

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): August 4, 2018

**CV SCIENCES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**000-54677**

(Commission File Number)

**80-0944970**

(I.R.S. Employer Identification No.)

**2688 South Rainbow Boulevard, Suite B  
Las Vegas, Nevada 89146**

(Address of principal executive offices)

**(866) 290-2157**

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a -12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d -2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e -4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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## **Item 2.02 Results of Operations and Financial Condition**

The information provided below in “Item 7.01 – Regulation FD Disclosure” of this Current Report on Form 8-K is incorporated by reference into this Item 2.02.

## **Item 7.01 Regulation FD Disclosure**

On August 4, 2018, Dr. Joseph C. Maroon, a Board-Certified Neurosurgeon presented materials titled *Cannabidiol (CBD): Therapeutic Uses for Health and Wellness* (the “Maroon Presentation”) as a guest of CV Sciences, Inc. (the “Company”) at its Investor Day following the conclusion of its 2018 Annual Meeting of Stockholders. Following Dr. Maroon’s presentation, the Company’s Chief Executive Officer, Joseph Dowling, presented materials titled *CV Sciences, a Life Sciences Company, CBD-Based Pharmaceutical & Consumer Products – Corporate Presentation* (together with the Maroon Presentation, the “Materials”). Some of the information in the Materials and disclosed at the Investor Day was not previously disclosed publicly and as a result the Materials are furnished as Exhibit 99.1 and Exhibit 99.2 hereto and incorporated herein by reference.

Exhibit 99.1 and Exhibit 99.2 contain forward-looking statements. These forward-looking statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Forward-looking statements are based upon assumptions as to future events that may not prove to be accurate. Actual outcomes and results may differ materially from what is expressed in these forward-looking statements.

The information set forth under Item 7.01 of this Current Report on Form 8-K (“Current Report”), including Exhibit 99.1 and Exhibit 99.2 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of such section. The information in Item 7.01 of this Current Report, including Exhibit 99.1 and Exhibit 99.2, shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any incorporation by reference language in any such filing, except as expressly set forth by specific reference in such a filing. This Current Report will not be deemed an admission as to the materiality of any information in this Current Report that is required to be disclosed solely by Regulation FD.

## **Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 [Cannabidiol \(CBD\): Therapeutic Uses for Health and Wellness Presentation, dated August 4, 2018.](#)

99.2 [CV Sciences, a Life Sciences Company, CBD-Based Pharmaceutical & Consumer Products - Corporate Presentation, dated August 4, 2018.](#)

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

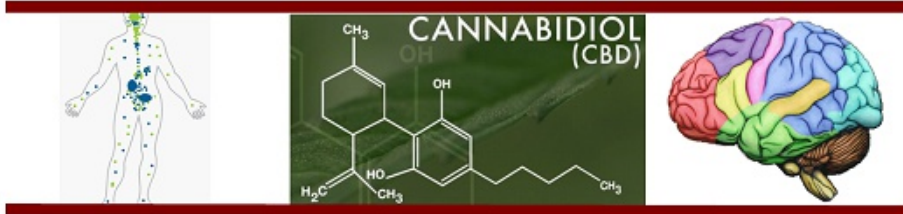
Date: August 7, 2018

**CV SCIENCES, INC.**

By: /s/ Joseph Dowling  
Joseph Dowling  
Chief Executive Officer and Chief Financial Officer

# Cannabidiol (CBD)

## Therapeutic Uses for Health and Wellness



**Joseph C. Maroon, M.D.**  
**Board-Certified Neurosurgeon**  
**Sports Medicine Consultant**  
**Health and Nutrition Expert**

Aug 4, 2018

**WHAT DOES  
HEALTHY  
MEAN TO YOU?**



# To be Healthy

Being physically healthy and fit involves not only how you look, but also how you feel and your overall health.

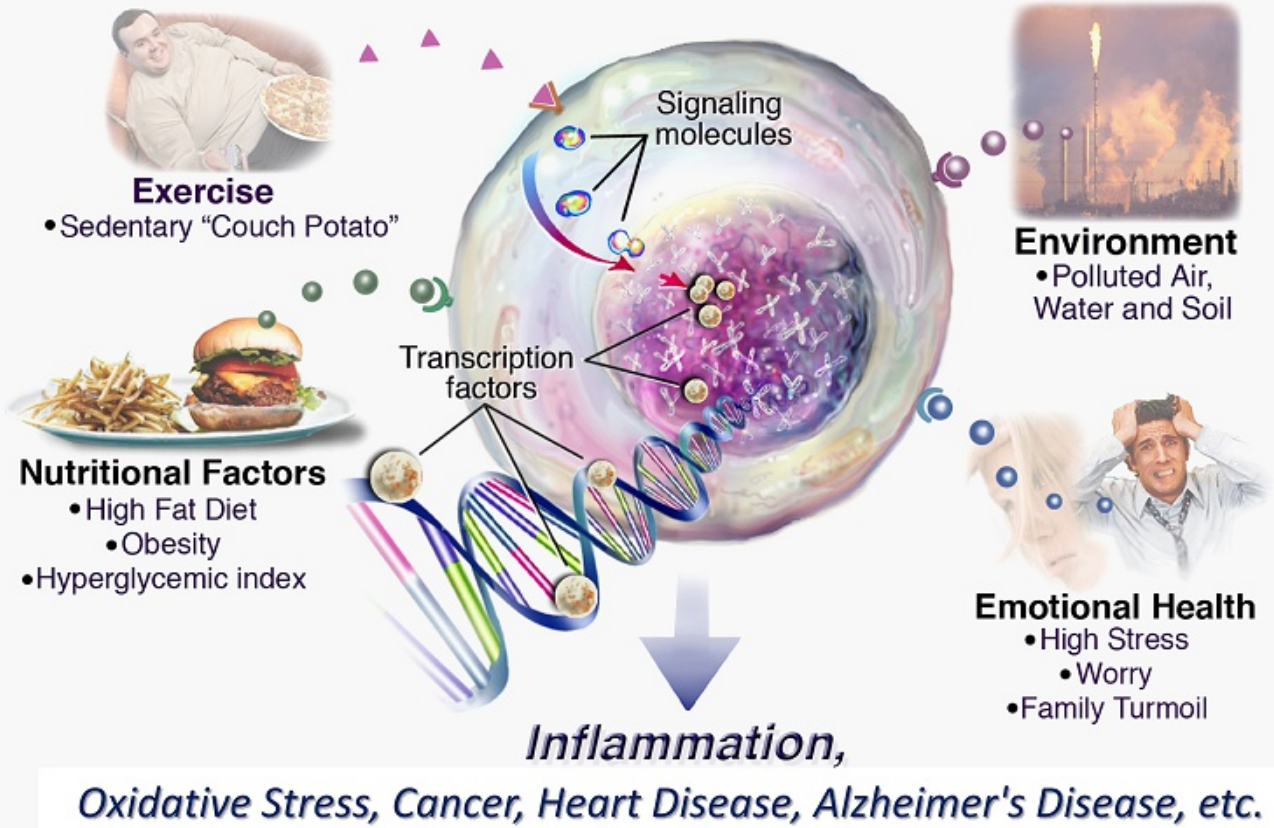
## Healthy Factors:

