"Competitive Intelligence and Business Development- Opportunities to strengthen pipeline product portfolio."

Dissertation submitted to

The IIHMR University, Jaipur

for the partial fulfilment for the award of the degree of

Master of Business Administration (MBA)

In

Pharmaceutical Management

By

SHUBHAM SUDHAKAR RUKME

IIHMR-U/02/2021-23/0345
MBA PM-13

Under the supervision and guidance of

Mr. RAHUL SHARMA

Assistant Professor
School of Pharmaceutical Sciences
IIHMR University
Jaipur

2023

IIHMR UNIVERSITY

JAIPUR, RAJASTHAN

DECLARATION BY THE STUDENT

I hereby declare that this dissertation titled **"COMPETITIVE INTELLIGENCE AND BUSINESS DEVELOPMENT- OPPORTUNITIES TO STRENGTHEN PIPELINE PRODUCT PORTFOLIO"** 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 Information derived from the published or unpublished work of others has been duly acknowledged in this text.

Date: 01-06-2023

Place: Jaipur

Signature of Student

Shubham Sudhakar Rukme

IIHMR-02/2021-23/0345

MBA PM-13

IIHMR University, Jaipur

IIHMR UNIVERSITY

JAIPUR, RAJASTHAN

DECLARATION BY THE FACULTY GUIDE

This is to certify that dissertation titled **"COMPETITIVE INTELLIGENCE AND BUSINESS DEVELOPMENT- OPPORTUNITIES TO STRENGTHEN PIPELINE PRODUCT PORTFOLIO"** is a record of the research work undertaken by **Shubham Sudhakar Rukme** in partial fulfilment of the requirements for the award of the degree of MBA – Pharmaceutical Management from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

Date: 01-06-2023 **Signature of Guide**

Place: Jaipur

Ms. Rahul Sharma

Assistant Professor

School of Pharmaceutical Management

IIHMR University, Jaipur

ACKNOWLEDGEMENT

It has been a privileged to receive my Dissertation at PharmaAce Analytics, Pune. These three months of my dissertation has helped me in gaining extensive knowledge in various departments.

I would like to thank **Dr. P.R. Sodani**, President of IIHMR University, Jaipur for his support during university placement and giving long period of time for research project.

I Consider Myself Most Lucky to work under the able guidance of **Mr. Rahul Sharma**, Assistant Professor, School of Pharmaceutical Management, IIHMR-U, Jaipur. I sincerely acknowledge his constant encouragement, incredible guidance, valuable suggestions, and timely advice given throughout my Research work.

I would like to extend my sincere regards to **Mrs. Pratima Choudhary (Practice Head, Competitive Intelligence, PharmaACE, LLP)** for providing me with such a great learning opportunity.

I would like to thank my industry mentor, **Dr. Shruti Singh, (Project Manager, Competitive Intelligence, PharmaACE)** for guiding me at each step and for providing me opportunities of judicious learning by allotting me projects and always being open for constructive discussions and would also like to express my immense gratitude for her for showing keen interest in my summer training and being cooperative and helpful throughout my time at PharmaACE.

I am overpowered in all humbleness and appreciation to perceive my significance to every single one of the people who have helped me to put these contemplations. I might want to communicate my unique gratitude to my parents and friends for their consistent good help.

ABSTRACT

This project put lights on the concept of Competitive Intelligence (CI) and its use within the Pharmaceutical Industry for Business Development. The complex nature of the pharmaceutical market in USA market, combined with intensified rivalry that happens among pharmaceutical firms, create an unstable environment forcing pharmaceutical companies to become more aware of the market's behaviors. A method to raise understand the market, to efficiently support business decisions, is Competitive Intelligence (CI). It also elaborates the utilization of such information gathered through CI within the SDM (strategic decision making) process. The goal of this study is to provide insights to the stakeholder to make informed business development decisions through competitive intelligence tools and understanding the importance of need of expanding pipeline products portfolio.

RATIONALE OF THE STUDY-

This study provides the key link between Competitive Intelligence and the strategic actions taken by a company to solve their business questions. The study is presented with an example of Company Z wants to expand their pipeline product portfolio in the non-opioid post operative analgesics market. Company Z has identified a Phase 3 ready Product A of Company X, which they wish to acquire. Company Z uses Competitive intelligence to provide key intel which would help them take the required strategic action to enhance their product portfolio in the non-opioid pain management market.

Company Z is a key market player in the post-operative pain management area, providing an effective alternative to opioids, especially morphine for major surgeries. Product B lost its exclusivity in Mid-2020, where now it gives other companies to manufacture generics with the similar mechanism of action. Company Z wants to understand the current market situation and they want to acquire a pipeline product (Product A) from Company Z for similar indication. Competitive intelligence tools are used to understand the Company overview, Disease overview, Product overview, Pipeline analysis, Inline and pipeline competitor products of non-opioid pain analgesics market, Approval Time Estimation, Impact Analysis and Attribute analysis to provide useful intel in making strategic decisions.

TABLE OF CONTENTS

LIST OF ACRONYMS

CI	Competitive Intelligence
SDM	Strategic Decision Making
R&D	Research & Development
APS	American Pain Society
POP	Post-Operative Pain
CAGR	Compounded Annual Growth Rate
FDA	Food And Drug Administration
LOE	Loss Of Exclusivity
EMA	European Medicine Agency
NDA	New Drug Application
IP	Intellectual Property
NSAIDs	Nonsteroidal Anti-Inflammatory Drug
ASPMN	American Society for Pain Management Nursing
APIs	Active Pharmaceutical Ingredients
AEs	Adverse Events
KOLs	Key Opinion Leaders
PCA	Patient Controlled Analgesia

LIST OF FIGURES

1) INTRODUCTION

Business development-

Business development refers to strategic relationships or Merger and Acquisition deals which enable pharmaceutical organisations to grow and strengthen their competitive position.

Building effective business development in pharmaceutical industry-

1) Prioritise what business development needs to accomplish for the company.
2) Build relationships with prospective targets.
3) Agree on how to access value.
4) Define integration issue early.
5) Enable agile business development teaming and governance.
6) Design an organisation structure suited to strategic priorities.

Business development types

1. Strategic alliances-
    - Old Products and Old Market helps in penetration in market and example- Collaborations, Co-marketing, Co-promotion agreements and Acquisition.
    - Existing Product and new market help in Market development example- Licensing, Co-promotion with partner.
2. Merger and Acquisitions
    - New Product and Existing market help in Product/Service development example- Outsourcing development, Co-branding, Co-development of back-up brands, Acquisition, and in-licensing.
    - New Product and New market- Acquisition, merger, joint-venture, and in-licensing.

Expected benefits form BD initiatives-

- Increased revenue.
- Increased profit.
- Reduce business risk.

The need to expand pipeline product portfolio through business development-

The high cost of research and development in pharmaceutical industry has led to finding new innovative ways to curb the cost required to develop new products. Specialty pharmaceutical companies which depend for funds on venture capital or private equity are acquired by multinational companies resulting in reduced cost of R&D and expanding their pipeline product portfolio.

Competitive Intelligence in Business Development-

Competitive Intelligence in business development helps creating new business opportunities for pharmaceutical organization through strategic alliances and merger and acquisition, Competitive intelligence helps in tracking and analyzing the products in pipeline as well as inline market. Competitive Intelligence tools come into play for analyzing the products and company.

Driving forces of Competitive Intelligence-

- Competitors
- Products
- Suppliers
- Customers
- Technology/Research
- Patent and IP
- Market Trends

2) LITERATURE REVIEW

Competitive Intelligence-

Competitive Intelligence is the get-together and investigation of information to envision serious movement, see past market interruptions and impartially decipher occasions. It is fundamental segment to building up a business procedure. CI gives knowledge into the commercial centre elements and difficulties during an organized, taught, and moral way utilizing distributed and non-distributed sources.

Functions of Competitive Intelligence-

- Incorporates outer competitive and financial procedure into key strategy.
- Generates pertinent bits of knowledge from research and organized analysis.
- Enhances promotional activities, decision making, financial and operational accounts and tasks.
- Conforms to antitrust and prized formula laws, legitimate and moral prescribed procedures, and the customer's corporate code of conduct.
- Minimizes decisive hazard and diminishes vulnerability about outside turns of events.

