

# DMK Pharmaceuticals Corporation

*Focused on reducing deaths and addiction*

January 2024



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# Experienced Management Team



**EBOO VERSI**  
M.D., Ph.D.  
CEO

## *New management team installed in Oct 2023*

### **Dr. Versi appointed CEO in May 2023**

- Large (Lilly, Pfizer, Astellas) and small companies (Odyssey, Plethora, Auxilium, Mt. Cook)
- Medical lead at Pfizer – team that created the overactive bladder market
  - Current OAB market >\$5B
- Planned and executed clinical studies for multiple approved products
- Authored over 100 scientific publications and inventor of several patents



**Seth Cohen,**  
MBA,  
CFO

### **Mr. Cohen appointed CFO in October 2023**

- 30+ Years in financial management, including multiple CFO roles in public, private equity-backed and private corporations
- Former trustee for City of New York's public pension systems, \$100+ billion in assets

LEHMAN BROTHERS



DEAN WITTER REYNOLDS



# New Corporate Strategy – Addiction and Pain Treatment

## New Management in October 2023

- Change in direction and strategy: Treatment of substance use disorder.
  - Focus on opioid crisis by commercializing ZIMHI® and developing DPI-125 with non-dilutive funding
- Business development activities to monetize non-core assets

## Laser focus on revenue generation & growth to drive stockholder value

- Increase U.S. sales of ZIMHI® our lead commercial product
  - White House and congressional initiatives to lift barriers to purchase ZIMHI with federal grants
  - Partnerships in US & ex-U.S. for ZIMHI
- Out-license SYMJEPI® and other assets that are not core to the addiction business
- Execute NIH funded program and continue to obtain non-dilutive government grants for development and discovery (~750 NCE) programs

# Opioid Crisis: A National Emergency

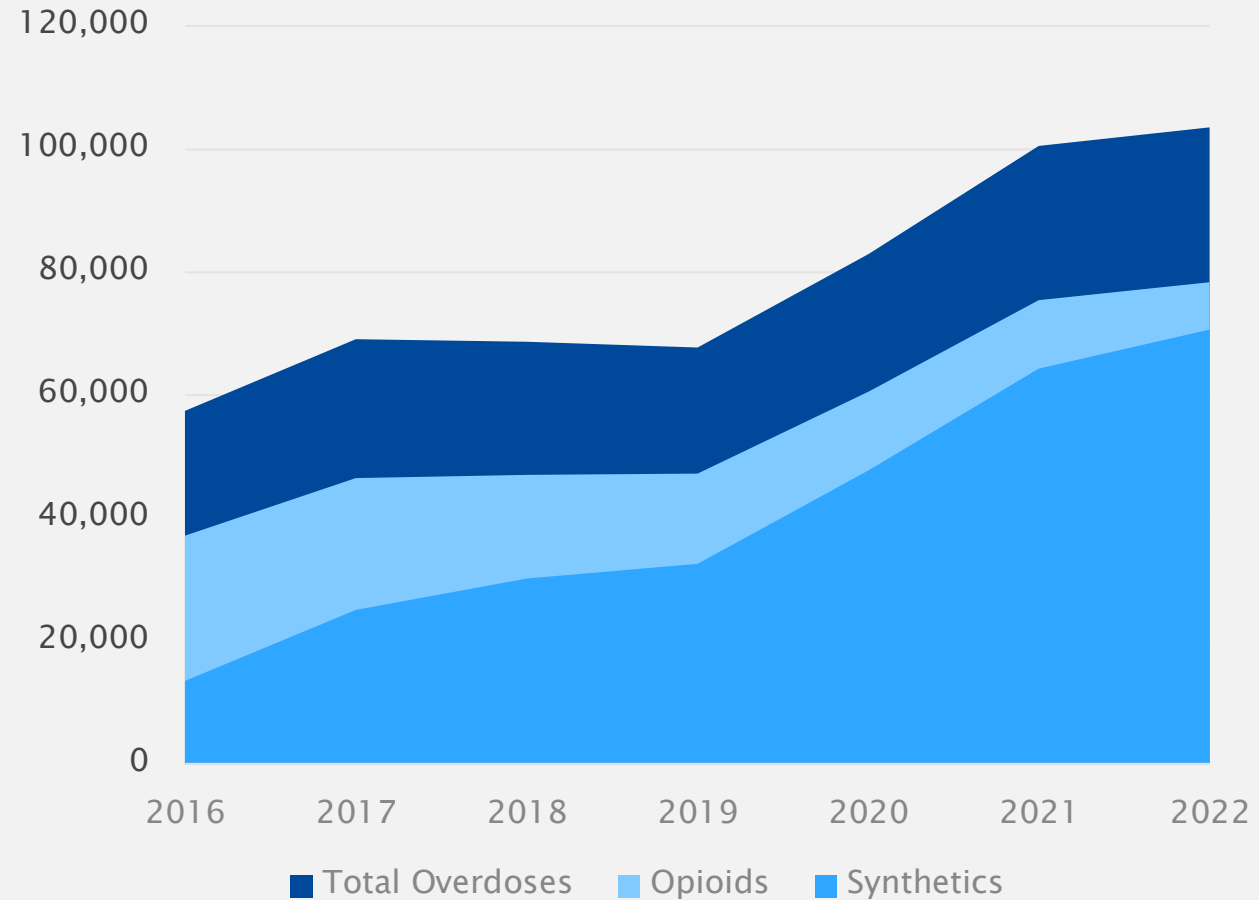
## Lethal fentanyl imports are increasing