1. **Physical**
2. **Nutritional**
3. **Toxin Free**
4. **Spiritual/ Emotional**

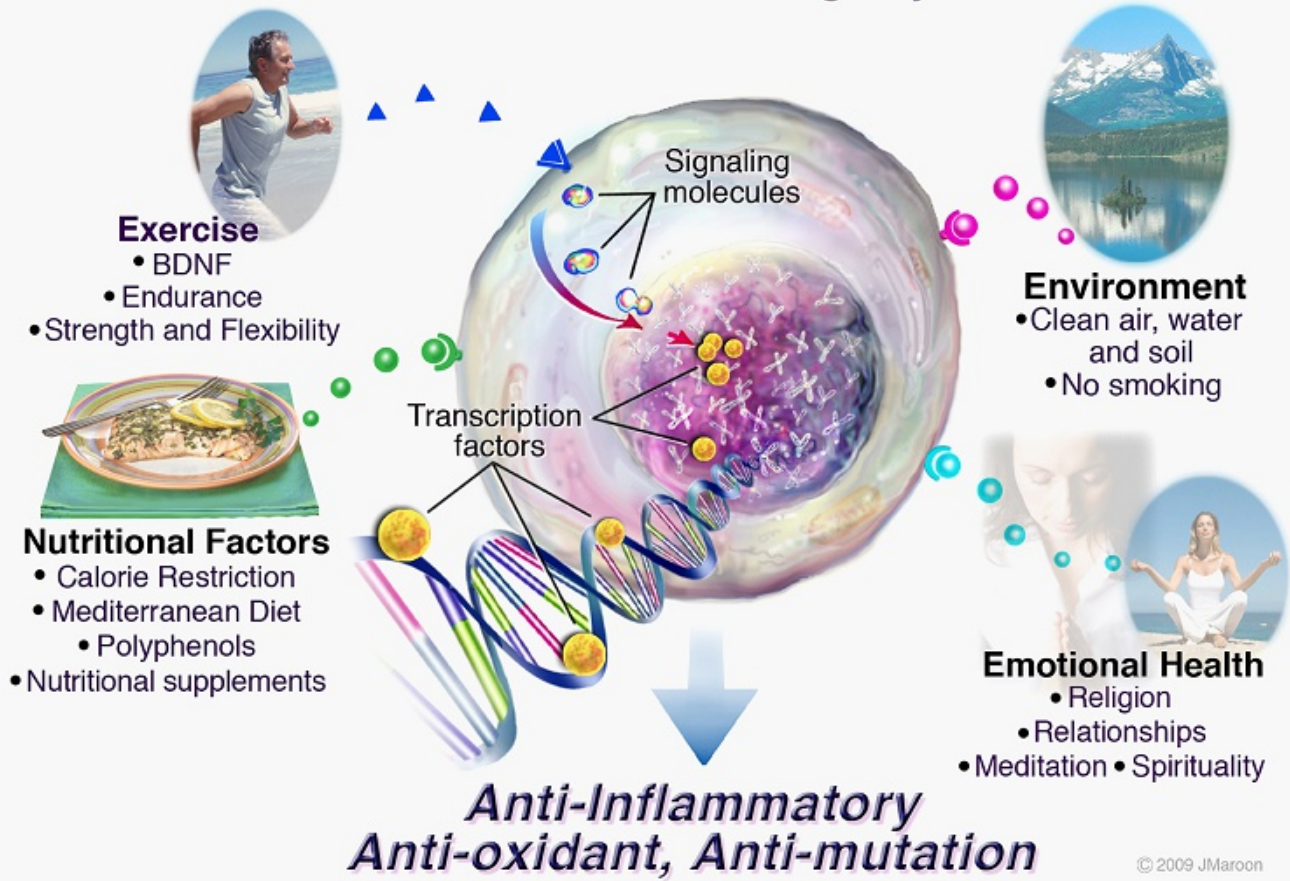


# Epigenetics and Gene Activation

## Poor Health and Reduced Longevity



# Epigenetics and Gene Activation For Health and Longevity



# CBD as Both a Dietary Supplement and Pharmaceutical

## Differences

### **Drug** – Requires Prescription

- FDA clearance, Drug Quality and Quantity Testing Required, Medical/Therapeutic Claim to Treat Something, possible higher dose than supplement

### **Dietary Supplement** – NO Prescription

- NO FDA clearance, Food Quality and Quantity Testing Required, NO Medical/Therapeutic Claim to Treat Something



# Best Example of Supplement and Prescription Drug using Same Product

## Omega-3 Fish Oil

- **Supplements** – 1.07 to 1.15B US annual sales, Global ~3.3 B
- **Pharmaceutical**
  - Lovaza (GlaxoSmithKline)
  - Generic versions of Lovaza
    - Omtryg (Trygg Pharma, Inc.)
    - Epanova (AstraZeneca Pharmaceuticals LP).
  - Vascepa (Amarin Pharma Inc.)

<https://www.futuremarketinsights.com/reports/essential-fatty-acids-market>

# FDA Approves First CBD Drug

Reuters

## **U.S. approves first marijuana plant-derived drug**

June 25, 2018

The U.S. Food and Drug Administration approved GW Pharmaceuticals' epilepsy treatment on Monday, making it the first cannabis-based drug to win approval in the country.

The landmark approval could potentially open floodgates for more research into the medicinal properties of cannabis.

"This approval serves as a reminder that advancing sound development programs that properly evaluate active ingredients contained in marijuana can lead to important medical therapies" said FDA Commissioner Scott Gottlieb.



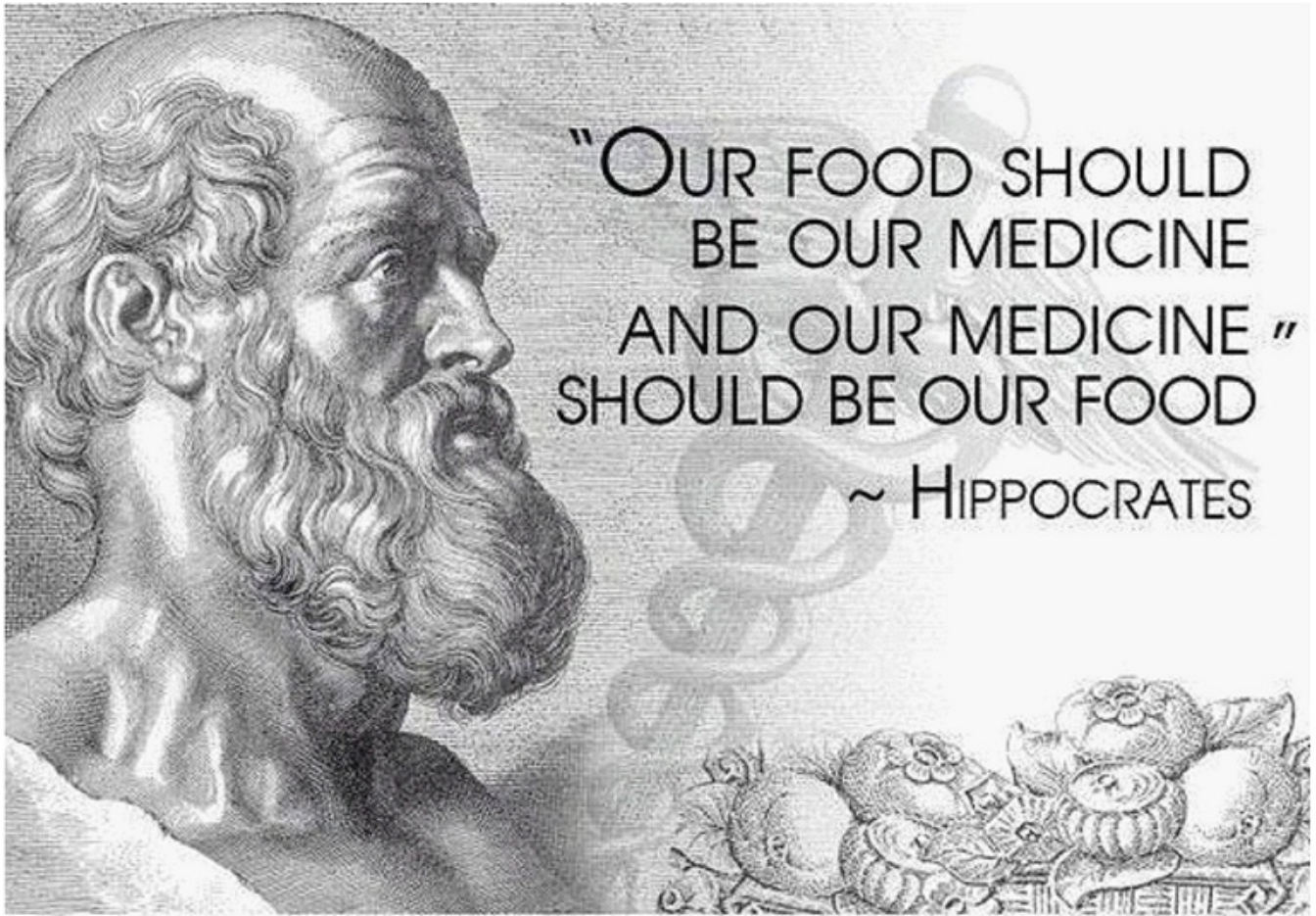
# What Does this Mean?

