

NASDAQ: MIRA

Investor Presentation October 2024

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### Management



### Erez Aminov

Chief Executive Officer & Excutive Chairman

- Experienced biotechnology investor and adviser with 18+years of experience
- Founder of Locate Venture Corp, a strategy and investment consulting firm which has advised multiple, early-stage life sciences companies including Telomir Pharma and Tyna Pharma on fundraising and strategic partnerships.
- Collaborated with major universities like University of Miami, Bascom Palmer Eye Institute, and helped form strategic partnerships.



#### **Itzchak Angel, PhD** Chief Scientific Advisor

- Over 40 years of experience in guiding medical, pharmaceutical, drug, and business development in both large and emerging companies.
- Expertise in sma I molecules, botanical drugs, biotechnology products, delivery systems, medical devices, and drug-device combinations.
- ► Former Head of Pharmacology at Synthelabo (Sanofi-Aventis, Paris, France) where he participated in research and development of drugs such as Xatral (alfuzosin), Ambien (zolpidem) and Mizollen (mizolastine).



#### Michelle Yanez, MBA

Chief Financial Officer, Secretary & Treasurer

- Senior financial executive with 25+ years of experience in public and privately held companies
- Former Director at BioDelivery Sciences International, Inc. (NASDAQ:BDSI) where she played apivotal role in guiding the company in a\$600 million exit
- Co-Founder of Santander Pharma, a privately held life sciences consulting firm that provides busin ess development and commercial strategy services to pharmaceutical, medical device, and life science companies offering guidance throughout all stages of commercial development.



#### Ryan Vandrey, PhD Scientific Advisor

- Professor of Psychiatry and Behavioral Sciences at the Behavioral Pharmacology Research Unit at Johns Hopkins Medical School.
- His research focuses primarily on the behavioral pharmacology of cannabis and includes controlled laboratory studies with adult research volunteers, clinical trials, web-based survey research, and natural history studies with patient populations using cannabis/cannabinoids for therapeutic purposes



#### Alex Weisman, PhD Scientific Advisor

- Occupied executive positions of VP R&D and Chief Scientist at numerous Israeli and international pharmaceutical companies. Currently serve as an advisor and management team member for companies developing new products for the chemicals, pharmaceuticals, and food industries.
- More than 30 years of experience in the development, characterization, scale-up, technology transfer, troubleshooting, production and registration of novel and generic drugs, and other pharmaceutical and chemical products.

### Corporate Overview

MIRA Pharmaceuticals is a pre-clinical-stage pharmaceutical development company with two neuroscience programs targeting a broad range of neurologic and neuropsychiatric disorders.

**Ketamir-2** ("Ketamir") is a novel ketamine analog with improved oral bioavailability and safety profile currently under investigation for the potential to treat neuropathic pain and to deliver ultra-rapid antidepressant effects, providing hope for individuals battling treatment-resistant depression (TRD), major depressive disorder with suicidal ideation (MDDSI).

**MIRA-55** is a novel oral pharmaceutical marijuana analogue under investigation for treating adult patients suffering from anxiety and cognitive decline often associated with early-stage dementia.

#### **Ketamir-2 Key Differentiating Factors**

- Predicted 80% oral bioavailability: More than double that of oral or intranasal absorption of ketamine<sup>1</sup>
- Enhanced safety and tolerability: Administration ease and aims for fewer side effects
- Unscheduled: Upon review of the chemical structure, the DEA has determined Ketamir-2 is not a controlled substance.

#### **MIRA-55 Key Differentiating Factors**

- Synthetic: Produced with high purity, consistency and safety.
- Optimized: Enhances cognitive performance, while simultaneously decreasing anxiety.
- Unscheduled: Upon review of the chemical structure, the DEA has determined MIRA-55 is not a controlled substance.

1 Zhang K, Yao Y, Hashimoto K. Ketamine and its metabolites: Potential as novel treatments for depression. Neuropharmacology. Jan 1 2023;222:109305. doi:10.1016/j.neuropharm.2022.109305 MIRA-55 and Ketamir-2 are in early stage pre-clinical development. There is no assurance that the products will proceed through development or will receive FDAapproval for marketing.