- Every 7 minutes a person dies in the U.S. of an opioid overdose
- Unsuspecting non-opioid users are being poisoned by recreation drugs spiked with fentanyl
- According to the CDC: ~1.6 million Americans report suffering from opioid use disorder (OUD)

## Treatment goals

- Intranasal naloxone treatments are less effective against fentanyl
- Intramuscular naloxone treatments are needed to counteract fentanyl poisoning or overdose: [ZIMHI](#)
- To treat and prevent addiction, a balanced physiological approach that mimics the body's own endorphins is needed: [DPI-125](#)

## U.S. Drug Overdose Deaths by Drug Class



# Lead Products Overview

*Our mission: To prevent deaths due to poisoning, overdose, and addiction*

## **ZIMHI (naloxone): To rapidly reverse fentanyl overdose**

- Market in US and Canada exceeds **\$725M with CAGR of 10.1%** to 2032
  - Significant market potential, with only two competitors
- Intramuscular results in more rapid increase in blood levels than intranasal delivery
  - More rapid, sustained effect needing fewer administrations: cost effective.

## **DPI-125 transdermal system for treatment opioid use disorder**

- US market **>\$3B** addressed by old Rx solutions with limitations of access, efficacy, and safety
  - NIH-sponsored studies show equal efficacy to treat withdrawal symptoms, with improved safety observed in pre-clinical studies
- Opportunity to expand into treatment of acute moderate to severe pain globally
  - Global pain market **>\$22B**

## **Additional portfolio candidates**

- Indicated for urology (clinical stage) and Parkinson's disease and other disorders
  - Opportunities for out-license revenues



# Commercial Product Opportunity

## ZIMHI

(Intramuscular naloxone injection)



An opioid antagonist indicated for emergency treatment of opioid overdose

- 90% of U.S. opioid overdose deaths are now caused by poisoning with potent synthetic opioids such as fentanyl<sup>1</sup>
  - Every minute counts to prevent death or brain damage
  - Treatment with Narcan® can be slow and require several doses<sup>2</sup>
  - ZIMHI's fast absorption and high dose/concentration may offer a 'one and done' solution
- U.S. naloxone market is changing
  - Intranasal Narcan (and generics) had >90% share in 2022<sup>3</sup>
    - Now OTC leaving a vacuum in first responder space