Uses of Competitive Intelligence:

- Develop corporate or venture unit systems.
- Shape counter-competitive systems against at least one contender
- Prepare a substitution item dispatch, new market passage, or other key move inside the market.
- Benchmark different associations
- Anticipate and plan for future market openings and disturbances.
- Assess viability of contenders showcase situating and stock informing.

CI Methods:

- Competitive Strategy (Scenario Planning, War Gaming)
- Early Warning / Monitoring
- Research and Analysis
- CI Process Development + Consulting
- Win/Loss Analysis

Competitive Intelligence in Pharmaceutical Industry-

The worldwide pharmaceutical industry, characterized for quite a while by its characteristic capacity to advance new things and organizations, should take certifiable note of Buffett's declaration since it pushes toward a tipping point. Epic load from payers also as regulatory and assessing masters has been pushing down pharma associations' working edges. At an equivalent time, overall markets and patients anticipate progressively critical partition from the associations. The continuous unsettling influences inside the buyer condition and patient fortifying are build up an impression which will impact the very strategies that have described the business for quite a while.

Thusly, it isn't, now sufficient to dispatch new things or organizations in business segments that are fast fixing off with generics and biosimilars. As patients despite everything become better taught and in this manner the enthusiasm for redid drugs goes up, pharma associations found the opportunity to move towards human administrations results rather than thing-based courses of action.

Key segments driving this move are:

Downward weight on assessing by governments and back up plans is pushing pharma associations to show progressively essential impetus from their therapies1.

Payers are beginning to set up treatment shows and mentioning progressively essential straightforwardness around sedate esteeming.

Digitalization in the pharma region is permitting patients the opportunity to end up being logically attracted, instructed, and empowered.

Despite these changes, pharma associations despite everything limit on standard strategies. At present, game plans for pharmaceutical associations are maintained their business community (strength/multi-distinguishing strength versus general prescription); treatment focus (exceptional ailment versus mass markets); business stage (clinical stage versus totally business); thing portfolio (checked versus generics); or land exertion (overall versus common, and so on.

Bits of information from Competitive Intelligence (CI) can help pharma associations recognize their middle characteristics inverse contenders. Such encounters can help associations with concentrating in on dismissed must change their commitments, yet their strategies as well. The examination of the serious condition also can control their Research and Development (R&D) focus.

Most pharma associations have quite recently got intricate CI limits that give steady bits of information on conditions and risks. Associations similarly can use inside knowledge to comprehend an evaluation of the affiliation itself, its R&D focus and business destinations. This helps an association benchmark its presentation, perceive its characteristics and highlight need regions.

Superimposing results from business and serious understanding would in this manner have the option to help pharma associations find new streets to isolate their picture and fulfil a need inside the market.

To have a key clutch the market, it has become significant that the organization has the privilege and complete picture of the occasions happening all around and potential circumstances that may influence their future deals.

Competitive Intelligence has increased a lot of thankfulness and become a significant apparatus to satisfy the prerequisites, for example,

- Drug and gadget improvement
- Patient populaces
- Clinical preliminaries
- Drug and gadget licenses

- Market moving occasions.
- Patient-based deals gauges

It encourages the pharmaceutical contenders to accomplish information, for example,

- Prioritize pharmaceutical R&D spend by discovering holes and neglected needs through the investigation of contenders' objectives and R&D needs.
- Understand ailment the study of disease transmission and sickness sub-populaces focused on clinical turn of events.
- Anticipate showcase changes through patent termination following.
- Earmark who is entering or leaving your market through authorizing or procurement, likewise as who is making sure about or giving subsidizing.
- Project income for your pipeline and promoted drugs.

Following is a contextual investigation stressing on the utilization of Competitive Intelligence as a device for Product A by Company Z to break down the conceivable modern scene the medication may confront.

Post-operative pain management

May be a branch of the that deals with the minimizing the pain occur thanks to tissue injury alongside spasm to the patients after surgery. It is the branch of pain management. Global post-operative pain management market is growing steadily thanks to increasing demand for the pain control drugs and devices. (Luu 2014). Increasing number of surgeries across the world and increasing prevalence of various diseases across the world is that the major factor for the expansion of the market. Increasing age rises the possibility of the different complication, this increasing aging population is also having a synergistic impact of the growth of the market. According to the Centre for Disease Control and Prevention during last decade due to overdose of the analgesic drugs number of deaths has increased. Analgesic drugs are habit forming drugs and thus side effects of the treatment and habit-forming nature of the drugs can hamper the growth of the market.

The postoperative pain management is that the most integral a part of the patient treatment because it provides patient comfort, initiates mobilization, lessens the likelihood of cardiac, pulmonary and neuropathic pain complications, reduced risk of thrombosis and low cost of care. The postoperative pain treatment consists mainly multimodal analgesic treatment that has combination of varied analgesics that act by various mechanism of actions. The various classes of medicine utilized in postoperative pain management are as follows:

- Opioids: morphine, meperidine, fentanyl, hydromorphone
- Non-steroidal anti-inflammatory drugs: paracetamol (acetaminophen), ibuprofen, ketorolac tromethamine
- Cyclooxygenase-2-selective inhibitors: celecoxib, etoricoxib, rofecoxib
- N-methyl-D-aspartate antagonists: ketamine, magnesium
- Alpha-2 adrenergic agonists: clonidine, dexmedetomidine
- Gabapentin-type drugs: pregabalin
- Glucocorticoids: dexamethasone
- Cholinergic drugs: nicotine
- Local anaesthetics

Global Market on Post-operative Pain Management

The worldwide postoperative market showcase is anticipated to be worth US$ 45,861.8 Mn in 2026, it's anticipated to increment at a CAGR of 5.1% through 2026. North America was the prevailing territorial commercial centre for postoperative torment the executives, representing US$ 12458.3 Mn in 2017, and is anticipated to develop at a CAGR of 4.4% over the estimate time frame (2018–2026). FDA is advancing the activity for misuse obstacle narcotics inside the U.S. all the while expanding the market open door for postoperative torment the executives advertise. North America followed by Europe is anticipated to hold most extreme income share inside the overall postoperative agony the executives showcase over the conjecture time frame. the organizations working inside the postoperative torment the board advertise are that focus on extending their business in Asia Pacific and China. China is anticipated to be the quickly developing provincial commercial centre for postoperative agony the board on account of expanding number of medical procedures and extension methodology followed by the key producers inside the locale. The developing mindfulness regarding repayment for postoperative agony the board in U.S.is expected to expand the appropriation of postoperative torment the board inside the overall market. The interest for postoperative torment the executives is principally exuding from nations like the U.S., Germany, the U.K. what's more, Australia.

Expanded medicinal services use including developing mindfulness are factors adding to developing interest for postoperative torment the board drugs.

Factors and Trends Impacting the Growth of the Market

- The constantly developing populace and expanding mindfulness about the careful medicines in malignant growth and other ceaseless ailments, for example, incessant obstructive pneumonic issue (COPD) is relied upon to actuate the interest for postoperative agony the board advertise.

- Thus, changing social insurance situation and developing mindfulness about the postsurgical torment and injury is relied upon to build the mindfulness about postoperative agony the board, and subsequently impel the interest for postoperative torment the board internationally.

- according to the American Cancer Society, the worldwide rate of malignant growth was 14.09 Mn in 2012, where around 20–30% out of all out-disease patients required to experience medical procedure and required postoperative torment the board medications to beat the torment. By 2030, the worldwide weight of malignant growth is relied upon to develop to 21.70 Mn new disease cases significantly because of developing maturing populace. Malignancy evacuation methodology including mastectomy or lumpectomy require high measurement of postoperative torment the executives' drugs. The developing pervasiveness of disease is another factor expected to actuate the extension of the postoperative agony the board showcase.

- according to the International Association for the Study of Pain, the commonness of postoperative agony as a rule populace is 3–4%. The expanding number of surgeries and careful intercessions in different malady conditions is anticipated to make massive development open doors for the postoperative torment the executives showcase.

