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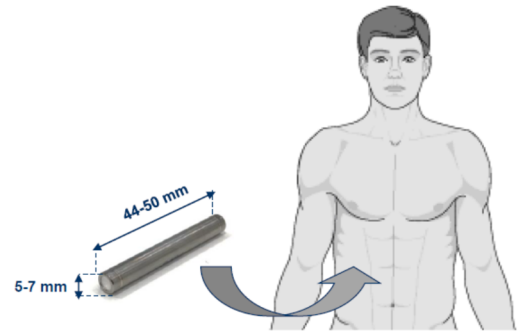
DELPOR'S PROZOR™ PLATFORM TECHNOLOGY



PRODUCT REQUIREMENTS FOR ONCE-YEARLY THERAPY

Reversible

- Must deliver daily dose for 365 days and be reversible at any time
- Reversible in case treatment interruption is required (washout in 24 hours)

Comfortable and Convenient

- Unnoticeable by the patient during daily activities

Steady Release

- Flat pharmacokinetics (PK) for 1 year without decline
- Does not drift below the therapeutic threshold

Source: Delpor, Inc.

DELPOR'S PIPELINE

Risperidone (lead asset)	Schizophrenia Maintenance	6 or 12 months	Ph-2 (Ph-3 expected 2025)
Naltrexone	Opioid Use Disorder	6 or 12 months	Ph-1 (Ph-2 expected 2025)
Tizanidine	Spasticity	6 months	Preclinical (Ph-1 expected 2025)
Undisclosed	CNS Conditions	6 or 12 months	Preclinical

Source: Delpor, Inc.

COMPANY DESCRIPTION

Delpor, Inc. ("Delpor" or "the Company") is a closely held clinical-stage biopharmaceutical company developing once-yearly therapeutic products to treat chronic conditions. The Company's unique and patented Prozor™ technology facilitates the release of specific insoluble drugs, such as most **antipsychotics†**, from a non-mechanical (passive) implantable drug delivery device (which is the length of a matchstick). This device is placed under the skin in the abdomen and employs a distinct formulation to allow for the consistent release of medications. The placement procedure for the device is brief, typically lasting only 10 minutes, and is conducted in a physician's office under local anesthesia. This enhances medication adherence, efficacy, safety, treatment outcomes, and patient quality of life. Delpor's clinical assets include a 6-12-month formulation of risperidone (DLP-114) for **schizophrenia** treatment as well as a 6-12-month formulation of naltrexone (DLP-160) for **Opioid Use Disorder (OUD)** and alcohol dependence treatment. Also in development are earlier stage preclinical candidates, with a 6-month drug formulation of tizanidine (DLP-208) for moderate to severe **spasticity**, as well as compounds for Parkinson's, Alzheimer's, and more. Delpor thinks of its technology as 'a once-a-year cure for an incurable disease.'

KEY POINTS

- Delpor's platform technology offers numerous advantages, including once-yearly dosing, enhanced medication adherence, reversibility, and consistent safety and efficacy. This enables immediate treatment initiation and rapid washout periods, promoting efficient healthcare resource management.
- Currently marketed **long acting injectables (LAIs)** enhance medication adherence and are available for risperidone and naltrexone, though they typically last for only up to two months.
- Delpor has launched its Phase 2b study for DLP-114 in Q2 2024, which could go through year end. The Company then plans to initiate both a registrational Phase III trial and a safety study in parallel, which could be sufficient for product approval.
- The Company's regulatory strategy focuses on leveraging the **505(b)(2)** regulatory pathway, which offers lower technical risk coupled with significant commercial potential. It also minimizes the need for efficacy trials in most cases.
- Delpor holds approximately 25 issued patents (9 families) with an additional 30+ pending; some are valid until 2033, while pending ones may extend coverage to 2040.
- The Company is guided by an experienced management team with a track record of success in pharmaceutical research, development, and commercialization.
- Delpor has raised approximately $40 million; having been awarded approximately $20 million in non-dilutive funding from the NIH, with the potential for an additional $15 million over the next 12 months. Additionally, the target for the Company's Series C round is approximately $40 to $60 million.

Table of Contents

Executive Overview

Delpor, Inc. ("Delpor" or "the Company") is a closely held clinical-stage biopharmaceutical company dedicated to developing once-yearly therapies for chronic ailments through cutting-edge technologies. The Company's patented Prozor™ technology enables the continuous release of certain insoluble drugs, including most antipsychotics, from a non-mechanical (passive) compact implantable drug delivery device, utilizing a unique formulation that ensures consistent medication delivery. The Company's technology empowers the administration of therapeutic agents within a predetermined therapeutic timeframe, while maintaining a consistent release rate (**zero-order release pharmacokinetics [PK]**). The advantages of this are significant as it enhances patient adherence to medication regimens and allows for reversible drug administration if treatment discontinuation becomes necessary. Moreover, Delpor's delivery mechanisms yield fewer adverse events (AEs) and heightened efficacy due to the smooth, peak and valley-free PK profiles.

Delpor is actively developing its unique drug delivery platform to advance clinical assets, including a 6-12-month formulation of risperidone (DLP-114) for schizophrenia maintenance treatment and a 6-12-month formulation of naltrexone (DLP-160) for the treatment of Opioid Use Disorder (OUD) and alcohol dependence. Currently available long-acting formulations for risperidone and naltrexone are long-acting injectables (LAIs), but typically LAIs last only for up to two months; Delpor's implantable devices can provide treatment for up to a year because of the stable and flat PK profile afforded by its drug delivery technology (while long acting injectables cause big bursts after the administration, followed by a fast drop before the end of the dosing period). The Company is also working on a 6-month formulation of tizanidine (DLP-208) for moderate to severe spasticity, as well as other earlier stage compounds within the central nervous system (CNS) arena, and other therapeutic areas.

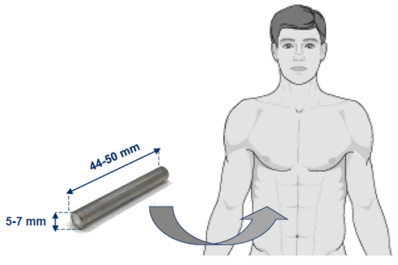
The Implant Device

As summarized in Figure 1, the Company's subcutaneous implant is cylindrical, measuring approximately 5-7 mm in diameter and 44-50 mm in length, and resembles the size of a matchstick. Constructed from non-magnetic titanium, the device incorporates diffusion membranes at both ends, enabling zero-order drug release through passive diffusion without the need for mechanical components. The hollow interior contains drug-filled tablets and excipients, ensuring sustained release for up to one year. Implanted beneath the skin in the abdomen during a brief 10-minute procedure under local anesthesia in a physician's office, the device continuously delivers therapeutic doses until replacement is needed, typically in the same location.

Figure 1

DELPOR'S PROZOR™ PLATFORM TECHNOLOGY

- Matchstick-length device placed just under the skin in the abdomen
- Simple in-office outpatient procedure (~10 min to complete)
- After placement, the device delivers therapeutic drug levels for 6-12 months
- Device is removed and replaced after 6-12 months (same site)



Source: Delpor, Inc.

Technology Benefits

Delpor's implant device technology offers the following key advantages:

- ***1-Year Duration*** ensuring consistent medication adherence throughout treatment and reducing relapse rates. This option caters to patients who respond positively to the selected drug but discontinue maintenance therapy.

- ***Zero-Order Release Pharmacokinetics (PK)*** without adverse event (AE)-generating peaks and sub-therapeutic troughs, ensuring steady-state drug delivery within the therapeutic window for up to one year.

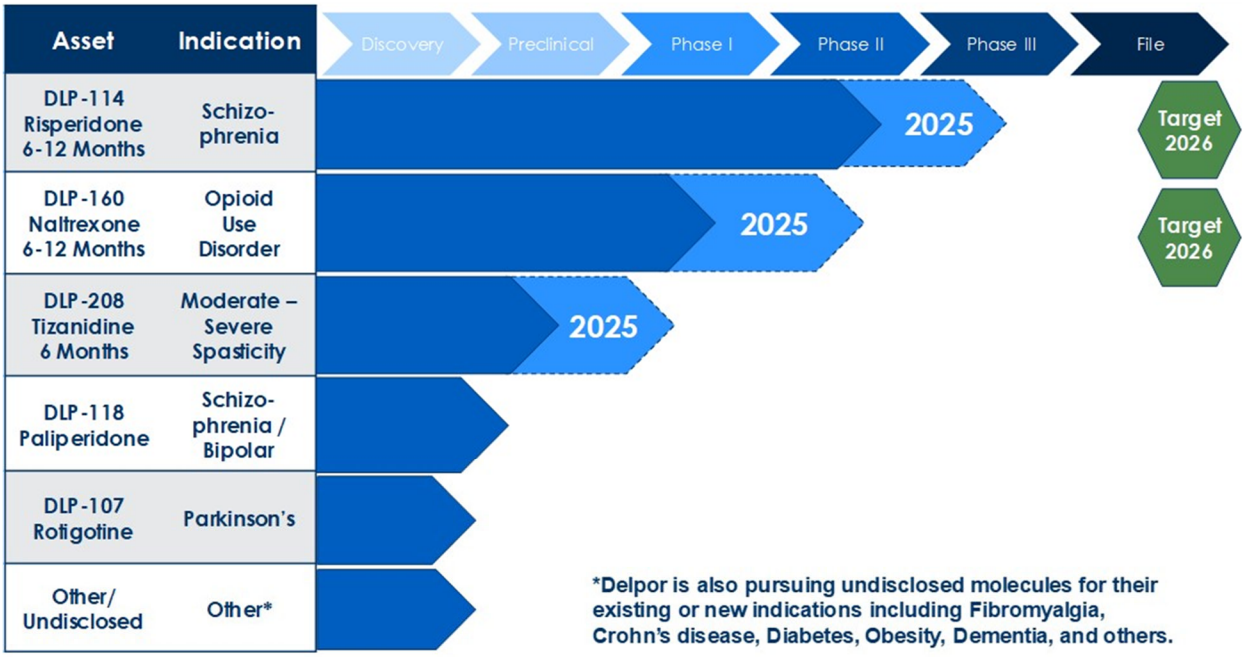
- ***Fully reversible system***, where the device can be easily removed within minutes and drug plasma levels decline to zero shortly after removal (~24 hours). This reversibility is crucial for safety, particularly compared to injectable systems that lack this feature.

- ***Comparable efficacy with lower drug exposure,*** where zero-order release obviates the need for an initial drug burst, achieving the same efficacy with reduced drug exposure.

Product Pipeline

Delpor possesses two clinical assets, outlined in the accompanying pages and further detailed within this Executive Informational Overview (EIO): risperidone (DLP-114) for schizophrenia maintenance and naltrexone (DLP-160) for Opioid Use Disorder. Earlier stage preclinical candidates in the Company's pipeline include tizanidine (DLP-208) for moderate to severe spasticity, paliperidone (DLP-118) for schizophrenia/bipolar disorder, rotigotine (DLP-107) for Parkinson's, as well as earlier stage undisclosed candidates targeting other conditions, including fibromyalgia, Crohn's disease, diabetes, obesity, and dementia, among others. A summary of Delpor's current platform and pipeline is provided in Figure 2, followed by brief descriptions of each candidate. Greater details are provided within the Core Story of this Executive Informational Overview (EIO) on pages 15-40.

Figure 2
DELPOR'S PLATFORM & PIPELINE FOCUSED ON CHRONIC CNS DISEASES



Source: Delpor, Inc.

Therapeutic Targets

Schizophrenia

Schizophrenia is a chronic and severe mental disorder characterized by disturbances in thinking, emotions, perceptions, and behavior. People with schizophrenia may experience hallucinations (seeing or hearing things that others do not), delusions (false beliefs), disorganized thinking, reduced emotional expression, and difficulties in social interaction and functioning. The exact cause of schizophrenia is not fully understood but it is believed to involve a combination of genetic, brain chemistry, and environmental factors. Schizophrenia stands as one of the leading contributors to disability in developed nations, impacting roughly 1.1% of the population.

Treatment typically involves a combination of antipsychotic medications, psychotherapy, and support services to help manage symptoms and improve quality of life. Second-generation (atypical) antipsychotics have largely been used to treat schizophrenia patients. While these medications have shown considerable efficacy in mitigating or alleviating symptoms of the illness, maintaining treatment success poses challenges due to suboptimal patient adherence. Moreover, despite their effectiveness, many atypical antipsychotics still carry the risk of **extrapyramidal symptoms (EPS)**—involuntary and uncontrollable movement disorders caused by certain drugs, especially anti-psychotic drugs—when administered at elevated plasma concentrations.

DLP-114 (Risperidone 6-12-month Formulation) for Schizophrenia

Delpor's most advanced development candidate, DLP-114, is targeting the market for schizophrenia therapeutics. Risperidone is dispensed via the Company's subcutaneous implant device and aimed at sustaining therapeutic levels for a minimum of 6 months and extending up to one year. The efficacy of DLP-114 has been measured during a Phase 2 study by using two exploratory treatment outcome endpoints—**Positive and Negative Syndrome Scale (PANSS)** and **Clinical Global Impression (CGI).** DLP-114 was well tolerated for 12 months and displayed comparable therapeutic benefits to oral risperidone. Plasma concentrations remained constant for 6-12 months and patients remained stable throughout the study's duration; only one out of 28 patients in the study displayed signs of impending relapse. Greater details of this data is provided on pages 26-28.

The Company recently launched its Phase 2b study, which is projected to extend until early 2025. Following the completion of the Phase 2b study, Delpor intends to launch a registrational Phase 3 trial and a safety study, aiming to facilitate product approval. The Phase 2b study is expected to enroll approximately 35-40 schizophrenia patients across U.S.-based sites, the registrational trial is expected to enroll approximately 50-80 participants, and the safety study 100-150 participants, with potential international inclusion. These trials are to specifically target stable schizophrenia patients, aligning with the Company's objective of securing approval for DLP-114 as a maintenance therapy.

Research for DLP-114 is backed by the National Institute of Mental Health (NIMH) of the National Institutes of Health (NIH) under Award Number R44MH094036. This award signifies that the project has received funding support from the NIMH, indicating the Institute's recognition of its potential significance in addressing mental health challenges, particularly in treating schizophrenia.

Delpor Sponsored Independent Market Research Study for DLP-114

The Company has commissioned a market research study conducted in collaboration with Symphony Health and KMK Consulting (further detailed on pages 33-34). Based on this research, it was observed that approximately 70% of physicians interviewed (all high antipsychotic prescribers) stated that they would definitely or probably be inclined to prescribe DLP-114 with a reported preference share of 15%. Physicians highlight key benefits of the product to include its reversibility, long duration, smooth PK profile, and lack of initiation dosing requirement. Market expansion opportunities could prove significant, with one in five bipolar patients identified as potential candidates for DLP-114, and three in four physicians indicating readiness to transition up to 22% of their patients from another antipsychotic drug (not risperidone) to oral risperidone, so they can eventually transition them to DLP-114. According to this study, DLP-114's pricing and reimbursement landscape indicates a potential average annual price of approximately $20,000

within the U.S., with payers across various countries expressing willingness to cover the product if priced at parity with currently marketed long-acting injectables (LAIs).

Opioid Use Disorder (OUD)

Opioids, which include both illicit substances like heroin as well as prescription pain relievers, such as morphine and fentanyl, are at the core of a growing health crisis. Opioid Use Disorder (OUD) is a medical condition characterized by problematic patterns of opioid use, leading to significant impairment or distress. This addiction represents a chronic and relapsing brain disorder marked by individuals persistently seeking reward and relief through substance use and associated behaviors. Those with OUD often contend with intense cravings for opioids, struggle to control or reduce their intake, and persist in its use despite experiencing adverse consequences across multiple areas of their lives, including health, social relationships, work, and legal matters.

Opioids' addictive properties, coupled with their potential for tolerance, dependence, and withdrawal symptoms, contribute to the development of OUD. The epidemic of drug overdoses has become the primary cause of accidental deaths in the U.S., predominantly driven by OUD, and resulting in a decline in life expectancy over the past few years. According to the National Institutes of Health (NIH), approximately 6.7 to 7.6 million adults in the U.S. currently live with OUD. Furthermore, since 1999, over 760,000 people have died from drug overdoses as of 2020, with opioids being involved in nearly 75% of these deaths. Greater details of the extent of this problem are provided on page 36.

DLP-160 (Once-Yearly Naltrexone Formulation)

Delpor is developing DLP-160, a 1-year sustained release naltrexone implant designed to prevent relapse from opioid dependence. Using the Company's PROZOR™ technology, the medication is dispensed from a subcutaneous implant device, aiming to sustain therapeutic levels of naltrexone in human plasma for potentially up to one year. The Company has completed a Phase 1 study in Australia and plans to file for an Investigational New Drug (IND) application in the U.S. later this year. The next clinical trial (Phase 1b) is expected to start in the first half of 2025.

Spasticity (Moderate to Severe)

Moderate to severe spasticity, characterized by muscle stiffness and involuntary spasms, significantly affects patients' mobility and comfort. Current treatments, including oral medications, botulinum toxins, and **intrathecal baclofen pumps (ITB)**, offer limited relief with various drawbacks, such as short duration, compliance issues, lack of efficacy, and invasiveness. There is a critical need for innovative therapies to provide sustained relief with improved tolerability. Currently, Medtronic's baclofen intrathecal pump is the only long-acting option, but its invasive nature limits its use.

DLP 208 (Tizanidine 3-6 month Formulation) for Moderate-Severe Spasticity

Delpor is developing DLP-208 for the maintenance treatment of moderate to severe spasticity for a sustained period of 6 months. DLP-208 is expected to increase patient compliance and provide several benefits compared to the existing therapies, including improved efficacy and safety. The Company is aiming to commence clinical trials next year.

Delpor's Innovative Approach to Medical Technology and Market Strategy

Delpor develops, acquires, and employs innovative medical technologies with the objective to improve the clinical and commercial value of new and existing drugs. The Company's vision is to create successful products in half the time and at a fraction of the cost compared to new agents by substantially reducing the technical risk involved. At the same time, Delpor focuses on markets where its technologies can provide a meaningful clinical benefit. As a result, the Company is able to develop products with comparable commercial upside to new drugs, but with substantially lower cost, shorter timelines, and lower failure rates.

Delpor's objective is to improve patient lives by increasing treatment success and by improving the patient's experience. This outcome is usually achieved through a combination of the following: improved patient medication adherence, increased efficacy, superior safety profile, improved patient convenience, and reduced cost.

The Company focuses on the following products and markets:

- Tested products where the clinical benefit is objectively linked to PK;
- Chronic diseases requiring ongoing "maintenance" medication; and
- Large markets with clear unmet needs.

Corporate Information (Headquarters, Employees, and History)

Delpor has headquarters in Brisbane, CA and currently employs 12 full-time individuals. The majority of Delpor's team is focusing on the functions that are directly related to the Company's core technology, specifically formulation development and device engineering (including human factors). To optimize the efficiency of its operations, the Company has adopted the virtual company model by outsourcing most of the remaining functions.