<sup>1</sup> <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

<sup>2</sup> Strauss et al 2023

<sup>3</sup> Bloomberg Intelligence Drug Explorer 2022

# ZIMHI: Competitive Advantages

## Greater bioavailability of ZIMHI versus intranasal naloxone products

- Longer effective duration of action to counter fentanyl induced deaths

## Faster and Stronger: More rapidly lowers fentanyl receptor occupancy

- Achieves naloxone blood levels ~6x faster than NARCAN

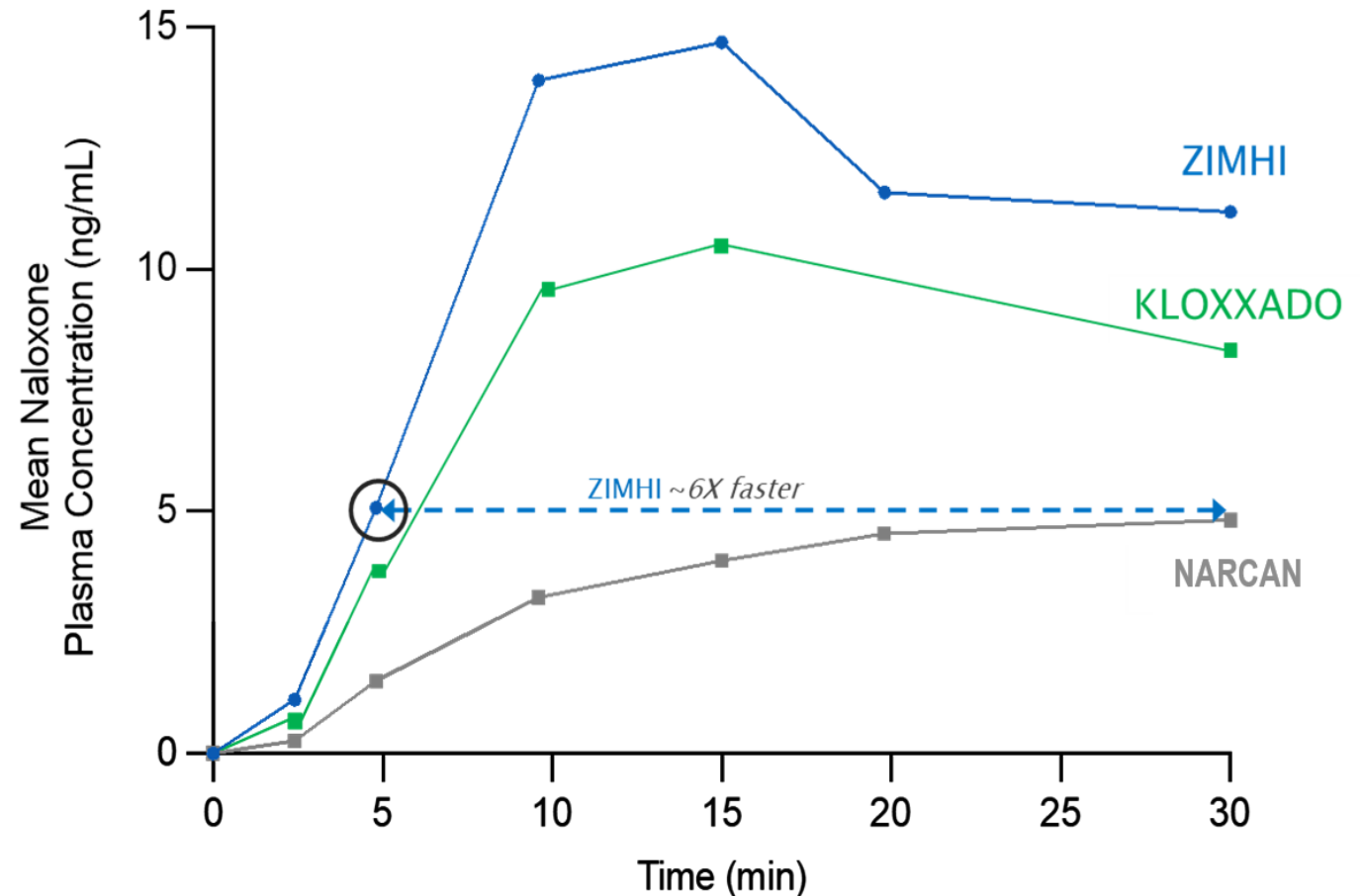
## Nasal delivery has limitations

- NARCAN, KLOXXADDO and other intranasal products have limited absorption likely compounded by hypotension in overdose patients

## ZIMHI intramuscular route should provide more prolonged effect to reverse fentanyl overdose/poisoning

- Decreased mortality and morbidity (brain damage)

Mean Plasma Concentration of Naloxone Over Time <sup>1</sup>



<sup>1</sup> Pharmacokinetic data from the approved package inserts for both Narcan, ZIMHI and KLOXXADO; not from head-to-head studies



# Fentanyl Recovery Depends on Optimal Naloxone Dosing

## Death due to respiratory depression <sup>1</sup>

- The more potent the opioid, the more profound the potential for respiratory depression
- Fentanyl and its analogues are the most potent opioids
- Reversal of fentanyl induced respiratory depression requires higher blood levels of naloxone