- According to the WHO displaying of information from part countries, it is assessed that about 234.2 million surgeries were acted in 2004. Roughly around 60-70% patient experience moderate to serious agony soon after 24 hours of medical procedure. All the patient experienced medical procedure required to be dealt with postoperative agony the executives' drugs.

- The steadily changing way of life inclinations and decisions, for example, corrective recreation and plastic medical procedure is affecting the development of the postoperative torment the board advertise. Consistent endeavours by the producers to grow new non-narcotic medications for worldwide postoperative agony the executive's showcase is foreseen to fuel rivalry inside the fabricates of postoperative torment the board drugs.

Opioid Crisis-

USFDA is making several updates to provide additional guidance on the use of powerful opioid medication for post- operative pain management. Opioid pain medication prescription has serious risks, including misuse and abuse, addiction, overdose, and death.

Guideline includes-

Acute pain conditions treated in the outpatient setting requires no more than few days of an opioid pain medicines. Including pain from surgical conditions or musculoskeletal injuries.

Opioid medication should not be used for extended periods and alternatives like non-opioid pain analgesics should be preferred.

Non-opioid Pain Analgesics-

The main difference between opioids and non-opioids is in the way they produce their analgesic or pain-relieving effects. Opioids reduce patient pain by working on special pain receptors in the nervous system, mostly focused on the brain and spinal cord. Non-opioids, however, work more directly on injured body tissues. While opioids reduce the brain's awareness of pain, non-opioids affect some of the chemical changes that normally take place wherever body tissues are injured or damaged. These chemical changes at the site of the injury typically result in inflammation and increased pain sensitivity.

Non-opioid analgesics are increasingly emphasized in a variety of clinical settings as a preferred, safe, and effective first-line therapy for mild to moderate acute and chronic pain.

These medications work either by reducing inflammation at the site of pain or by changing the way the brain processes and perceives pain.

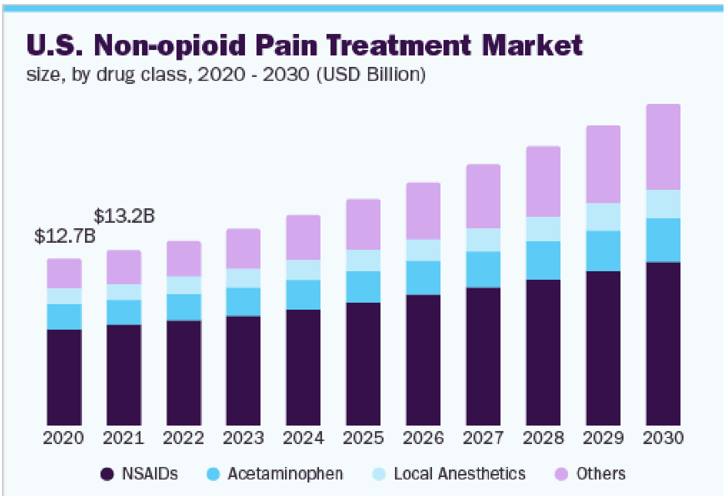
List of Drugs-

- Acetaminophen
- NSAIDS (COX Inhibitors)
- Antidepressant medications
- Antiepileptic medications
- Local Anesthetics

Market Share and Size of Non-Opioid Pain Treatment USA

The Global non-opioid pain treatment market size was valued at USD 38.64 billion in 2021 and is expected to grow at a CAGR of 8.3% from 2022 to 2030. The growth of the industry can be attributed to the increasing R&D investments by the key players for developing novel non-opioid analgesic drug and government and private organizations for introducing favorable initiatives and creating awareness about available treatment. During the initial phases of the COVID-19 pandemic, the market for NSAIDs was moderately impacted due to the low hospitalization rate and declining sales of non-opioid analgesics for treatment.

Figure 1:



Nationwide lockdown imposed by governments to control the spread of infection restricted people's access to pharmacy and hospital services such as surgeries leading to low demand for NSAID products. According to the National Library of Medicine, approximately a 91% reduction was seen in the number of elective surgeries performed in hospitals. However, the sale of acetaminophen drugs such as Tylenol had increased due to the scarcity of ibuprofen during the pandemic.

Increasing limitations on the use of opioid analgesics products for pain treatment create significant opportunities for the non-opioid analgesic drugs market. Opioid addiction and misuse of prescription drugs like oxycodone and fentanyl is a serious global issue that adversely impacts public health and economic and social wellbeing. According to CDC, around 93,665 deaths were estimated from opioid-related overdoses in 2021 in the U.S.

In addition, according to Medicare report data, opioid prescriptions from oncologists declined by 21% and 23% from other doctors in the last decade due to serious adverse effects associated with it coupled with strict government regulations. Likewise, according to the National Cancer Institute, the same trend had been observed among last-stage cancer patients in 2021. This trend is projected to remain throughout the forecast period, which has created a huge growth opportunity for the industry.

However, side effects associated with the treatment may impede market growth during the forecast period. Geriatric people commonly use NSAIDs for pain management. There are several studies that showed that long-term use of NSAIDs increases the risk of heart failure, myocardial infraction, stroke, and peptic ulcers, thereby restraining market growth.

Market Segmentation

Drug Class Outlook

- NSAIDs
- Acetaminophen
- Local Anesthetics
- Others

Pain Type Outlook

- Chronic Pain
- Post-Operative Pain
- Cancer Pain
- Others

Route of Administration Outlook

- Oral
- Injectable
- Topical
- Others

Distribution Channel Outlook

- Hospital Pharmacy
- Retail Pharmacy
- Others

Regional Outlook

- North America
- Europe
- Asia Pacific
- Latin America
- Middle East and Africa

Types of Surgeries for Non-opioid pain medication-

1) Hallux Valgus rigidus- Hallux rigidus involves a loss of motion and can potentially result in osteoarthritis of the first metatarsophalangeal joint (MPJ). It can be associated with a hallux valgus deformity so patients may have symptoms of both hallux valgus and hallux rigidus.
2) Total Knee Arthroplasty (TKA)- Total knee arthroplasty (TKA) is generally accepted as the definitive treatment for advanced knee arthritis after patients fail nonoperative treatments. TKA is an excellent treatment option for the young osteoarthritic knee with a >50% improvement in functional knee scores. Satisfaction is high and the revision rate remains 0.5% per year.
3) Ventral Hernia Repair- Ventral hernia is the type of hernia that is typically combined with abdominoplasty.

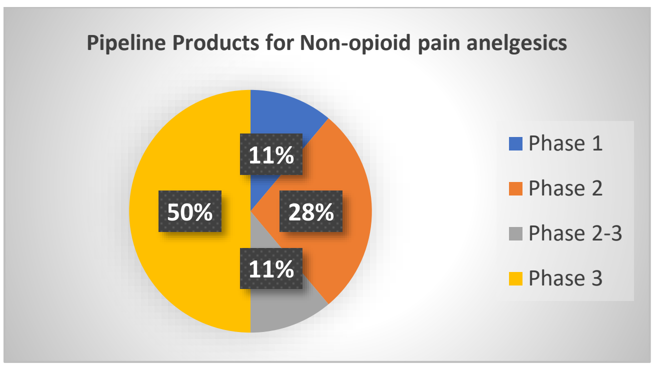
3) METHODOLOGY

OBJECTIVE

- To analyse Product A and Company X using secondary research and Competitive Intelligence tools to provide information to stakeholder for strategic decision making for Business Development.
- To track and analyse competitors of Product A, (pipeline and inline products) in non-opioid pain analgesic therapeutics market using competitive intelligence tools, like Pipeline Analysis, Launch Time Estimation and Attribute analysis. This analysis provides insightful information for our stakeholder Company Z which wants to acquire Product A of Company X. This analysis helps in strategic decision-making for business development.

Pipeline Analysis- Pipeline Analysis is done by creating competitive landscape of Product A, by identifying the direct competitors of Product A in non-opioid pain analgesic treatment. Data is collected form clinicialtrials.gov.