- Requires FDA to rule on whether to change CBD Schedule Classification from Schedule I
- Will require public release of Safety Data from GW Pharma Animal and Human Trials
- Resultant Effects:
  - Will unlikely need to complete expensive and time consuming safety trials for CBD
  - Schedule change will ease acceptance of CBD medications by FDA



- CBD will *no longer be listed as a banned substance* for international sport competition for 2018
- $\Delta$ 9-THC will *still be prohibited*
- CBD extracted from the hemp plant has than 0.3%  $\Delta$ 9-THC.

SUMMARY OF MAJOR MODIFICATIONS AND EXPLANATORY NOTES 2018 PROHIBITED LIST, World Anti-Doping Agency, [https://www.wada-ama.org/sites/default/files/prohibited\\_list\\_2018\\_summary\\_of\\_modifications\\_en.pdf](https://www.wada-ama.org/sites/default/files/prohibited_list_2018_summary_of_modifications_en.pdf)



# Case Report – Pain Reduction



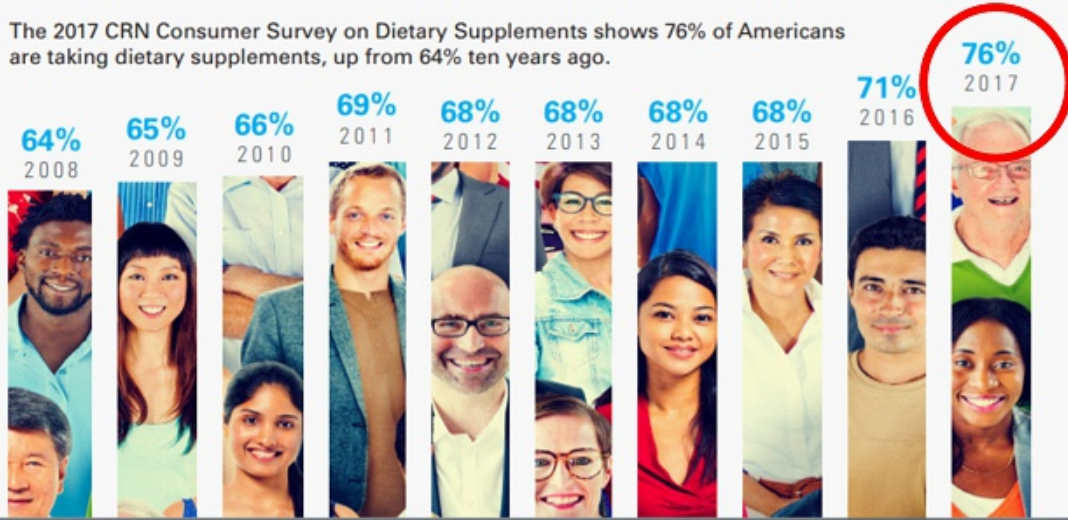
# WHO TAKES DIETARY SUPPLEMENTS?

2017  
**76%** of  
U.S. ADULTS



## GROWTH OF DIETARY SUPPLEMENT USE OVER THE LAST DECADE

The 2017 CRN Consumer Survey on Dietary Supplements shows 76% of Americans are taking dietary supplements, up from 64% ten years ago.



<https://www.crnusa.org/resources/crn-2017-annual-survey-dietary-supplements>

*Cannabis*, genus



*Cannabis sativa*, species



## Marijuana

Cultivated to have maximum  
**(5 to 20%) psychoactive THC**



## Hemp

Significantly more  
**Cannabidiol (CBD)** **No Cognitive**  
**side effects**

**THC (< 0.3%)**



Trends in new crops and new uses. 2002. J. Janick and A. Whipkey (eds.). ASHS Press, Alexandria, VA. Hemp: A New Crop with New Uses for North America Ernest Small and David Marcus



# Plant-based Medical Marijuana

(Whole Plant and Extracts THC, CBD, Terpenes)

**Cannabis source** Requires a **prescription/certification of need in most States where it has been legalized, Not FDA approved:**

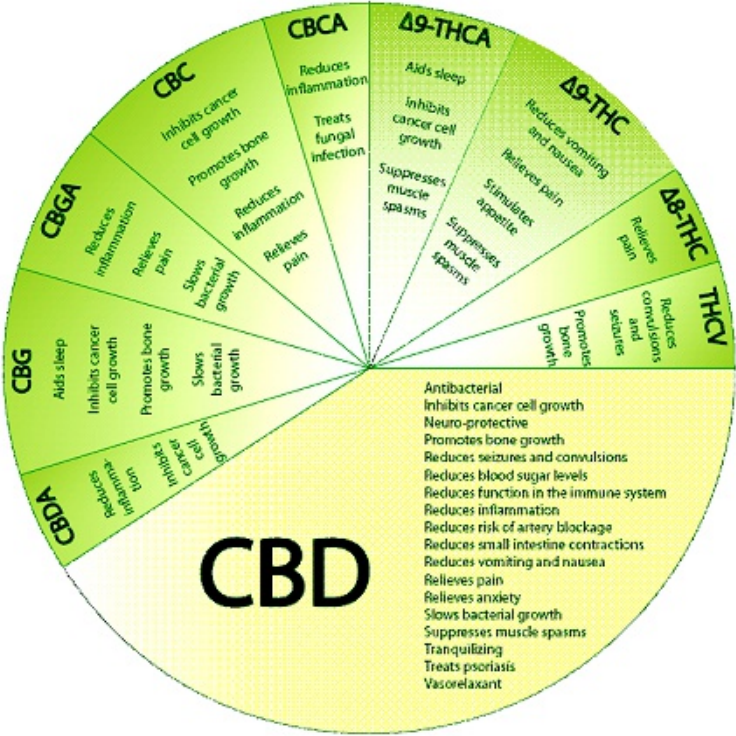
## Indications: (selected List)

- Intractable headaches
- Cancer pain
- Nerve pain
- Muscle spasms/spasticity
- Glaucoma
- Nausea from cancer chemotherapy
- Poor appetite and weight loss caused by chronic illness, such as HIV
- Crohn's disease
- PTSD
- Intractable Seizures and more



*cannabis sativa* –  
**Selectively Cultivated  
Commercially to have  
Higher Levels of THC**

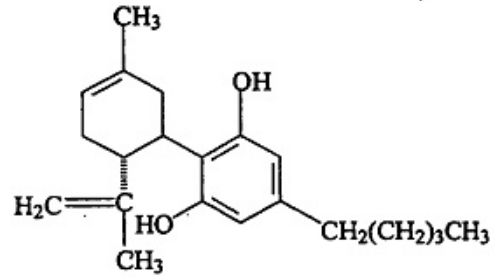
There are over 60 Phytocannabinoids found in Marijuana and Hemp with a Wide Variety of Actions



