

All You Need to Know about the Bipolar Disorder Market

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Bring innovation to your local Bipolar Market

STAND OUT FROM THE CROWD IN THE CNS MARKET

Nobody should have to spend millions in new product development to be successful, but standing out of the masses in the crowded CNS market can be a struggle. By partnering with Lo.Li. Pharma International and being an exclusive distributor of Deplesin®, you will bring an innovative product to your local market while increasing your net revenue in a smart way.

Get ready to win with Deplesin®.

The Bipolar Disorder (BD) market is crowded, and there has been very little innovation over the last decades. It can be difficult to stay competitive, especially when competing with bigger, global companies who have even bigger budgets. Developing every novel product in-house, to keep your company relevant, can be both risky and very expensive.

The good news is that Lo.Li. has already developed a novel product which meets a huge unmet clinical need for bipolar patients.

Our partners will get the exclusive opportunity to be the first and only company in their country to provide an innovative product to their psychiatrist customer base.

This BD Market Landscape Guide is your key to understanding the latest developments in this important therapeutic area, so your company can best take advantage of the market growth.



THE LO.LI. PHARMA
INTERNATIONAL TEAM



INTRODUCTION

BIPOLAR DISORDER OVERVIEW

Bipolar Disorder (BD) is a prevalent, costly and life-threatening illness, characterized by mood swings from depression to mania or hypomania, interspersed with periods of normal mood.

Bipolar I, bipolar II, cyclothymic disorder, 'unspecified' or 'other specified' bipolar disorders are now recognised as various subtypes of bipolar disorder.

Medication will almost certainly be part of the treatment strategy.

Pharmacotherapy focuses on acute stabilisation, in which the first goal is to bring a patient with mania or depression to a symptomatic recovery with euthymic (stable) mood. Once maintenance is achieved, the goals become relapse prevention, reduction of subthreshold symptoms, and enhanced social and occupational functioning.

As a chronic, inherently recurrent illness, successful treatment of BD relies on long-term drug therapy, including polypharmacy, to prevent future mood episodes.

Because BD is a chronic illness, treatment must be ongoing.

BD is treated with mood stabilizers, anticonvulsants, antipsychotics, and, while their safety and effectiveness for the condition are sometimes controversial, antidepressants.

The **BD** market is crowded and competitive, with a large number of products available, the majority of which are inexpensive generics.

Typically, treatment entails a combination of at least one mood-stabilizing drug and/or atypical antipsychotics.

Lithium is widely considered to be the gold standard for BD based on its efficacy as a maintenance treatment and its ability to treat acute episodes of both mania and depression. It is also the only drug reported to reduce suicidal thoughts and behavior.



million people around the world are affected by Bipolar Disorder

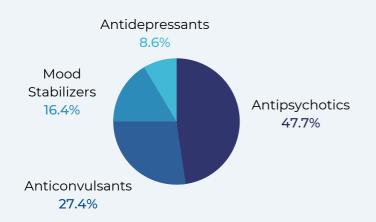


leading cause of disability in the world, leading to cognitive and functional impairment and raised mortality

KEY INSIGHTS

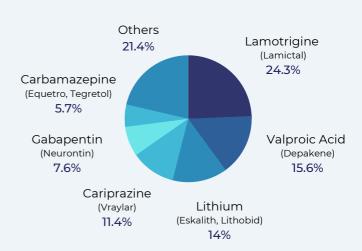
The global bipolar disorder drugs market was valued at USD 5.3 billion in 2021 and expected to reach **USD 6.5** billion by 2028, growing at a CAGR of 2.9% over the forecast period.

MARKET SHARE VALUE BY DRUG SEGMENT



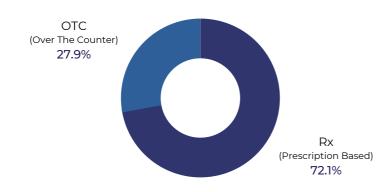
The antipsychotics segment dominates the market, valued at USD 2.5 billion in 2021 and expected to reach USD 3.2 billion by 2028 with a CAGR of 3.4% in the forecast period.

MARKET SHARE VALUE BY DRUG NAME



Lamotrigine holds the largest market share (24.3%), valued at USD 1.3 billion in 2021. While decades old, Lithium and Valproic Acid still hold a significant amount of market share, demonstrating prescriber preference and perceived efficacy.