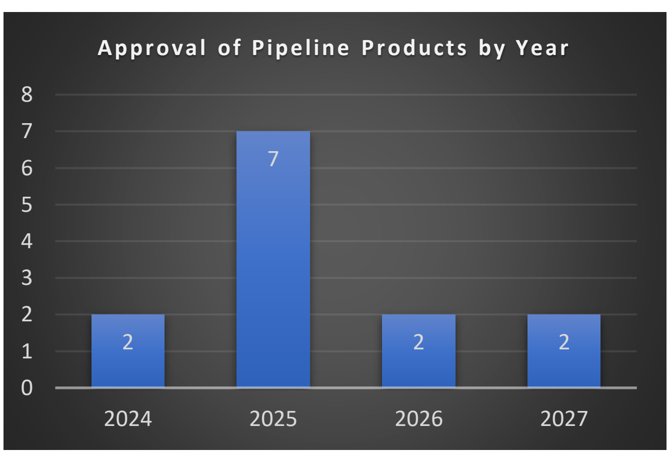
Graph 1:



Based on data obtained, 18 products are in clinical trials for non-opioid pain analgesics. Out of 9 products are in Phase 3. Product A is a Phase 3 ready product. Through CI landscape we could identify competitors in pipeline which could help in making Business Development decisions

Impact Analysis- Impact analysis is used to calculate the launch time estimation of pipeline products in non-opioid pain analgesics which are competing with Product A. Explanation of the Launch Time Estimation Assumption is on Page no 26.

Graph 2:



Launch time estimation results-

7 products are expected to launch in 2025. Only 2 products are expected to launch in 2026. Product A is expected to launch is 2026 and could face competition from one asset. Product A also received breakthrough and fast-track designation from FDA, which resulted in reduction of Approval time of Product A by 4 months.

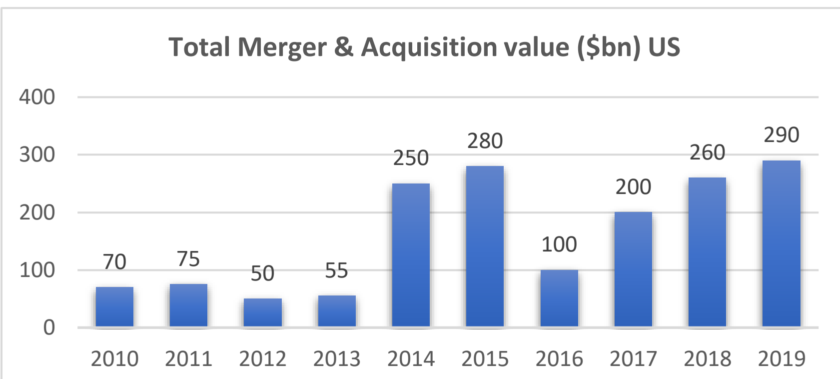
Attribute Analysis of Inline products-

Products	FDA Approval Year
Zynrefel	2021
Posimir	2021
Xaracoll	2020
Dyloject	2014
Exparel	2011
Ofirmev	2010
Sprix	2010
Product A	2026

Based on the Competitive Intelligence we could help track the competitors and the merits and demerits of Product A, which could help in making business development decisions.

The biopharmaceutical industry struck a total of 596 major M&A deals over the last decade, with a collective $1.6tn changing hands in these transactions.

Graph 3:



Reason for Business development-

$2.6bn is needed for each new drug to reach the market,1 with costs including direct spend on preclinical and clinical development, sunk costs on science that ultimately fails, and inflation considering the lengthy period required to commercialize the discovery.

Business development are the highest profile deals, involving the most risk and reward for participants, and activity among large biopharma companies acquiring smaller players provides essential investor confidence, driving smaller value deals and venture capital investment.

Drivers of Business Development

Drivers for high-value M&A deals include drug delivery tech, genomics, and implantable devices.

Drivers of Business Development

Figure 2:

Industry	Volume	Value ($bn)	Average ($m)
Pharmaceuticals	***577***	***1,553***	***2,691***
Generic Drugs	96	186	1,940
OTC, Consumer	92	373	4,052
Specialty Pharmaceuticals	80	343	4,282
Drug Delivery	18	44	2,429
Controlled Release	37	191	5,151
Topical Delivery	22	91	4,122
Macromolecule	21	35	1,676
Transdermal	15	84	5,632
Pulmonary	15	33	2,168
Site Specific	12	76	6,315
Vaccines	34	69	2,027
Nutraceuticals	34	48	1,421
Radiopharmaceuticals, Contrast Agents	13	14	1,110
Biotechnology	***156***	***254***	***1,625***
Large Molecule	66	135	2,044
Antibodies	57	89	1,560
Gene Therapy, Cell Therapy	52	158	3,045
Drug Discovery Tools	19	50	2,628
Genomics-Proteomics	18	113	6,297
Synthesis Technologies, Production Processes	17	54	3,175
Nanotechnology, Chips, etc.	10	8	829
Services	***71***	***358***	***5,047***
Medical Devices	***58***	***100***	***1,727***
Implantable Devices	17	86	5,074
Biomaterials	11	23	2,124
Contract Research, Toxicology Testing-CRO	***35***	***90***	***2,570***
Research, Analytical Equipment & Supplies	***21***	***56***	***2,680***
In Vitro Diagnostics	***19***	***39***	***2,069***

SCOPE

In this study competitive intelligence is used to solve the business question of business development. Company Z wants to expand their pipeline product portfolio in non-opioid post operative analgesics market. Company Z has identified a Phase 3 ready Product A of Company X, which they wish to acquire. Company Z uses Competitive intelligence to provide relevant information which would help in strategic decision making and to enhance their product portfolio in non-opioid pain management market.

Company Z has a Product B which is a key market player in the post-operative pain management area. The Product B has lost its patent rights and exclusivity in 2020, several generic products have been developed for the same. Company Z wants to acquire a pipeline product (Product A) of Company Z for similar indication which is non-opioid pain analgesics. Competitive intelligence tools are used to understand the Company overview, Disease overview, Product overview, Pipeline analysis, Inline and pipeline competitor products of non-opioid pain analgesics market, Approval Time Estimation, Impact Analysis and Attribute analysis to provide useful intel in making strategic decisions.

METHODOLOGY-

1) **Type of Research**- Qualitative study

2) **Data collection method**- Secondary Research

In this study we have done secondary research through various public and paid sources, in order to understand the overview of Product A, its activity and milestones, as well as we have identified and analysed the competitors of Product A in non-opioid pain therapeutics market through Competitive Intelligence tools like Pipeline analysis, Impact analysis and Attribute analysis.

Competitive Intelligence tools are used to analyse Product A in the clinical trials which is a Phase 3 ready products as well as track the competitor products in pipeline as well as inline market.

Based on competitive intelligence landscape created through clinical trials.gov we could identify eight products in Phase 3 which are direct competitors of Product A for similar indication which is non-opioid pain analgesic therapeutics market. Product A has been approved for two surgeries as non-opioid pain analgesics in Phase 2 and two other surgeries in Phase 3. In preclinical trials it has been approved for Refractory pain and Osteoarthritis. The Product A has received Fast track designation and Breakthrough Therapy Designation.

The company has been raised by five lead investors; with help of secondary research, we could find a lawsuit filed by investors against the Company for inaccurate statistical significance of end point efficacy study.

Sources used-

• Company overview- Company website, financial website, and News.

• Disease overview- WebMD, WHO/ CDC/ NIH, PubMed

• Pipeline Analysis- Clinical Trials Registry, Company websites, Animal Study Registry, Preclinicaltrials.EU

• Regulatory- Orange book, Purple Book, FDA/ EMA, USPTO, Espacenet.

• Drugs- Drug@FDA, Company/ product website, Trial registries, Journals, News

• Paid/Subscription database- AdisInsights, EvaluatePharma

4) RESULTS, DATA ANALYSIS, FORECASTING, RECOMMENDATIONS AND LIMITATIONS

Based on Competitive Intelligence landscape we could identify the direct competitors of Product A

Company Z-

Organization Z is pharmaceutical organisation which is 150-year-old. It is headquartered in Ireland. It is American Irish domiciled manufacturer of speciality pharmaceutical (adrenocorticotrophin hormone), generic drugs and imaging agents.