# Hemp Cannabidiol (CBD)

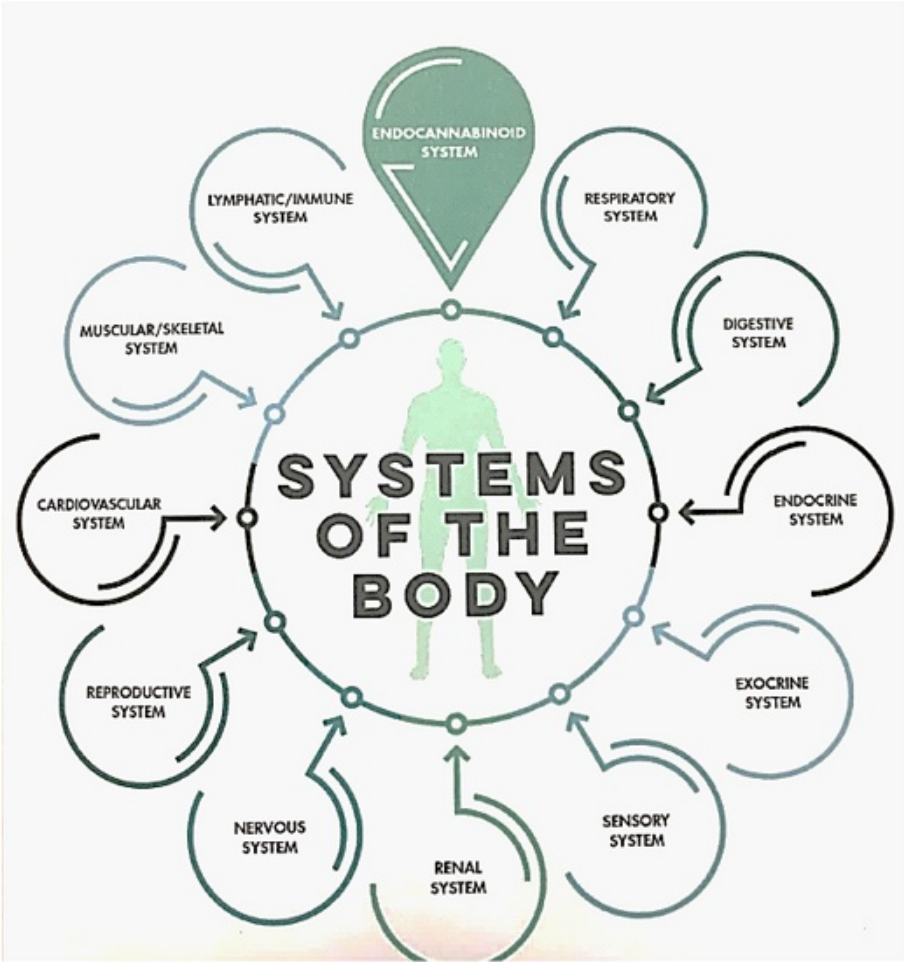
## Human health benefits:

- *Anti-inflammation -Decreased Cytokine and chemokine actions*
- *Analgesic Effects*
- *Anxiolytic*
- *Neuroprotective*



**Cannabidiol (CBD)**

Schurman LD, Lichtman AH., Endocannabinoids: A Promising Impact for Traumatic Brain Injury. Front Pharmacol. 2017 Feb 17;8:69. doi: 10.3389/fphar.2017.00069. eCollection 2017.  
Pertwee RG. Cannabidiol as a potential medicine. Cannabinoids as Therapeutics. Milestones in Drug Therapy MDT. 2005;47-65. Evans FJ: Cannabinoids: the separation of central from peripheral effects on a structural basis. Planta Med 1991; 57(7 suppl):60-67

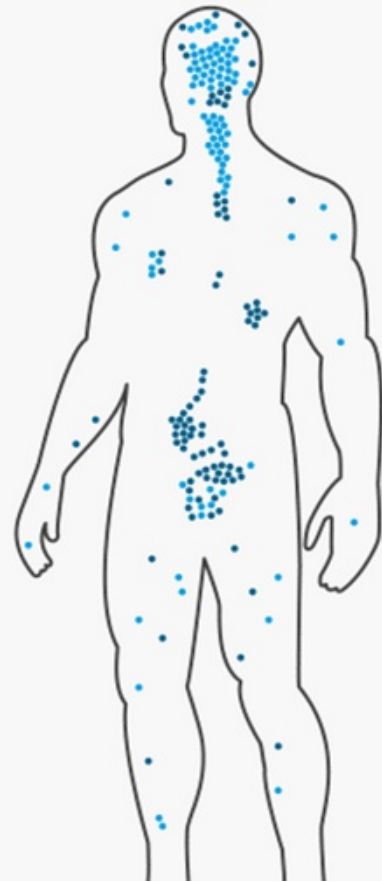


# Endocannabinoid System

**Acts via the Endogenously Produced Endocannabinoids**  
(on demand neuromodulators)

- **Anandamide (AEA)**
- **2-Acylglycerol (2-AG)**

Receptors are found  
on cell surfaces



# Endocannabinoid System

## CB1 Receptor (THC)

Central and Peripheral  
Nervous System

Distributed throughout the brain:

Pleasure  
Memory  
Thought  
Concentration  
Sensory and time perceptions  
Coordinated movement

**Sparsely found in the  
cardiopulmonary centers  
in the brainstem**

## CB2 Receptor (CBD)

Located on immune cells,  
and Peripheral Nervous System

When activated, affects pain,  
inflammatory and immune  
modulation

Control release of cytokines  
and cell migration

# Case Reports: Failed Traditional Tx



On Feb 23, 2018,  
Dr. Maroon,

## **Post-concussion syndrome**

*Overall, I am extremely happy with the results of this supplement. .... able to sleep easily and soundly through out the night and my anxiety has been reduce tremendously.*

## **Post-concussion syndrome and Migraine Headache**



On Sept 15, 2017,  
Dr. Maroon,

*I believe it truly makes a huge difference!*

**Table 2. Total Number and Percentages of Medical Cannabis Users Reporting Use for Each Medical Condition**

<b>Pain</b>	<b>874 (61.2)</b>
<b>Anxiety</b>	<b>830 (58.1)</b>
<b>Depression</b>	<b>719 (50.3)</b>
Headache/migraine	507 (35.5)
Other	488 (34.1)
Nausea	392 (27.4)
Muscle spasticity	263 (18.4)
Arthritis	245 (17.1)
Irritable bowel	211 (14.8)
Intractable pain	164 (11.5)
Anorexia	142 (9.9)
Cancer	47 (3.3)
Ulcerative colitis/Crohn's disease	45 (3.1)
Other seizure disorder	37 (2.6)
Tics	36 (2.5)
Tremor	33 (2.3)
Glaucoma	25 (1.7)
Epilepsy	18 (1.3)
Multiple sclerosis	16 (1.1)

In 2016

A total of 1429 participants identified as medical Cannabis users Surveyed

*86% reported improvement in symptoms*

**How can this Be?**

A Cross-Sectional Survey of Medical Cannabis Users: Patterns of Use and Perceived Efficacy, Cannabis and Cannabinoid Research Vol. 1, No. 1 Original Research, 2 Jun 2016



Published in final edited form as:

*Recent Pat CNS Drug Discov.* 2012 April 1; 7(1): 25–40.

## Cannabinoid-related agents in the treatment of anxiety disorders: current knowledge and future perspectives

Simone Tambaro and Marco Bortolato

Department of Pharmacology and Pharmaceutical Sciences, School of Pharmacy, University of Southern California, Los Angeles (CA), USA