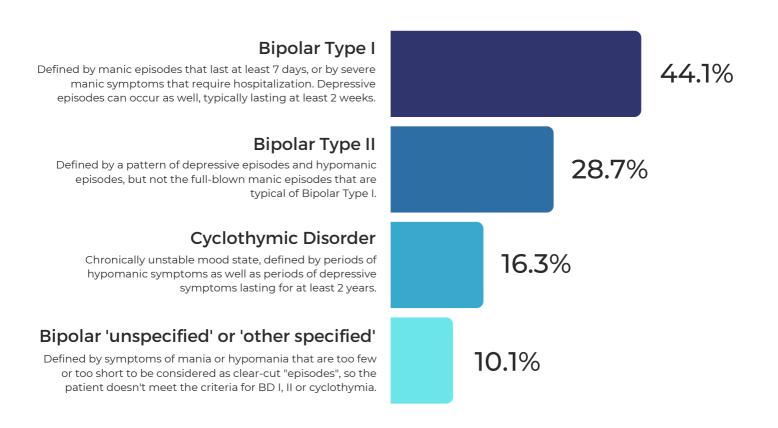
DISTRIBUTION CHANNEL



While the Prescription Based segment holds the majority position, nearly 30% of the market is based on OTC therapies.

Bipolar Disorder Type I is the most common diagnosed subtype.

VALUE MARKET SHARE BY BIPOLAR DISORDER TYPE



BD patients are classified as Bipolar Type 1 nearly 45% of the time, and the segment was valued at USD 2.3 billion in 2021. It is expected to reach USD 2.9 billion by 2028 at a CAGR of 3% in the forecast period.

COVID-19 IMPACT

In terms of prevalence, the top five mental health disorders include anxiety, depression, attention deficit hyperactivity disorder (ADHD), bipolar disorder and schizophrenia.

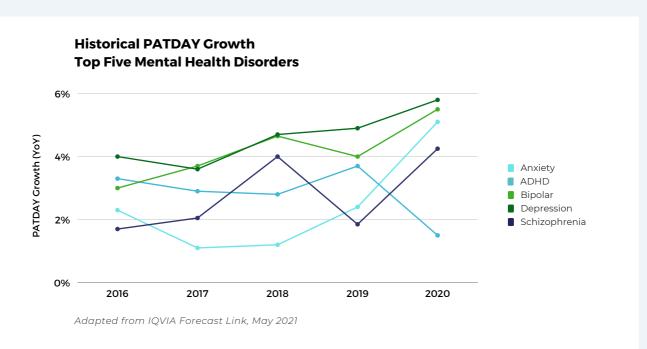
Collectively these disorders account for 87% of all people living with a mental health condition.

In 2020, they were also the highest in value sales among mental health disorders, collectively reaching approximately USD 38.6 billion in sales.

Recently, however, there has been much speculation about the shortand long-term impacts of the Covid-19 pandemic on the prevalence of mental health disorders.

The following data from IQVIA's Forecast Link appears to confirm that there has been a noticeable impact from the pandemic as evidenced by increased patient days (PATDAY*) growth in 2020 for all the mentioned conditions except ADHD.

Indeed, the impact on anxiety seems to be the most striking.



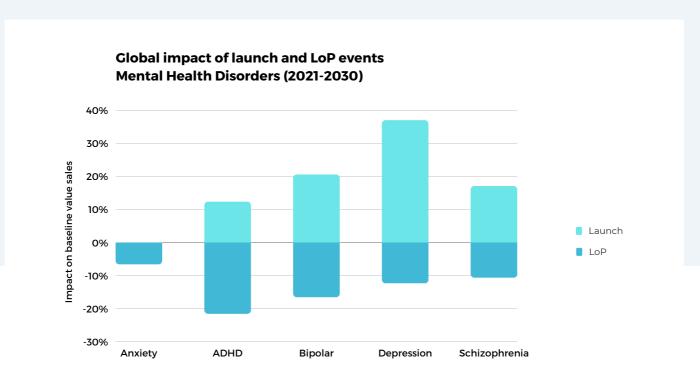
*PATDAY: number of patients admitted to a facility multiplied by the number of days each patient has been in the hospital.

PATDAY GROWTH WILL CONTINUE OVER THE NEXT DECADE

It is the most likely scenario, given population growth and the short-term impact of the pandemic. This will result in increased volume forecasts for the top five mental health disorders.

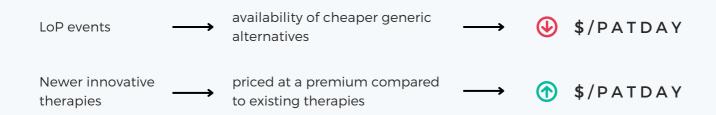
Value sales of pharmaceutical therapies for mental health disorders will be impacted not only by volume forecasts, but new launch and loss of protection (LoP) events and changes in the implied cost per patient day (\$/PATDAY) of existing and new therapies.