Investment Highlights

- Delpor is focused on advancing clinical-stage development of once-yearly therapeutics for chronic conditions.
- The Company has pioneered a platform technology capable of sustaining drug release for up to one year, promising transformative advancements in long-term therapeutic delivery.
- With two clinical assets already in development and a robust pipeline, the Company demonstrates promising growth potential in delivering innovative treatments to address unmet medical needs.
- Delpor's pipeline includes:
    - DLP-114 (Once-Yearly Risperidone), its lead asset, targeting schizophrenia maintenance with a 6 or 12-month dosing interval, in Phase 2b (Phase 3 expected during 2025);
    - DLP-160 (Once-Yearly Naltrexone) for Opioid Use Disorder (OUD), in Phase 1 (Phase 1b expected in 2025), also offering a 6 or 12-month dosing option;
    - DLP-208 (6-Month Tizanidine), in preclinical development for spasticity, focused on a 6-month dosing interval, with Phase 1 expected in 2025; and
    - Undisclosed molecules targeting CNS, diabetes, obesity, and other conditions, which have shown promising potential for future development, in preclinical development or feasibility evaluation.
- The long-acting antipsychotics market, valued at over $6 billion, is growing at approximately 10%, while the U.S. OUD market, exceeding $2 billion, is expanding at a rate of around 10%.
- Delpor's technology stands out as the sole option within the target markets capable of providing once-yearly dosing, reversibility, a one-day washout period, smooth PK, and no initiation dosing requirement.
- In recent years, progress in drug development for schizophrenia has slowed, while the pharmaceutical industry has largely overlooked substance use disorder. Delpor is working to revolutionize treatments for CNS conditions with its focus on product longevity and stability.
- Primary market research has validated the Company's adoption, pricing, and reimbursement strategies, with physician and payer feedback indicating potential for premium pricing, favorable reimbursement, and potential peak sales of $2 billion for the Company's lead asset, according to the Company's recently commissioned market research study by Symphony Health and KMK Consulting.
- The Company's regulatory strategy prioritizes the utilization of the 505(b)(2) pathway, which presents reduced technical risk while offering substantial commercial opportunities. The primary focus lies in pursuing 505(b)(2) submissions, aiming to minimize or eliminate the necessity for efficacy trials in most instances.
- Delpor holds 25 issued patents across 9 patent families, with an additional 30+ patent applications currently pending.
- Delpor's team comprises experienced management personnel with a track record of developing products in drug delivery and drug/device combination fields, as well as achieving successful exit strategies.
- The Company has raised a total of approximately $40 million, with investments from Kairos Ventures, Ulu Ventures, HIT, Seedfolio, Cloudstone, HTH (part of the Zambon Group), Mario Family Partners, and other contributors. Delpor has been awarded approximately $20 million in non-dilutive funding from the NIH, with the potential for an additional $15 million over the next 12 months. Additionally, the target for the Series C round is approximately $40 to $60 million.

Intellectual Property

The Company has been issued approximately 25 patents (9 families) with an additional 30+ patents currently pending. Some of the issued patents are valid until the end of 2033, while pending patents could potentially provide coverage until 2040. A summary of Delpor's current granted and pending patents is provided in Figure 3.

Figure 3
PENDING PATENT APPLICATIONS AND GRANTED PATENTS

Title	Country	Application Number	Filing Date	Status	Grant Number	Grant Date
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Australia	2019228497	Feb-27-2019	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Australia	2020340385	Aug-27-2020	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Australia	2017331340	Sep-22-2017	Granted	2017331340	Jan-11-2024
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Brazil	112019005542-8	Sep-22-2017	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Canada	3037531	Sep-22-2017	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Canada	3092085	Feb-27-2019	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Canada	3149545	Aug-27-2020	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	China	201780065098.0	Sep-22-2017	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	China	201980026900.4	Feb-27-2019	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Europe	17784087.3	Sep-22-2017	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Europe	19710271.8	Feb-27-2019	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Europe	20768794.8	Aug-27-2020	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Hong Kong	62020001430.1	Sep-22-2017	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Hong Kong	62021034331.0	Feb-27-2019	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Japan	2024-028252	Feb-27-2019	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Japan	2019-537753	Sep-22-2017	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Japan	2020-567467	Feb-27-2019	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Japan	2022-513687	Aug-27-2020	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Japan	2022-144103	Sep-22-2017	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Korea	10-2020-7027852	Feb-27-2019	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Korea	10-2022-7009690	Aug-27-2020	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Korea	10-2023-7019611	Sep-22-2017	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Mexico	MX/a/2023/003010	Sep-22-2017	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	Mexico	MX/a/2019/003052	Sep-22-2017	Granted	402065	Apr-25-2023
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	PCT	PCT/US2019/019837	Feb-27-2019	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	United States	16/336088	Sep-22-2017	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	United States	16/976420	Feb-27-2019	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	United States	202080075519.X	Aug-27-2020	Pending		
COMPOSITIONS FOR SMALL MOLECULE THERAPEUTIC AGENT COMPOUNDS	United States	17/637755	Aug-27-2020	Pending		
COMPOSITIONS OF OPIOID ANTAGONISTS, IMPLANT DEVICES, AND TREATMENT METHODS FOR OPIOID USE DISORDER	PCT	PCT/US2020/048289	Aug-27-2020	Pending		
COMPOSITIONS OF OPIOID ANTAGONISTS, IMPLANT DEVICES, AND TREATMENT METHODS FOR OPIOID USE DISORDER	United States	17/637756	Aug-27-2020	Pending		
DEVICE AND METHOD FOR THE SUSTAINED RELEASE OF ANTIPSYCHOTIC MEDICATIONS	United States	14/432103	Sep-27-2013	Granted	10137081	Nov-27-2018
DEVICE AND METHOD FOR THE SUSTANED RELEASE OF ANTIPSYCHOTIC MEDICATIONS	Europe	13840378.7	Sep-27-2013	Granted	2900220	Dec-12-2018
DEVICE AND METHOD FOR THE SUSTANED RELEASE OF ANTIPSYCHOTIC MEDICATIONS	France	13840378.7	Sep-27-2013	Granted	2900220	Dec-12-2018
DEVICE AND METHOD FOR THE SUSTANED RELEASE OF ANTIPSYCHOTIC MEDICATIONS	Germany	13840378.7	Sep-27-2013	Granted	2900220	Dec-12-2018
DEVICE AND METHOD FOR THE SUSTANED RELEASE OF ANTIPSYCHOTIC MEDICATIONS	Japan	2015-534757	Sep-27-2013	Granted	6538559	Jun-14-2019
DEVICE AND METHOD FOR THE SUSTANED RELEASE OF ANTIPSYCHOTIC MEDICATIONS	United Kingdom	13840378.7	Sep-27-2013	Granted	2900220	Dec-12-2018
EX-PARTE REEXAMINATION OF US PATENT 8,603,076	United States	90/013264	Jun-06-2014	Granted	8603076C1	Apr-28-2015
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	Belgium	10751445.7	Mar-11-2010	Granted	2405967	Sep-23-2020
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	Canada	2792484	Mar-11-2010	Granted	2792484	Oct-31-2017
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	Europe	10751445.7	Mar-11-2010	Granted	2405967	Sep-23-2020
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	France	10751445.7	Mar-11-2010	Granted	2405967	Sep-23-2020
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	Germany	10751445.7	Mar-11-2010	Granted	2405967	Sep-23-2020
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	Italy	10751445.7	Mar-11-2010	Granted	2405967	Sep-23-2020
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	Japan	2011-554209	Mar-11-2010	Granted	6199539	Sep-01-2017
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	Netherlands	10751445.7	Mar-11-2010	Granted	2405967	Sep-23-2020
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	Spain	10751445.7	Mar-11-2010	Granted	2405967	Sep-23-2020
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	Switzerland	10751445.7	Mar-11-2010	Granted	2405967	Sep-23-2020
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	United Kingdom	10751445.7	Mar-11-2010	Granted	2405967	Sep-23-2020
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	United States	12/918369	Mar-11-2010	Granted	9561352	Feb-07-2017
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	United States	15/388298	Dec-22-2016	Granted	10391288	Aug-27-2019
IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	United States	16/508200	Jul-10-2019	Granted	10974036	Apr-13-2021
IMPLANTABLE DEVICES FOR THE SUSTAINED DELIVERY OF AN OPIOID ANTAGONIST AND METHODS FOR TREATING INFLAMMATORY, NEUROINFLAMMATORY AND METABOLIC DISORDERS	PCT	PCT/US2023/062962	Feb-21-2023	Pending		
METHOD OF TREATING SCHIZOPHRENIA WITH AN IMPLANTABLE DEVICE FOR LONG-TERM DELIVERY OF DRUGS	United States	17/205092	Mar-18-2021	Pending		
MICROFABRICATED NANOPORE DEVICE FOR SUSTAINED RELEASE OF THERAPEUTIC AGENT	United States	95/002099	Aug-24-2012	Pending		
MICROFABRICATED NANOPORE DEVICE FOR SUSTAINED RELEASE OF THERAPEUTIC AGENT	United States	11/530729	Sep-11-2006	Granted	7955614	Jun-07-2011
MICROFABRICATED NANOPORE DEVICE FOR SUSTAINED RELEASE OF THERAPEUTIC AGENT	United States	13/756291	Jan-31-2013	Granted	9005650	Apr-14-2015
STABLE COMPOSITIONS FOR INCRETIN MIMETIC COMPOUNDS	United States	18/328678	Jun-02-2023	Pending		

Source: Delpor, Inc.

Company Leadership

Delpor is led by a highly experienced management team with proven success in pharmaceutical research, development, and commercialization. Biographies of its management team and Board of Directors are provided in the accompanying section.

Management

Tassos Nicolaou, President and Chief Executive Officer

Tassos Nicolaou serves as the Company's President and Chief Executive Officer. He is responsible for setting Delpor's strategic vision, managing its operations, as well as leading the Company's corporate development activities. Mr. Nicolaou brings over 25 years of business experience working with life sciences companies as an executive, strategy consultant, and entrepreneur. Prior to founding Delpor, he served as the Chief Executive Officer at AlphaDetail, a rapidly growing online market research company focused on the pharmaceutical and biotechnology industry. During his tenure at AlphaDetail, he was responsible for setting the company's vision, developing and executing its corporate strategy, as well as for corporate development and financial management. Under his leadership, AlphaDetail grew from an idea to an established company with over 50,000 physician members and a long list of blue-chip pharmaceutical and biotech clients. Prior to becoming an industry executive, Mr. Nicolaou spent the first half of his career as a strategy consultant. As a Senior Engagement Manager at Strategic Decisions Group (SDG), Mr. Nicolaou assisted Fortune 500 companies in strategy development and selection. While at SDG, he worked with several large pharmaceutical and biotech companies, including Pfizer, Serono (now Merck Serono), and Searle (now Pfizer), and supported senior executives in pipeline portfolio evaluation, marketing optimization, partner negotiations, as well as other key strategic and operational activities. Mr. Nicolaou also led SDG's client education practice, where he structured and delivered strategy seminars to executives worldwide. In addition to collaborating with large public corporations, Mr. Nicolaou has held several senior management positions at venture-backed, early-stage companies, where he identified and negotiated key strategic partnerships. During his career as an executive and entrepreneur, he has developed the value proposition for many startups and has launched (as well as assisted others to launch) several new ventures. Mr. Nicolaou holds a BA in Physics from Franklin and Marshall College and a master's in Management Science and Engineering from Stanford University.

Frank Martin, PhD, Chief Science Officer

Dr. Frank Martin serves as Delpor's Chief Science Officer. He is responsible for leading the Company's scientific innovation and managing all R&D activities. Dr. Martin has worked in drug delivery for over 30 years and is the inventor of Delpor's PROZOR™ technology. Prior to founding Delpor, he held positions at several pharmaceutical companies, including ALZA, Johnson and Johnson, and SEQUUS Pharmaceuticals. As the Chief Science Officer at SEQUUS, Dr. Martin assembled and led the research team which developed long circulating pegylated liposomes ("Stealth Liposomes"). A product derived from this technology is doxorubicin liposome injection (DOXIL). DOXIL is now approved worldwide for the treatment of ovarian and breast carcinoma and generates sales in excess of $800 million annually. During his tenure at SEQUUS, Dr. Martin also served as a member of the senior operating management team. His responsibilities included formulation of company-wide research strategy, management of the research unit, and supervision of the Company's network of extramural investigators (10 academic labs). He also functioned as principal technical spokesman with the FDA, Wall Street analysts, key investors, professional organizations, activist groups and commercial partners, and played a key role in setting patent policy and priorities, and in patent prosecution. Following the acquisition of SEQUUS by ALZA, Dr. Martin served as Distinguished Research Fellow at ALZA Corporation, a company devoted to the development of advanced drug delivery systems. While at ALZA, he was responsible for the assessment of new drug delivery technologies. Dr. Martin has presented to the FDA on multiple occasions and has developed a good working relationship with the Agency. He is the inventor of 45 issued U.S. patents, and several more in prosecution—all related to drug delivery systems. He has also been awarded the prestigious NIH Postdoctoral Fellowship award. Dr. Martin holds a BS in Biology from the University of San Francisco and a PhD in Biochemistry from Northwestern University.

Jay Smith, Chief Commercial Officer

Jay Smith serves as Delpor's Chief Commercial Officer. In this role, Mr. Smith is responsible for leading Delpor's commercialization efforts, leveraging more than 25 years of global biopharmaceutical leadership and experience. Prior to joining Delpor, he served as Chief Experience Officer at Intarcia Therapeutics, where he was responsible for the commercial go-to-market strategy to optimize the customer experience and drive Intarcia's innovative implant technology platform. While at Intarcia, Mr. Smith led multiple usability studies and oversaw the clinical team responsible for over 23,000 implant insertion and removal procedures in over 30 countries. Before joining Intarcia in 2013, he held senior executive commercial positions at J&J, Novartis, and Sunovion, launching several blockbuster brands. Mr. Smith is known for his customer-centric approach, his ability to access new markets and is considered a thought leader in the implant space. Mr. Smith earned his B.A. in Biology from Westmar College, and completed several executive courses at Harvard, including the 32-week Program for Leadership Development.

Board of Directors

Carl Spetzler, PhD, Director

Dr. Carl Spetzler serves as a Director on Delpor's Board of Directors. He is the founder, chairman, and CEO of Strategic Decisions Group (SDG) and is also the leader of the firm's North American Strategy Practice. Over the past three decades, Dr. Spetzler has been a leader in strategy and innovation processes, helping corporate leaders cope with the lack of explicit strategic alternatives, deal with the complexities of uncertainty and risk over long time horizons, and achieve lasting change. He works with top management and boards of directors to improve the quality of decisions and decision-making processes. His methods stress that boards be collaboratively engaged in a few truly strategic decisions rather than simply serve in an approval role on a myriad of items. Before co-founding SDG, Dr. Spetzler directed the Financial Industries and Strategic Methodologies Center at SRI International. One of his many achievements while at SRI was a consulting engagement that changed the landscape of American financial services. Dr. Spetzler and the SRI team persuaded Merrill Lynch that the time was right to offer a one-stop financial service, called the Cash Management Account (CMA). Merrill Lynch finally pursued this opportunity and by the mid-1980s more than 1 million customers used CMAs. Dr. Spetzler serves on the boards of the Illinois Institute of Technology and the Decision Education Foundation, a nonprofit organization dedicated to improving the decision-making skills of youth. In 2004, he received The Ramsey Medal, the highest honor awarded by the Decision Analysis Society of INFORMS for lifetime contributions to the field. In 2006, he was elected to the SRI Hall of Fame for his leadership in the growth of decision analysis at SRI and for his key role in instigating a fundamental change in the U.S. financial service industry. In 2008, Dr. Spetzler was named by Treasury & Risk magazine one of the 100 most influential people in finance for his work in Enterprise Risk Management. Dr. Spetzler holds a BS in Chemical Engineering as well as an MBA and a PhD in Economics and Business Administration from the Illinois Institute of Technology.

Todd Thomson, Director

Todd Thomson serves as a Director on Delpor's Board of Directors. He is currently Chief Operating and Financial Officer at Kairos Ventures. Mr. Thomson is an accomplished operating executive and entrepreneur, having served as Citigroup's CFO for 5 years and as CEO of Citigroup's $10 billion Global Wealth Management division for 2.5 years. He is a leading practitioner on M&A and business strategy, having led the acquisition and strategy efforts for Citigroup and GE Capital, as well as serving as advisor to Fortune 500 firms while at Bain & Co., Booz Allen Hamilton, and Barents Group. He has extensive investing experience as CEO of Citigroup Alternative investments, Chairman of the Citi Pension investment Committee, Chairman of the Dynasty Investment Committee, and a member of the Investment Committees for the Davidson College and World Resources Institute endowments. Prior to joining Kairos, Mr. Thomson has been Co-Founder and Chairman of Dynasty Financial Partners, the leading investment and technology platform for sophisticated independent advisors. Founded by him and his colleagues in 2010, Dynasty serves nearly 50 Registered Investment Advisor (RIA) firms nationally, with $50 billion under management. In addition to serving as Chairman, Mr. Thomson has served in several operating roles since the firm's founding, including Chairing the Investment Committee, serving as CIO, and designing and leading Dynasty Capital Strategies. Mr. Thomson received his MBA with Distinction from the Wharton School of Business and his BA in Economics from Davidson College.

Ernest Mario, PhD, Advisor and Former Director

Dr. Ernest Mario served as a Director for the Company for over eight years (until 2020) and has been a Company advisor since then. He is an industry veteran that brings a wealth of business experience in several areas, including biotech and drug delivery. Dr. Mario has served as CEO, Chairman, and Director at a variety of large life sciences companies where he has created billions of dollars in shareholder value. From 1989 to 1993, he served as Chief Executive of Glaxo, then the second-largest drug company in the world. After leaving Glaxo, he became Chairman and CEO of Alza Corporation, a major drug delivery company sold to Johnson & Johnson for $10.5 billion in 2001. Dr. Mario subsequently served as Chairman and CEO of Reliant Pharmaceuticals, which was sold to GlaxoSmithKline in 2007 for $1.65 billion. He currently is Chairman and CEO of Capnia, a private pharmaceutical company developing novel therapeutic products to treat migraine and allergic rhinitis using a proprietary gas delivery system. He is also a Venture Partner with Pappas Ventures and serves on a number of corporate boards. Dr. Mario is also active in numerous educational and healthcare organizations. He is Chairman of the American Foundation for Pharmaceutical Education, a Director of the Gladstone Foundation, and past Chairman of the Duke University Health System. He holds honorary doctorates from the University of Rhode Island and Rutgers University, the latter of which in 2001 renamed its pharmacy school the Ernest Mario School of Pharmacy.

Douglas Crawford, PhD, Advisor and Former Director

Dr. Douglas Crawford served as a director for over six years (until 2018) and has been a company advisor since then. Dr. Crawford's goal is to help entrepreneurial scientists create successful startups. To this end, he and his colleagues have systematically lowered the barriers between great ideas and successful companies. For instance, Dr. Crawford created and manages MBC BioLabs. This state-of-the-art co-working laboratory network in San Francisco and San Carlos allows entrepreneurs to rapidly generate data without getting bogged down in facility management. Rather than spending months getting a facility up and running, MBC BioLabs startups can generate important data in their first week. In the first six years, this program has helped launch 210 companies that have brought 53 programs to the clinic and have raised over $4.75 billion. This incubator program reflects Dr. Crawford's passion for startups and his eagerness to help entrepreneurs overcome challenges. Dr. Crawford is also the Managing Partner of Mission BioCapital and has overseen the investment in 52 companies, 11 of which have already enjoyed successful liquidity events (Alector, Atreca, Calithera, Cell Design Labs, iPierian, Pionyr, Principia, Redwood Biosciences, True North, Vedere, and Zephyrus). He is a board member of Avexegen, Alessa, Epiodyne, Graphwear, Invenio, Magnamosis, Magnap, Mitokinin, SiteOne (observer), and Tangible Sciences. Dr. Crawford received a PhD in Biochemistry from UCSF.