Company Z's Product B was a key market player in non-opioid pain therapeutics, which lost its patent exclusivity in mid-2020. To sustain the growth in non-opioid pain therapeutics market, Company Z is looking for business development opportunity to acquire an efficient pipeline product in non-opioid pain therapeutics market. Company Z has identified Product A of Company X which is Phase 3 ready product and is expected to launch by 2026 (as per CI estimations). Company Z wants to understand how efficient and effective the Product A is before acquiring the product. Company Z uses Competitive intelligence through third party service to analyse the Company X, Product A, its competitors (inline and pipeline), financial activity and future trends before acquiring Product A.

Company X-

Organisation X was founded in 2014. It is U.S based private biopharmaceutical organisation, and is headquartered in San Francisco, California, U.S.A. Mission of Company X is to develop breakthrough non-opioid pain therapeutic that address significant medical needs.

Product A-

Product A is Phase 3 ready product, which is expected to launch by Q4-2026 (as per CI estimation). It has been approved for 2 major surgeries (Total Knee Replacement and Bunionectomy) as non-opioid pain medication in Phase 2. Product A has received Fast Track Designation and Breakthrough Therapy designation in post-surgical pain by FDA. Product A is New Molecule Entity (NME) with first new mechanism of action for postsurgical pain by FDA.

Competitive Intelligence Business Question and Solutions-

- Company profiling
- Disease Overview / Cleaning Clinical trials / Validation/Plotting pipeline
- Launch time estimation / Threat analysis.
- Attribute Analysis
- Source Validation
- Social Media Monitoring

Company Profiling-

- Mission and Vision of company- Source Company website
- Senior Management Team- Company CEO, CFO, CSO, President and Directors- Company website
- Company about- When was it founded (year), Company headquarters, Products (pipeline and inline), Number of employees.
- Core therapeutic areas in which the company is working.
- Financial Summary
- Deals and Agreements

Product Overview

1. Alternative name- Generic name
2. Originator- Parent Pharmaceutical Company, Sponsor of Clinical trials Example- Company X
3. Class- Medications that are grouped together because of their similarity. Example- Non-opioid analgesics
4. Indication- Example- Post operative skeletomuscular, perioperative pain management.
5. Contraindication-Situation in which a drug, should not be used because it may be harmful to the person. Example- Pregnancy, hypersensitivity
6. Mechanism of Action- How the drug works on a molecular level. Example- TRPV1 (transient receptor vanilloid 1) receptor agonists.
7. Route of Administration- Example- Oral, Intravenous, Infiltration
8. Type of molecule- Chemical or biological medical product
9. Most recent events- Recent news on company websites.

Cleaning Clinical trials / Validation/Plotting pipeline

Clinical trials data is obtained through clinical trials.gov website applying appropriate filters based on the need.

Information covered in Pipeline analysis-

Competitor products in pipeline for similar indication based on

- Phases, Approved Drugs
- Clinical Trials
- Mechanism of Action
- Route of Administration
- Geography

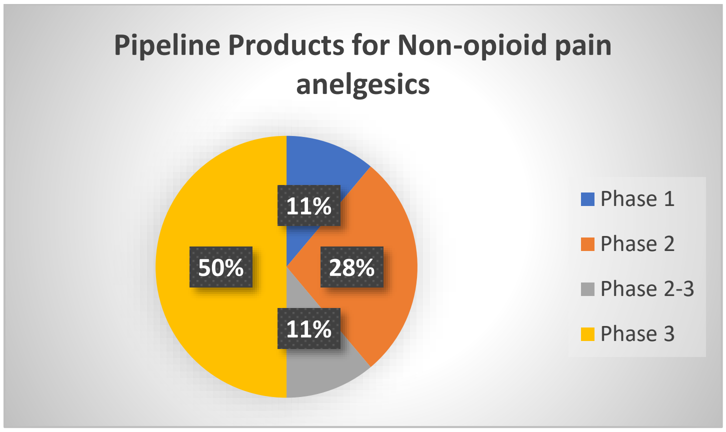
Sources used-

- Clinicaltrial.gov
- Data monitor Healthcare
- Global Data
- AdisInsight

- Evaluate

Pipeline products for non-opioid pain analgesics in different phases in clinical trials.

Graph 4:



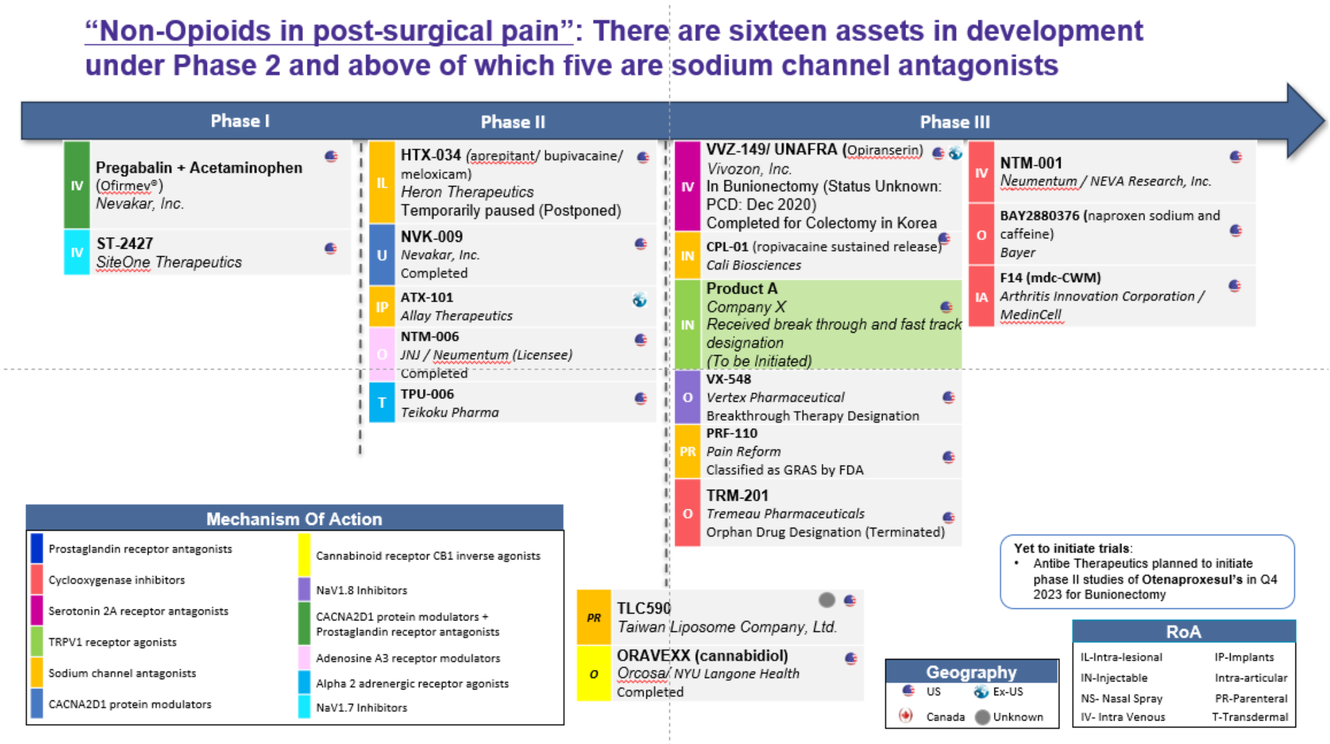
Product A is Phase 3 ready product for non-opioid pain analgesics. There are 10 different assets competing with Product A in Phase 3 for non-opioid pain analgesics.

CI Landscape Pipeline Analysis

There are a total of 11 assets in Phase 3 trial for non-opioids in post-surgical indication. Product A has a distinct mechanism of action as compared to other competitors, New Molecular Entity (NME) by FDA; In Phase 3, four assets have similar mechanism of action which is cyclooxygenase inhibitor. Product A phase 3 trials are yet to be initiated and are expected to initiate around Q4-2023. Trial design has been ready. Product A also offers a unique route of administration, with only one asset having a similar route of administration. Product A offers a unique mechanism of action in comparison to marketed products for non-opioid in post-surgical indication. ATX-101 of Allay Therapeutics and UNAFRA of Vivozon, Inc is a pipeline asset which has been conducting trials out of U.S.