The Global impact of new launch and LoP events on baseline value sales for the top five mental health disorders over the next decade is illustrated below. The net impact of events on value sales is negative for anxiety, ADHD, and bipolar disorder, and positive for depression and schizophrenia. The impact of LoP events will outweigh gains due to new launches particularly in the ADHD and bipolar markets, where a large amount of patent expiries is expected in the coming decade. On the other hand, innovative new therapies for depression and schizophrenia will offset value losses due to LoP events resulting in a positive net impact on baseline value sales.



Adapted from IQVIA Forecast Link, May 2021

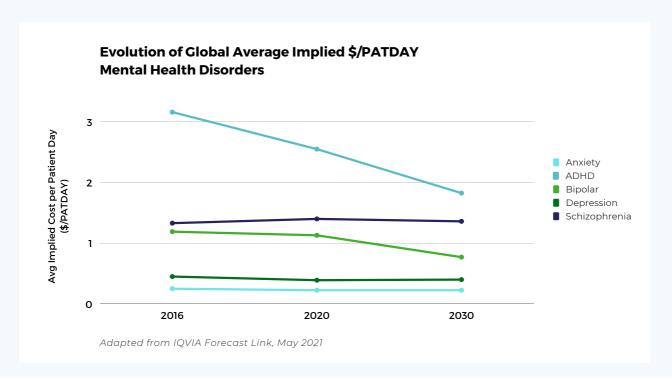
NEW LAUNCHES AND LOP EVENTS WILL HAVE AN IMPORTANT IMPACT ON THE AVERAGE IMPLIED \$/PATDAY



In the BD market, there is a lack of new product innovations, resulting in higher competition.

The net impact of LoP and New Launches allow the markets of Anxiety, Depression and Schizophrenia to maintain or increase their respective average implied \$/PATDAY.

On the other hand, while the ADHD and BD markets are expected to experience positive PATDAY growth, LoP events and a significantly lower average implied \$/PATDAY for both, will result in value contraction in these markets over the next decade.



THERE IS A CLEAR NEED FOR AN INNOVATIVE NEW MARKET ENTRANT Without significant innovation, the average \$/PATDAY in the BD market is expected to decline.

PREMIUM INSIGHTS



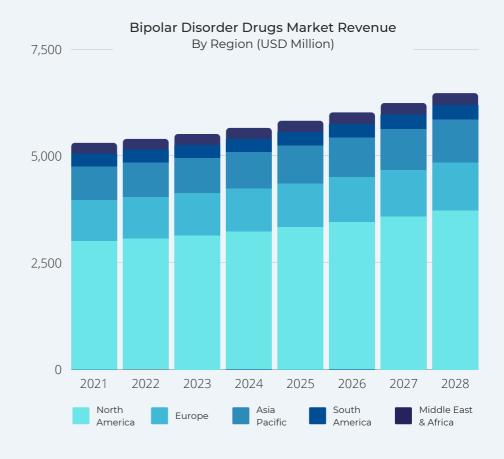
IN TERMS OF REGIONAL INFLUENCE,

North America dominates the global BD market, in part, due to increased awareness.

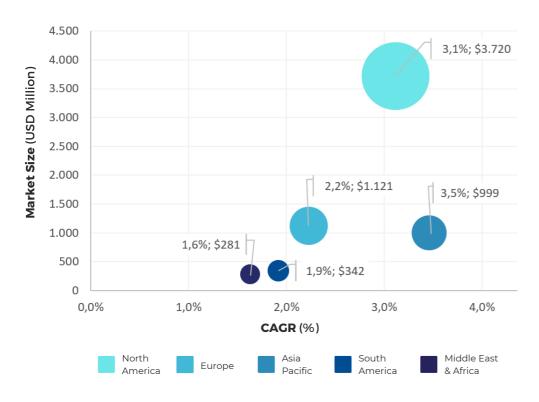
This market was valued at USD 3.0 Billion in 2021, and it is expected to reach a value of USD 3.7 Billion by 2028. The U.S. holds the largest market share in North America followed by Canada and, lastly, Mexico.

Europe has the second largest market, valued at USD 0.96 Billion in 2021.
In this region, Germany, the U.K.,
France, Russia, Italy and Spain hold major shares of the BD market.

In 2021, Asia Pacific, South America and Middle East & Africa were valued at USD 0.79, 0.30 and 0.25 Billion respectively, collectively accounting for 25% of the Global BD market share.