Scientific Advisory Board

Peter Weiden, MD, Chairman

Dr. Peter Weiden brings a wealth of expertise and leadership to his role as Chairman of Delpor's Scientific Advisory Board. Renowned as a Key Opinion Leader (KOL) in the field of antipsychotic formulations, Dr. Weiden's career has been marked by significant contributions to psychiatric medicine. Having served as the Executive Director of Medical Affairs at Alkermes, Dr. Weiden played a central role in shaping the development and deployment of antipsychotic medications. Prior to his tenure at Alkermes, Dr. Weiden held the position of Professor of Psychiatry at the University of Illinois, Chicago. During his time there, he made profound contributions to research, education, and clinical practice, earning recognition as a leading authority in the field.

Christoph Correll, MD

Dr. Christoph Correll, a member of Delpor's Scientific Advisory Board, brought extensive expertise in child and adolescent psychiatry to the team. Holding the distinguished position of Professor and Chair of the Department of Child and Adolescent Psychiatry at Charité University Medicine in Berlin, Germany, Dr. Correll is a globally recognized authority in his field. In addition to his role at Charité University Medicine, Dr. Correll serves as a Professor of Psychiatry at The Zucker School of Medicine at Hofstra/Northwell in New York. As a member of Delpor's Scientific Advisory Board, Dr. Correll brings invaluable insights and expertise to the development of innovative solutions for mental health care, furthering the company's mission to improve outcomes for patients worldwide.

Leslie Citrome, MD, MPH

Dr. Leslie Citrome is a member of Delpor's Scientific Advisory Board. Currently serving as a Clinical Professor in the Department of Psychiatry and Behavioral Sciences at New York Medical College in Valhalla, NY. Dr. Citrome plays a pivotal role in shaping the education and training of future psychiatric professionals. In addition to his academic contributions, Dr. Citrome serves as the Editor-in-Chief of the *International Journal of Clinical Practice*.

Andrew J. Cutler, MD

Dr. Andrew J. Cutler is a member of Delpor's Scientific Advisory Board. Currently serving as a Clinical Associate Professor in the Department of Psychiatry at Norton College of Medicine, State University of New York, Upstate Medical University in New York, Dr. Cutler plays a crucial role in educating and mentoring the next generation of psychiatric professionals. In addition to his academic role, Dr. Cutler serves as the Chief Medical Officer at the Neuroscience Education Institute in Carlsbad, California. In this leadership position, he is instrumental in developing and disseminating educational resources and programs aimed at enhancing the knowledge and skills of clinicians in the field of neuroscience and psychiatry.

Jonathan M. Meyer, MD

Dr. Jonathan M. Meyer is a member of Delpor's Scientific Advisory Board, renowned for his expertise in psychiatry and psychopharmacology. Currently serving as a Voluntary Clinical Professor in the Department of Psychiatry at the University of California, San Diego School of Medicine in La Jolla, CA, Dr. Meyer plays a vital role in shaping the education and training of future psychiatric professionals. Dr. Meyer received his medical training at Stanford University and completed his residency in psychiatry at Harvard Medical School.

Milestones

The accompanying section highlights the Company's recently achieved milestones as well as those anticipated by Delpor. These milestones illustrate the Company's progress in developing once-yearly therapeutics for sustained drug release, showcasing its commitment to innovation, as well as addressing unmet medical needs.

Recent Milestones (last 12-18 months)

- Successfully completed a Phase 2 study for DLP-114. This was the first time that a product provided schizophrenia maintenance therapy for as long as one year after a single administration. Safety, efficacy, and PK data was positive, with most patients indicating that they prefer DLP-114 over pills or injections. Greater details are provided in the accompanying press release.

  https://www.prnewswire.com/news-releases/delpors-investigational-risperidone-implant-product-provides-schizophrenia-therapy-for-up-to-one-year-after-a-single-administration-in-phase-1b2a-patient-study-301990628.html

- Launched a Phase 2b study for DLP-114 evaluating an improved device and multiple doses
- Published and presented topline Phase 2b data for DLP-114 (NEI and ASCP)
- Successfully completed a Phase 1 study for DLP-160
- Launched a Scientific Advisory Board with five schizophrenia key opinion leaders (KOLs)
- Completed a bridge funding round of approximately $8.5 million, with the majority of funds coming from new investors, including Ulu ventures, Seedfolio, and HIT

Expected Milestones (next 12-18 months)

- Complete DLP-114 Phase 2b study
- Launch pivotal Phase 3 study for DLP-114
- IND filing for DLP-160 (6-12-month naltrexone for Opioid Use Disorder [OUD] and alcoholism)
- Launch of DLP-160 Phase 1b study
- Pre-IND meeting and IND filing for DLP-208 (6-month tizanidine for spasticity)

Core Story

Delpor, Inc. ("Delpor" or "the Company") is a closely held advanced clinical stage biopharmaceutical company, harnessing a cutting-edge platform technology to create once-yearly therapeutics designed to treat chronic ailments. The Company's clinical portfolio contains a 6-12-month formulation of risperidone for combating schizophrenia, as well as a similar formulation of naltrexone to address Opioid Use Disorder (OUD) and alcohol dependence. Delpor is further actively developing 6-12-month formulations of various drugs targeting Central Nervous System (CNS) and other conditions, such tizanidine for moderate to severe spasticity, as well as undisclosed compounds in development for Parkinson's, Alzheimer's, diabetes, obesity, and other disorders.

The Company's vision, as shown in Figure 4, is rather than taking daily pills or making frequent trips to the doctor for injections every few weeks or months, individuals with chronic illnesses can opt for a once-a-year administration of the therapeutic drug product. In a 10-minute physician office visit, patients receive one administration of the product, which provides therapy for an entire year. This ensures 100% adherence to prescribed therapy without the need for daily medication concerns. This would be a year free from symptoms or relapses without the stigma of taking medication, or the daily reminder for the patient (or to those around them) that they are sick.

Figure 4

COMPANY VISION

Vision: Develop Once-Yearly Therapies for Chronic Conditions

- One Administration = Therapy for 1 Year

One Administration = Therapy for 1 Year

- 100% Medication Adherence for 1 Year
- No Symptoms or Relapses for 1 Year
- No Stigma of Taking Meds or Reminder of the Underlying Disease for 1 Year

Delpor thinks of its technology as a once-a-year cure for an incurable disease

Source: Delpor, Inc.

Delpor thinks of its technology as a once-a-year cure for an incurable disease. Importantly, the goal of the Company's technology is less frequent administrations, not less frequent doctor visits (in-person or virtual). The technology allows physicians to focus on treatment and eliminate any concerns about medication non-adherence. The physician does not need to be concerned about a patient's level of oral therapy medication adherence, or whether the patient may miss their next long-acting injection. Furthermore, with Delpor's technology, one procedure can potentially replace as many as 12 injections in one year.

The accompanying section details each of the therapeutic areas in which the Company is focused. As its most advanced candidate, DLP-114 is targeting schizophrenia patients, an extremely underserved and inadequately treated market, affecting approximately 20 million people globally with an annual incidence rate of 1.5 per 10,000 individuals. Among the top 15 leading causes of disability worldwide, about 5% of individuals with schizophrenia die by suicide, often with a higher risk at illness onset, while approximately 20% attempt suicide at least once. In the U.S., schizophrenia affects approximately 2.4 million adults annually, typically diagnosed in young people aged late teens to early 30s with symptoms manifesting earlier in males than females and resulting in an average life loss of 28.5 years. Delpor's other later stage candidate, DLP-160 for Opioid Use Disorder (OUD), is addressing a market in which there were an estimated 103,000 overdose deaths in only one year, according to the Centers for Disease Control and Prevention (CDC) 2022 data, where 89% of these overdose deaths involved fentanyl.

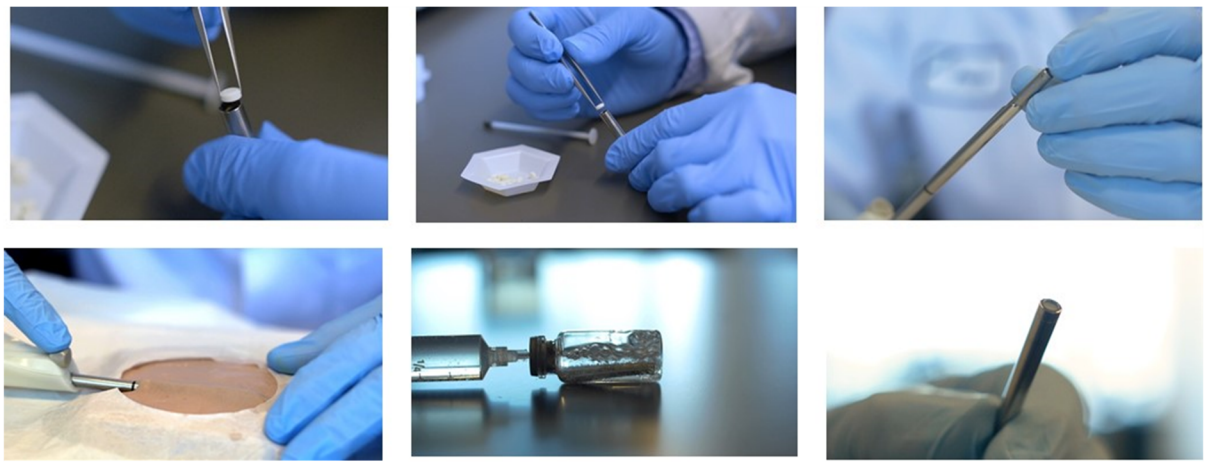
Delpor is dedicated to developing therapeutic products that improve patient outcomes and quality of life by focusing on ultra-long-acting and controlled drug release systems. The goal is to enhance medication adherence, efficacy, and patient convenience across various therapeutic areas. Delpor's commitment to research and development is driven by a vision to address unmet medical needs and revolutionize treatment options for patients worldwide.

Platform Technology

PROZOR™ Enables Once-Yearly Therapies

Delpor is pioneering technology for prolonged drug delivery through non-mechanical (passive) implantable devices, powered by **Fickian diffusion**. Named after physiologist Adolf Fick, Fickian diffusion involves molecular transport from high to low concentration areas due to particle thermal motion. This innovation caters to sustained delivery of antipsychotics and other poorly soluble small molecules, addressing a critical need in medication delivery. Delpor's PROZOR™ patented technology (illustrated in Figure 5) facilitates the sustained release of insoluble drugs, including antipsychotics, from non-mechanical implantable devices. These devices utilize a unique formulation comprising the drug, such as risperidone, naltrexone, or tizanidine, and pH-regulating excipients. The formulation, held in a small reservoir with conventional membranes, maintains an acidic pH, enhancing drug solubility. This acid generation creates a concentration gradient that enables predictable efflux through diffusion, ensuring steady drug release over time.

Figure 5
PROZOR™ PLATFORM TECHNOLOGY



Source: Delpor, Inc.

Product Specifications for Once-Yearly Treatment

Delpor has dedicated significant time and effort into developing its technology due to the numerous requirements involved in creating such a product, as summarized in Figure 6 (page 17). One crucial requirement is reversibility to achieve treatment interruption if required. Since one year is a substantial duration, the ability to reverse treatment is essential for peace of mind in situations where therapy may need to be interrupted, such as due to adverse events, pregnancy, a desire to switch to another treatment, and so forth. The product must also be comfortable and convenient for the patient, where the patient does not notice it during their daily activities. Most significantly, and the challenge Delpor has effectively tackled, is ensuring that its system is capable of delivering the drug steadily for a year without any decline.

Figure 6

PRODUCT REQUIREMENTS FOR ONCE-YEARLY THERAPY

Reversible

- Must deliver daily dose for 365 days and be reversible at any time
- Reversible in case treatment interruption is required (washout in 24 hours)

Comfortable and Convenient

- Unnoticeable by the patient during daily activities

Steady Release

- Flat PK for 1 year without decline
- Does not drift below the therapeutic threshold

Source: Delpor, Inc.

Flat pharmacokinetics (PK) is essential. The rationale behind it is if a drug's concentration decreases over time, it may eventually fall below the therapeutic threshold and become ineffective. This is the aspect that Delpor has successfully solved. To the best of the Company's knowledge, there is currently no product on the market capable of delivering drugs with flat kinetics, devoid of any decline. All existing technologies, including pills, injections, patches, implants, etc., exhibit declining PK. Enabling the Company to prolong its effectiveness for one year is what sets Delpor's technology apart.

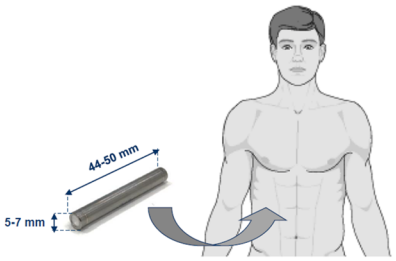
How the Product Works

Delpor's product is a compact drug-device combination resembling a small cylinder (approximately the length of a matchstick) with membranes at each end. It is implanted under the skin in the abdomen (Figure 7) through a straightforward procedure performed in a doctor's office under local anesthesia. The entire process typically takes around 10 minutes. Once placed, the device releases therapeutic levels of the drug for either six or twelve months, after which the patient returns to have it replaced with another device, typically at the same site.

Figure 7

DELPOR'S PROZOR™ PLATFORM TECHNOLOGY

- Matchstick-length device placed just under the skin in the abdomen
- Simple in-office outpatient procedure (~10 min to complete)
- After placement, the device delivers therapeutic drug levels for 6-12 months
- Device is removed and replaced after 6-12 months (same site)



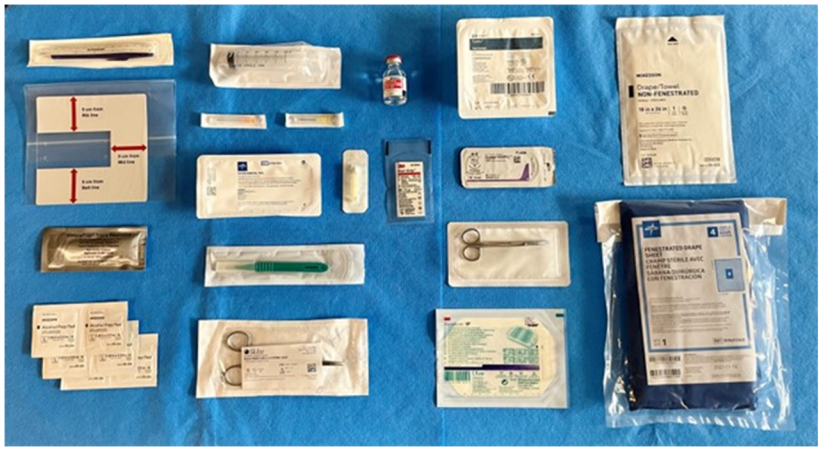
Source: Delpor, Inc.

Procedure Kit and Placement Tool

The Company's goal is to simplify the administration procedure for the end-users (physicians or nurses). For this reason, Delpor's product includes additional components: a procedure kit containing all necessary items for the nurse or doctor to perform the procedure, such as disinfectant, lidocaine for anesthesia, a disposable scalpel for incision, and absorbable sutures for closure (Figure 8). Additionally, it features a proprietary single-use placement tool, depicted in Figure 9, utilized to insert the device under the skin. The process involves disinfecting the area, anesthetizing the area with lidocaine, making a small incision, advancing the canula of the placement tool under the patient's skin until reaching the depth indicator, then retracting the actuator button to leave the device in place.

Figure 8

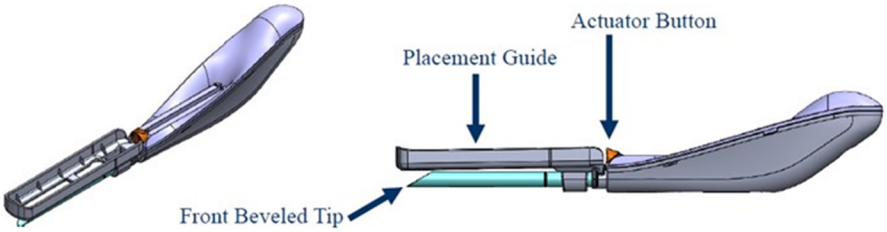
SINGLE USE PROCEDURE KIT



Source: Delpor, Inc.

Figure 9

PROPRIETARY SINGLE USE PLACEMENT TOOL



Source: Delpor, Inc.

Technology Benefits

Delpor's technology platform offers the following key benefits:

- *Improved Medication Adherence.* Non-compliance with medication significantly influences treatment effectiveness. Specifically for conditions like schizophrenia and other mental health disorders, bolstering patient adherence stands out as a prominent unmet medical requirement. Doing so holds the potential to significantly diminish relapse rates and enhance overall treatment efficacy.

- *Reversibility.* In contrast to injectable formulations, which lack reversibility, Delpor's delivery systems enable the development of long-acting therapeutic products that last up to one year, while still ensuring complete reversibility. The Company's implant device can be easily removed by any healthcare professional in the event of a drug-related adverse event needing immediate treatment interruption.

- *Improved Safety and Efficacy with Consistent PK Profile.* Peak plasma concentrations of a drug are often correlated with increased adverse events, while insufficient efficacy is commonly associated with subtherapeutic drug levels. The typical PK profile of many drugs is characterized by fluctuations, including peaks that precipitate adverse events and troughs that fall below therapeutic levels. Through Delpor's sustained-release technologies, the Company achieves a consistent PK profile, maintaining drug levels within the therapeutic range for several months. This consistency enables Delpor to enhance efficacy while utilizing lower drug doses, thereby improving safety.

- *No Treatment Initiation Required.* Several injectable treatments necessitate oral supplements or intricate dosing schedules at the outset of therapy. Delpor's implant device begins efficacy promptly following implantation, eliminating the necessity for complex dosing regimens during treatment initiation or re-initiation protocols if a dose is inadvertently missed.

- *1-Day Washout Period.* Injectable treatments entail extended washout periods, adding complexity to the dosing regimen during therapy transitions. However, upon the removal of Delpor's implant device, drug plasma levels decline to zero within a day. This rapid clearance enables patients to promptly switch to alternative therapies without concerns pertaining to the simultaneous use of different medications.

- *Cost Efficiency.* Efficiency in healthcare extends beyond the mere cost of resources; it encompasses their utilization as well. Among efforts to rein in healthcare expenses in the U.S. and globally, the focus largely centers on enhancing system efficiency rather than curtailing overall resource consumption. Strengthening treatment effectiveness and diminishing reliance on physician intervention are key strategies in seeking to manage healthcare expenditure.

- *Enabling Drug Development.* Numerous drugs possess significant therapeutic promise, yet they encounter substantial hurdles in their delivery. For instance, specific peptides exhibit high potency but suffer rapid clearance from the body. Delpor's advancements in drug delivery technology facilitate prolonged drug release over months. This sustained delivery is crucial in various scenarios, empowering certain agents to fully realize their therapeutic efficacy.