## New data for fentanyl overdose reversal

- Results of FDA funded study conducted by [Dr. Albert Dahan](#) compared recovery from fentanyl with 1, 2 or 4 doses of Narcan (generic equivalent) <sup>2</sup>
  - For the most effective recovery, 4 doses should be administered within 2.5 minutes (this is off-label use)
  - This data is currently in press to be published soon
- DMK's independent PK study suggests that a single dose of ZIMHI would be more effective than the standard of care <sup>3</sup>
- Currently a head-to-head study of ZIMHI against Narcan (generic equivalent) as follow up to FDA funded study (Dr. Dahan) is being performed to attempt to demonstrate superiority in fentanyl overdose reversal

# Higher Dose Availability of Naloxone is Necessary

## Anecdotal data from patients and first responders facing the prevalence of fentanyl poisonings

“Prescription strength ZIMHI is the best remedy available for opioid overdose. If we had had some in the house when our son Sammy died, he would still be with us” – *Samuel P. Chapman, Director – Parents for Safer Children*<sup>1</sup>

“.....but with fentanyl, we are needing to use about 3 doses [NARCAN] to achieve a recovery” – *David B. Rausch, Director of the Tennessee Bureau of Investigation*<sup>1</sup>

“He wasn’t waking up, so I gave him a third [NARCAN]...” – *Law enforcement perspective:*<sup>1</sup>

<https://healthandjusticejournal.biomedcentral.com/articles/10.1186/s40352-022-00172-y>

“...it can take three to four doses [of NARCAN] to revive somebody because the strength of the fentanyl that people are using right now” – *Scott Kerman, Blanchet House Executive Director*<sup>1</sup>

“It has become apparent that many overdoses require much higher initial doses to reverse...as high as 10–12mg of naloxone”<sup>1,2</sup>

“In Indiana, Ohio, and Michigan, we are seeing a lot more synthetic drugs and a need for repeat dosing. We are using naloxone more and more...for these super high potent derivatives, Narcan just isn't enough.”<sup>1,2</sup>

# Accelerate ZIMHI Sales with Data and Awareness

## Already launched strategic government relations campaign to facilitate market access

- First win: Invited to private White House meeting with Director of National Drug Policy, Advisor to the President, Assistant Secretaries for HHS and SAMHSA in June 2023 – goals and outcomes discussed include:
  - Implementing naloxone saturation policy
  - Increasing grant funding to states to purchase more naloxone
  - Creating guideline templates to roll out to states and municipalities to remove barriers to naloxone access
  - Director may issue a directive to mandate removal of barriers to naloxone access when using Federal funds <sup>1</sup>
- Interactions with Capital Hill
  - Met with 19 congressional offices, Senators and House members of both parties to explain the cost savings and potential to reduce mortality with ZIMHI based on scientific data
  - The value proposition of ZIMHI was well received by all offices visited
  - HR 4007, introduced with bipartisan support, would remove barriers to naloxone access that currently favor NARCAN

## New targeted publicity campaigns to make purchasers aware of the value of ZIMHI

- Leverage completed FDA funded study demonstrating need for higher doses of naloxone to treat fentanyl overdoses
- Disseminate survey data on number of Narcan doses needed to achieve recovery
- Publicize head-to-head data (ZIMHI vs Narcan/generic), when available <sup>2</sup>

<sup>1</sup> There is no assurance that any of these measures will actually be implemented

<sup>2</sup> Assuming favorable results from this study

# Development Candidate

DPI-125 Targets the Opioid Crisis



ADAMIS

Pharmaceuticals Corporation

# Opioid Crisis: Treatment and Prevention

## Opioid use is a worsening health crisis

- Every 7 minutes a person dies in the U.S. of an opioid overdose <sup>1</sup>
- According to the CDC: ~1.6 million Americans report suffering from opioid use disorder (OUD) <sup>2</sup>
- Rx options include methadone, buprenorphine and naltrexone (all old), but 87% do not receive evidence-based medical treatment <sup>3</sup>

## Market concerns

- Prescription and illicit opioids target the mu opioid receptor, which provides potent pain relief
- However, binding only to the mu receptor can lead to addiction and death
- A balanced physiological approach that mimics the body's own endorphins is needed