# What is **Ketamir-2?**

- Ketamir-2 ("Ketamir") is an innovative ketamine analog with improved oral bioavailability and safety profile currently under investigation for the potential to treat neuropathic pain and to deliver ultra-rapid antidepressant effects.
- Neuropathic pain affects approximately 7-10% of the general population
- It is designed to address the challenges presented by major depressive disorder (MDD), which affects over 264 million individuals globally and poses substantial economic and societal burdens.
- Ketamir-2 is being developed to address the demand for a rapid-acting antidepressant, particularly for Treatment-Resistant Depression (TRD). It provides hope for individuals who have not responded to existing treatments.

- The development of Ketamir-2, with its improved bioavailability and safety profile, potentially decreased side effects and abuse liability, is poised to offer a significant advancement in the treatment of MDD and neuropathic pain.
- The U.S. Drug Enforcement Administration's review concluded that Ketamir is not considered controlled substances or listed chemical under the Controlled Substances Act and its regulations, facilitating its development and potential approval.

It may potentially reduce adverse effects and risks associated with ketamine use, offering a safer treatment option.

# Therapeutic **Focus Areas**

Ketamir-2 is under investigation to potentially treat neuropathic pain with a higher safety profile.



#### **Neuropathic Pain**

- Neuropathic Pain is a complex pain condition that arises from dysfunction or damage to the nervous system.
- Key Therapeutic Area
- Affecting approximately 7-10% of the general population<sup>1</sup>. Examples include diabetic peripheral neuropathy, postherpetic neuralgia, and multiple sclerosis related neuropathy.

- Existing treatments may involve medications like anticonvulsants or antidepressants. However, their effectiveness can be limited, and they might carry side effects. Opiates are used when other treatments fail, but are burdened by the risk of addiction.
- Developing targeted and efficient therapies for neuropathic pain stands as a priority for numerous pharmaceutical companies to address this common source of suffering and morbidity for treatment-resistant cases. Innovative strategies, including cannabinoid therapies, are under exploration to tackle the distinctive challenges posed by this type of pain.

### Therapeutic Focus Areas

Ketamir-2 is under investigation to potentially deliver ultra-rapid antidepressant effects as early as four hours after dosing.

#### **Major Depressive Disorder**

- Major depressive disorder (MDD) is defined by depressed mood, diminished interests, impaired cognitive function & vegetative symptoms (ex., disturbed sleep / appetite)
- This disorder symptoms can totally hinder one's ability to focus on daily activities such as work, eat and sleep
- MDD causalities majorly include 60% of cases caused by environmental factors such as life events & trauma and the rest affected by heritability<sup>1</sup>
- Approximately 17.6M Americans are diagnosed with Major Depressive Disorder, of which 5.5M report suicidal ideation of any kind, and ~2M report suicidal ideation with intent
- Cognitive-behavioral therapy (CBT) is the most common non-pharmacological option combined with multiple pharmacological options (SSRIs, SNRIs, TCAs, and recently esketamine)
- Despite several available treatments (some generic), treatments with greater overall efficacy and faster onset of action are needed
- Identification of patients that will respond best to specific treatments remains a challenge



# Major Depressive Disorder with Suicidal Ideation (MDDSI)

- Characterizes patients with MDD who have reported suicidal ideation and need intervention
- The age-adjusted suicide rate for MDDSI is 15.3 per 100,000 persons in the US, significantly higher than the global rate of 10.5 per 100,000 persons
- Solution Solution

#### **Treatment Resistant Depression (TRD)**

- Refers to patients with inadequate response to at least two/three antidepressant trials of adequate dose and duration
- Treatment resistance (2+ treatments) to standard therapies occurs in up to 30% of the treated MDD patient population
- Age, gender and health status may increase risk for treatmentresistant depression
- The total annual burden of medication-treated MDD among the US population was \$92.7 Bn, with \$43.8 Bn (47.2%) attributable to TRD



# Market Opportunity

#### Summary of US Epidemiology

The eligible patient pool analysis for Ketamir-2 highlights a potential large patient pool looking for potential treatments to their conditions.