Addressing Two Categories of Unmet Needs

As depicted in Figure 10 (page 20), the Company's platform technology is addressing two distinct sets of applications and corresponding unmet needs.

(1) *Patient driven.* One category of unmet needs pertains to patients and their respective medication adherence. In certain disease areas, medication adherence is notably poor. Many relapses during the maintenance phase occur not due to the drug's inefficacy, but rather because patients fail to adhere to prescribed therapy. Delpor's most advanced efforts address two distinct areas, each with a clear unmet need: (1) mental illness, particularly schizophrenia, and (2) Opioid Use Disorder (OUD).

(2) *Molecule driven.* The second category of unmet needs arises not from patient factors, but from the properties of certain molecules within specific therapeutic areas. Some molecules exhibit short half-lives and poor oral bioavailability, rendering them unsuitable for oral delivery. One example of this is the treatment for spasticity. Two commonly used drugs in this category are tizanidine and baclofen (both muscle relaxants commonly used to treat spasticity, muscle pain, and cramps). Despite their effectiveness, both of these drugs have such short half-lives that when taken orally, their effects typically last only 3 hours. In this scenario, having such a product would essentially offer extended effectiveness in an area where no other options are available due to the limitations of existing drugs, which stem from their inherent properties.

Figure 10
PLATFORM TECHNOLOGY –TARGETING TWO CATEGORIES OF UNMET NEEDS

Unmet Needs

Patient Driven	Molecule Driven
	
Medication Adherence	*Short Half-Life, Poor Oral Bioavailability*
Examples: – Risperidone for Schizophrenia – Naltrexone for Opioid Use Disorder	Examples: – Tizanidine for Spasticity – Low Dose Naltrexone for MS, Fibromyalgia – Nalfurafine for pruritus

Source: Delpor, Inc.

Social Impact

Many of the fields in which Delpor is focused, particularly those related to mental health and addiction, carry significant social implications (Figure xx). Specifically, considerable coverage in the media is given with regard to mental illness, the opioid crisis, homelessness, and their intersections. Given the widespread attention to these issues, particularly in the U.S. amidst an opioid epidemic and rising overdose deaths, there is potential for Delpor to make a meaningful social impact.

Figure 11
DELPOR'S PIPELINE IS FOCUSING ON HIGH SOCIAL IMPACT INDICATIONS

- Overdose deaths remain a leading cause of injury-related death in the United States
- 20 to 25% of the homeless population in the US suffers from severe mental illness
- 38% of homeless people abused alcohol while 26% abused other drugs
- Overdose deaths accelerated during the COVID-19 pandemic

Schizophrenia & Addiction

Source: Delpor, Inc.

Challenges to Developing an Implantable Drug Delivery System

Developing a product based on a subcutaneous implant system presents hurdles; this explains the scarcity of technologies capable of sustaining drug delivery over extended periods. Consequently, there is a limited array of implant products on the market. Amidst this scarcity, however, there are examples of product/technology successes, as described below and on page 21.

Examples of Implant Products

Non-biodegradable implants (such as those being developed by Delpor) are currently being used in other therapeutic areas, such as for contraceptives, prostate cancer, and **central precocious puberty (CPP)**, as illustrated in Figure 12 (page 21). Non-biodegradable implants are also often used for a variety of medical purposes, such as replacing a missing or damaged joint or repairing a fracture. They can further be used to correct medical conditions, such as scoliosis or deafness.

Figure 12

EXAMPLES OF OTHER NON-BIODEGRADABLE IMPLANTS

Company	Product	API / Indication	Technology	Material
ORGANON	Nexplanon® 68 mg etonogestrel	Etonogestrel Contraception	Ethylene Vinylacetate Copolymer	Plastic
endo Pharmaceuticals	ONCE-YEARLY VANTAS (histrelin acetate) subcutaneous implant	Histerlin Prostate Cancer	Hydron® Implant Hydrogel polymers	
endo Pharmaceuticals	ONCE-YEARLY Uninterrupted SUPPRELIN LA (histrelin acetate) subcutaneous implant	Histerlin CPP	Hydron® Implant Hydrogel polymers	
Intarcia	ITCA 650	Exenatide Diabetes	DUROS®	Titanium

Source: Delpor, Inc.

Merck/Organon

Nexplanon® (etonogestrel implant), a contraceptive implant by Organon stands out, with nearly a billion dollars in revenue. Etonogestrel's potency allows for effective drug delivery through a plastic implant, which maintains its efficacy over time. While its kinetics may decline, the wide therapeutic window renders this a negligible concern.

Endo Pharmaceuticals

Another notable implant is Histrelin (VANTAs®) by Endo Pharmaceuticals, primarily used for prostate cancer treatment. However, as of 2020, VANTAs is no longer accessible due to the manufacturer's announcement of issues with the production batches of the medication. The preferred treatment for advanced prostate cancer remains Leuprolide, administered via injections. Histrelin (Supprelin LA) is also used to treat central precocious puberty (CPP), a condition accelerating puberty in children. The implant, sold as Supprelin LA, helps manage CPP symptoms, combined with addressing cases of gender dysphoria.

Intarcia Therapeutics, Inc.

Intarcia Therapeutics, Inc., represents another significant participant in the realm of implant technologies. Their proprietary subcutaneous delivery platform, the Medici Drug Delivery System™, stands out for its innovative approach. For this therapeutic, a healthcare professional performs an in-office procedure to implant the small device beneath the skin. Once in position, the device's osmotic engine, fueled by water from the extracellular fluid diffusing through a semi-permeable membrane, expands to propel a piston at a controlled pace. This mechanism ensures a consistent, steady release of the drug from the opposite end of the device. Each osmotic mini pump is tailored to contain an adequate volume of medication for up to a full year of treatment. Notably, this product, constructed from titanium and implanted into the abdomen, stands as a unique offering in its class, as further described below.

Intarcia's Medici Drug Delivery System™ Versus Delpor's PROZOR™ Platform Technology

The Intarcia Medici Delivery System™ closely mirrors Delpor's PROZOR™ platform technology in appearance, shape, material, and implantation site. However, what sets Intarcia's device apart from Delpor's is the release mechanism and the specific drugs utilized. Intarcia employs ITCA 650, a continuous subcutaneous delivery of exenatide, for diabetes treatment.

ITCA 650 successfully completed its Phase 3 clinical program, FREEDOM, targeting Type 2 diabetes through continuous exenatide delivery. After successfully implanting their product in approximately 5,000 patients and witnessing positive outcomes and patient acceptance, they secured $2 billion in funding. However, the FDA rejected Intarcia's product not due to the concept, but rather due to concerns regarding the drug, exenatide, being used, which was found to induce acute kidney injury. Crucially, the FDA's rejection of this drug stemmed from issues with the drug itself, not the overall implant approach.

Delpor views Intarcia's story as highly favorable. The non-approval of Intarcia's ITCA 650 was attributed to a safety signal linked to the peptide used and unrelated to the overall concept of implantable drug delivery technology. This incident served as validation for Delpor and its technology on a large scale, affirming the patient acceptance and efficacy of implant technology in chronic disease treatment. In the Intarcia study, the technology garnered widespread acceptance, with over 5,000 patients across 32 countries participating in the clinical program. Additionally, it validated the market strategy, both domestically and internationally, demonstrating the feasibility of commercializing a product requiring a brief 10-minute procedure.

Another aspect that was validated is the absence of significant procedure-related adverse events (AEs). There was a prevailing belief that conducting a 10-minute procedure in an outpatient setting during a regular doctor's office visit might result in higher infection rates. However, throughout the entire Intarcia study, there were no notable increases in infection rates. In fact, the infection rate for the Phase 3 study was merely 0.3%, indicating minimal risk.

An alternative lesson learned from Intarcia regarding its peptide is that the product cannot undergo sterilization prior to being dispatched to the patient. Consequently, **aseptic manufacturing** is necessary, which is a challenging process. Delpor, however, has discovered that it can **terminally sterilize** its product post-manufacturing, eliminating the need for aseptic manufacturing. This not only enhances safety but also streamlines the **Chemistry, Manufacturing, and Controls (CMC) process**, reducing overall product costs, as described below.

Two Critical Attributes

There are two critical attributes for a product such as the one being developed by Delpor, which play a pivotal role in the success in overcoming regulatory hurdles and achieving commercial success:

(1) *Human factors*, Although the placement and removal procedure is straightforward, any deviation from the Instructions for Use (IFU) by the end user may result in complications, such as infections, deep placements, etc. Delpor has followed the FDA's guidance of achieving quality by design first. Accordingly, the Company's product has been engineered to thwart any attempt by the end user (doctor or nurse) to mishandle it. Given the challenges encountered by other companies with prior implants, Delpor has placed significant emphasis on addressing these key human factors.

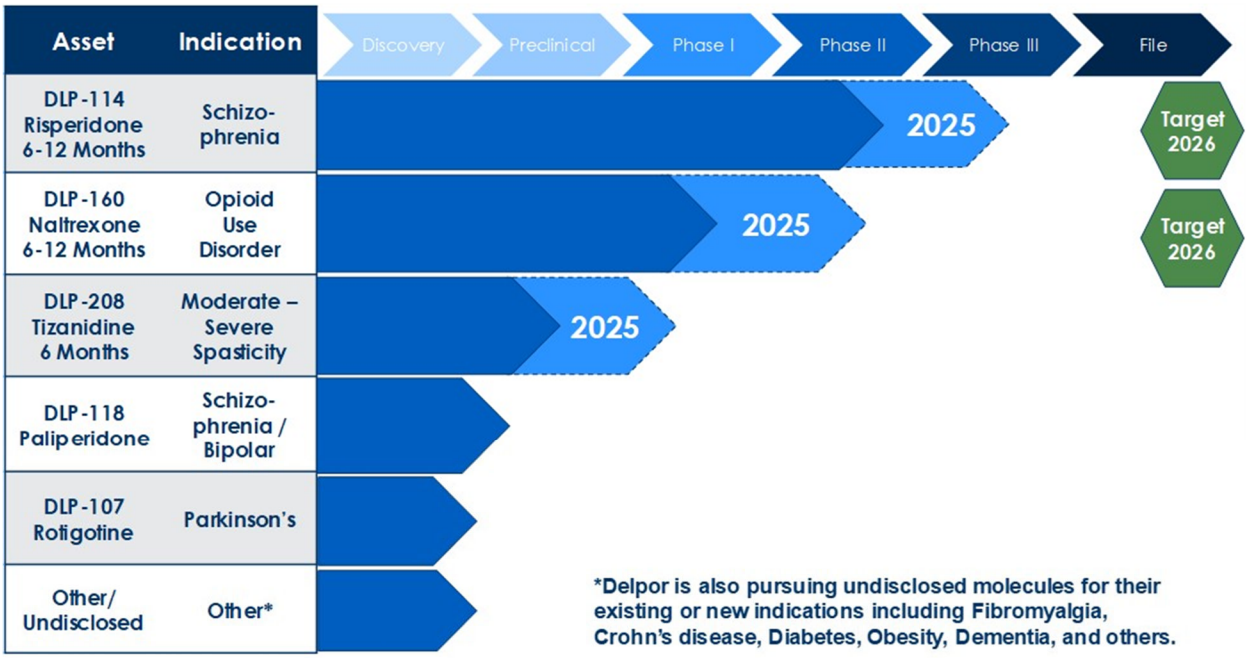
(2) *Chemistry, manufacturing, and controls (CMC).* The CMC aspect, particularly in terms of the **terminal sterilization** process, is critical to the success of the product. The ability to terminally sterilize the product significantly simplifies the manufacturing process compared to the complexities associated with aseptic manufacturing.

Therapeutic Targets

Pipeline

Delpor possesses two clinical stage assets: risperidone (DPL-114) for schizophrenia maintenance and naltrexone (DLP-160) for Opioid Use Disorder (OUD), as further summarized in Figure 13 and described in the accompanying pages. Earlier stage preclinical candidates in the Company's pipeline include tizanidine (DLP-208) for moderate to severe spasticity, paliperidone (DLP-118) for schizophrenia/bipolar disorder, rotigotine (DLP-107) for Parkinson's, as well as earlier stage undisclosed candidates targeting Type 2 diabetes, weight loss, multiple sclerosis (MS), fibromyalgia, Crohn's disease, dementia, among others.

Figure 13
DELPOR'S PLATFORM & PIPELINE FOCUSED ON CHRONIC CNS DISEASES



Source: Delpor, Inc.

- ***DLP-114 (Once-Yearly Risperidone for Schizophrenia).*** Delpor has completed a Phase 2 study for DLP-114 for schizophrenia, yielding promising clinical data indicating positive patient response and marking the first instance in history where a product in this domain has offered year-long therapy following a single administration—a breakthrough for this patient population. Out of the 28 participants in the study, only one exhibited signs of impending relapse, while the rest remained stable throughout. Consequently, both safety and efficacy data were favorable.

- ***DLP-160 (Once-Yearly Naltrexone for OUD).*** Naltrexone, prescribed for OUD, is one of only three drugs currently utilized for this condition. Unlike methadone and buprenorphine, which are partial agonists and essentially opioids themselves, naltrexone functions as an antagonist. This means that it prevents individuals from experiencing the high associated with opioids, making it necessary for patients to be drug-free before starting naltrexone treatment. This poses a significant issue as patients often struggle with medication adherence and consequently experience relapses. Delpor completed a Phase 1 study in Australia and is now preparing to transition to a Phase 1b or Phase 2 study in the U.S. during the next 12 months.

- ***DLP-208 (6-Month Tizanidine for Spasticity).*** Delpor possesses preclinical data and anticipates submitting the Investigational New Drug (IND) application within the next 12 months for tizanidine in treating moderate to severe spasticity, followed by clinical trials.

- ***Other Candidates.*** The Company has also evaluated multiple other drugs, predominantly focusing on CNS, but also on other conditions. These include paliperidone for schizophrenia, rotigotine for Parkinson's, as well as several other undisclosed molecules for Type 2 diabetes, weight loss, MS, fibromyalgia, Crohn's disease, dementia, and others.

Schizophrenia

Schizophrenia is a chronic and severe mental disorder characterized by a range of cognitive, emotional, and behavioral symptoms. It affects how a person thinks, feels, and behaves, often leading to disruptions in daily functioning. Symptoms of schizophrenia can include hallucinations, delusions, disorganized thinking, reduced motivation, social withdrawal, and impaired cognitive abilities.

Schizophrenia stands as one of the leading contributors to disability in developed nations, impacting roughly 1.1% of the population. Globally, schizophrenia is estimated to affect approximately 20 million people, making it one of the most prevalent psychiatric disorders worldwide. In the U.S., approximately 2.4 million people are affected by schizophrenia, with 2.3 million of these individuals having been diagnosed and 1.6 million being treated. Of this treated population, only 200,000 are being treated with LAIs. In addition to medication-based treatments, other approaches, such as psychotherapy, social support programs, and lifestyle interventions are utilized to manage schizophrenia and improve the quality of life for affected individuals. Despite the availability of treatments, there remains a critical need for ongoing research and innovation to develop more effective therapies, reduce the burden of symptoms, and enhance long-term outcomes for individuals living with schizophrenia.

Lack of Medication Adherence

A key issue in managing schizophrenia is ensuring patients stick to their medication regimens, where studies suggest that only 30% to 70% of patients adhere to their prescribed medications. This lack of adherence significantly undermines the effectiveness of neuroleptic drugs in preventing hospitalizations, contributing to approximately 40% of all relapses. Discontinuation of medication leads to a roughly 74% relapse rate within eighteen months and 80% of patients experience multiple relapses over the first five years of treatment compared to 40% for those who maintain treatment. Additionally, schizophrenia alone occupies 20% of hospital bed-days and more than half of all psychiatric beds in the U.S. Each relapse further diminishes the long-term outlook for the patient, making it increasingly difficult to regain previous levels of functioning.

The Cost of Medication Non-Adherence

The cost of medication noncompliance for schizophrenia in the U.S. medical system is significant. According to the *Journal of Clinical Psychiatry*, economic burdens associated with schizophrenia are high, with an estimated cost of more than $150 billion annually in the U.S., based on 2013 figures. Non-adherence to psychiatric treatment by patients with schizophrenia and related disorders is associated with higher medical service utilization and increased personal and societal medical costs. Additionally, beyond direct healthcare expenses, relapse incurs additional costs, such as productivity loss, utilization of social services, and involvement of criminal justice resources. These direct healthcare costs represent around 30% of the total financial impact of schizophrenia, equating to a yearly cost of non-adherence exceeding $2.3 billion.

The Impact of Long-Acting Formulations

The introduction of **depot formulations** into the schizophrenia treatment landscape has showcased the beneficial effects of long-acting formulations on clinical outcomes. A milestone in this realm occurred in 2003 with the launch of the first atypical depot, Risperdal® Consta®, described on pages 30-31. A two-week injectable formulation of risperidone rapidly demonstrated the pharmacoeconomic advantages of extended-release formulations by enhancing patient adherence.

Limitations of Depot Formulations

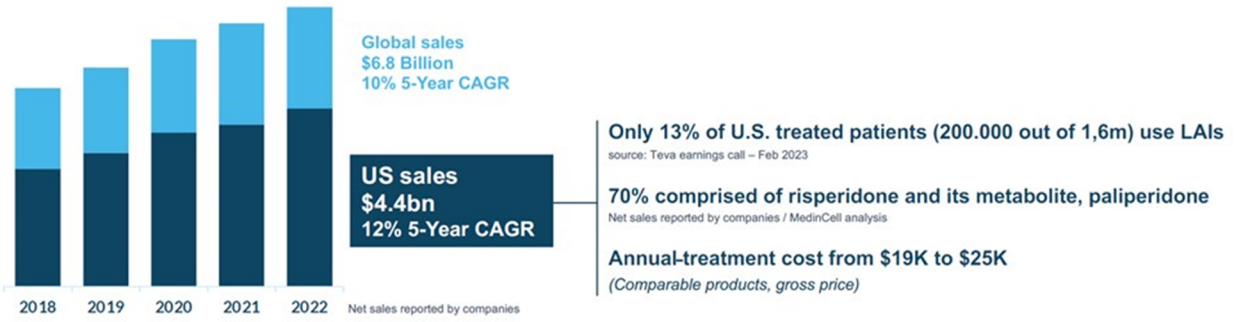
Despite demonstrating notable advantages, depot formulations exhibit certain limitations, such as:

- Technical constraints in maintaining consistent blood levels beyond a few weeks.
- Safety concerns as the drug cannot be withdrawn if necessary.
- Treatment initiation (or re-initiation after a missed dose) resulting in a cumbersome dosing schedule.
- Complications of switching treatments due to long washout periods.
- Poor PK profiles, which can lead to side effects at elevated plasma levels.

Antipsychotics Market and Competitive Advantage

The market for treatments targeting schizophrenia is substantial, reflecting both the prevalence of the disorder and the need for effective interventions. Globally, the market for antipsychotics stands at roughly $15 billion, with the long-acting segment comprising approximately $6.8 billion. In the U.S. alone, this market amounts to about $4.4 billion with a CAGR of 10%, as summarized in Figure 14 (Source: MediCell). Although the long-acting segment represents more than a third of the total market value, it accounts for only around 13% in terms of prescriptions. This indicates that the majority of patients still rely on oral medications, highlighting significant untapped potential for expansion.

