophrenia	Tablet, suppository, short-acting intramuscular injection		Hypotension, hyperprolactinemia, EPS, akathisia, dystonia
Thioridazine (Mellaril)	Schizophrenia	Tablet, oral concentrate		Akathisia, EPS, pigmentary retinopathy (at high dosages) sedation, weight gain, hypotension, constipation, hyperprolactinemia, dystonia, prolongation of QTc interval
Trifluoperazine (Stelazine)	Schizophrenia	Tablet, suppository, short-acting intramuscular injection		Akathisia, EPS, sedation, hypotension, constipation, hyperprolactinemia, dystonia
Thiothixene (Navane)	Schizophrenia	Capsule, short-acting intramuscular injection		Akathisia, EPS, sedation, hypotension, constipation, hyperprolactinemia, dystonia

3.2.12 Key Pipeline therapies for Schizophrenia- US Market

Following are the steps used for extracting drugs in pipeline which are under clinical trials for treatment of schizophrenia ^(5,7)

1. Go to site Clinicaltrials.gov
2. Select Schizophrenia as disease/condition
3. Apply filters
4. In Recruitment: select all except suspended, terminated and withdrawn
5. In study type: Select Interventional
6. In funder type: Select industry
7. Download CSV/Excel format

Total of 486 drugs are under pipeline at different stages of development and their expected approval in the Schizophrenia market shall uplift the market revenue significantly out of which some of the drugs are mentioned in the table below: ^(5,7)

Table 04: Drugs in pipeline for Schizophrenia

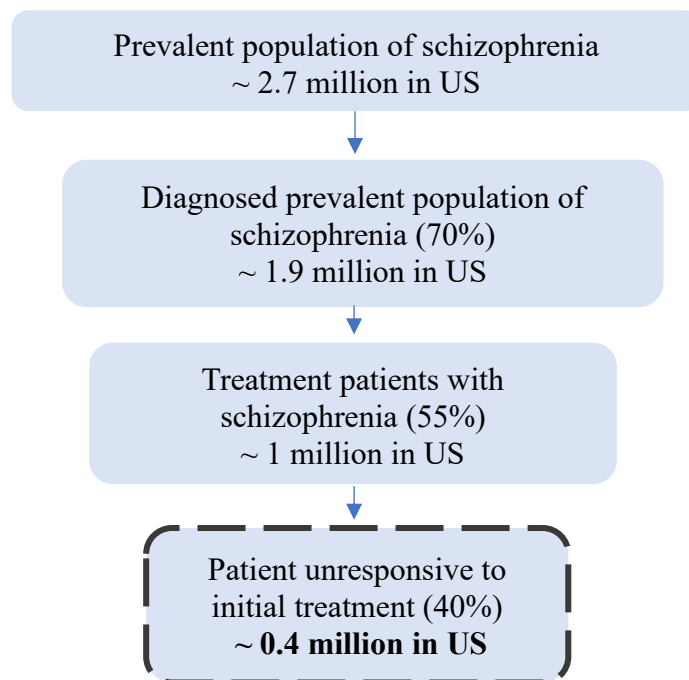
Drugs in Pipeline	Molecule Name	Company	Mechanism of Action	Development Phase	Type of molecule	Route of Administration
AVP-786	Deudextromethorphan	Avanir Pharmaceuticals	NMDA receptor antagonist; Sigma 1 receptor agonist	Phase III	Small molecules	Oral
CAD-9303	Plazinemdor	Novartis	NMDA Receptor modulator	Phase I	Small molecules	Oral
CVL 231	Emraclidine	Cerevel Therapeutics	Muscarinic M4 receptor agonists	Phase II	Small molecules	Oral
SEP-363856	Ulotaront	Sunovion Pharmaceuticals	Serotonin 1A receptor agonists; Trace amine-associated receptor 1 agonists	Phase III	Small molecules	Oral
--	Doria	Rovi Pharmaceuticals Laboratories	Dopamine D2 receptor antagonists; Serotonin 2A receptor antagonists	Phase III	Small molecules	Intramuscular (IM)
--	Roluperidone	Minerva Neurosciences	Alpha-1a adrenergic receptor antagonists; Serotonin 2A receptor antagonists; Sigma-2 receptor antagonists	Phase III	Small molecules	Oral
Kar XT	Tropium chloride & Xanomeline	Karuna Pharmaceuticals	Muscarinic M1 receptor agonists; Muscarinic M4 receptor agonists; Muscarinic receptor antagonists	Phase III	Small molecules	Oral
MK - 8189	--	Merck	Phosphodiesterase 10A inhibitors	Phase II	Small molecules	Oral
NaBen	Sodium Benzoate	SyneRx International	D amino acid oxidase inhibitors	Phase III	Small molecules	Oral
TAK - 831	Luvadaxistat	Takeda	D amino acid oxidase inhibitors	Phase II	Small molecules	Oral
RL 007	--	Recognify Life Sciences	Cholinergic receptor modulators; GABA B receptor modulators; NMDA receptor modulators	Phase II	Small molecules	Oral