| Total Eligible<br>Population | Diagnosed<br>Prevalence                                   | Treatment<br>Rate                                                              | Total Addressable<br>Population                                                                             |
|------------------------------|-----------------------------------------------------------|--------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| 20.0M                        | 10-15%                                                    | 25-35%                                                                         | 1.0-1.5M                                                                                                    |
| 246.7M                       | 3%                                                        | 65%                                                                            | 4.9M                                                                                                        |
| 246.7M                       | 2%                                                        | 65%                                                                            | 3.8M                                                                                                        |
|                              | Total Eligible<br>Population<br>20.0M<br>246.7M<br>246.7M | Total Eligible<br>PopulationDiagnosed<br>Prevalence20.0M10-15%246.7M3%246.7M2% | Total Eligible<br>PopulationDiagnosed<br>PrevalenceTreatment<br>Rate20.0M10-15%25-35%246.7M3%65%246.7M2%65% |

### **Key Highlights**

- Total addressable populations for Neuropathic Pain, MDDSI, and TRD are derived from published literature on epidemiology for each disease and by applying estimated diagnosis and treatment rates (except where diagnosed prevalence used).
- Treatments paradigms for these conditions can differ from patient to patient due to the vast array of potential root causes, external factors, and treatment options
- Healthcare professionals are consistently looking for more efficacious treatments with fewer side effects and a faster onset of action to help patients

# IQVIA Analysis

#### **Revenue Projections**

- Ketamir-2 in the U.S. market is projected to be between approximately \$10.9 billion and \$87.8 billion
- Base case estimate of around \$3 billion by the year 2035

#### **KETAMIR-2** could potentially reach peak annual sales

KETAMIR – Revenue Forecast Summary (Base Case)



### Key Growth Drivers in Base Case

Superior Profile: Delivering superior efficacy / safety vs existing options, as well as a comparable experience to other approved drugs in a similar class (Spravato) will drive uptake. Strategic Positioning: The potential within the branded TRD market to enter after 2-3 generics, provided superiority over other branded options can be demonstrated, will preserve pricing & share. Branded Pricing: Pricing below Spravato (considered to be the upper end of what Payors consider achievable) but higher than Rexulti (a known branded option) will minimize payor restrictions.



Surgical Procedure:

The Chung model involves tightly ligating of two (L5 and L6) segmental spinal nerves in rats. This procedure creates a partial nerve injury that mimics neuropathic pain conditions.

#### **Behavioral Outcomes:**

Following the spinal nerve ligation, rats exhibit long-lasting behavioral signs indicative of neuropathic pain, including mechanical allodynia. Response to Von Frey Filaments is measured at 14 and 21 days after the operation.





Comparative effects of several oral doses of Ketamir-2 to Ketamine, Pregabalin and Gabapentin in the Chung model of Neuropathic pain in rats



Figure 1. Comparative effects in male rats



Figure 2. Comparative effects in female rats





Comparative effects of several oral doses of Ketamir-2 to Gabapentin in the PTX model of Neuropathic pain in mice



Figure 3. Comparative effects in male and female mice

The open field test is a commonly employed behavioral assays used to evaluate the efficacy of anxiety and depression medications.

Mice treated with antidepressants typically exhibit greater locomotor activity, moving more extensively and exploring a larger area of the open field compared to control mice. These treated mice are also more inclined to spend time in the central region of the open field, which indicates a decrease in anxiety and an increase in exploratory tendencies.

Mice treated with all tested concentrations of Diketamir-2 moved larger distance than vehicle treated mice. They also significantly were faster, with higher velocity compared to control. Mice treated with Diketamir also showed a trend of more time spent in the center.







Figure: Open field parameters. (A) Distance moved (cm); (B) mean velocity (cm/seconds) and (C) cumulative time spent in center (seconds). Significance values were obtained through One-Way ANOVA

In the forced swimming test (FST), mice treated with antidepressants are generally more mobile. They also show reduced immobility time compared to control mice. Instead of remaining immobile, they exhibit increased active behaviors such as swimming and climbing. This increased activity is interpreted as a sign of decreased behavioral despair and an antidepressant-like effect.

Mice treated with Diketamir-2 show reduction in traveled distance and lower velocity. When mobility state was analyzed, 300mg/kg of Diketamir is the only Diketamir treatment that reduced hyper-mobility, and increased mobility significantly. No treatment significantly induced immobility compared to vehicle treated, however-100 and 200mg/kg Diketamir and Ketamine showed a trend of reduced immobility.