Figure 14
LONG-ACTING ANTIPSYCHOTICS GROWTH

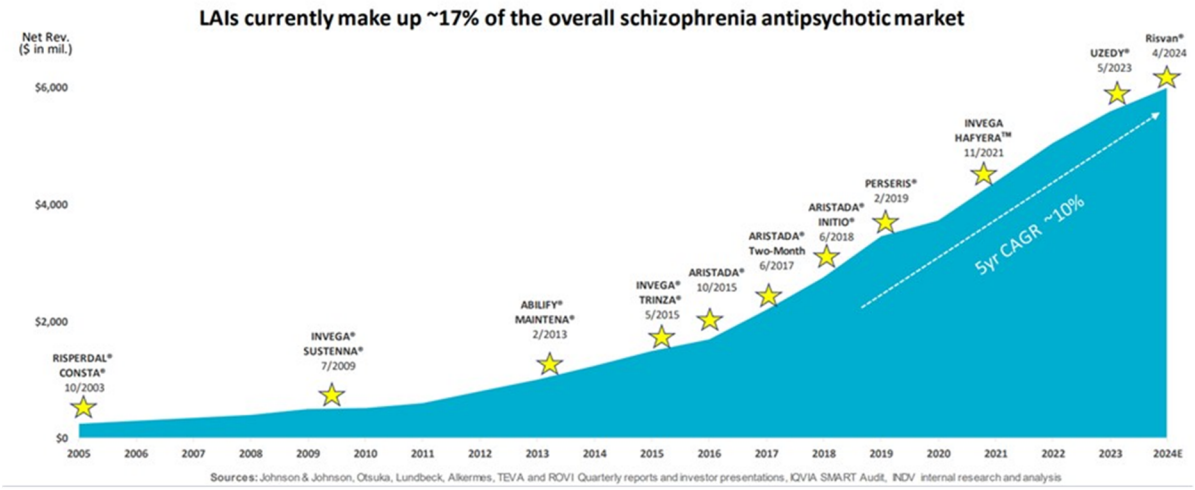


Source: MedinCell SA.

The current LAI U.S. market is made up the products listed in Figure 15. These medications have shown considerable efficacy in mitigating or alleviating symptoms of the illness; yet, maintaining treatment success poses challenges due to suboptimal patient adherence. Moreover, despite their effectiveness, many atypical antipsychotics still carry the risk of extrapyramidal symptoms (EPS) when administered at elevated plasma concentrations. Delpor seeks to create annual therapies that surpass the constraints of depot technologies, as the Company believes that these new sustained release treatments could enhance clinical outcomes and offer distinctive advantages, as described below.

Figure 15

ANTIPSYCHOTIC LONG ACTING INJECTABLES (LAI) U.S. MARKET



Source: Indivior PLC and Johnson & Johnson, Otsuka, Lundbeck, Alkermes, TEVA and ROVI Quarterly reports and investor presentations, IQVIA SMART Audit, INDV internal research and analysis.

DLP-114 (Once-Yearly Risperidone for Schizophrenia)

Delpor's DLP-114 is an investigational implant device, approximately the length of a matchstick, which provides continuous dosing of risperidone. The device is implanted into the abdominal area and can last for 6 to 12 months. There are four areas which makes DLP-114 unique from currently available LAI antipsychotics on the market, as summarized below and in Figure 16 (page 27).

(1) *Up to one-year dosing.* While most injectables offer durations of about 1 or 2 months (with only two exceptions), Delpor's product stands out as it can provide a duration of one-year post-placement.

(2) *Reversable.* Unlike traditional injectables, Delpor's product offers easy reversibility, allowing for removal within five minutes, providing flexibility in therapy interruption situations.

(3) *Smooth PK.* Competing injectables rely on a large initial burst to maintain therapeutic plasma levels at the end of the dosing period, which can lead to specific side effects at high plasma levels. In contrast, Delpor's technology ensures smooth PK levels, achieving comparable efficacy with lower drug exposure.

(4) *No initiation dosing required.* Johnson & Johnson has two paliperidone products—one goes out for three months and the other goes out for six months. However, both of those products require patients to be on weekly and monthly injections for at least four months prior to switching to the less frequent dosing. With Delpor's product, a patient stable on daily oral dosing can be switched immediately to a 6-month or a 12-month dosing.

Figure 16
COMPETITIVE ADVANTAGE

	LAIs	Delpor's Products
Up to 1-Year Dosing	X	✓
Reversible	X	✓
Smooth PK	X	✓
No Initiation Dosing Required	X	✓

Source: Delpor, Inc.

Another distinguishing feature of Delpor's product is its 100% adherence rate. Unlike oral therapies and LAIs, which often experience significant drop-offs in patient compliance, Delpor's product ensures continuous treatment. With oral medications, there is typically a 50% drop-off within the first three to six months, while LAIs generally have a patient lifetime value of around six months (sometimes slightly longer), before they discontinue treatment. By offering both six-month and twelve-month options, Delpor's product significantly impacts the lifetime value of the patient. Patients only need to receive the drug product once every six months or once a year for a dose, ensuring continuous treatment for the following six months or year.

Interruptions in antipsychotic therapy often lead to heightened symptoms and a higher risk of relapse. An effective strategy to enhance medication adherence is through long-acting formulations, commonly administered via injection. While implantable technology has proven successful in several therapeutic domains, such as contraception as well as treatments for prostate cancer and central precocious puberty (CPP), as described on pages 20-22, its utilization for maintaining schizophrenia treatment remains unexplored. Delpor's investigational risperidone implant (DLP-114) has been engineered to sustain therapeutic drug levels for up to 12 months.

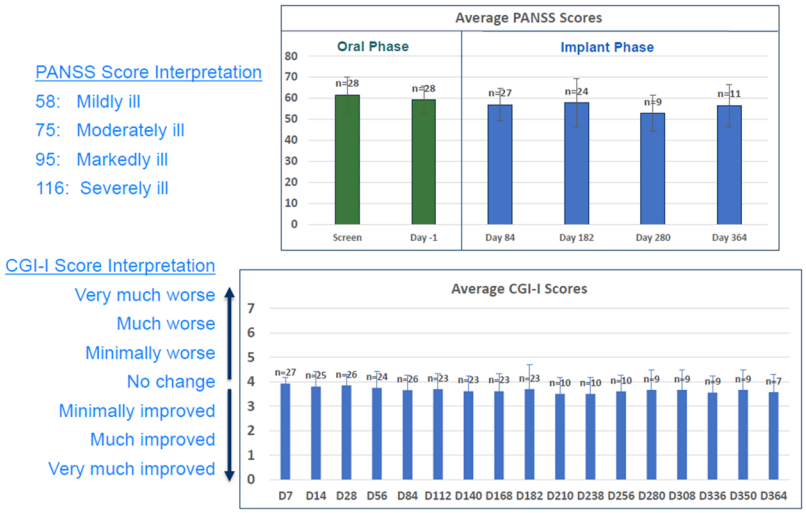
DLP-114 Phase 2 Study: Feasibility of a Risperidone Implant for the Maintenance Treatment of Schizophrenia for Up to 12 Months After Single Administration

A study was conducted as an open-label investigation to assess the safety, tolerability, and PK of transitioning from oral risperidone to DLP-114. The study involved two phases: an oral phase and an implant phase. Participants diagnosed with schizophrenia, stabilized on a 2-3 mg dose of oral risperidone for at least two weeks, were randomly assigned to receive either 6- or 12-month DLP-114 implant devices. Each participant underwent implantation of DLP-114, a brief procedure lasting around 10 minutes, conducted under local anesthetic using a custom placement tool. Primary endpoints included subject safety and local tolerance, while secondary endpoints encompassed active moiety (risperidone + 9-OH-risperidone) PK, as well as symptom assessment via PANSS (Positive and Negative Symptom Schedule) and CGI-I (Clinical Global Impression-Insanity) scores, which are commonly used instruments for assessing the severity of mental illness, specifically schizophrenia.

Twenty-eight participants were enrolled, divided equally between the 6-month and 12-month groups. During the study, two participants were lost to follow-up, and one requested early removal of the implant. A single serious adverse event unrelated to the treatment (pulmonary embolism) was reported. Both the placement and removal procedures were well tolerated. Treatment-related adverse events were generally mild and included symptoms such as implant site pain, drowsiness, ecchymosis, increased appetite, insomnia, and headache. The PK profile in both groups demonstrated near zero-order kinetics throughout the study, with average steady-state active moiety plasma concentrations ranging between 7-13 ng/mL. One participant was withdrawn from the study due to signs of impending relapse, while all other participants remained clinically stable for the duration of the study. Average PANSS scores ranged from 50-60, and CGI-I scores ranged from 3-4, with comparable results observed between the oral and implant phases. A summary of this efficacy data is provided in Figure 17 (page 28).

Figure 17

RISPERIDONE EFFICACY DATA

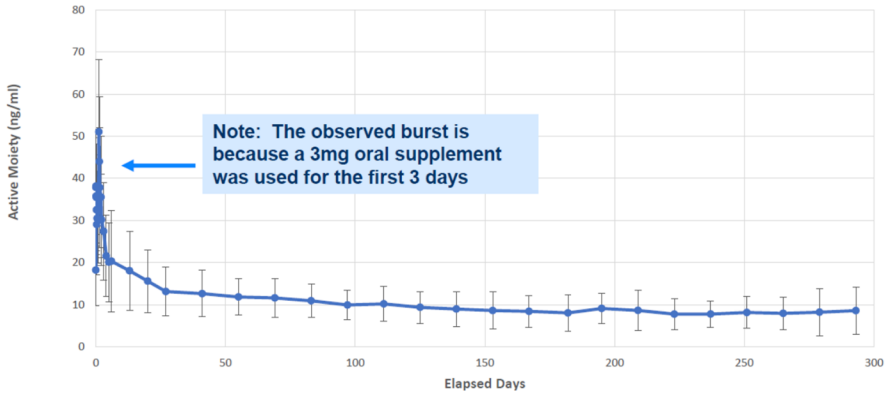


Source: Delpor, Inc.

Over the course of 12 months, DLP-114 demonstrated good tolerability, with the placement and removal procedures also being well tolerated. Average PANSS and CGI-I scores showed similarity between the oral and implant treatment phases, indicating a potential comparable therapeutic benefit of DLP-114 to oral Risperidone, although further evidence is needed to confirm this. Plasma concentrations of risperidone and 9-OH-risperidone remained relatively constant for 6-12 months (Figure 18). Future studies are anticipated to explore strategies for achieving higher plasma concentrations and enhancing dosing flexibility.

Figure 18

PHASE 2 PRELIMINARY CLINICAL DATA (DLP 114 RISPERIDONE) STUDY ONGOING



Source: Delpor, Inc.

Update: On Track With Schizophrenia Implant Late-Stage Trials

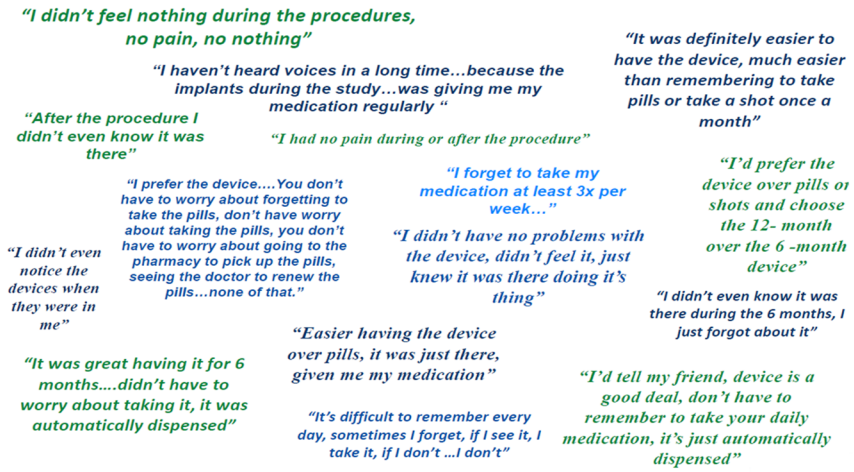
The Company recently launched the Phase 2b study for DLP-114, which is expected to go on until the end of the year. Subsequently, Delpor plans to initiate both a registrational Phase 3 trial and a safety study in parallel, which are expected to be sufficient for product approval. In the Phase 2b study, Delpor anticipates enrolling approximately 35-40 schizophrenia patients across sites based in the U.S. Approximately 50-80 participants are expected to be enrolled into the registrational trial and 100-150 participants in the safety study, with a possibility to include countries outside of the U.S. The trials are expected to focus only on stable schizophrenia patients as the Company aims to get DLP-114 approved as a maintenance therapy.

Testimonials

At the conclusion of the completed Phase 2 study, Delpor was able to collect information from all patients, including interviews and testimonials, revealing remarkable anecdotes. Many patients reported significant alleviation of symptoms, including hearing voices, seeing shadows, and insomnia upon starting the product. This qualitative market research conducted by the Company garnered positive feedback from most patients, who expressed a preference for the Delpor product over traditional injections. Figure 19 depicts some of these testimonials.

Figure 19

MAJORITY OF PATIENTS PREFER THE IMPLANT TO PILLS OR INJECTIONS



Source: Delpor, Inc.

NIMH Funding Supports Research for DLP-114

Research for DLP-114 is backed by the National Institute of Mental Health (NIMH) of the National Institutes of Health (NIH) under Award Number R44MH094036. This award signifies that the project has received funding support from the NIMH, indicating the Institute's recognition of its potential significance in addressing mental health challenges, particularly in treating schizophrenia. The NIH is a prominent federal agency in the U.S. responsible for supporting biomedical and health-related research, making this grant a significant endorsement of Delpor's innovative approach to drug delivery for mental health disorders. The funding provided by the NIMH supports various aspects of the research and development process, including preclinical studies, clinical trials, and regulatory activities, ultimately advancing the potential availability of DLP-114 as a novel treatment option for individuals affected by schizophrenia.

Suitable Patients for DLP-114

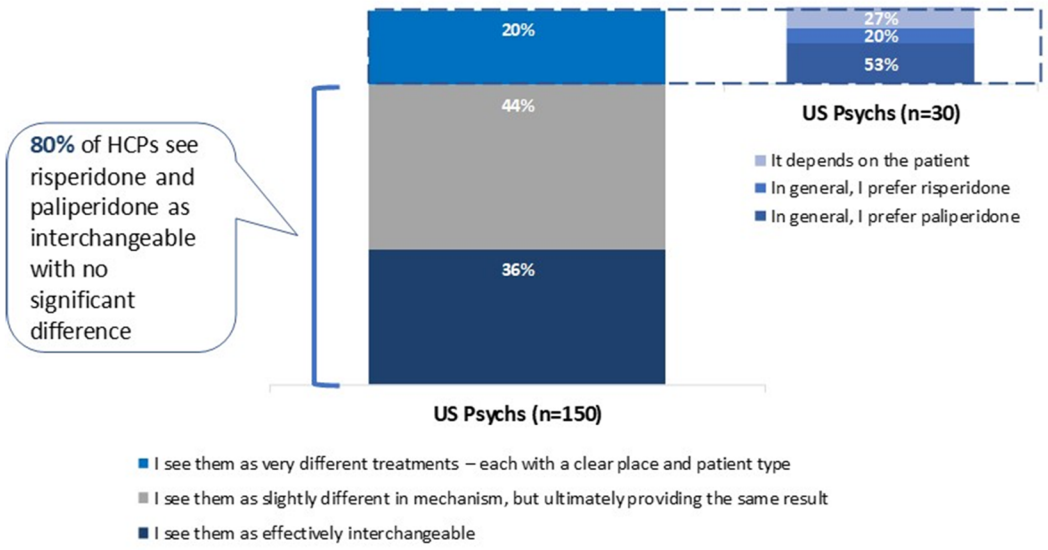
With approximately 85% of schizophrenia patients using oral drugs, it is estimated that 26% of patients on oral anti-psychotic therapy and 37% patients on LAI anti-psychotic therapy are good candidates for DLP-114, as well as 22% of bipolar patients who would consider switching over to DLP-114 as the long-acting treatment, assuming no issues/challenges with regard to access.

Currently Available Schizophrenia Drugs in LAI Arena

LAIs are an important part of the treatment landscape for schizophrenia, with the market experiencing robust growth with double-digit increases attributed to the launch of numerous products. Divided into first-generation antipsychotics (FGAs) and second-generation antipsychotics (SGAs), there are currently 11 available FDA-approved second-generation long-acting injectable antipsychotics, including aripiprazole (3), olanzapine (1), paliperidone (3), and risperidone (4), with risperidone and paliperidone collectively representing approximately 40% of all prescriptions in this segment. Although oral products do dominate the majority of the market, LAI prescriptions account for around one-third of the market's value in terms of revenue.

The following drugs are the leading participants in the LAI space: Risperdal Consta® (risperidone); Invega Sustenna® (paliperidone palmitate), Abilify Maintena® (aripiprazole), Invega Trinza® (paliperidone palmitate), and Abilify Maintena® (aripiprazole), as described below and further detailed in the Competition section (pages 42-44). These medications are often preferred for individuals who cannot adhere to an oral medication regimen or who experience more side effects from oral medications. Worth noting is that 80% of healthcare providers perceive risperidone and paliperidone as either similar or interchangeable given they are the most prescribed antipsychotics, while among the remaining 20% who distinguish between them, approximately half exhibit a preference for paliperidone over risperidone (Figure 20).

Figure 20
RISPERIDONE VERSUS PALIPERIDONE



Source: Delpor, Inc. and KMK Market Research Study.

- *Risperdal Consta® (risperidone).* Risperdal Consta® is a long-acting injectable (LAI) formulation of risperidone, a potent antipsychotic medication used in the treatment of schizophrenia and bipolar disorder. Risperdal Consta® is administered as a biweekly injection, providing a convenient alternative to daily oral medications. With its proven efficacy, safety, and tolerability profile, this LAI is a valuable option for individuals requiring long-term management of psychiatric conditions. In the U.S., Risperdal Consta® is manufactured by Alkermes and marketed by Jansen Pharmaceuticals (a subsidiary of Johnson & Johnson). It is the first FDA-approved, long-acting, injectable, atypical antipsychotic indicated for the maintenance treatment of Bipolar I Disorder as monotherapy.

- Recently, Teva Pharmaceuticals introduced a generic form of risperidone, offering an extended-release injectable suspension as an alternative to Risperdal Consta®. Approved by the FDA on December 5, 2023, this generic version is available in various strengths, including 12.5 mg, 25 mg, 37.5 mg, and 50 mg per vial. Moreover, Teva, in collaboration with MedinCell, has received FDA approval for UZEDY™ (risperidone) extended-release injectable suspension for the treatment of schizophrenia in adults. This treatment option offers a long-acting formulation with flexible dosing intervals (further detailed on page 43).

- *Perseris® (risperidone).* Perseris® is an LAI formulation of risperidone, an antipsychotic medication used in treating schizophrenia in adults. This medication provides sustained release of risperidone as a once-monthly injection, offering continuous symptom control and stabilization for patients and a convenient alternative to daily oral medications. Perseris® is manufactured by Indivior PLC.

- *Invega Sustenna® (paliperidone palmitate).* Invega Sustenna® is an LAI formulation of paliperidone palmitate, an antipsychotic medication used in the treatment of schizophrenia. This medication provides sustained release of paliperidone over a period of one month, offering continuous symptom control and stabilization for patients. Administered as a once-monthly injection, Invega Sustenna® provides a convenient alternative to daily oral medications. The drug is manufactured by Jansen Pharmaceuticals (a subsidiary of Johnson & Johnson).

