ing Insights: “Analyzing Patent Expiry Dates and Projecting Future Sales for Pharmaceutical

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OCTAVUS CONSULTING

- Octavus is a boutique consulting company, engaged in comprehensive business research, market intelligence, market research and data analytics by providing support and outsourcing solutions to bio-pharma, medtech, diagnostics, digital health companies and healthcare start-ups.
- They strive to deliver high-quality services involving competitive intelligence, product strategies, marketing & analytics and digital health which are backed by a meticulous and experienced team from life sciences and healthcare domain.

MISSION

Our mission is to cater business needs with the right sources at the right time to enable our clients’ take strategic decisions. Redefining intelligence reinforced with dynamic data, knowledge and technology.

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VISION

- To be a valued partner to our clients and an asset to our communities.
- To undertake and deliver every project, with the same enthusiasm & zeal.
- To provide a differentiated offering resulting in the value-for-value return.

SWOT ANALYSIS

STRENGTHS

- Expertise and Experience
- Diverse Service Portfolio
- Client-Centric Approach
- Strong Reputation:
- Technological Integration

WEAKNESSES

- Limited Global Presence
- Size and Scale
- Talent Attraction and Retention

OPPORTUNITIES

- Market Expansion
- Digital Transformation Consulting.
- Strategic Partnerships
- Industry-Specific Expertise

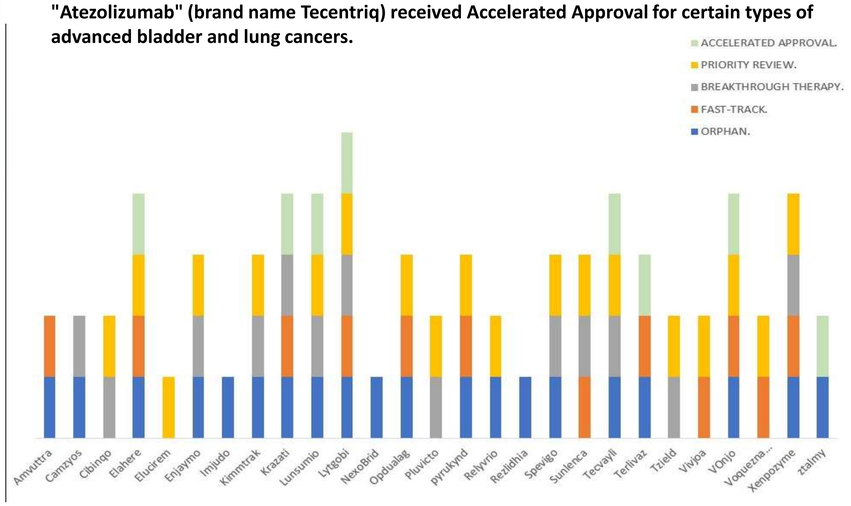
THREATS

- Intense Competition
- Economic Volatility
- Changing Industry Trends
- Regulatory Changes (norms)

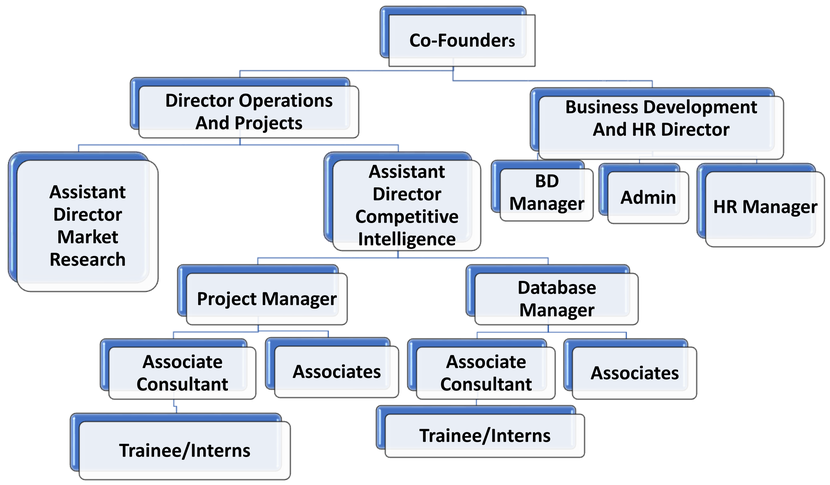
LEARNING OBJECTIVES

I conducted secondary research by utilizing press releases and the FDA website to gather information about drug designations by customizing the dates according to me i.e. from 2014.
Press releases are official statements from pharmaceutical companies, while information from the FDA website is directly from the regulatory authority. This ensures the accuracy and authenticity of the drug designations was gathered.