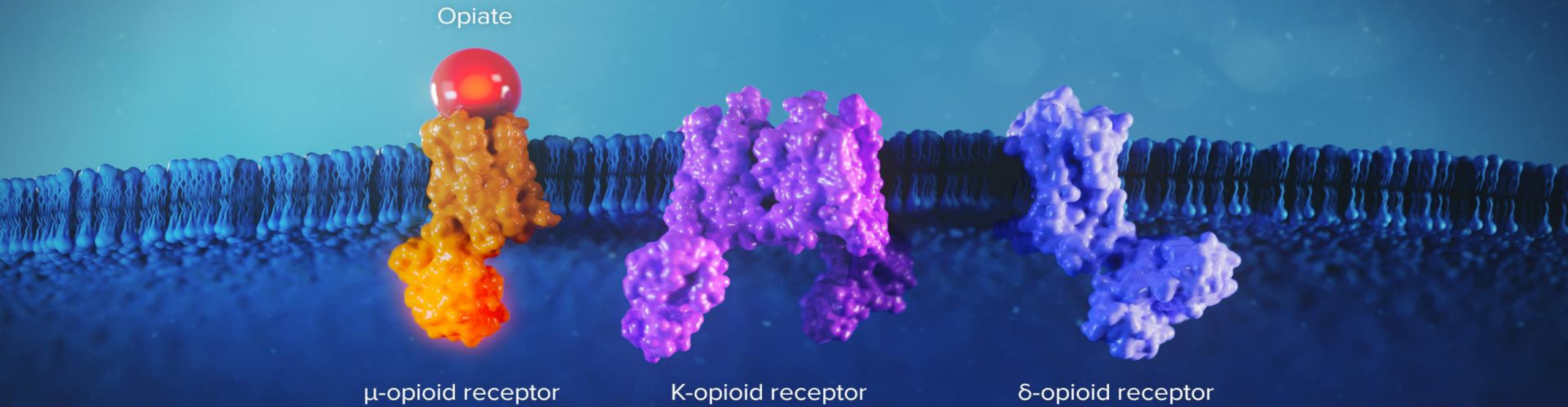
<sup>1</sup> [www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm](http://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm)

<sup>2</sup> <https://www.cdc.gov/stopoverdose/stigma/index.html>

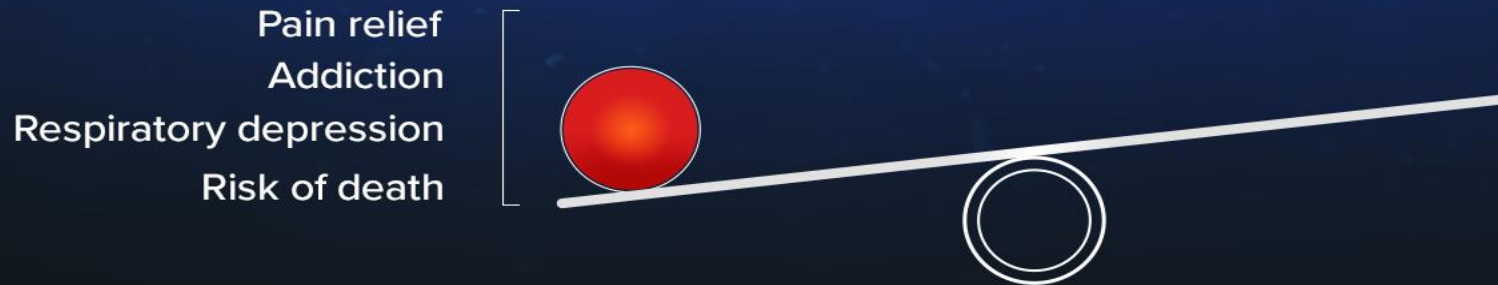
<sup>3</sup> <https://www.sciencedirect.com/science/article/pii/S0955395922002031>