- *Invega Trinza® and Invega Hafyera® (paliperidone palmitate).* Invega Trinza® and Invega Hafyera® are both extended-release injectable formulations of paliperidone palmitate, an antipsychotic medication used in the treatment of schizophrenia. The main difference between the two is the dosing frequency. Invega Trinza® provides sustained release of paliperidone over an extended period of three months, requiring administration once every three months. Invega Hafyera® provides sustained release of paliperidone over a period of six months, requiring administration once every six months. Both medications offer continuous symptom control and stabilization for patients with schizophrenia, providing convenient alternatives to more frequent dosing regimens. They are both developed by Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson. Greater details of the initial dosing requirement for Invega Trinza® and Invega Hafyera® are described below.

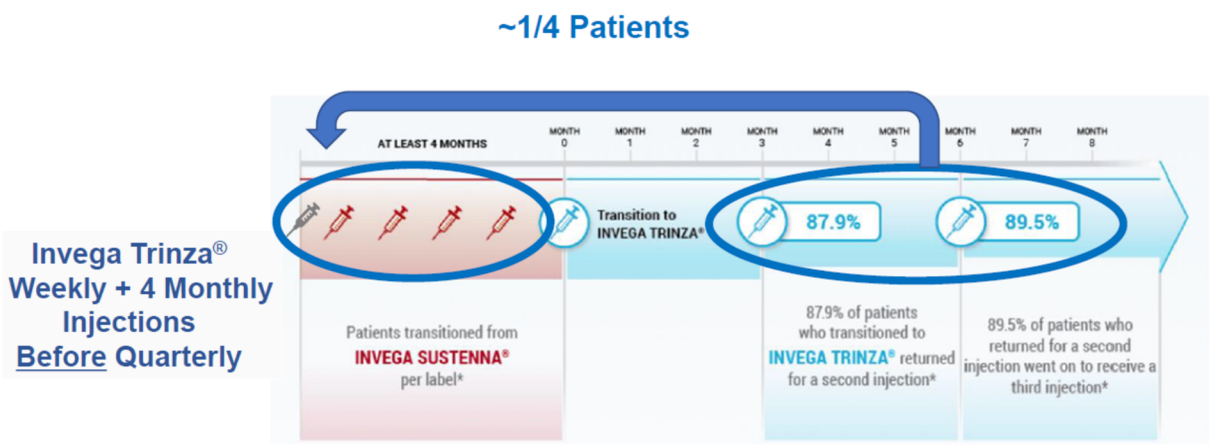
  Initiation Dosing Requirement – Invega Trinza® and Invega Hafyera®

  With regard to Invega Trinza® (3 months) and Invega Hafyera® (6 months), which offer three and six-month formulations of paliperidone, respectively, patients using these products typically undergo at least four monthly injections of initiation dosing before transitioning to less frequent dosing intervals. This initiation dosing requirement also applies to patients who miss a dose. According to the manufacturer, up to 20-25% of patients may fail to return for their subsequent injection within three to six months after receiving their initial Invega Trinza® injection. In such cases, patients must resume monthly initiation dosing before transitioning back to quarterly dosing. This process is illustrated in Figure 21 (page 32).

- *Abilify Maintena® (aripiprazole).* Abilify Maintena® is an LAI formulation of aripiprazole, an antipsychotic medication used in the treatment of schizophrenia. This medication provides sustained release of aripiprazole over a period of one month, offering continuous symptom control and stabilization for patients. Abilify Maintena® provides a convenient alternative to daily oral medications for individuals requiring long-term management of schizophrenia. Notably, it is the sole FDA-approved maintenance therapy for Bipolar I Disorder in adults, offering up to two months of symptom management with a single dose. Abilify Maintena® was developed by Otsuka Pharmaceutical Co., Ltd. and Lundbeck.

Figure 21

INITIATION DOSING REQUIREMENT – INVEGA TRINZA® AND INVEGA HAFYERA®



Source: Janssen Pharmaceutica NV.

DLP-114 Versus Other Injectable Products

Figure 22 provides a comparison of Delpor's DLP-114 to other injectable products available on the market.

Figure 22

COMPARISON OF DLP114 TO INJECTABLE PRODUCTS

	Risperdal® Consta®	Perseris®	Invega® Sustenna®	Invega Trinza® Invega Halfyeara®	DLP-114
Duration	2 Weeks	4 Weeks	4 Weeks	3-6 Months	6-12 Months
API	Risperidone	Risperidone	Paliperidone	Paliperidone	Risperidone
Reversibility	Not Reversible	Not Reversible	Not Reversible	Not Reversible	Reversible
Initiation Dosing & Re-Initiation When Missing a Dose	Oral Supplements For 3 weeks	No Initiation but Requires 3 Doses to reach Steady State	2 Initiation Doses Re-Initiation Needed if Dose is Missed*	4 Months Sustenna Initiation (6 doses) & Re-Initiation Needed If Dose is Missed **	No Initiation or Re-Initiation Required
Drug Accumulation/ Switching to Another Product	A few Weeks Washout	A few Weeks Washout	Several Weeks Washout	Several Months Washout***	1 Day Washout
PK	Peaks & Troughs	Peaks & Troughs	Peaks & Troughs	Peaks & Troughs	Smooth

* Requires initiation doses on Days 1 & 8 before monthly injections begin, and Re-initiation if dose is missed by 2+ weeks

** Requires Re-initiation Regimen with 2 Sustenna injections (Days 1 & 8) if Trinza dose is missed by 1-6 months

requires full Re-initiation Regimen with at least 6 Sustenna injections if Trinza dose is missed by over 6 months

*** Requires 3 tier dose escalation schedule during ~6 months for switching to oral paliperidone. No data available for switching to another drug.

Safety data involving concomitant use of Trinza with other antipsychotics is limited, Paliperidone has been detected in plasma (7% of Cave) up to 18 months after a single-dose administration

Source: Delpor, Inc.

Delpor-Sponsored Independent Market Research Study for DLP-114

In seeking to create a value proposition for the Company's DLP-114, Delpor recently sponsored an independent market research study. The sponsored study, conducted in collaboration with Symphony Health and KMK Consulting, spanned the U.S. and the five major European countries and engaged 195 high-prescribing physicians in a quantitative 30-minute survey. In addition, the research also included 45 psychiatrists that were part of a qualitative 60-minute tele-depth interview (as shown in Figure 23). Symphony Health is a health sciences company that provides data analytics, technology solutions, and actionable insights for healthcare and life sciences manufacturers, payers, and providers. KMK Consulting is a management consultancy firm that provides strategic planning, operational improvement, and organizational development services to a variety of industries.

Figure 23

DLP-114: INDEPENDENT MARKET RESEARCH STUDY

Qualitative 60-minute tele-depth interviews	US	UK	DE	FR	IT	ES	Total
Psychiatrist	20	5	5	5	5	5	45
NP/PA/APN	5	-	-	-	-	-	5
Payer	5	2	2	2	2	2	15

Quantitative 30 Minute Survey	US	UK	DE	FR	IT	ES	Total
Psychiatrist	150	45	-	-	-	-	195

Source: Delpor, Inc.

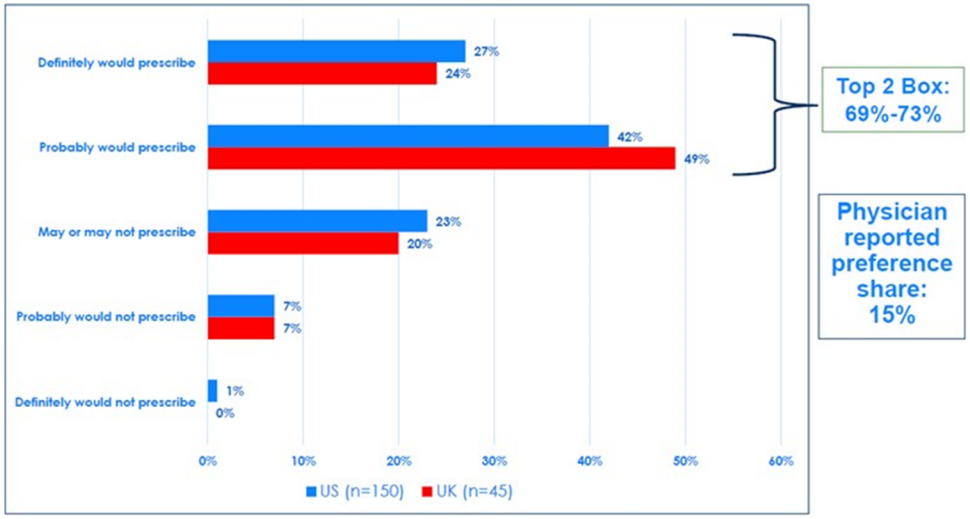
The Target Product Profile (TPP) of DLP-114 describes it as a drug/device combination product that delivers therapeutic levels of risperidone for 6 or 12 months through a device inserted under the skin in the abdomen. The device is indicated for patients diagnosed with schizophrenia or schizoaffective disorder who are stable on oral risperidone. The discussion guide included questions about the preferences in treatment, triggers for moving patients to LAI, the role of psychiatrists in administering LAIs, the preferred duration of LAIs, initial thoughts and feedback on DLP-114, potential patient segments for the product, and the impact on the treatment of patients with schizophrenia. The study incorporated secondary research, which encompassed the final reports from KMK detailing commercial insights into the market, as well as specific feedback about Delpor's product from physicians and patients.

The objectives of the study included several key areas. Initially, the study delved into the current patient journey and treatment algorithm. By doing so, it was able to gain insights into the existing logistical and emotional gaps within the treatment algorithm, with a specific focus on identifying potential opportunities for DLP-114. Furthermore, the study aimed to identify the drivers and barriers influencing the adoption and uptake of DLP-114. It investigated feedback on the TPP in schizophrenia and evaluated its impact in bipolar disorder. Moreover, the study aimed to explore perceptions of and receptivity to DLP-114, examining variations across patient types, healthcare provider (HCP) segments, and payer perspectives. It also aimed to assess how DLP-114 may position itself within the competitive landscape among other LAIs (such as those profiled on pages 30-31). Finally, the study intended to define target patient segments based on both clinical and non-clinical characteristics. The study was carefully designed to delve into key aspects, such as product adoption, pricing strategies, and reimbursement potential. To ensure the accuracy and relevance of the findings, the study specifically targeted high-prescribing physicians, who hold influence in driving adoption within the medical community.

The study offered compelling evidence in support of DLP-114, indicating widespread acceptance among physicians, payers, and patients, as shown in Figure 24. Notably, all payers consulted by KMK across various countries expressed readiness to cover the product if priced equivalently to LAIs, aligning with Delpor's pricing strategy. With Delpor intending to price DLP-114 similarly to injectables, estimated at around $20,000 annually in the U.S., payers have indicated that they are inclined to cover its costs. Moreover, approximately 70% of physicians expressed their intent to prescribe the product, with a reported physician preference share of 15%. With this in mind, KMK's modeling conservatively reduced the preference share to 5%, and projected peak sales could potentially exceed $2 billion. As it relates to market expansion, 22% of bipolar patients are identified as strong candidates for DLP-114, while a substantial 73% of physicians express their willingness to transition as many as 22% of their patients currently on other antipsychotics to oral risperidone as a precursor to transitioning them to DLP-114.

Figure 24

RESEARCH RESULTS SUGGEST THAT c.70% OF PHYSICIANS WOULD BE INTERESTED IN PRESCRIBING DLP-114



Source: Delpor, Inc.

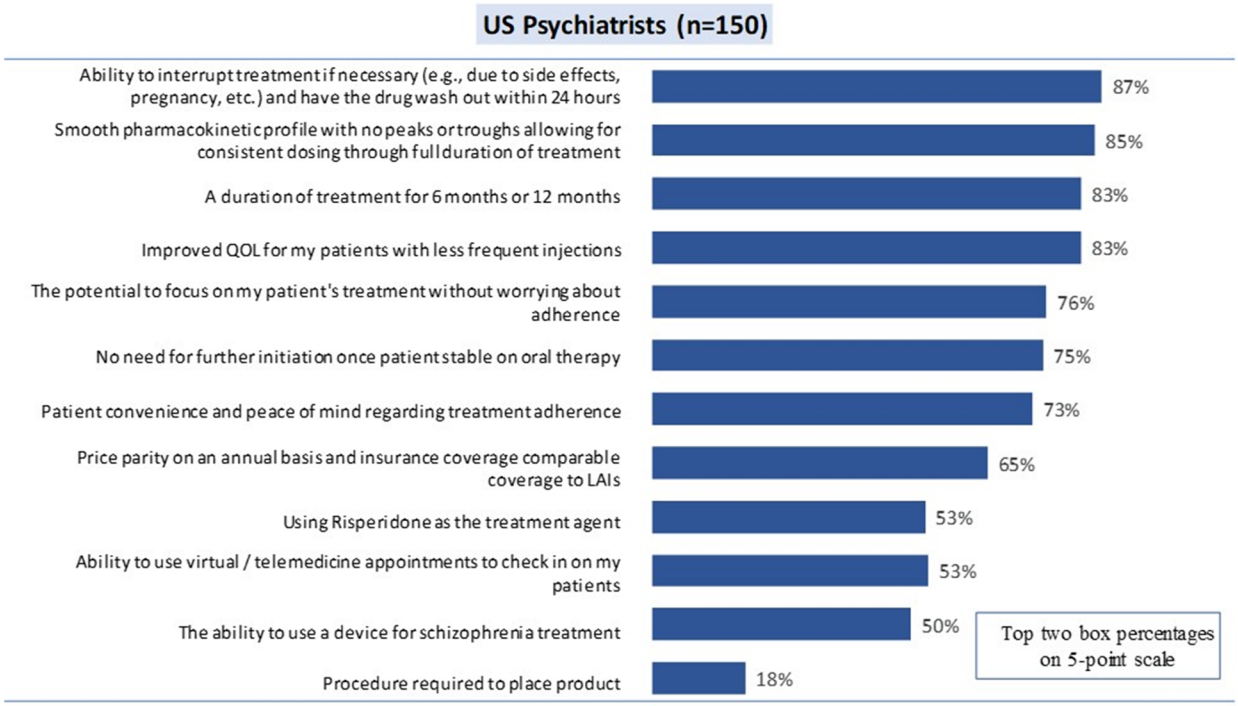
Physicians overwhelmingly cite key benefits of DLP-114, including its reversibility (87%), smooth PKs (85%), long duration (83%), and no initiation dosing requirement (75%). Importantly, 100% of payers from all countries indicated that they would cover DLP-114 given price parity with LAIs. Figure 25 (page 35) provides a summary of top reasons physicians are interested in using DLP-114, according to the Company's commissioned KMK Market Research Study.

DLP-114 Regulatory Path

Delpor is advancing new therapeutic products based on existing drugs, a strategy with significant benefits. The FDA has accepted the notion that the Company can utilize the 505(b)(2) regulatory path for DLP-114, simplifying the approval process, and waiving the necessity for an efficacy study. Consequently, Delpor intends to initiate a Phase 3 pivotal study early next year for risperidone, focusing on PK comparability. This study will enroll patients stabilized on the drug, transition them to the implant, and demonstrate that the implant's PK profile remains above the minimum threshold experienced orally. Rather than hundreds of patients which are typically required for placebo-controlled efficacy studies, the Phase 3 pivotal study will enroll just 50 to 80 patients, significantly simplifying and de-risking the regulatory process, and potentially offering a smoother route to approval. While Delpor's commercial potential remains consistent (and in certain cases perhaps even greater), the technical risks associated are significantly lower.

Figure 25

TOP REASONS PHYSICIANS ARE INTERESTED IN USING DLP-114



Source: Delpor, Inc.

Opioid Use Disorder (OUD)

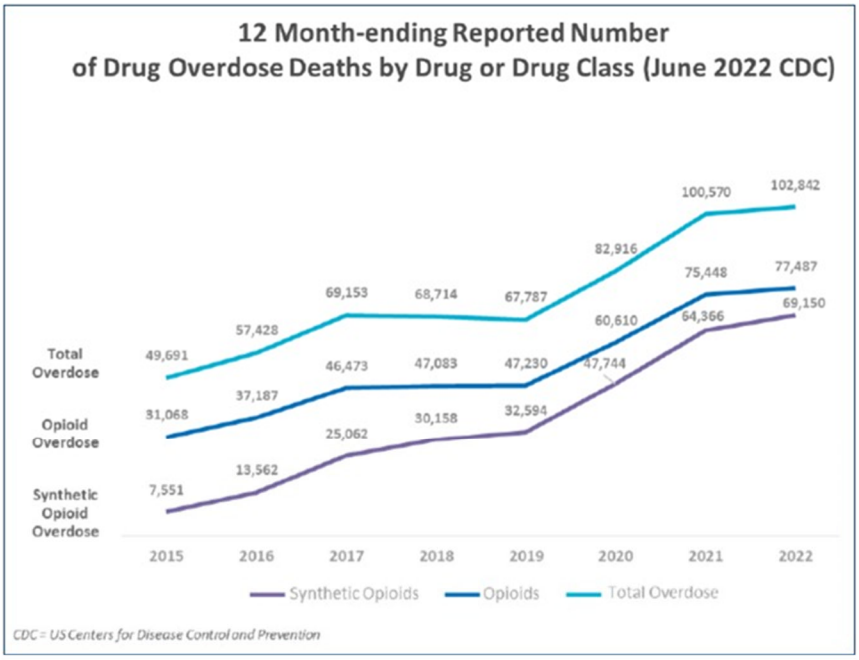
Opioids constitute a class of medications frequently employed to alleviate intense pain. These potent pain relievers function by attaching to receptors in the brain and spinal cord, thereby interrupting pain signals. Morphine, oxycodone, and fentanyl are among the commonly used opioids. They find application across diverse settings, such as hospitals, clinics, and for managing chronic pain at home. Nonetheless, opioids carry a significant risk of addiction and overdose, potentially leading to fatalities.

Opioid Use Disorder (OUD) is a medical condition characterized by problematic patterns of opioid use, leading to significant impairment or distress. Addiction to opioids represents a chronic and relapsing brain disorder marked by individuals pathologically seeking reward and relief through substance use and related behaviors. Individuals with OUD often experience a strong desire to use opioids, struggle to control or reduce their opioid intake, and continue using opioids despite experiencing adverse consequences in various aspects of their lives, such as health, social relationships, work, and legal issues. Opioids, including prescription painkillers like oxycodone and hydrocodone, as well as illicit drugs like heroin, can lead to the development of OUD due to their addictive properties and potential for tolerance, dependence, and withdrawal symptoms.

The epidemic of drug overdoses stands as the primary cause of accidental deaths in the U.S., largely driven by OUD and contributing to a decline in life expectancy over the past three years. According to the National Institutes of Health (NIH), approximately 6.7 million to 7.6 million adults in the U.S. are currently living with OUD. Additionally, more than 760,000 people have died since 1999 from a drug overdose as of 2020, with nearly 75% of drug overdose deaths in 2020 involving an opioid. Amidst the opioid epidemic, overdose deaths in the U.S. have reached unprecedented levels, particularly exacerbated by the pandemic. In the latest 12-month period ending June 2022, for the first time in U.S. history, fatal overdoses peaked above 103,000 deaths, with 89% of these opioid overdose deaths involving fentanyl (with young people and people of color among the hardest hit). Figure 26 shows the extent of these opioid overdate deaths.