### Abstract

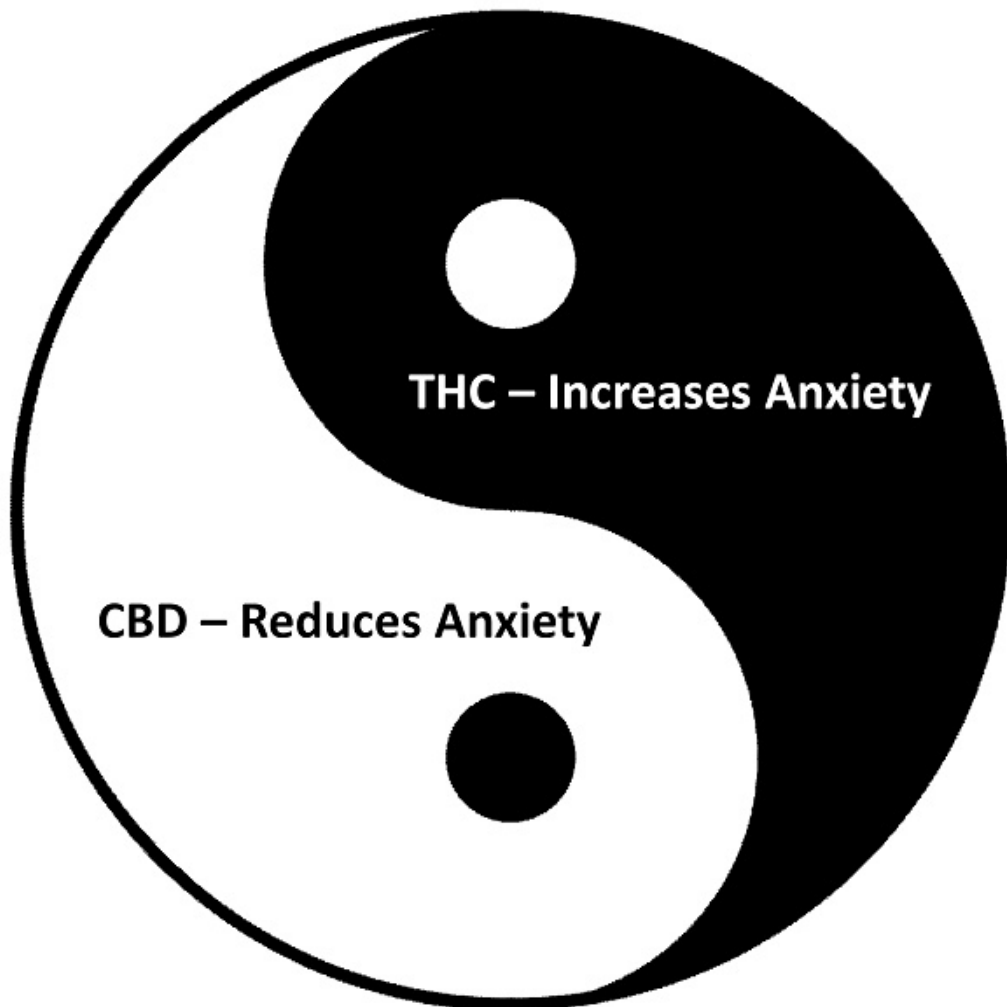
Rich evidence has shown that cannabis products exert a broad gamut of effects on emotional regulation. The main psychoactive ingredient of hemp,  $\Delta^9$ -tetrahydrocannabinol (THC), and its synthetic cannabinoid analogs have been reported to either attenuate or exacerbate anxiety and fear-related behaviors in humans and experimental animals. The heterogeneity of cannabis-induced psychological outcomes reflects a complex network of molecular interactions between the key neurobiological substrates of emotion and fear, the endocannabinoid system, and

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### Keywords

cannabi

THC and CBD exert **opposite actions** on brain function and psychopathology. CBD reduces the effects of THC on several behavioral functions **including reduced anxiety and improve the sensation of wellbeing**



# CBD & Wellness Universal Truths

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Common link for almost all **'unwell'** conditions, i.e., pain, chronic disease and addiction?

- **Anxiety / Depression / Stress**
- **Loss of Control**
- **Loss of Resilience**
- **Pain – Mental /Physical**



# CBD & Wellness Universal Truths

People Feel Better When  
Taking CBD

- **Improved  
Mood/Outlook**
- **Clearer Thinking**
- **And Resilience**



# Resilience

re·sil·ience

*noun*

1. the capacity to recover quickly from difficulties; toughness



# ANXIETY FACTS



## THE MANY FACES OF ANXIETY

### 40 MILLION

Americans age 18 and older are affected by anxiety disorders.

### 6.8 MILLION

adults are affected by Generalized Anxiety Disorder (GAD) – women twice as much as men.

### 15 MILLION

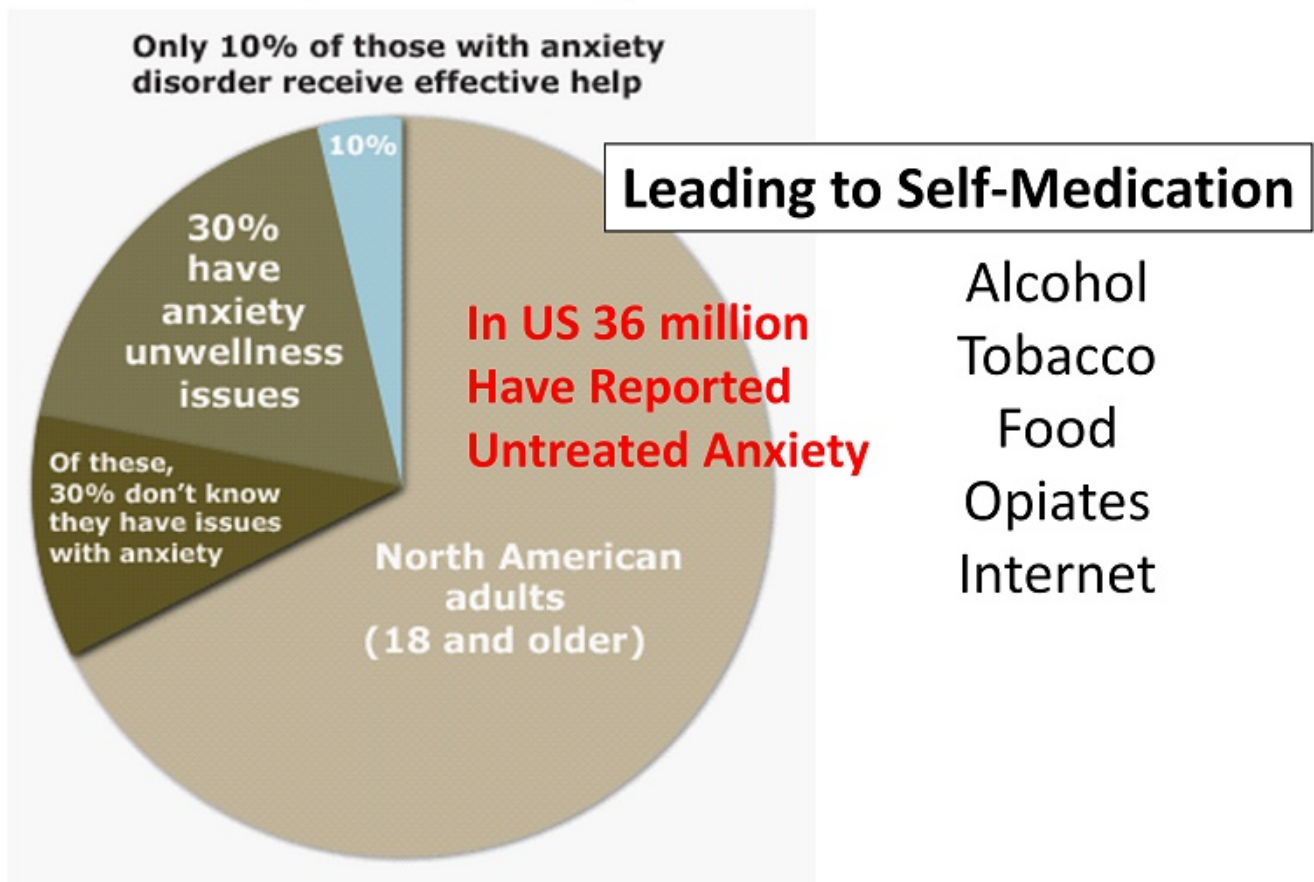
adult men and women are affected by Social Anxiety Disorder. The symptoms usually start at about age 13, a socially difficult time for many people, and can stick around for years before someone seeks help.

### 19 MILLION

adults suffer from specific phobias that can begin in early childhood, at about age 7.