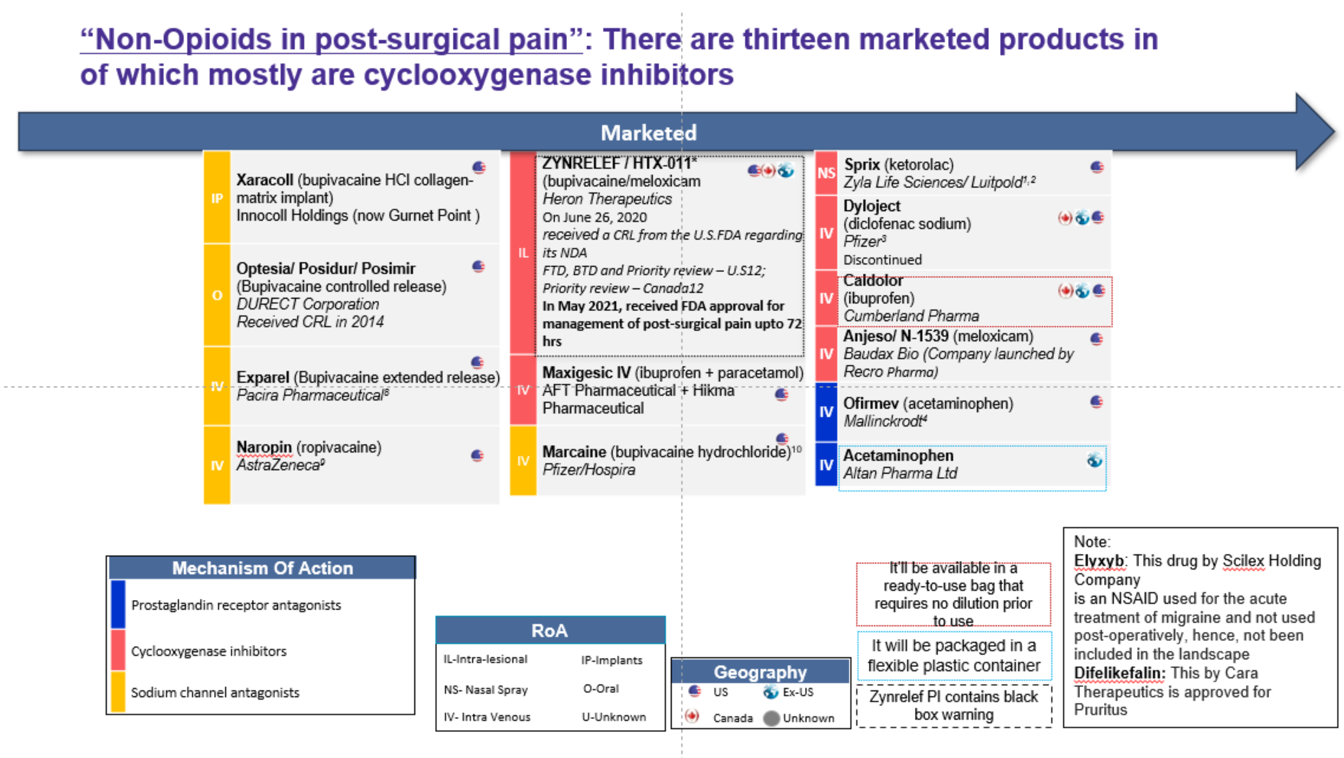
There are total of 13 assets which are marketed for non-opioid pain anelgesic treatment, out of which three assets Zynrelef of Heron Therapeutics, Dyloject of Pfizer and Caldolor of Cumberland Pharma have been apporved of US as well as Ex-US and Canada market. 6 assets are of similar mechanism of action which is Cyclooxegenase inhibitors and 5 assets having similar mechanism of action which is Prostaglandin receptor antagonist. This offers and advantage for Product A which has a unique mechanism of action. Most of marketed drugs have IV as route of administration. Optesia of Durect Corporation is the only asset with oral route of administration.

Figure 3:



Source- Search of: non-opioid pain analgesics - List Results - ClinicalTrials.gov

Figure 4:



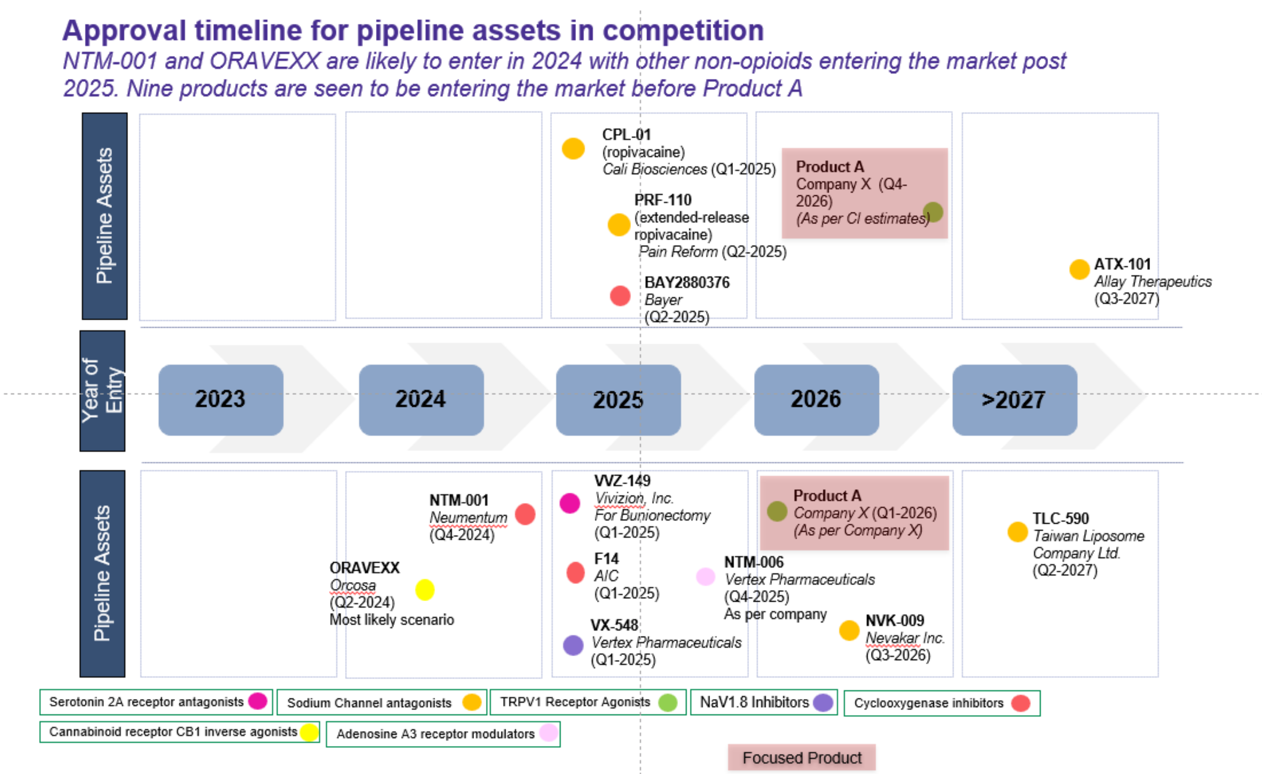
Source- Search of: non-opioid pain analgesics - List Results - ClinicalTrials.gov

Launch time estimation / Impact analysis
Assumptions for approval time are –
• Completion of Exploratory Analyses (we estimate that it would take around 3-4 months)
• Initiation of Phase 3 clinical trials- 3 months
• Completion of Phase 3 clinical trials- Primary Completion Date
• Submission of NDA: 3 months
• Approval FDA review - 10 months
• If applied for Priority Review then it will be reviewed by FDA in 6 months.