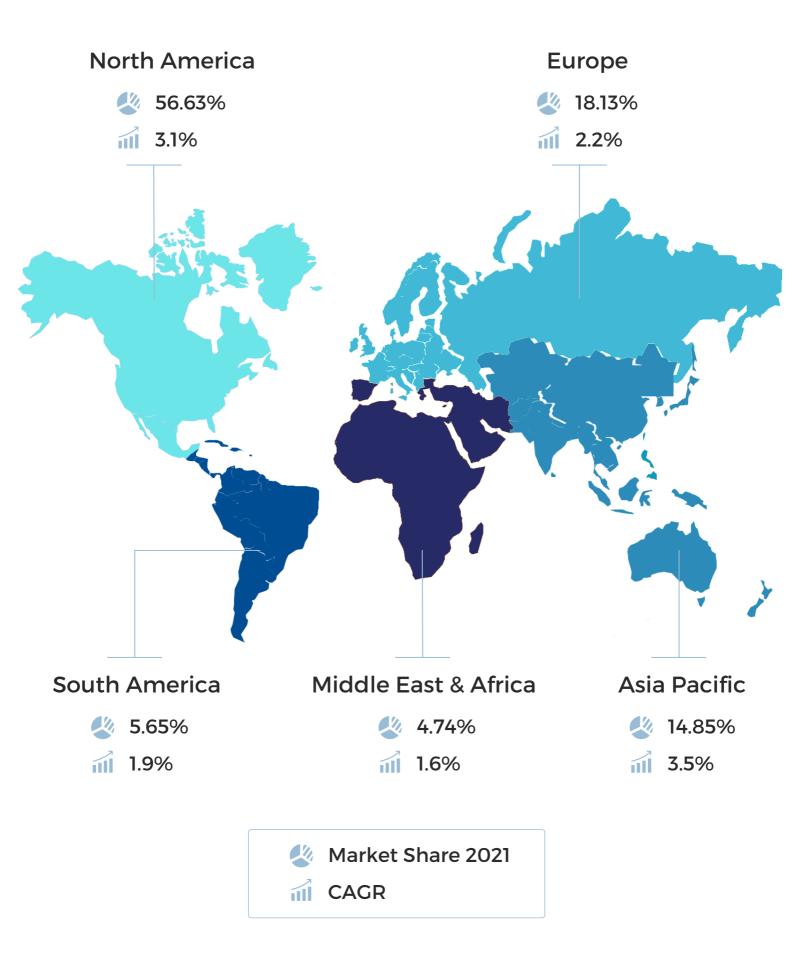
MARKET ATTRACTIVENESS: BY REGION



Asia is expected to show high growth rates in the coming years.

It is expected that many companies construct their manufacturing facilities in the region. Less stringent wages and availability of skilled labor attracts them to invest in Asia. In addition, increasing awareness about BD is also supporting the growth of the market in the region.

China, Japan and India are expected to be the fastest growing BD markets in Asia.



S.W.O.T. ANALYSIS

Bipolar Disorder Drugs Market

The BD drugs market is competitive and crowded with a multitude of approved therapies, many of which are available as inexpensive generics.

The current key players in the BD market are those that market atypical antipsychotics. However, many products have lost market exclusivity or are facing imminent patent expiry. As such, many of the respective companies are expected to lose their positions in this market over the forecast period due to generic competition.

Technological advancements that facilitate accurate detection of patient's mood and mental state and growing government initiatives for creating awareness about BD are key factors driving growth of the global BD market. In addition, increasing incidence of BD across the globe is a major factor expected to fuel growth in the global market over the forecast period.

Opportunities remain for healthcare companies to develop and/or market drugs with improved safety profiles or novel mechanisms of action specific to BD pathologies and natural, alternative therapies.

Many of the drugs used to treat BD have associated side effects such as weight gain, damage to the liver, thyroid disorders, etc. Side effects are a key factor in slowing growth of the global BD market, since they aggravate the problem of patient non-adherence.

Additionally, market growth is being hampered by both stringent government regulations on drug manufacturing and underdiagnosis of BD.

Strengths

- Sustained market growth
- New, accurate detection methods
- Government initiatives supporting awareness and treatment

Weaknesses

- Crowded with generic alternatives
- Lack of innovative products
- Patient non-compliance

Opportunities

- · Increasing prevalence of BD
- Growing mental health awareness
- Raising need for natural alternatives
- Drugs or treatments with novel, specific MOAs

Threats

- Economic slowdown
- Stringent regulations
- Misdiagnosis
- Loss of patent protection



Given the current treatment landscape and expected market growth, it is clear that there is a great opportunity for niche products within the BD market.

Deplesin® is a novel, direct approach to alleviating side effects associated bipolar disorder pharmacotherapy.

Imagine how selling a product which meets a large unmet need for both patients and psychiatrists can add real, tangible value to your business.

You and your sales force will stand out from the crowd, while significantly increasing your net revenues.



Get ready to win with Deplesin®