*Statistics from Anxiety and Depression Association of America:  
<http://www.adaa.org/about-adaa/press-room/facts-statistics>*

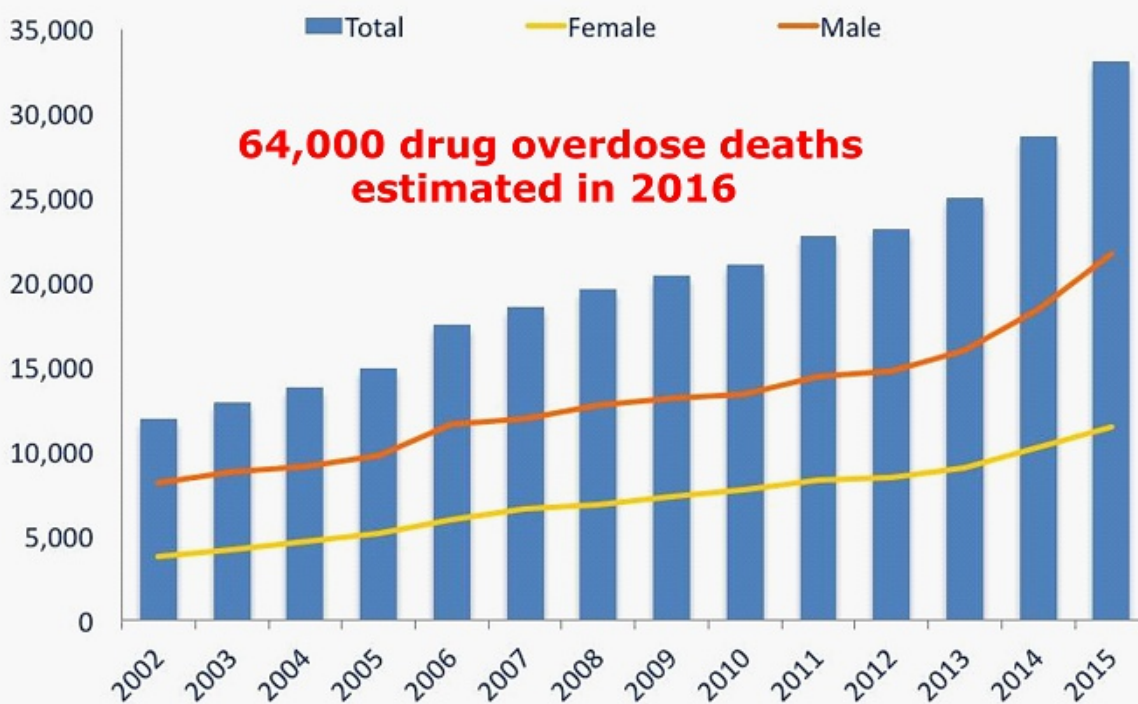
# Anxiety – Leading Cause of Addiction





# National Overdose Deaths

## Number of Deaths from Opioid Drugs

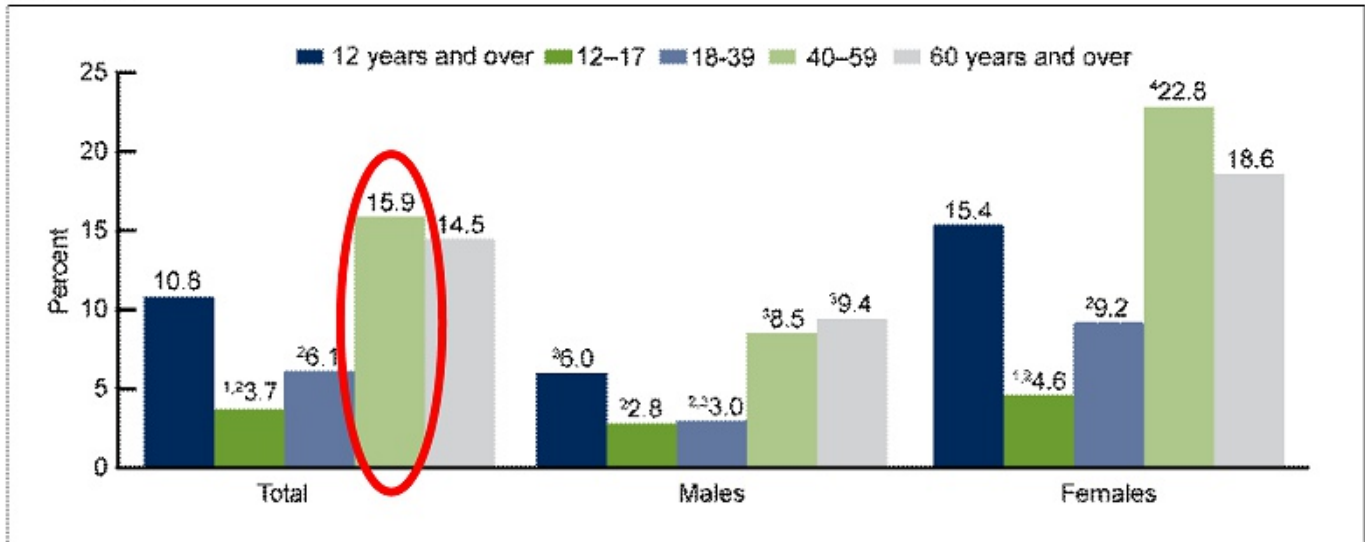


Source: National Center for Health Statistics, CDC Wonder



# ~16% of Ages 40-59 Take Antidepressants

Figure 1. Percentage of persons aged 12 and over who take antidepressant medication, by age and sex: United States, 2005–2008

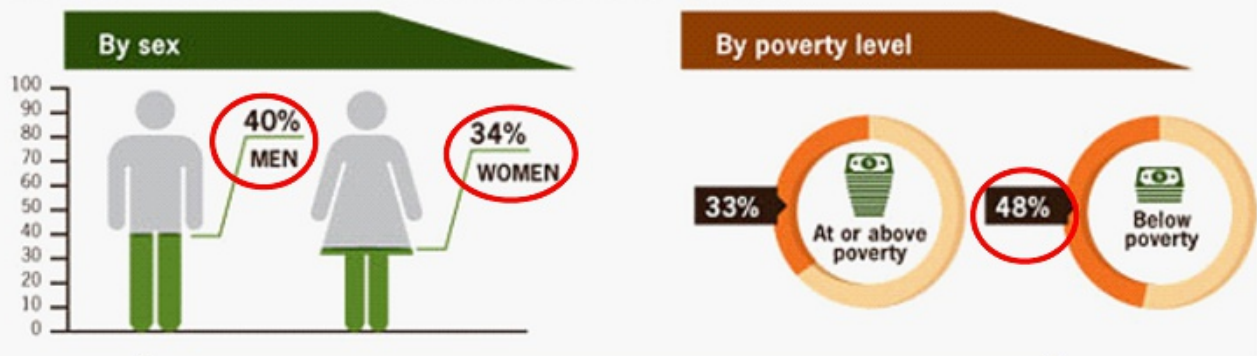


<sup>1</sup>Significantly different from age group 18–39. <sup>2</sup>Significantly different from age groups 40–59 and 60 years and over. <sup>3</sup>Significantly different from females. <sup>4</sup>Significantly different from age group 60 years and over.

NOTE: Access data table for Figure 1 at: [http://www.cdc.gov/nchs/data/databriefs/db76\\_tables.pdf#1](http://www.cdc.gov/nchs/data/databriefs/db76_tables.pdf#1).

SOURCE: CDC/NCHS, National Health and Nutrition Examination Surveys, 2005–2008.

## Percent of Adults with Mental Illness Who Smoke



### What Is the Link Between Smoking and Mental Health Conditions?

- Smoking is much more common among adults with depression and anxiety, than in the general population
- About **3 in 10 cigarettes smoked by adults in the United States are smoked by persons with mental health conditions**

## Smoking Epidemic – Fear of Withdrawal

- **Nicotine withdrawal is the primary addictive driver of cigarette smoking**
- Withdrawal includes:
  - physiological symptoms (headaches, nausea)
  - Affective symptoms (**anxiety, depression and irritability**)
  - Impaired cognitive performance (delay discounting, response inhibition)
- Withdrawal severity predicts relapse

# How Can CBD Alter Addiction?

- The “Pleasure Centers” of the brain reinforce the effects of drugs and the prolonged risk of relapse
- The endocannabinoid system (ECS) influences the acquisition and maintenance of drug-seeking behaviors
- ***CBD modulated the ECS and thereby alters addictive cravings and reduces drug seeking related anxiety***
- CBD functions the same way as common SSRI antidepressants (Prozac, Zoloft, Celexa etc.)