Launch Time Estimation is a CI tool used to estimate the Launch time of a drug in pipeline. Primary Completion Date in clinical trials is used as base to calculate launch time estimation of the drug. FDA review period changes based on whether the drug is given breakthrough designation, fast-track designation or whether the drug is orphan drug. 10 months are required for FDA Review, if applied for priority review then it will be reviewed by FDA in 6 months.

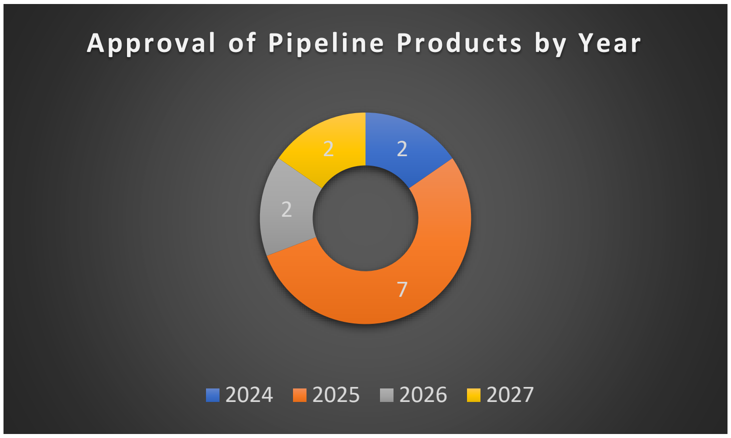
- **Breakthrough Designation**- The FDA's approval for serious conditions and not available therapy for remedy to cure it.
- **Fast-track Designation**- Granted by FDA for serious conditions and if there is a need in the market.
- **Orphan Drug Designation-** This designation is granted by FDA to treat rare diseases and disorders.

Figure 5:



Source- Search of: non-opioid pain analgesics - List Results - ClinicalTrials.gov

Graph 5:



7 products are expected to lauch by 2025 based on launch time estimation. Product A is expected to launch in 2026, only one other asset is expected to launch by 2026 with different mechanism of action and route of administration as compared to Product A. This suggests there is less competition for Product A, due to distinct mechanism of action.

Attribute Analysis-

Comparison of seven other inline post-surgical non-opioid analgesics

Product A is expected to launch by Q4-2026. It is necessary to access high threat inline assets in non-opioid pain anelgesic market. Attribute analysis is comparison of different marketed assets in same indication based on different attributes like FDA Approval, Company name, Drug Class, Indication, Dosage form, Designation, Cost of Drug, Mechanism of action, route of administration, Efficacy, Safety profile, Market Status and Sales number of the products. These attribute comparison helps in analysing the inline products and its market share. Exparel of Pacira Pharmaceutics is a leading product in non-opioid pain anelgesic market based on sales ($536.9 M in 2022) and efficacy. Posimir of Durect Corporation is the recent launch product (2022) and has 5 patent protection for non-opioid pain therapeutics and it has long patent term and marketing exclusivity as compared to other marketed products for similar indication. It also has similar route of administration (Infiltration) with Product A. Ofirmev of Mallinckrodt Pharmaceutical is the only marketed drug with unique mechanism of action (Prostaglandin Receptor Antagonist). These attribute comparison help in understanding the market leader and comparing the inline products for similar indication.

Figure 6:

Attributes	Zynrelef	Posimir	Xaracoll	Dyloject
Generic Name	Bupivacaine and meloxicam	Bupivacaine (sustained-release)	Bupivacaine hydrochloride (Drug-device)	Diclofenac sodium
FDA Approval	May 2021	February 2021 US Launch-2022	August 2020	December 2014
Company	Heron Therapeutics	Durect Corporation/ Innocoll	Innocoll Holdings	Pfizer
Drug Class	NSAID	Local Anaesthetic	Local Anaesthetic	NSAID
Indications	TJA, Foot & Ankle, Open-Abdominal	ASD surgery	Open Inguinal Hernia Repair	Cataract & other ocular surgeries
Dosage Form	Solution	Solution for Infiltration	Implant	Injection/ Solution
Designations	FTD, BTD, Priority Review	-	-	-
Cost of Drug	$22.76/unit (7 ml)	$319/procedure	$88.19/unit	$16.79/ml
RoA	Intra-lesional	Oral	Implants	Intravenous
MoA	Cyclooxygenase Inhibitors	Na Channel Antagonist	Na Channel Antagonist	Cyclooxygenase Inhibitors
Efficacy	Upto 72 hrs post-surgery	Upto 72 hrs post-surgery	Upto 24 hrs post-surgery	Upto 6 hrs effect
Safety Profile	Not established in intrathoracic,, spinal & H&N procedures Contraindicated in CABG	Boxed Warning: Risk of potential adverse embolic effects resulting from inadvertent intravascular injection	Dose-related Toxicity, Methemoglobinemia, Death in case of Obstetrical paracervical block anaesthesia	Risk of serious cardiovascular and gastrointestinal events
Market Status	Received CRL in 2020 Limitations in efficacy and lack of block indication, despite lower price, Lack of awareness and promotional presence	Recently launched. Has 5 patent protection	Drug-device combination launched through a partnership between MNK Acute Care Sales Team and Innocoll's Hospital Sales Team	Discontinued in UK due to presence of white particulate matter in vials
Sales Number (2022)	$10.2Mn	$2Mn as of Sept 2022, $10Mn Milestone payment	-	-

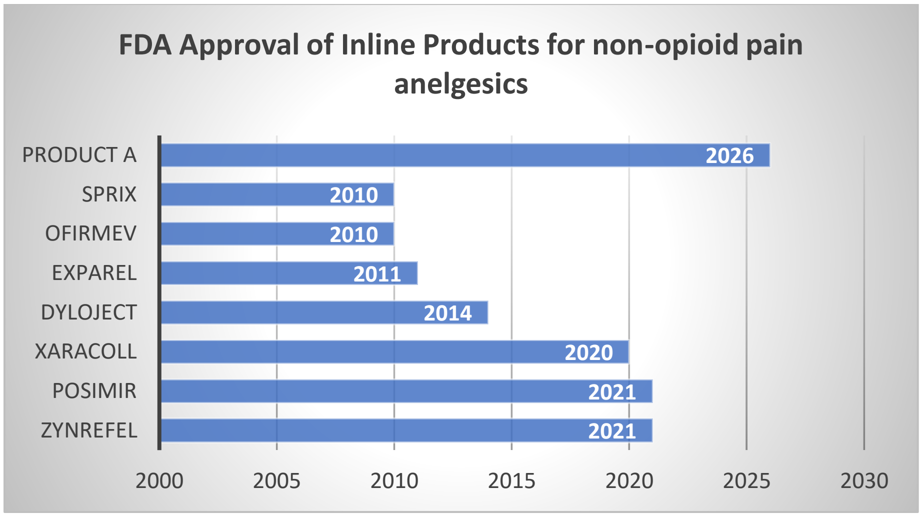
Source- Secondary Research

Figure 7:

Attributes	Exparel	Ofirmev	Sprix
Generic Name	Bupivacaine (extended-release)	Acetaminophen	Ketorolac tromethamine
FDA Approval	October 2011 US Launch- 2012	November 2010	May 2010
Company	Pacira Pharmaceutical	Mallinckrodt	Zyla Lifesciences
Drug Class	Local injectable anaesthetics	Miscellaneous Analgesics	NSAID
Indications	Shoulder Surgery, Brachial Nerve Plexus	Pediatric Use	Abdominal & Orthopaedic surgery
Dosage Form	Injection/Suspension/Liposomal	Injection/ Solution	Nasal Spray
Designations	-	-	-
Cost of Drug	$22.85/ml	$0.5/ml (1 unit)	$521.72/spray
RoA	Intravenous	Intravenous	Nasal Spray
MoA	Na Channel Antagonist	Prostaglandin Receptor Antagonist	Cyclooxygenase Inhibitors
Efficacy	Upto 48 hrs	Every 4 hrs upto 4000 mg per day	Spray after every 6-8 hrs
Safety Profile	Should not be injected in spine, joints and veins	Risk of medication errors and hepatotoxicity	Risk of serious cardiovascular and gastrointestinal events
Market Status	Shift in strategy from surgeons to anesthesiologists to continue to grow due to lack of ability to meet need in TJA	Declining sales due to loss of exclusivity in 2020	Zyla (earlier known as Egalet) acquired Luitpold in 2018
Sales Number (2022)	$536.9Mn	$2.2Mn	-

Source- Secondary Reseach

Graph 6:



Based on attribute analysis of inline products for non-opioid pain anelgesics. We have identified the FDA Approval Year of the marketed assets. We could identify that Posimir and Zynrefel are the recent lauch products for the same indication. These products are expected to have long patent exclusivity as compared to other assets. Product A which is expected to launch by 2026 could face competition from Zynrefel and Posimir.