BXCL 501	Dexmedetomidine	BioXcel Therapeutics	Alpha 2 adrenergic receptor agonists	Phase III	Small molecules	Oral
NW-3509	Evenamide	Newron Pharmaceuticals	Glutamate modulation and voltage-gated sodium channel blockade.	Phase III	Small molecules	Oral
BI 409306	Osoresnontrine	Boehringer Ingelheim	Phosphodiesterase 9A inhibitors	Phase II	Small molecules	Oral
PF 6412562	--	Pfizer	Dopamine-1 receptor partial agonist	Phase II	Small molecules	Oral
ALKS 3831	Olazapine & Samidorphan	Alkermes Plc	Dopamine D1&D2 receptor antagonists; Opioid mu receptor antagonists; Serotonin 2A receptor antagonists	Phase III	Small molecules	Oral
ACP-103	Pimavanserin	ACADIA Pharmaceuticals	Serotonin 2A receptor antagonists; Serotonin 2A receptor inverse agonists	Phase III	Small molecules	Oral

Table 04: Drugs in pipeline for Schizophrenia

- ❑ More than 90 key pharma players are proactively working to propel the Schizophrenia market landscape by 2026-27

3.2.13 Epidemiology Flow for year 2021



According to research conducted in 2020, there were approximately 2.8 million people with schizophrenia. Out of this total population, it was found that around 70% had been diagnosed with the condition. Further analysis showed that approximately 55% of those diagnosed with schizophrenia were receiving treatment. However, it was also estimated that 40% of the treated individuals did not respond well to the available treatments.

4.3 Forecasting

Assumptions	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Schizophrenia prevalence	28,00,000	28,56,000	29,13,120	29,71,382	30,30,810	30,91,426	31,53,255	32,16,320	32,80,646	33,46,259	34,13,184	34,81,448
Diagnosis rate	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Treatment rate	55%	55%	55%	55%	55%	55%	55%	55%	55%	55%	55%	55%
Unresponsive patient rate	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%
Eligible pool*	4,31,200	4,39,824	4,48,620.5	4,57,592.9	4,66,744.7	4,76,079.6	4,85,601.2	4,95,313.3	5,05,219.5	5,15,323.9	5,25,630.4	5,36,143.0
Market Share of Evenamide**	0%	0%	0%	0%	0%	2%	5%	7%	9%	11%	14%	16%
Patients treated with Evenamide***	-	-	-	-	-	10,882	22,199	33,964	46,191	58,894	72,086	85,783
Cost of therapy per year (in USD) [#]	-	-	-	-	-	4,946	5,045	5,146	5,249	5,354	5,461	5,571
Gross revenue****	-	-	-	-	-	5,38,26,598	11,20,02,385	17,47,90,923	24,24,69,968	31,53,32,193	39,36,85,937	47,78,55,990

Table 05: Forecasting for schizophrenia from year 2020 to 2031

*Eligible Pool (number of patients) = (Schizophrenia prevalence in US * Diagnosis Rate * Treatment Rate * Unresponsive Rate)