Figure 26

OPIOID USE DISORDER –U.S. OVERDOSE DEATHS



102.8k

annual overdose deaths in latest 12-month period ending June 2022 *(CDC)*

89%

of Opioid overdose deaths involved fentanyl in latest 12-month period ending June 2022 *(CDC)*

Source: Indivior PLC.

Medication-Assisted Treatment

Medication-Assisted Treatment (MAT) involves the use of FDA-approved medications alongside counseling and behavioral therapies to address OUD. It stands as a crucial component to the federal response to the U.S. opioid crisis. According to a consensus report released by the National Academy of Sciences in March 2019, MAT is effective and lifesaving, yet remains underutilized. Naltrexone, among the three medications commonly prescribed for OUD, is also approved for treating alcohol use disorders. By binding and blocking opioid receptors, naltrexone inhibits the euphoric and sedative effects of opioids, thereby reducing cravings without inducing addiction. It is available in oral form (Revia®) for daily use or as a monthly injectable (Vivitrol®), described in the accompanying section. However, adherence to medication among OUD patients is poor, with discontinuation rates of naltrexone ranging from 50% to 85% within 6 weeks and 25 weeks, respectively. Other studies report retention rates of less than 10% after 4 months without incentives.

DLP-160 (Once-Yearly Naltrexone for OUD)

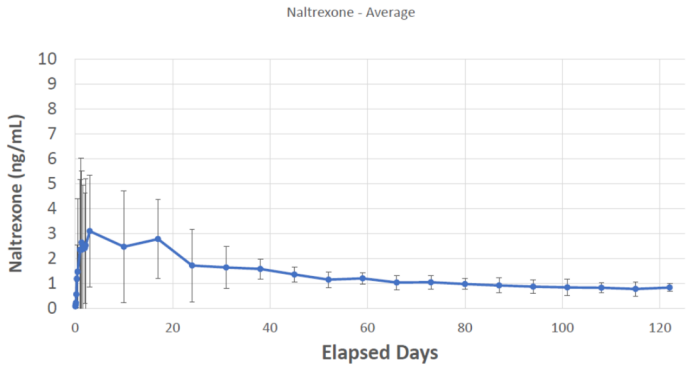
Delpor is developing DLP-160, a naltrexone implant designed for sustained release over a one-year duration. The delivery system ensures consistent medication adherence throughout treatment and reduced relapse rates, particularly benefiting patients who respond positively to naltrexone but struggle with maintenance therapy. With zero-order release PKs, the system provides comprehensive prophylaxis for one year, avoiding sub-therapeutic troughs. Moreover, it is fully reversible and allows for quick removal within minutes, with drug plasma levels declining rapidly to zero following removal in case pain treatment is needed due to injury or surgery. If pain treatment is not sufficient, former addicts may seek to self-medicate with illicit opioids. This reversibility enhances safety and distinguishes DLP-160 from other systems lacking this feature. Additionally, the system achieves comparable efficacy with lower drug exposure, as zero-order release eliminates the need for an initial drug burst.

There is currently only one long-acting naltrexone product, called Vivitrol® from Alkermes, which is their highest selling product with $400 million in sales in 2023. Vivitrol is a medication to treat opioid addiction that works by blocking the effects of opioids in the brain, which can help individuals overcome their addiction and maintain sobriety. It is administered once per month by injection. Vivitrol provides an improvement over the oral formulation, but still has several limitations. The product does not deliver the drug at a constant rate; much of the applied dose is wasted in the beginning when naltrexone plasma levels greatly exceed the therapeutic threshold of 1-2 ng/mL, followed by a rapid decline after 3 days. This places a practical upper limit upon the duration of action, limiting it to 1 month. The limited duration of the product reduces patient retention while the declining PK profile may result in incomplete prophylaxis during the dosing period. A product that is able to deliver treatment over six month or one year can make a significant difference in terms of ensuring medication adherence.

Phase 1 Preliminary Clinical Data (DLP-160 Naltrexone)

Figure 27 shows Phase 1 clinical PK data of patients dosed with DLP-160 naltrexone over 120 days.

Figure 27
PHASE 1 PRELIMINARY CLINICAL DATA (DLP-160 NALTREXONE)



Source: Delpor, Inc.

Naltrexone Program Funding

Delpor has collaborated with the NIH over the past few years, with the NIH providing substantial support for various projects. To date, the NIH has invested approximately $20 million in the Company, with approximately $6 million allocated to this specific program. Delpor anticipates accessing an additional $15 million in non-dilutive NIH funding dedicated to the naltrexone program following the submission of the U.S. IND later this year. This funding not only bolsters the Company's financial position but also enhances its credibility, given that these are peer-reviewed applications that have received favorable feedback from the NIH. Delpor believes that naltrexone holds significant promise, especially considering that Vivitrol® currently stands as the sole alternative option.

DLP-160 Regulatory Path

Similar to DLP-114, the FDA has accepted the notion that the Company can utilize the 505(b)(2) regulatory path for DLP-160, simplifying the approval process, and waiving the necessity for an efficacy study. While Delpor's commercial potential remains consistent (and in certain cases perhaps even greater), the technical risks associated are significantly lower.

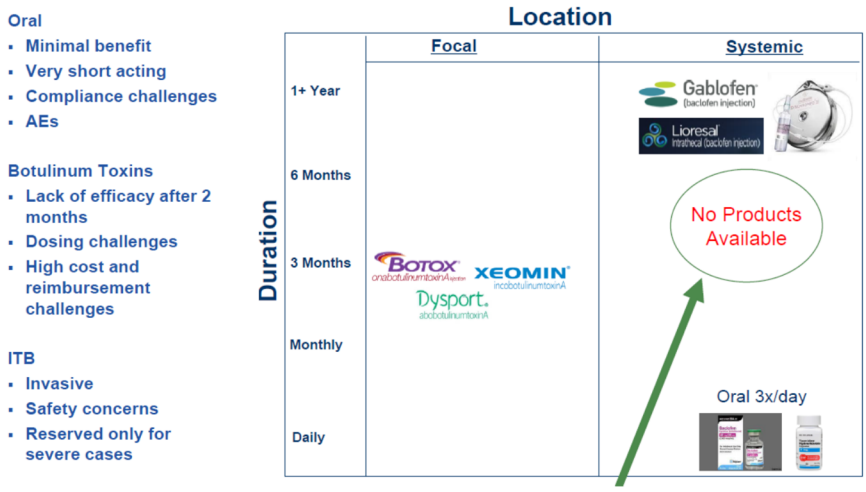
Moderate to Severe Spasticity

Moderate to severe spasticity is a condition characterized by the stiffening and limited mobility of muscles. This condition can stem from various sources, such as brain or spinal cord injuries, multiple sclerosis (MS), cerebral palsy, and other neurological conditions. Common symptoms include challenges in walking, restricted range of motion, and an elevated risk of falling. Each of these symptoms presents significant challenges to patients, impacting their mobility, comfort, and overall quality of life. Current treatment options, while offering some relief, often come with limitations, such as inadequate efficacy, tolerability issues, and the need for frequent dosing. Physicians primarily characterize severity based on the level of interference with activities of daily living and degree of discomfort. Because of this, there is a critical need for innovative therapies that can provide sustained relief with improved tolerability.

Spasticity Market Landscape

Current treatment options for patients with moderate to severe spasticity include oral, botulinum toxins, and intrathecal baclofen (ITB) pumps. Figure 28 illustrates the potential issues that may arise with each of these options. Specifically, oral treatments are short acting, have compliance challenges, potentially adverse events, and offer minimal benefits. Botulinum toxins have shown to lack of efficacy after two months, pose dosing challenges, and have a high cost with reimbursement challenges. For the ITB pumps, the device is invasive, poses safety concerns, and is reserved only for severe cases. Because of this, there is significant opportunity for market expansion.

Figure 28
SPASTICITY MARKET LANDSCAPE



Source: Delpor, Inc.

DLP-208 (6-Month Tizanidine for Spasticity)

Regarding existing spasticity treatments, the only long-acting product currently available is manufactured by Medtronic. This product consists of a sizable ITB pump, approximately fifty times larger than Delpor's implant, resembling a substantial thick disk with a catheter that extends into the patient's spine. Due to its highly invasive nature, implanting the device into the abdomen necessitates anesthesia and is typically considered a last resort by patients. Apart from this pump, there are no other long-acting options on the market. Regardless of efforts by various companies to develop once-daily oral formulations, there has been no successes despite significant investments. Delpor's spasticity program has completed the formulation process and has obtained promising pre-clinical data with the Company anticipating an IND filing within the next 12 months and subsequently progressing it to clinical trials.

NIH Grant Award

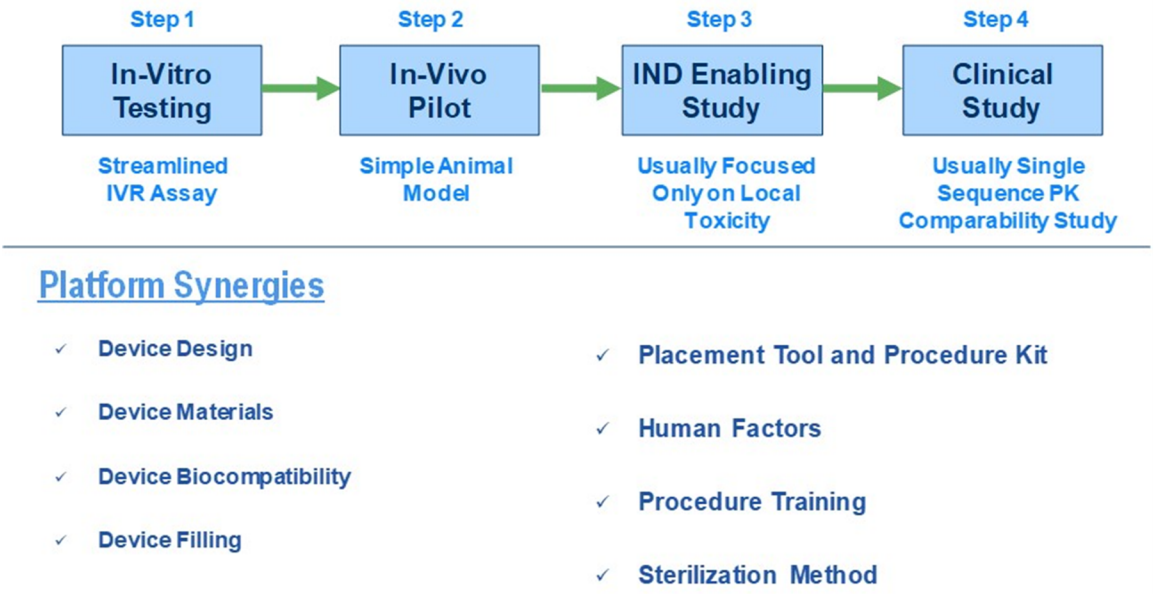
In 2021, Delpor announced an NIH grant award of $2.5 million for the further advancement of the Company's tizanidine implant product (DLP-208) for moderate to severe spasticity.

Other Platform Applications

It took a considerable amount of time to advance the lead asset (DLP-114) into the clinic as it was the first asset and, as such, faced numerous challenges, particularly related to CMC issues. The process spanned approximately eight years due to various platform-related obstacles that needed resolution. Conversely, the timeline for advancing naltrexone into the clinic was significantly shorter, taking only a couple of years.

Based on prior learnings from the development of its current clinical assets, Delpor has now developed a streamlined process, which enables drugs to transition rapidly from the laboratory to clinical trials, offering potential benefits for numerous other medications that could benefit from this delivery approach. Figure 29 illustrates the drug screening process and the corresponding platform synergies. Steps 1 and 2 of the process are used to select the preferred formulation, while Step 3 enables the asset to advance to the clinic. Although the formulation is typically different for each drug, the overall manufacturing process and device design are either identical or similar. Furthermore, the placement/removal procedures and associated human factor issues are usually identical. These platform synergies, combined with the streamlined processes mentioned above, substantially simplify the development of new therapeutic products, thus enhancing the value of the overall Prozor™ drug delivery platform.

Figure 29
PLATFORM SCREENING PROCESS – USUALLY LAB TO CLINIC IN <12 MONTHS



Source: Delpor, Inc.

Delpor has already screened ~20 compounds and has generated non-clinical data for over one-third of them. The Company has identified several compounds and therapeutic areas where its technology may provide a clinical benefit either by improving the efficacy of the compounds in their existing therapeutic areas, or by enabling the efficacy of compounds in new therapeutic areas. The therapeutic areas currently pursued or considered by the Company include inflammatory, neuroinflammatory, gastrointestinal, and metabolic disorders, including psoriasis, fibromyalgia, Crohn's disease, MS, diabetes, and obesity.

Acquisition Activity

There has been, and will likely continue to be, acquisition activity within this therapeutic category as the value and need for more effective antipsychotics is commonly recognized by both the medical and financial community, particularly for individuals grappling with these debilitating medical conditions. This is underscored by the widespread non-compliance observed within this patient demographic. Examples of some recent acquisitions in this space are included below.

Bristol Myers Squibb Acquired Karuna Pharmaceuticals

In a significant move, Bristol Myers Squibb acquired Karuna Pharmaceuticals primarily for its groundbreaking antipsychotic medication, KarXT (xanomeline-trospium) M1-M4 muscarinic agonist, anticipated to receive approval by year end. Bristol Myers invested $14 billion in this acquisition (which closed in March 2024), banking on the potential of this single antipsychotic to pioneer a new class of medications, potentially yielding billions in sales. Given this recent acquisition and their plans to establish a foothold in the psychiatry sector, coupled with their lack of long-acting products, Bristol Myers may find Delpor's technology of interest.

Abbvie to Acquire Cerevel Therapeutics

In December 2023, AbbVie Inc. and Cerevel Therapeutics announced a definitive agreement, marking AbbVie's acquisition of Cerevel Therapeutics and its robust neuroscience pipeline. This pipeline comprises multiple clinical-stage and preclinical candidates holding promise across various ailments, including schizophrenia, Parkinson's disease (PD), and mood disorders. The deal values Cerevel at roughly $8.7 billion. Anticipated to conclude in mid-2024, pending Cerevel shareholder endorsement, regulatory green lights, and standard closing prerequisites, this transaction marks a significant milestone. Notably, Cerevel emerged as a spinoff from Pfizer, wherein Pfizer divested its entire CNS asset portfolio.

Among its pipeline assets, Cerevel boasts a Phase 3 contender, emraclidine, a late-stage asset serving as a positive allosteric modulator (PAM) of the muscarinic M4 receptor. Emraclidine represents a next-generation antipsychotic, potentially effective in treating schizophrenia patients. Encouraging results from a Phase 1b study highlight emraclidine's promising efficacy and safety in schizophrenia, with ongoing Phase 2 trials designed for registration. Moreover, emraclidine holds promise for addressing dementia-related psychosis in Alzheimer's disease and PD. Currently, emraclidine is undergoing Phase 1 evaluation in elderly healthy volunteers, supporting a potential Alzheimer's disease psychosis program.

Notably, none of these assets possess long-acting formulations.

Competition

As Delpor continues to develop and seeks to commercialize its products, the Company may encounter competition from other pharmaceutical or biotechnology companies, including those that currently market approved products for the indications the Company is targeting, as well as those developing new and innovative therapeutic treatments. An example of the potential competition that the Company may face is profiled in the accompanying section. It is not intended to be an exhaustive collection of the Company's competitors; however, it is believed to be a selection of the type of competition that Delpor may face as it strives to commercialize its product candidates.

With regard to LAIs approved to treat schizophrenia, there are approximately 18 LAIs—seven first-generation antipsychotics (FGAs) and eleven second-generation antipsychotics (SGAs)—approved in the U.S. and/or in EU member states for the treatment of schizophrenia. As it compares most directly to Delpor, some of what the Company believes may be the most direct competitors within the risperidone extended-release subcutaneous injectable market are profiled below.

Schizophrenia: Risperidone LAIs

Alkermes PLC/Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson

Risperdal® Consta® (injection – 2 weeks), approved in 2004

Manufactured by Alkermes plc and marketed in collaboration with Janssen Pharmaceuticals, Risperdal® Consta® is an LAI formulation of risperidone for the treatment of schizophrenia and bipolar disorder. This unique formulation delivers sustained release of risperidone, a potent antipsychotic medication, over a period of two weeks, providing consistent therapeutic plasma levels to help manage symptoms effectively. Risperdal® Consta® offers a convenient alternative to daily oral medications, reducing the burden of treatment adherence for patients and enhancing continuity of care. With its proven efficacy and tolerability profile, Risperdal® Consta® represents a valuable option for individuals requiring long-term maintenance therapy for these debilitating psychiatric conditions. Alkermes plc's headquarters are located in Dublin, Ireland. Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson, has its headquarters located in Beerse, Belgium.

Indivior PLC

Perseris® (injection – 1 month), approved in 2018

Indivior is a global pharmaceutical company dedicated to addressing the needs of individuals living with addiction and serious mental health disorders. Its product, Perseris®, is a once-monthly LAI formulation developed for the treatment of schizophrenia in adults, which was approved by the U.S. FDA on July 31, 2018. This innovative medication delivers extended-release risperidone over a period of one month, providing continuous symptom control and stabilization. Perseris® offers a convenient and effective alternative to daily oral medications, helping to reduce the risk of relapse and improve patient adherence to treatment. With its proven efficacy, safety, and tolerability profile, Perseris® represents a valuable option for individuals requiring long-term management of schizophrenia. Indivior's headquarters are located in Slough, Berkshire, United Kingdom.

Janssen Pharmaceuticals (a subsidiary of Johnson & Johnson)

Invega Sustenna®, approved in 2009

Invega Sustenna® is an LAI formulation of paliperidone palmitate, an antipsychotic medication used in the treatment of schizophrenia. This medication, approved by the U.S. Food and Drug Administration (FDA) on July 31, 2009, for the treatment of schizophrenia, provides sustained release of paliperidone over a period of one month, offering continuous symptom control and stabilization for patients. Administered as a once-monthly injection, Invega Sustenna® provides a convenient alternative to daily oral medications. The drug is manufactured by Janssen Pharmaceuticals (a subsidiary of Johnson & Johnson). Janssen Pharmaceuticals' headquarters is located in Beerse, Belgium.

Invega Trinza® and Invega Hafyera®

Invega Trinza® and Invega Hafyera® are both extended-release injectable formulations of paliperidone palmitate, an antipsychotic medication used in the treatment of schizophrenia. The main difference between the two is the dosing frequency. Invega Trinza® provides sustained release of paliperidone over an extended period of three months, requiring administration once every three months. Invega Hafyera® provides sustained release of paliperidone over a period of six months, requiring administration once every six months. Both medications offer continuous symptom control and stabilization for patients with schizophrenia, providing convenient alternatives to more frequent dosing regimens. They are both developed by Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson. Greater details of the initial dosing requirement for Invega Trinza® and Invega Hafyera® are provided on page 31.