#### **Forced Swim Test**



Figure: Forced swimming test (FST) parameters. (A) Distance moved (cm); (B) mean velocity (cm/seconds), (C) highly mobile (seconds), (D) mobile, and (E) immobile (seconds). Significant values were obtained through One-Way ANOVA. 8

In the elevated plus maze mice treated with antidepressants typically demonstrate increased exploratory behavior and reduced anxiety. These mice are more likely to enter and spend more time in the open arms of the maze, areas that anxious animals usually avoid. This increased presence in the open arms suggests an anxiolytic effect and enhanced willingness to explore novel environments.

Mice treated with Diketamir-2 moved larger distance than vehicle treated mice. They were also significantly were faster, with higher velocity, and spent more time in the center of the maze, compared to control.



#### **Elevated Plus Maze**



Figure Elevated plus maze (EPM) parameters. (A) Distance moved (cm); (B) mean velocity (cm/seconds), (C) cumulative time spent in open arms (seconds. Significant values were obtained through One-Way ANOVA



Ketamine-induced hyperlocomotion is considered a schizophrenia-like effect because it models the hyperactive and psychotic symptoms observed in schizophrenia patients.

Unlike Ketamine, which resulted in marked and significant hyperlocomotion, Ketamir-2 did not produce incidences of inducing hyperlocomotion, schizophrenia-like behaviors in animal models, indicating a safer profile for patients, especially those with a predisposition to psychotic disorders.

#### Spontaneous hyperlocomotion



Figure: Spontaneous hyperlocomotion in mice (1 hour) Results are expressed as mean±SEM

\*\*\*: p<0.001 for ketamir(50 mg/kg, ip) vs vehicle (ip) by one-way ANOVA test followed by a Dunnett's multiple comparisons test

###: p<0.001 for ketamine (20 mg/kg, ip) vs vehicle (ip) by two-tailed Student's t test for independent samples.



# Pre-Clinical

Ketamir was evaluated on a large array of receptors, transporters and binding sites. It was found that Ketamir is a low affinity NMDA receptor antagonist, that selectively binds to the PCP-site. Its IC50 on this receptor site is  $\sim$ 100 µM.

While Ketamine is known to also interact with several neurotransmitter transporters, including the serotonin transporter (SERT) and norepinephrine transporter (NET) and to additional sites at the NMDA-receptor complex, Ketamir-2 does not bind to the AMPA, Kainate, sigma, glutamate or to the glycine ion sites.



Figure: Data obtained from the Binding to the PCP-site at the NMDA receptor.

- Unlike ketamine, Ketamir-2 was shown not to be a substrate of PgP, enabling a better bioavailability and brain penetration.
- Oral bioavailability is predicted to be 80% based on a model of intestinal absorption and metabolism, more than double that of oral or intranasal absorption of ketamine.
- Improved oral bioavailability currently under investigation for its potential to deliver ultra-rapid antidepressant effects.
- Potential shift to observed oral, home administration, granting patients greater autonomy, convenience, and accessibility to a potentially effective depression treatment



CaCO-2 Bioavailability Ketamir vs Ketamine

**Figure:** Data obtained from the CaCO-2 model of intestinal absorption. Propranolol, a commonly prescribed beta-blocker that is taken orally and used to treat hypertension, is included as a positive control. The intestinal absorption (AB), Intestinal efflux (BA) and net absorption (AB-BA) are shown.





### Anticipated Timeline for Ketamir-2

Pre-clinical work is underway and expected be completed by Q4'24

Positioning Ketamir-2 for an initial IND submission in 2024



# What is MIRA-55?

#### **Key Differentiating Factors**

#### THC

- Schedule 1, which means no accepted medical purpose
- >> Negative side effects
- >>> Legal/regulatory hurdles
- >> Heightened competition
- Shipping/manufacturing issues

#### MIRA-55

- Pure Synthetic
- Based on preclinical studies, better side effect profile (e.g. decreased anxiety across the dose range, improved rather than impaired cognition)
- Being developed to be a prescription medication



### Therapeutic Focus Areas

MIRA-55 is under evaluation for two key therapeutic areas with high disease burden and significant unmet needs



#### **Cognitive Impairment**

- Cognitive Impairment encompasses conditions marked by notable decline in one's cognitive abilities including Alzheimer's disease and dementia
- ~16 million people in the US are living with cognitive impairment<sup>4</sup>
- Current treatments for cognitive impairment can not restore lost function and instead transiently delay the progression of the disease.