Kalivas PW, Lalumiere RT, Knackstedt L, Shen H. Glutamate transmission in addiction. *Neuropharmacology*. 2009;56(suppl 1):169–73. Pierce RC, Kumaresan V. The mesolimbic dopamine system: the final common pathway for the reinforcing effect of drugs of abuse? *Neurosci Biobehav Rev*. 2006;30(2):215–38. Olliere S, Joliette-Riopel A, Potvin S, Jutras-Aswad D. Modulation of the endocannabinoid system: vulnerability factor and new treatment target for stimulant addiction. *Front Psychiatry*. 2013;4:109. Gardner EL. Endocannabinoid signaling system and brain reward: emphasis on dopamine. *Pharmacol Biochem Behav*. 2005;81(2):263–84. Heifets BD, Castillo PE. Endocannabinoid signaling and long-term synaptic plasticity. *Annu Rev Physiol*. 2009;71:283–306

## Mechanisms

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CBD inhibits the reuptake of Anandamide and explains some of its effectiveness in withdrawal syndrome and addictive processes

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CBD's effect on serotonergic receptors may be highly relevant in drug reward and stress vulnerability

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Antianxiety properties of CBD mitigate withdrawal symptoms

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Pain reduction reduces chronic pain that can induce or perpetuate drug abuse

# Human Addiction Studies

## CBD on tobacco-related addictive behaviors

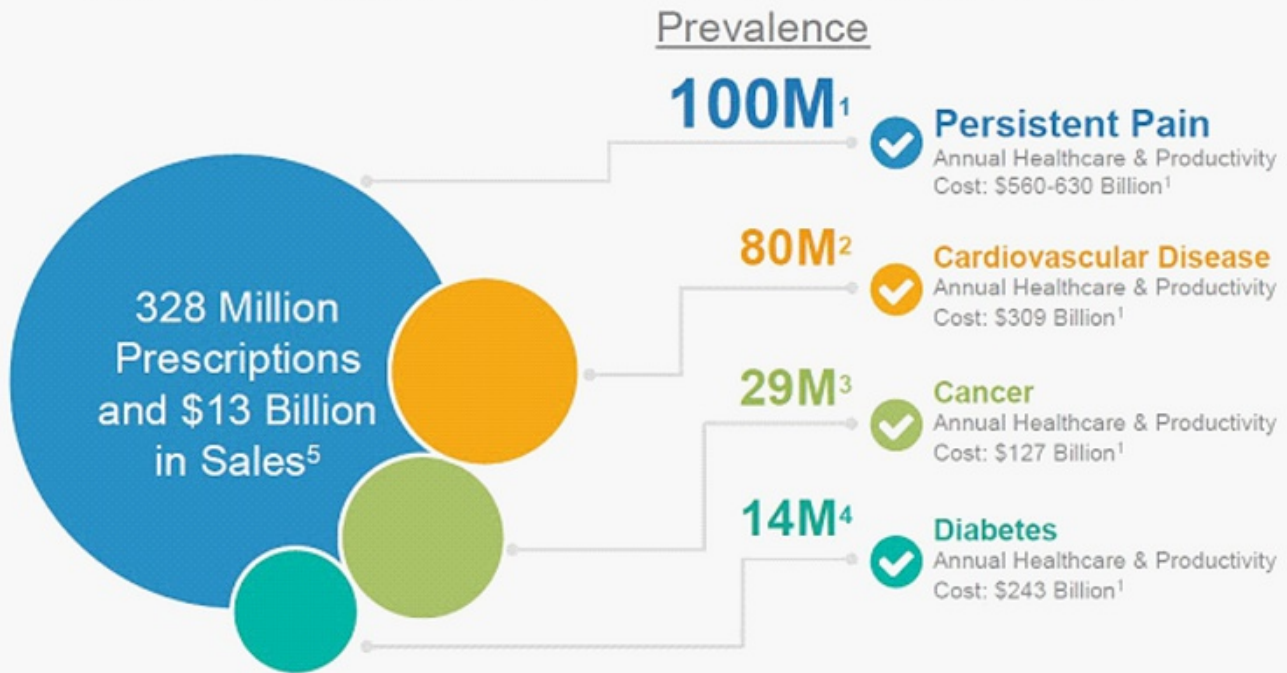
**Design** - randomized, double-blind, placebo-controlled  
24 smokers, 2 groups CBD inhaler (400 µg/inhalation) vs. a placebo inhaler . Told to use the inhaler whenever they felt the urge to smoke for 1 wk

Monitored - daily cigarette and inhaler use and craving for 2 wk

**Results-** 2 wks showed *significant reduction* in the number of cigarettes smoked (*≈40% less*) in the **CBD inhaler group** during the week of treatment, with a trend indicating a reduction after follow-up.

Morgan CJ, Das RK, Joye A, Curran HV, Kamboj SK. Cannabidiol reduces cigarette consumption in tobacco smokers: preliminary findings. *Addict Behav.* 2013;38(9):2433–6.

# Pain: Largest U.S. Public Health Crisis



<sup>1</sup> Institute of Medicine 2011: *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*

<sup>2</sup> The Heart Foundation (<http://www.theheartfoundation.org/heart-disease-facts/heart-disease-statistics/>)

<sup>3</sup> American Cancer Society. *Cancer Facts & Figures 2014*. Atlanta: American Cancer Society; 2014.

<sup>4</sup> American Diabetes Association (<http://www.diabetes.org/diabetes-basics/statistics/>)

<sup>5</sup> IMS Health; 2014 data

# Scope of and Evidence for use in Chronic Pain and Addiction



[https://newfrontierdata.com/wp-content/uploads/2015/11/CIAR\\_Webinar\\_FINAL.pdf](https://newfrontierdata.com/wp-content/uploads/2015/11/CIAR_Webinar_FINAL.pdf)



# CBD and Opiates

- Reduces drug craving
- Allows for lower opiate dosing
- Lowers anxiety associated with pain
- Reduces withdrawal symptoms
- Improves sleep
- Studies show 25 % drop in opioid overdose rates in states where patients could access medical marijuana



<http://icahn.mssm.edu/profiles/yasmin-hurd>  
<https://link.springer.com/article/10.1007/s13311-015-0373-7>  
<https://www.ncbi.nlm.nih.gov/pubmed/25154332>

## Summary

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CBD has a beneficial impact on the intoxication, withdrawal, and relapse phases of cannabis addiction in humans

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CBD is associated with many neural circuits involved in the acquisition of addiction and subsequent drug seeking behaviors.

# CBD Safety




- Safe compound in both animals and humans
- No significant or serious adverse events, other than mild sedation and nausea.
- Daily doses as high as 1500 mg were well tolerated in humans

Mélissa Prud'homme, et al. Cannabidiol as an Intervention for Addictive Behaviors: A Systematic Review of the Evidence. Substance Abuse: Research and Treatment 2015:9

## Safety Study done for CV Sciences Hemp-based CBD

Research Article

### An Assessment of the Genotoxicity and Subchronic Toxicity of a Supercritical Fluid Extract of the Aerial Parts of Hemp

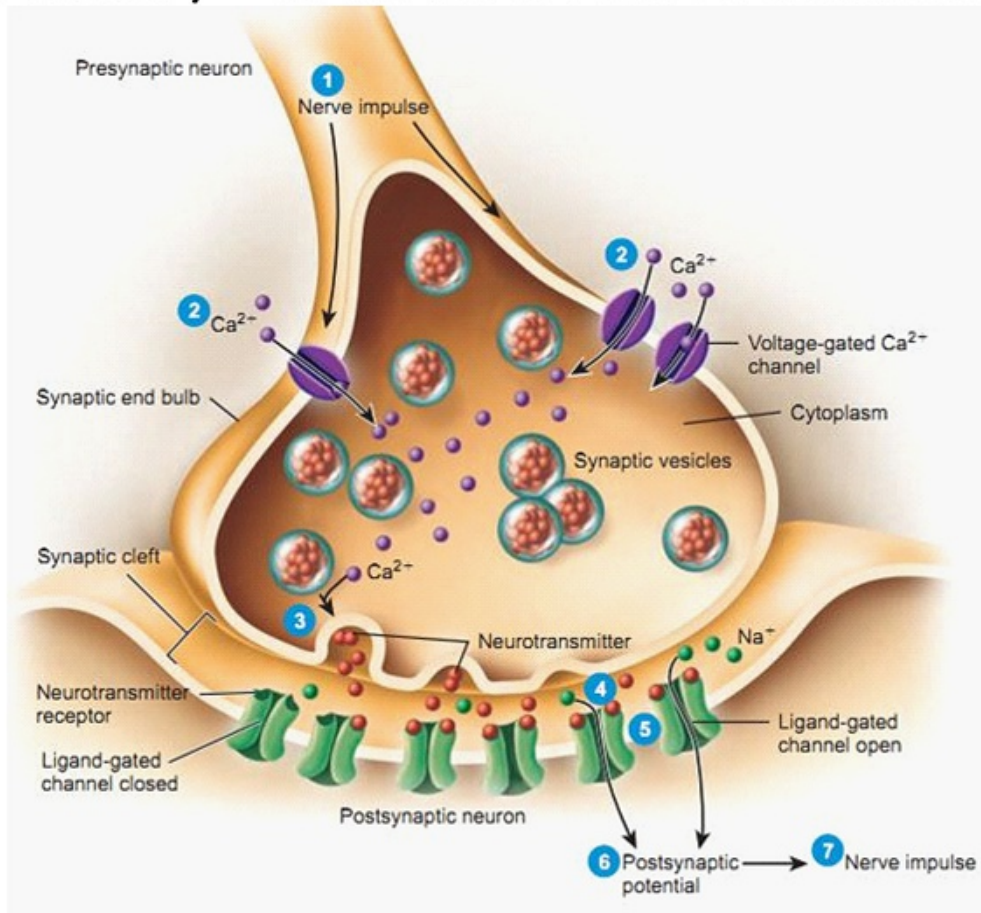
Tennille K. Marx <sup>1</sup>, Robin Reddeman <sup>1</sup>, Amy E. Clewell <sup>1</sup>, John R. Endres <sup>1</sup>,  
Erzsébet Béres,<sup>2</sup> Adél Vértesi,<sup>2</sup> Róbert Glávits,<sup>2</sup> Gábor Hirka,<sup>2</sup> and Ilona Pasics Szakonyiné<sup>2</sup>