**Market share = Calculated by using linear forecast considering 0% before launch and 16% in peak year 2031

***Patients treated with Evenamide = Market share * Eligible pool of Evenamide

****Gross revenue (in USD) = Patients treated with Evenamide * Cost of therapy per year (in US \$)

[#]Cost of therapy per year is taken from Newron analyst report and forecasted with rise of 2%

Diagnosis, treatment and unresponsive patient rate have been kept constant for forecasted period (2020-2031)

According to an analyst report, Evenamide is a potential add-on treatment for schizophrenia, specifically for patients who do not adequately respond to or have become resistant to current antipsychotic therapy. It is considered to be the first treatment of its kind since the introduction of clozapine.

The analyst report selected Evenamide for forecasting its potential revenue. The forecast was based on a compound annual growth rate (CAGR) of 2% from 2021 to 2031, which is the general population growth rate in the United States.

Schizophrenia affects over 24 million people worldwide, with more than 2.7 million in the United States. Evenamide could potentially target a significant market considering that approximately 70% of schizophrenia patients experience positive symptoms and are treated with antipsychotics. However, only 25% of patients adhere to their treatment due to various reasons.

The unresponsive population, which represents around 431,200 individuals in the United States, is the target market for Evenamide as an add-on to standard schizophrenia treatment. The forecasted gross revenue for Evenamide in 2031 is estimated to be \$477.9 million.

Evenamide has the potential to improve patient compliance and reduce the need to switch antipsychotic therapies by providing longer-lasting response to combination therapy. This could lead to positive outcomes and contribute to the projected revenue growth in the treatment of schizophrenia.

4.4 Recommendations

Currently available medications for schizophrenia mainly target the positive symptoms of the condition but are not effective in treating negative and cognitive symptoms. Unfortunately, it is estimated that 75% of all patients stop taking their medications, regardless of the generation of the drug, because they did not experience significant improvement or had intolerable side effects. Even when patients are switched to a different medication, the discontinuation rates remain high.

Based on the projected revenue, Evenamide is expected to generate \$477.9 million in 2031. The potential advantage of Evenamide is that it may lead to improved patient compliance, meaning that more patients would continue taking their medication as prescribed. Additionally, Evenamide could potentially reduce the need to switch antipsychotic therapies because patients may respond better and for a longer duration to the combination therapy involving Evenamide. These factors are expected to have a positive impact on the forecasted outcomes in the treatment of schizophrenia.

4.5 Limitations

The study is done based on the limited data (open sources) available.

Chapter 5: Conclusion

Antipsychotic drugs are commonly used to treat schizophrenia and have other therapeutic uses as well. The global market for antipsychotic drugs was valued at \$12.42 billion in 2020 and is projected to reach \$26.81 billion by year 2030, growing at a rate of 8.0% from year 2021 to 2030. This market is expected to experience positive growth due to the increasing prevalence of psychotic disorders, the rise in the number of people with mental disorders, the growing elderly population, and the implementation of awareness programs about mental health.

Schizophrenia affects approximately 1% of the population and is expected to become more common in future as the world population increases and people live longer. The highest prevalence of schizophrenia is observed among individuals in late adolescence and their twenties.

The global market offers various drugs for treatment of schizophrenia, including typical and atypical antipsychotics. However, there are still unmet needs in the treatment of schizophrenia, such as low patient adherence and a high discontinuation rate, as well as the limited treatment options for negative and cognitive symptoms. The drugs currently in the pipeline aim to address these unmet needs and have the potential to make a positive impact on the market in the near future.

One such drug in the pipeline is Evenamide, which has been forecasted in an analyst report by Newron. The projected gross revenue for Evenamide in 2031 is \$477.9 million. Evenamide has the potential to improve patient compliance and reduce the need for switching antipsychotic therapies, as patients may respond better and for a longer duration to the combination therapy involving Evenamide. This forecast suggests that Evenamide could significantly contribute to the advancement of treatment options for schizophrenia.

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