#### **Anxiety and Cognitive Decline in the Elderly**

- Anxiety disorders are chronic conditions marked by an excessive & persistent sense of apprehension, with physical symptoms such as sweating, palpitations, and feelings of stress
- ~40 million US adults have an anxiety disorder<sup>2</sup>, including phobias, Social Anxiety Disorder, PTSD, Generalized Anxiety Disorder, and Panic Disorder<sup>3</sup>

Standard pharmacological options include SSRIs, SNRIs, and TCAs (all of which take weeks for the anxiety to respond)\*

#### MIRA<sup>®</sup> Pharmaceutical

# Market Opportunity

#### Summary of US Epidemiology

The eligible patient pool analysis for MIRA-55 highlights a potential large patient pool looking for potential treatments to their conditions

| MIRA-55 Target<br>Indications                  | Total Eligible<br>Population | Diagnosed<br>Prevalence | Treatment<br>Rate | Total Addressable<br>Population |
|------------------------------------------------|------------------------------|-------------------------|-------------------|---------------------------------|
| Mild Cognitive<br>Impairment/Early<br>Dementia | 33.0M                        | 15-20%                  | 35-45%            | 4.95-6.6M                       |
| Anxiety                                        | 40.0M                        | 15-20%                  | 35-50%            | 6.0-8.0M                        |
|                                                |                              |                         |                   |                                 |

### **Key Highlights**

- Total addressable populations are derived from published literature on epidemiology for each disease and by applying estimated diagnosis and treatment rates (except where diagnosed prevalence used)
- Treatment paradigms for these conditions can differ from patient to patient due to the vast array of potential root causes, external factors, and treatment options
- Healthcare professionals are consistently looking for more efficacious treatments with fewer side effects and faster onset of action to help patients
- In many patient populations, non-US legal, and cultural settings, marijuana may not be the first or a viable option for treatment of neurological disorders. As a result, these patients will typically use non-steroidal anti-inflammatory drugs (NSAIDs) or various mood management drugs, opening them up to a range of non-ideal outcomes

What was tested: The effect of MIRA-55 on anxiety in mice.

How it was done: Mice received an injection of either MIRA-55 or a placebo (like saline). They were then placed in a special maze called the Elevated Plus Maze, designed to measure anxiety.

Why this maze: The maze has open and closed areas. Generally, anxious mice avoid open areas.

**Results:** Mice treated with MIRA-55 spent more time in open areas, suggesting they were less anxious. Importantly, they didn't show signs of being sedated or intoxicated.

Implication: MIRA-55 could potentially be a good treatment for anxiety disorders without the side effects of drowsiness or intoxication.







The Elevated Plus Maze (EPM) test was conducted to evaluate the anti-anxiety effects of a Mira-55. In this study, mice were administered an intraperitoneal injection of either a placebo or MIRA-55 at a dosage of 50mg/kg. Thirty minutes following the administration, the mice were introduced to the EPM for testing. The EPM test is designed to measure anxiety levels in rodents, where the X-Axis of the data representation indicates the two different conditions (Placebo and MIRA-55 treatment), and the Y-Axis represents the percentage of time spent in the open arms of the maze. This duration is a crucial indicator of the reduced anxiety levels in the subjects. The findings from this test were significant; MIRA-55 demonstrated a remarkable anti-anxiety effect, as evidenced by a notable increase in the time spent in the open arms of the maze by the mice treated with MIRA-55, in comparison to those who received the placebo.



What was tested: The pain-relieving potential of MIRA-55.

How it was done: Mice were given MIRA-55 or a placebo. Then, they were placed on a warm plate, and the time they took to react to the heat (by lifting their paws) was measured.

**Results:** Mice treated with, MIRA-55 took longer to react, meaning they felt less pain.

**Implication:** MIRA-55 could be an effective pain reliever, potentially for conditions where managing pain is crucial.



#### **Thermal Sensitivity for Pain**



The Thermal Sensitivity test aimed to assess the potential of MIRA-55 for this type of pain relief. In this model, following the treatment with either a placebo or MIRA-55, mice were placed on a heated plate. The response to the heat stimulus was measured by recording the time taken for each mouse to lift its paw, an action indicative of experiencing pain. The data representation for this test included an X-Axis, which delineated the treatment conditions (Placebo and MIRA-55), and a Y-Axis, which showed the latency to paw lifting, a measure of pain sensitivity. The findings from this study were promising; mice treated with MIRA-55 exhibited a significantly increased latency in paw lifting, suggesting that MIRA-55 is effective in providing pain relief and enhancing pain tolerance, as compared to the placebo group.