Forecasting- Competitive Intelligence in Business Development helps in forecasting the launch time of a particular drug in pipeline. Product Approval Time estimation is a tool to identify launch date based on assumptions. Trend based forecasting, is used which helps in estimation, based on historical data of time taken by marketed drug with similar indication for approval for a particular phase. Duration for data readout, Phase clinical trial initiation period is fixed. Approval time may vary based on designations provied for a particular drug by FDA like breakthrough designation, fast-track designation and Orphan drug designation. This forecasting helps in tracking the competitors of a particular drug we are interested in. Forecasting is a key methodology and tool used in competitive intelligence for business development.

Assumptions for approval time are –
- Completion of Exploratory Analyses (we estimate that it would take around 3-4 months)
- Initiation of Phase 3 clinical trials- 3 months
- Completion of Phase 3 clinical trials- Primary Completion Date
- Submission of NDA: 3 months
- Approval FDA review - 10 months
- If applied for Priority Review then it will be reviewed by FDA in 6 months.

Recommendation- Based on the analysis done through competitive intelligence, Product A of Company X is an effective and efficient drug for acquistion by Company Z in non opioid pain anelgesics market. Product A is a Phase 3 ready product approved for non-opioid pain analegesic for four major surgeries. It is a promising drug provided with breakthrough and fast-track designation and New Molecular Entity (NME) having unique mechanism of action, provided by FDA. There are few competitors with similar route of administration. It is expected to launch in

2026 with only one competitor asset expected to launch in the similar year. The Product A has high potnetial and has given good efficacy results in clinical trials.

Limitation- There are few limitations for this acquistion of Product A, based on the financial report of Company X, the main investors have filed a lawsuit against Company X for providing statisticaly insignificant efficacy results of Clinical trials. This lawsuit could be a major red flag for this acquistion, as the Company Z need to keep track of the lawsuit before making any business development decisions.

Objective- To track and analyse Product A of Company X and their direct competing pipeline and inline products in non-opioid pain analgesic therapeutics using competitive intelligence tools, like Pipeline Analysis, Launch Time Estimation and Attribute analysis. This analysis provides insightful information for our stakeholder Company Z which wants to acquire Product A of Company X. This analysis helps in strategic decision-making for business development.

Objective met-

Before making business development decision, it is necessary to analyse the Product or Company which is involved in Business development, which helps in making strategic decisions . Competitive Intelligence is the get-together and investigation of information to envision serious movement, see past market interruptions. It is fundamental segment to building up a business development procedure. CI gives knowledge into the commercial centre elements and difficulties during an organized, taught, and moral way utilizing distributed and non-distributed sources.

Competitive Intelligence in business development help to develop corporate or venture unit systems. Shape counter-competitive systems against at least one contender, identify new market passage, or other key move inside the market. Anticipate and plan for future market openings and disturbances.

CI tools used in this study to make strategic business decisions for business development.

Company Overview-

- Mission and Vision of company, Senior Management Team- Company CEO, CFO, CSO, President and Directors, Company about- When was it founded (year), Company headquarters, Products (pipeline and inline), Number of employees. Core therapeutic areas in which the company is working. Financial Summary Deals and Agreements. This data is obtained through secondary research to provide a brief overview of the company which is involved in BD decisions.
- Company overview in this study could help find a lawsuit of Company X with their investor, which could be a red flag for making strategic decisions of business development.

Product Overview-

- Information of Product like Alternative name, Originator, Class, Indication Contraindication, Mechanism of Action, Route of Administration, Type of molecule Most recent events is identified through secondary research which helps in analyzing the product based on all parameters and attributes.

- Product Overview helped in finding the unique mechanism of action of Product a New Molecular Entity (NME) granted by FDA which provides a competitive edge.

Pipeline Analysis

- Competitive Intelligence landscape is created by capturing data from clinicaltrials.gov.in website, the data is filtered based on country, and plotted in landscape. The products are distinguished based on different phases, mechanism of action and route of administration which helps in analyzing the products.
- CI landscape helps in tracking the competitors of Product A for similar indication which is non-opioid pain analgesics.

Launch Time Estimation

- Launch time estimation helps in estimating the launch year of the products in pipeline.
- This helps in tracking the competitors of the Product A and the impact it would have on the market.

Attribute Analysis

- Attribute analysis is done to distinguish inline products on different attributes like FDA Approval, Company name, Drug Class, Indication, Dosage form, Designation, Cost of Drug, Mechanism of action, route of administration, Efficacy, Safety profile, Market Status and Sales number of the products.
- This analysis helps in analysing the market share of the product in particular segment and also impact analysis

Competitive Intelligence tools helped in provding insightful data to the stakeholder which included the Company and Product Overview, Pipeline and Inline Competitor tracking, this significant data in strategic decision making in business development.

5) DISCUSSION

Competitive intelligence in business development is a rational approach for making any decisions. Tools of competitive intelligence not only track the interested product but also the competitors of the interested product. Competitive intelligence tools help in tracking the pipeline, as wel as inline market. Company Overview, Product Overview and Disease Overview helps in understanding the overall charecteristcics and mission and vision of the company. It helps in providing better understanding of the activities and financials of the company and product.

6) CONCLUSION

Based on the study we could conclude thet, Product A of Company X is an effictive and efficient product, with high efficacy reults in clinical trials, it is a Phase 3 ready product which is estimated to launch by Q4-2026 (as per CI estimation). It is a new moleular entity (NME) with unique mechaism of action as compared to marketed products. Looking at its benefits and Competitive intelligence tools it would be beneficial for Company Z to acquire this product in non-opioid pain anelgesics treatment. Looking at its efficacy and safety results in clinical trials results, Product A has competitive advantage in non-opioid pain anlegesic market. To expand pipeline product portfolio business development and competitive intelligence plays a crucial role in making strategic business decisions. It not only provides the overview of product and company, but also tracks the various factors that affect the product like competitors and market analysis. Competitive Intelligence provides insightful information to the organisation which helps in making key decisions.

7) BIBLIOGRAPHY

- n.d. https://www.crayon.co/blog/6-steps-to-design-a-successful-competitive-intelligence-process.
- n.d. *https://fletchercsi.com/what-is-competitive-intelligence/.* https://fletchercsi.com/what-is-competitive-intelligence/.
- n.d. *https://www.crayon.co/blog/6-steps-to-design-a-successful-competitive-intelligence-process.* https://www.crayon.co/blog/6-steps-to-design-a-successful-competitive-intelligence-process.
- n.d. *https://www.spyfu.com/blog/tutorial-researching-competitors-marketing-strategy/.* https://www.spyfu.com/blog/tutorial-researching-competitors-marketing-strategy/
- Luu, Tuan. 2014. *competitive intelligence.* London: Marketing Intelligence & Planning ISSN: 0263-4503 Vol. 32 No. 3,pp. 269-292.
- Pategou, Joseph. 2016. *Pharmaceutical Industry:Turn Strategic & Technologic Watches into business advantage.* International Strategy and Influence.
- Persidis, Aris. 2005. *Competitive information gathering and analysis in biotechnology.* California: Expert Opinion on Therapeutic Patents.
- Daniel Chancellor. 2020. *A Decade of Biopharma M&A and Outlook for 2020. New York. U.S.A.* MA Whitepaper.pdf
- ClinialTrials.gov. 2023. U.S. NIH U.S. National Library of Medicine ClinicalTrials.gov. Search of: non-opioid pain analgesics - List Results - ClinicalTrials.gov