<sup>4</sup> U.S. Centers for Disease Control and Prevention

# Opioid Crisis Caused by Imbalance

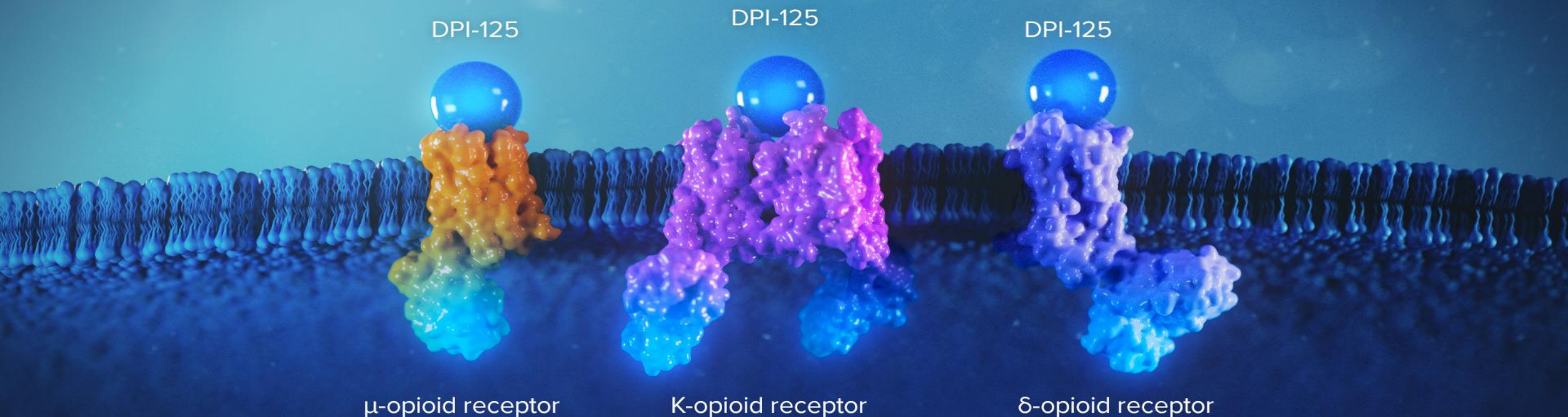


## Targeting Single Receptor (Mu) Drives Addiction and Death





# DPI-125 Takes a Balanced Approach



## Mimicking the Body's Own Endorphins

Pain relief



Target Goals:

Counteracts addiction

Counteracts respiratory depression

# DPI-125: Combating Opioid Addiction

## New solution: DPI-125<sup>1</sup>

- Clinical stage asset
- Animal studies have shown efficacy and safety in terms of respiratory depression and addiction with potent analgesia<sup>2</sup>

## Alternative treatment for OUD and pain

- Current options methadone and buprenorphine (>40 years old) but they work and yet only ~13% get this medical treatment
  - They are addictive, are difficult to access (drug scheduling) and patients have to undergo withdrawal symptoms.
- DPI-125 is not expected to have these issues so could significantly grow the >\$3 billion OUD treatment market<sup>3</sup>
  - Potential to reduce the OUD crisis **by prevention** with a safer, effective, non-dependent pain treatment (100 million Americans: \$22B market)



Overdose deaths in San Francisco are largely be driven by fentanyl, an opioid about 50 times more potent than heroin, and often in combination with other substances such as methamphetamine. <sup>4</sup>

Assuming adequate funding to develop the product, successful trial results, FDA approval, and subject to market factors, competitive factors and other risks and uncertainties

<sup>2</sup> Company's interpretation of the data from rodent and non-human primate studies

<sup>3</sup> Bloomberg Intelligence Drug Explorer 2022

<sup>4</sup> SF Examiner, Overdose deaths in S.F. decline but one community hit hardest by crisis, Nov. 22

# Preventing OUD

## 100 million Americans suffer with pain

- The global prescription market for opioids in 2021 was greater than \$22 billion <sup>1</sup>
- For many, the treatment of pain, using currently marketed, single-receptor opioids was the root cause for their cycle of addiction

## DPI-125 may also offer a safer treatment for acute and chronic pain <sup>2</sup>

- Animal models have demonstrated DPI-125 to be a powerful analgesic
- However, mimicking the body's natural endorphins by binding to all three receptors (delta, mu & kappa), may be a safer and less addictive option



<sup>1</sup> Grand View Research Report ID: GVR-2-68038-131-3

<sup>2</sup> Assuming clinical trial results demonstrate safety compared to standard of care and product label reflects this positive data



# Strategic Priorities: FY 2024

## Execute new partnership to sell ZIMHI

- Focus on first responders by selling to government entities, hospitals and other institutions
- Expand into Canada

## Fund product pipeline via non-dilutive funding (grants)

- DMK previously received NIH funding, we have an active grant to explore portfolio for a novel treatment of alcohol use disorder and have just applied for a \$11.7m follow up grant to further develop DPI-125

## Divest SYMJEPI

- Low-cost, EpiPen-like product does not fit with current product mix but has value as intellectual property
- Currently evaluating US and ex-US companies to either sell or out-license

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