What was tested: The impact of MIRA-55 on memory and learning in mice.

How it was done: This study used a special test where mice learn to associate a specific place with a mild shock. After training, they were given MIRA-55 before being placed back in the same place the next day.

Measure of memory: Researchers measured how much the mice 'froze' in the place they associated with the shock. More freezing indicates better memory.

**Results:** Mice given MIRA-55 showed significantly more freezing behavior, indicating they remembered the shock association better than those who didn't receive MIRA-55.

**Implication:** MIRA-55 could enhance memory and learning, separate from its anti-anxiety effects, which is a unique finding not seen in other similar compounds.



#### **Context Fear Conditioning for Cognitive Performance**

**Context Conditioning** 



The Context Fear Conditioning test was designed to evaluate the impact of MIRA-55a on cognitive performance, focusing particularly on memory and associative learning. The method involved conditioning mice with a mild foot shock in a specific chamber on the first day, followed by a test on the second day for memory recall of this event on the second day when the mice received for the first time MIRA-55. The X-Axis in the data representation highlighted the different treatment conditions – Placebo and various doses of MIRA-55. In contrast, the Y-Axis represented the percentage of time the mice spent freezing, a behavioral response indicative of memory recall. The findings from this test were groundbreaking; MIRA-55 significantly enhanced memory recall, as demonstrated by the increased duration of freezing behavior in mice. This marked improvement in cognitive performance, particularly in memory and associative learning, was noted as being unprecedented among cannabinoid compounds, highlighting the potential of MIRA-55 in cognitive enhancement.



# Regulatory Pathway to Commercialization

To develop, **MIRA-55** as a commercialization asset, we are proceeding on a well-established regulatory pathway designed to establish its safety and efficacy

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#### **Pre-Clinical Testing**

Focus on pre-clinical testing including genetic toxicology, safety pharmacology and general toxicology testing to enable the filing of an IND application with the USFDA.

#### **Clinical Trials**

Clinical testing and trials based on guidance from FDA with a focus on our initial prioritized indications while preserving optionality to add 1 or 2 more indications with strategic partners.





### Anticipated Timeline for MIRA-55

Pre-clinical work is underway

# Positioning MIRA-55 for an initial IND submission in 2025



# Growth Strategy



**Continue pre-clinical development** of Ketamir-2 and MIRA-55 across a range of central nervous system diseases and progress into clinical development



Advance Ketamir-2 and MIRA-55 through clinical development and FDA approval



Identify additional product candidates and expand current candidates into additional neurological disorders



**Explore strategic collaborations** and partnerships to maximize the value of our product candidates

Investment Highlights



#### **KETAMIR-2**

**Ketamir-2** is an innovative analog of Ketamine developed as an oral formulation designed to potentially reshape the landscape of neuropathic pain and depression treatment. A predicted 80% oral bioavailability is more than double that of oral or intranasal absorption of ketamine.

The neuropathic pain market across the U.S., Canada, and Mexico is projected to reach \$5.2 billion by 2030, and the potential to address the \$92.7 billion annual burden of medication-treated major depressive disorder (MDD), Ketamir-2 is poised to make a significant impact in the field.

The U.S. Drug Enforcement Administration (DEA) determined that Ketamir-2 is not a controlled substance or listed chemical. Ketamir-2 avoids the risk/challenges of legal and regulatory hurdles, elevated production costs, heightened competition and manufacturing/transportation issues.

#### **MIRA-55**

**MIRA-55** is a new chemical entity and pharmaceutical marijuana that, if approved, potentially enhances the therapeutic potential for treating anxiety and cognitive decline that is potentially less intoxicating than THC while still providing beneficial therapeutic effects.

MIRA-55 will potentially have access to \$90B+ traditional neurological markets AND \$30B cannabis markets, representing a potential large revenue opportunity





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