MedinCell/Teva

UZEDY™ (injection – 1- and 2-month dosing intervals), approved 2023

Teva Pharmaceuticals and MedinCell jointly announced the successful FDA approval of UZEDY™, an extended-release risperidone injectable suspension, marking a significant milestone in addressing the therapeutic needs of adults with schizophrenia. This innovative pharmaceutical solution offers a long-acting subcutaneous atypical antipsychotic injection, promising enhanced treatment efficacy, and potentially better outcomes. MedinCell, a biopharmaceutical company specializing in drug delivery innovation, developed the LAI formulation to provide sustained release of therapeutics over extended periods, aiming to improve treatment adherence, enhance patient convenience, and optimize therapeutic outcomes across various therapeutic areas. Headquartered in Montpellier, France, MedinCell collaborated with Teva, headquartered in Petah Tikva, Israel, and operating in over 60 countries, to achieve this FDA approval. The approval is supported by Phase 3 data from two pivotal studies: the RISE Study, which assessed the efficacy of UZEDY™ in preventing relapse in patients with schizophrenia, and the ongoing SHINE Study, evaluating its long-term safety and tolerability. Interim results from the SHINE Study align with the findings of the RISE Study, indicating the potential for UZEDY™ to be a valuable treatment option for patients with schizophrenia. Teva will lead the clinical development, regulatory process, and commercialization, with MedinCell eligible for development milestones, royalties, and future commercial milestones.

Rovi (Laboratorios Farmaceuticos Rovi SA)

Risvan® (injection – 1 month), approved 2024

Rovi is a leading pharmaceutical company committed to developing innovative treatments for a range of therapeutic areas, including mental health, oncology, and infectious diseases. The company's Risvan® is an LAI intramuscular (IM) formulation that utilizes in situ-forming microparticle (ISM) technology to deliver medication. This type of formulation is designed to release the drug over an extended period, reducing the frequency of doses required and potentially improving patient adherence to the treatment regimen. The ISM technology allows for the drug to be dissolved in a polymer, forming microparticles that release the medication in the body over time. This innovative approach can offer advantages over traditional LAI formulations, such as not requiring loading doses or oral supplementation. In 2019, Rovi announced positive topline results from a Phase 3 study of Doria® in patients with schizophrenia. The study demonstrated promising outcomes for Doria®, with results indicating favorable efficacy and safety profiles compared to placebo, marking a significant advancement in the treatment of schizophrenia. This successful Phase 3 trial led to the approval of Risvan in Q2 2024. Rovi's head office is located in Madrid, Spain.

Opioid Use Disorder (OUD)

For the treatment of opioid use disorder (OUD), there are three main medications that are commonly prescribed in the U.S.: buprenorphine, available as a dissolving tablet, cheek film, or extended-release injection and can be prescribed by a clinician for use outside of a clinic; methadone, typically administered in a clinic setting due to its potential for abuse and overdose; and naltrexone, available as a pill or as an extended-release injectable and it blocks the euphoric effects of opioids. These medications are designed to normalize brain chemistry, relieve physiological cravings, and normalize body functions without the negative and euphoric effects of the substance used.

Alkermes, Inc.

Vivitrol® is an extended-release injectable suspension of naltrexone that is administered intramuscularly and marketed by Alkermes, Inc. to treat opioid addiction. It works by blocking the effects of opioids in the brain, which can help individuals overcome their addiction and maintain sobriety. It is typically administered as an injection once a month and can be used in combination with other treatments, such as counseling and therapy. Alkermes has headquarters in Dublin, Ireland, with a significant presence in Waltham, Massachusetts.

Also marketed by Alkermes, XR-naltrexone (also known as extended-release naltrexone), is an injectable formulation that has been shown to be effective when started within five to seven days of seeking treatment, as opposed to the standard method of starting within 10-15 days. Recent studies suggest that a more rapid treatment protocol could make XR-naltrexone more viable as a treatment option for OUD.

Spasticity

Medtronic

The Medtronic Intrathecal Baclofen Pump, part of the SynchroMed™ II programmable drug infusion system, is designed to deliver precise doses of Lioresal® Intrathecal (baclofen injection), a muscle relaxant and antispasticity agent, directly to the intrathecal space and cerebrospinal fluid. This therapy is indicated for the management of severe spasticity of spinal or cerebral origin. The system consists of an implanted pump and a catheter, with the pump being surgically placed under the skin of the abdomen. The pump delivers programmed amounts of medication through the catheter to the desired area. It is a chronic therapy option for individuals who require long-term management of severe spasticity when oral medications are not effective or cause intolerable side effects. Medtronic has headquarters in Minneapolis, Minnesota.

Recent Events

December 7, 2023—Delpor is developing late-stage clinical trial plans for its drug-device combination implant DLP-114 (risperidone) in schizophrenia. After presenting topline results from a Phase 1b/2a trial (NCT04418466) in November, the Company is currently making some changes to the product based on the learnings from the previous study. The Company is set to launch the Phase 2b study in Q2 2024, which is expected to go on until 2025. Subsequently, Delpor plans to initiate both a registrational Phase 3 trial and a safety study in parallel, which should be sufficient for product approval.

November 16, 2023—Announced topline results of its DLP-114 Phase 1b/2a clinical study during which schizophrenia patients received treatment for up to one year after a single administration. The topline study results were reported for the first time at the 2023 NEI Congress poster session in Colorado Springs on November 10, 2023.

April 19, 2022—Announced that it has initiated and dosed the first subjects in a Phase 1 clinical trial of DLP-160, a 6-12-month formulation of naltrexone for the treatment of opioid use disorder (OUD). This is an open-label study in healthy volunteers to evaluate the safety, tolerability, and PKs of naltrexone when administered in sequence of Naltrexone HCL (Oral), DLP-160 (Naltrexone Implant), followed by Vivitrol® (Intramuscular).

November 16, 2021—Announced an NIH grant award of $2.5 million for the further advancement of the Company's tizanidine implant product (DLP-208) for moderate-severe spasticity.

April 22, 2021—Announced that it has initiated and dosed the first patient in a Phase 1b/2a clinical trial of DLP-114, a long-acting formulation of the antipsychotic risperidone for schizophrenia maintenance therapy. This is an open-label study in stable schizophrenia patients to evaluate the safety, tolerability, and PKs of switching from oral risperidone to a once-yearly or twice-yearly risperidone implant (DLP-114).

March 31, 2021—Announced the appointment of Jay Smith to the newly-created position of Chief Commercial Officer, where he will lead Delpor's commercialization efforts, leveraging more than 25 years of global biopharmaceutical leadership and experience.

October 10, 2019—Announced that the National Institutes of Health (NIH) has awarded the Company a grant for the development of a once-yearly naltrexone product for the prevention of relapse to opioid dependence. The award comes through the NIH Helping to End Addiction Long-term Initiative, or the NIH HEAL Initiative, which aims to improve treatments for chronic pain, curb the rates of opioid use disorder and overdose, and achieve long-term recovery from opioid addiction.

June 14, 2017—Announced the awarding of a Phase 2 SBIR grant from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for the further advancement of the Company's exenatide implant product (DLP-414).

March 7, 2017—Announced that the U.S. Patent and Trademark Office (USPTO) issued on February 7, 2017 U.S. Patent No. 9,561,352 covering Delpor's implantable device for the long-term delivery of therapeutic agents. The device uses Delpor's proprietary PROZOR™ technology for the sustained release of drugs for several months after subcutaneous implantation.

May 31, 2017—Announced that the National Institutes of Health (NIH) has selected it to exhibit and showcase its technology at the International Convention of the Biotechnology Innovation Organization (BIO). The Convention took place in San Diego, CA on June 19-22, 2017.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by Crystal Research Associates, LLC ("CRA") with the assistance of Delpor, Inc. ("Delpor" or "the Company") based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in Delpor's statements on forms filed from time to time.

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In addition, the risks and uncertainties covered in the accompanying sections are not the only risks that the Company faces. Additional risks and uncertainties not presently known to Delpor or that it currently believes to be immaterial may also adversely affect the Company's business. If any of such risks and uncertainties develops into an actual event, Delpor's business, financial condition, and results of operations could be materially and adversely affected.

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Risks Related to Delpor, Inc.

Clinical Development and Regulatory Approval

Delpor's success hinges on its ability to navigate the complex and rigorous process of clinical development and regulatory approval. Clinical trials may fail to demonstrate the safety and efficacy of the Company's product candidates, leading to delays or outright termination of development programs. Regulatory agencies, such as the FDA, impose stringent requirements for approval, and any failure to meet these standards could result in significant setbacks, increased costs, or inability to commercialize products. Moreover, the regulatory landscape is subject to change, with evolving guidelines and standards potentially impacting the development and approval process.

Market Acceptance

Despite successful clinical development once the Company receives regulatory approval, Delpor's products may face challenges in gaining market acceptance. Healthcare providers, patients, and payers may be hesitant to adopt novel once-yearly therapeutics, preferring established treatment modalities with proven track records. Additionally, pricing and reimbursement dynamics within the healthcare system could pose obstacles to widespread adoption, limiting the Company's revenue potential and market penetration.

Intellectual Property

Protecting intellectual property rights is essential for safeguarding Delpor's competitive advantage and market position. However, the biopharmaceutical industry is rife with intellectual property disputes, and the validity and enforceability of patents can be subject to legal challenges. Despite efforts to secure patents and proprietary technology, the Company may encounter infringement claims from competitors or difficulties in defending its intellectual property rights, which could undermine its ability to commercialize products and generate revenue.

Product Manufacturing and Supply

Successfully scaling up manufacturing processes and ensuring a reliable supply chain are critical for Delpor's commercial success. However, manufacturing biopharmaceutical products can be complex and costly, with stringent quality control requirements. Any disruptions in manufacturing operations or supply chain logistics, such as raw material shortages, equipment failures, or regulatory compliance issues, could lead to production delays, product shortages, or quality control issues. These challenges may impede the Company's ability to meet market demand and fulfill contractual obligations, resulting in lost revenue opportunities and reputational damage.

Financial Risks

Delpor operates in a capital-intensive industry characterized by substantial upfront investments and prolonged development timelines. As a clinical-stage biopharmaceutical company, it is likely to incur significant operating losses and negative cash flows for the foreseeable future. Raising additional capital through equity or debt financings is essential to fund ongoing operations, research and development activities, and potential acquisitions or strategic partnerships. However, there is no guarantee that the Company will be able to access capital markets on favorable terms or at all, especially during periods of economic uncertainty or market volatility. Failure to secure adequate funding could jeopardize Delpor's ability to execute its business plan, leading to delays in product development, loss of key personnel, or even bankruptcy.

Risks Related to the Biopharmaceutical Industry

Regulatory Environment

The biopharmaceutical industry operates in a highly regulated environment, subject to oversight by various regulatory agencies worldwide. Changes in regulatory requirements, including clinical trial design, manufacturing standards, labeling guidelines, and post-market surveillance obligations, can significantly impact the development, approval, and commercialization of products. Compliance with evolving regulations often requires substantial financial resources, time, and expertise, increasing the cost and complexity of bringing products to market. Moreover, unexpected regulatory actions, such as product recalls, warning letters, or enforcement actions, can have serious consequences for Delpor's reputation, financial stability, and legal liabilities.

Clinical Development Risks

The biopharmaceutical industry is inherently risky, with a high failure rate in clinical development. Despite promising preclinical data, many product candidates ultimately fail to demonstrate safety and efficacy in later-stage clinical trials, leading to costly setbacks and delays. Factors contributing to clinical trial failures include inadequate study design, patient recruitment challenges, unforeseen safety issues, and lack of efficacy endpoints. Delpor's success depends on its ability to mitigate these risks through rigorous clinical trial management, robust data analysis, and proactive risk assessment strategies. However, there is no guarantee that the Company's product candidates will achieve clinical endpoints or receive regulatory approval, and any setbacks could have a material adverse effect on its business, financial condition, and prospects.

Market and Economic Risks

The biopharmaceutical industry is subject to various market and economic risks. Economic downturns can reduce demand for Delpor's products, lead to decreased capital expenditure, and increase pricing pressure. Additionally, changes in government policy or healthcare legislation could have an impact on the Company's profitability. For instance, changes in approval policies, reimbursement practices, or drug pricing could limit Delpor's revenue potential.

Dependence on Key Personnel

Delpor's success depends heavily on the expertise and experience of its management team and key research personnel. The loss of these key individuals could delay or prevent the development and commercialization of its products. Retaining and motivating key personnel with the necessary skills can be challenging due to the intense competition for qualified personnel among biopharmaceutical companies.

Competitive Landscape

Delpor faces intense competition from pharmaceutical and biotechnology companies, academic institutions, research organizations, and generic drug manufacturers. The biopharmaceutical market is crowded and highly competitive, with numerous players competing for market share and intellectual property rights. Competing products may offer similar therapeutic benefits, improved safety profiles, or lower costs, posing significant challenges to Delpor's commercialization efforts. Additionally, rapid advances in technology, scientific innovation, and healthcare delivery models may disrupt traditional market dynamics, requiring the Company to adapt quickly to changing competitive pressures and consumer preferences. Failure to differentiate its products or effectively compete in the marketplace could result in lost market opportunities, declining revenues, and erosion of shareholder value.

Risks Related to Private Company Status

Lack of Liquidity

Delpor's status as a private company means that its securities are not publicly traded on stock exchanges, limiting liquidity and investment options for shareholders. Unlike publicly traded companies, which have established markets for buying and selling securities, private companies may offer limited avenues for investors to exit their positions or realize returns on their investment. Illiquidity can make it challenging for shareholders to sell their shares at fair market value, especially during periods of economic downturn or market volatility. Additionally, restrictions on transferability and lack of transparency in pricing may deter potential investors from participating in private placements or secondary offerings, further exacerbating liquidity constraints for existing shareholders.

Limited Information Availability

Private companies are not subject to the same disclosure and reporting requirements as publicly traded companies, resulting in limited information availability for investors. Delpor may choose to disclose financial and operational information selectively, providing only essential details to prospective investors or regulatory authorities. This lack of transparency can make it difficult for investors to assess the Company's financial performance, growth prospects, and risk exposure accurately. Without access to timely and comprehensive information, shareholders may face challenges in making informed investment decisions and evaluating the Company's valuation relative to its peers and industry benchmarks.

Glossary

505(b)(2)—A USFDA regulatory pathway for approving a new drug product based on some data from studies not conducted by or for the applicant. It is a type of New Drug Application (NDA) that allows the applicant to use the Agency's finding of safety and/or effectiveness for a listed drug or published literature, without obtaining a right of reference or use. It is also known as a "hybrid application."

Antipsychotics—A type of medication used to treat psychosis, which is a term used to describe a group of mental health conditions, including schizophrenia, bipolar disorder, and some types of depression. These medications work by blocking the action of certain neurotransmitters in the brain and can be effective in reducing symptoms, such as hallucinations, delusions, and disorganized thinking.

Aseptic manufacturing—The process of producing products in a sterile environment to prevent contamination with harmful bacteria. This process involves strict adherence to strict hygiene protocols and the use of sterilizers to eliminate any microorganisms that may be present. The goal of aseptic manufacturing is to ensure the safety and quality of the final product. It is particularly important in the pharmaceutical industry, where products must meet strict quality standards before being taken on the market.

Central Precocious Puberty (CPP)—The development of secondary sexual characteristics in children before the age of 8 or 9. It is less common than adolescent-onset puberty and can be caused by various genetic and environmental factors.

Chemistry, Manufacturing, and Controls (CMC)—A crucial aspect of pharmaceutical product development. It encompasses defining manufacturing practices, product specifications, and quality control measures to ensure product safety and consistency between batches.

Clinical Global Impression (CGI)—A widely used framework in psychiatry to measure the severity of mental health symptoms. It is a standardized tool that allows clinicians to track changes in a patient's mental status over time. The CGI consists of a set of raters who assess the patient's symptoms in six domains, including positive symptoms, negative symptoms, mood symptoms, cognitive symptoms, behavioral symptoms, and global impression.

Extrapyramidal symptoms (EPS)—Refers to a group of motor symptoms that can occur as side effects of certain medications, particularly those used to treat Parkinson's disease. These symptoms include tremors, involuntary movements, stiffness, and difficulty with coordination and balance. EPS can be mild or severe and may negatively impact a person's quality of life.

Depot formulations—The parenteral formulations containing multiple doses of drug that are designed to release the drug over a specified, often prolonged, period of time. They are used to overcome the problems of conventional parenteral drugs, such as frequent injections, poor patient compliance, and variable drug levels.

Fickian diffusion—The process where particles under random thermal motion spread from a region of higher concentration to a region of lower concentration to equalize concentration. It is described by Fick's laws of diffusion, which are mathematical statements explaining this movement of molecules.

Intrathecal baclofen (ITB) pump—A medical device used to treat spasticity, a common complication of stroke, brain injury, cerebral palsy, and multiple sclerosis (MS).

Long Acting Injectables (LAIs)—A type of medication that is injected into the body and provides a slow release of the drug over an extended period, typically several weeks or months. LAIs can be used to treat a variety of conditions, including chronic pain, mental health disorders, and hormone imbalances. They are typically administered by healthcare professionals in a medical setting and can be a useful option for patients who may not be able to take other forms of medication, such as tablets or capsules.

Non-biodegradable implants—Devices or materials that are not naturally broken down by the body's biological processes. These implants are often used in surgeries to replace or repair damaged or missing body parts. Examples of non-biodegradable implants include metal plates, screws, and pacemakers. Unlike biodegradable implants, which are designed to break down over time and be absorbed by the body, non-biodegradable implants typically remain in the body indefinitely.

Opioid Use Disorder (OUD)—A chronic and relapsing condition in which an individual experiences cravings and difficulties controlling their use of opioids, such as heroin or prescription pain medications. It is considered a type of substance use disorder and can have severe consequences on an individual's physical, mental, and social well-being. Treatment for OUD often involves a combination of medications, such as methadone or buprenorphine, and therapy. Recovery from OUD is possible with appropriate treatment and support.

Positive and Negative Syndrome Scale (PANSS)—A widely used psychiatric rating scale that measures the severity of positive and negative symptoms of schizophrenia. It consists of 39 items rated on a scale of 0 to 4, with higher scores indicating more severe symptoms. The PANSS is used to assess treatment response and to monitor the course of schizophrenia over time.

Schizophrenia—A mental disorder characterized by hallucinations, disordered thinking, and behavioral disturbances. It affects approximately 1% of the population and is typically diagnosed in early adulthood. The exact cause of schizophrenia is unknown, but there is growing evidence that it involves a combination of genetic, environmental, and neurological factors. Treatment for schizophrenia typically involves antipsychotic medication, psychotherapy, and social support. Early diagnosis and treatment can help manage symptoms and improve outcomes.

Spasticity—Refers to abnormally stiff muscles, either due to increased muscle tension or decreased muscle flexibility. It is a common symptom of various neurological and neuromuscular conditions, such as stroke, cerebral palsy, multiple sclerosis, Parkinson's disease, and brain injuries.

Terminal sterilization—The process of sterilizing aseptic products (such as medical devices, pharmaceuticals, and food products) after they have been packaged in a sterile environment. This method involves exposing the products to high heat, radiation, or chemicals to kill any remaining microorganisms that may be present. When a medical device is “terminally sterilized,” it means it has undergone sterilization while already within its packaging. The goal is to ensure that no microbial contaminants are present when the product is used.

Zero-order release pharmacokinetics (PK)—A scenario where a drug is released from its formulation at a constant rate, regardless of its concentration. This means that a fixed amount of drug is eliminated per unit of time. This type of kinetics is contrasted with first-order kinetics, where the rate of drug release is proportional to its concentration.

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