- **Orphan Drug Designation** is granted to drugs intended to treat rare diseases or conditions that affect a small number of patient. An example of a drug with Orphan Drug Designation is "Ibrutinib" (brand name Imbruvica), used to treat certain types of leukemia and lymphoma.
- **Fast Track Designation** is given to drugs that treat serious conditions and have the potential to address unmet medical needs. "Keytruda" (generic name pembrolizumab) is an example of a drug that received Fast Track Designation for its use in certain types of cancer.
- **Breakthrough Therapy Designation** is granted to drugs showing early evidence of substantial improvement over existing therapies for serious or life-threatening conditions "Entresto" (generic name sacubitril/valsartan) received Breakthrough Therapy Designation for its use in heart failure.
- **Priority Review Designation** is given to drugs that offer significant advances in treatment or provide a treatment where no adequate therapy exists. An example is "Glecaprevir/Pibrentasvir" (brand name Mavyret), used to treat chronic hepatitis C infection.
- **Accelerated Approval** is a pathway that allows earlier approval of drugs for serious conditions based on a surrogate endpoint, such as tumor shrinkage or reduction of disease symptoms, rather than a traditional clinical endpoint like improved survival. "Atezolizumab" (brand name Tecentriq) received Accelerated Approval for certain types of advanced bladder and lung cancers.



ORGANIZATION STRUCTURE



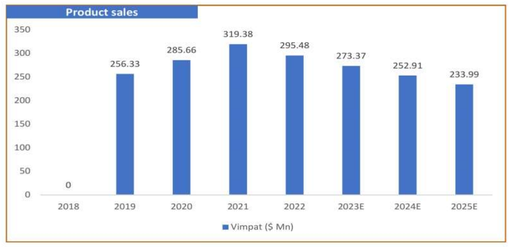
BRIEF ABOUT PROJECT

Unlocking Insights: Analyzing Patent Expiry Dates and Projecting Future Sales for Pharmaceutical Drugs“

VIMPAT (lacosamide) tablets Vimpat

Generic Name	Lacosamide
MoA	sodium channels blocker
Status	Approved
RoA	PO (Film coated tablets)
Indications	Partial Epilepsy
Formulations Dose (if approved)	50 mg, 100 mg, 150 mg, 200 mg
Proprietary Technology	NA
Designations	NA
Indication Under Evaluation	Episodic Migraine, Lower Limb or Combined Lower Limb and Upper Limb Spasticity Due to Stroke or Traumatic Brain Injury, Glabellar Frown Lines, Cardiac Surgery, Degenerative Rotator Cuff Disease
List of Competition (Status)	Extrovis EU Ltd.; Accord Healthcare S.L.U.

Patent Number	Patent expiry date	Patent Title
EP-1799635-B1	30 Sep 2025	Improved synthesis scheme for lacosamide
EP-2462990-B1	15 Jun 2027	Pharmaceutical composition comprising lacosamide and levetiracetam with synergistic anticonvulsant effect
EP-2695618-B1	15 Jun 2027	Pharmaceutical composition comprising lacosamide and levetiracetam for use in the treatment of epilepsy
EP-2992891-B1	15 Jun 2027	Pharmaceutical composition comprising brivaracetam and lacosamide with synergistic anticonvulsant effect
EP-2444390-B1	11 Mar 2031	Process for producing Lacosamide
EP-2528892-B1	22 Dec 2030	Process for the synthesis of lacosamide
EP-2598476-B1	26 Jul 2031	Process for preparation of lacosamide and some n-benzyl-propanamide intermediate derivatives
EP-2496220-B1	3 Nov 2030	Modified release formulation of lacosamide
EP-2645997-B1	1 Dec 2031	Once daily formulation of lacosamide
EP-2345455-B1	29 Jun 2027	Lacosamide for the treatment of hyperexcitability disorders associated with sodium channel dysfunction
EP-2026788-B1	6 Jun 2027	Therapeutic combination for painful medical conditions



Rationale for Selection

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- The purpose of this report is to analyze the impending patent expiry dates for Vimpat in Europe and forecast the potential effects on its sales trajectory.
- Vimpat (lacosamide) is expected to face patent expirations in Europe in upcoming year . This will mark the end of exclusivity for the drug.
- Our research involves a data-driven approach that combines historical sales data, market trends, and potential competitive dynamics to predict Vimpat's sales performance post-patent expiry
- As patent exclusivity for Vimpat ends, the drug is likely to face increased competition from generic versions. This could lead to a decline in Vimpat's market share and subsequent sales.
- The entrance of generic alternatives could drive down Vimpat's prices, affecting its profitability. Other companies may also launch products with similar efficacy, potentially leading to market fragmentation.
- Based on our analysis, we anticipate a gradual decrease in Vimpat's sales in the months and years following patent expiry. This decline could be influenced by factors like the availability of generics and shifts in physician and patient preferences.
- Pharmaceutical companies can adopt various strategies to mitigate the impact of patent expiry, such as:
- Diversifying their product portfolio to reduce dependence on Vimpat
- Exploring new indications or formulations for Vimpat
- Implementing lifecycle management tactics to extend product relevance
- Strengthening brand loyalty through educational campaigns and patient support programs

CHALLENGES

- Secondary research relies on existing sources, so there were challenges in finding comprehensive and up-to-date data that aligns with the research objectives.
- Not all sources are equally trustworthy, so assessing the reliability and credibility of secondary sources was challenging.
- Secondary research projects can take longer than expected due to the extensive nature of data collection

SUGGESTIONS

- Basic training for any new trainee/intern on consulting methodologies, industry trends, software tools, and communication skills to enhance their skillset.
- Involve interns in client interactions such as meetings, presentations, or conference calls.
- Improvement of new technology, techniques that can