<sup>1</sup>AIBMR Life Sciences, Inc., 2800 E. Madison St., Suite 202, Seattle, WA 98112, USA

*The toxicological assessment that is reported herein is the first known of its kind since the 1981 Rosenkrantz et al.'s publication with respect to published toxicology data on CBD, hemp, or hemp extracts*

*Given the broad physiological actions of CBD and other hemp-derived phytocannabinoids, this battery of OECD compliant toxicological studies is a salient contribution to the literature, providing a more extensive assessment of this supercritical CO<sub>2</sub> extract of the aerial parts of the hemp (*C. sativa*) plant.*

# In Summary – Its all About Neurotransmitters



## In Summary:

- FDA Approval of GW Pharma is a **game changer** for allowing prescription CBD products to market
- The use of CBD as a dietary supplement is **now past the tipping point** and accepted by general public and medical professionals as:
  - **Safe**
  - **Effective** for a wide range of conditions, by reduction of anxiety, improved sleep, potential for **treat addictive disorders**, i.e. opiate crisis, nicotine addiction
  - **Reduce the need to opiates** in chronic pain
  - **Improve mood** related to depression and anxiety conditions
- **Prescription CBD will allow for higher CBD dosing and better therapeutic results**

Thank you





**CV SCIENCES™**  
A LIFE SCIENCE COMPANY

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**CBD-BASED PHARMACEUTICAL & CONSUMER PRODUCTS**  
Corporate Presentation – August 4, 2018  
Symbol: CVSI



# SAFE HARBOR & DISCLAIMER

This presentation may contain certain forward-looking statements and information, as defined within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and is subject to the Safe Harbor created by those sections. This material contains statements about expected future events and/or financial results that are forward-looking in nature and subject to risks and uncertainties. Such forward-looking statements by definition involve risks and uncertainties.

This Overview does not constitute an offer to sell or a solicitation of an offer to buy any securities of CV Sciences, Inc. The company is not soliciting any investment from this presentation or event attendees. Offers to sell or solicitations of offers to buy securities of the company will be made pursuant to the registration requirements of the Securities Act of 1933, or regulations of the Securities and Exchange Commission, and under relevant state securities laws; or in accordance with lawful exemptions from registration requirements under applicable federal and state securities laws and regulations.

# CORPORATE OVERVIEW

## CV Sciences, Inc.

- Operations in:
  - San Diego, CA
  - Lexington, KY
  - Las Vegas, NV
- Founded in 2012
- 70+ employees
- Two operating divisions:
  1. Consumer products
  2. Drug development
- Active ingredient - “Cannabidiol” (CBD)



# TRADING SNAPSHOT

Stock Symbol	CVSI
Trading Price (as of 8/1/18)	\$3.07
52-Week Range	\$0.14 - \$3.31
Avg. Daily Volume (3 mos)	2.1 M
Shares Outstanding	91 M
Market Cap	\$278 M
Float	76 M



# CONSUMER PRODUCTS DIVISION

# CONSUMER PRODUCTS OVERVIEW

## Overview

- 50+ SKUs of branded products
- Sales channels include:
  - 1968 retail locations nationwide
  - 1000+ doctor offices nationwide
  - Strong wholesale presence
  - Growing ecommerce channel
- #1 Selling Hemp-based CBD Products\*  
#2 Company in the Natural Products Retailer\*  
*\*According to SPINS Scan Data*
- Category sales forecast for hemp-based CBD products ≈ \$1.6 Billion by 2021



# CONSUMER PRODUCTS

Branded Product: PlusCBD Oil™  
50+ SKUs



Raw Formula

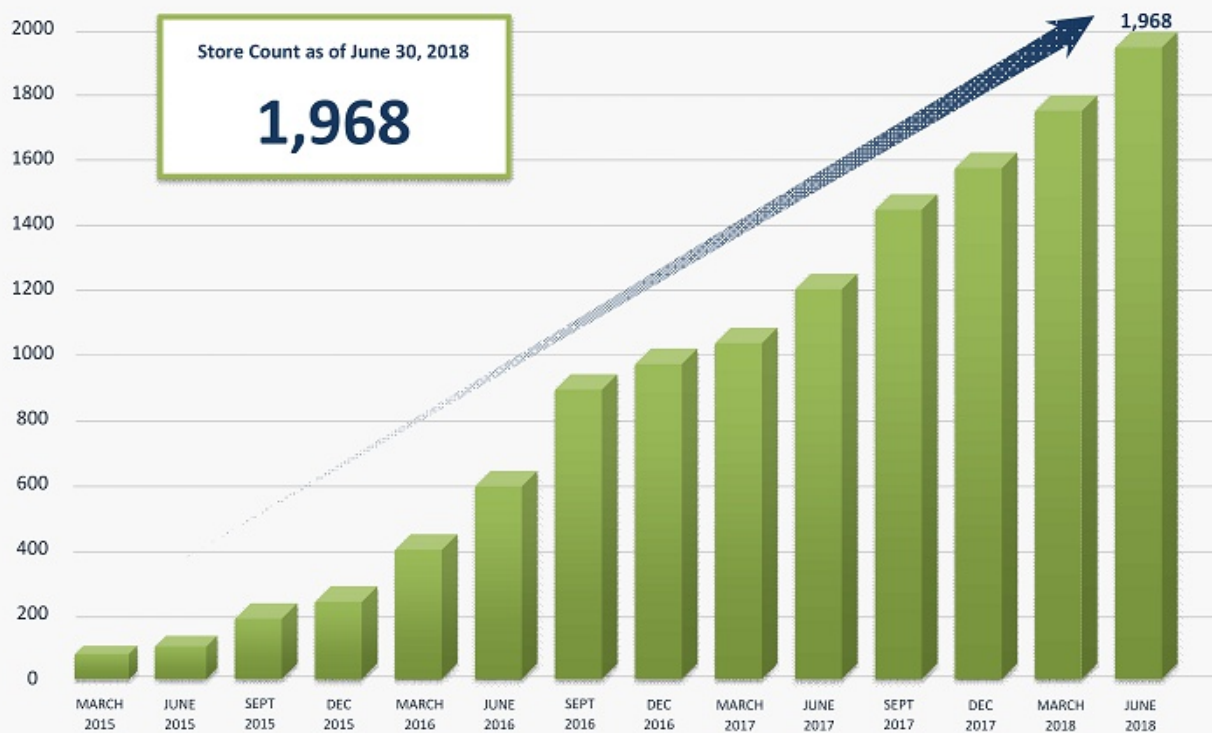
Total Plant Complex

Gold Formula

# RETAIL STORE PLACEMENT



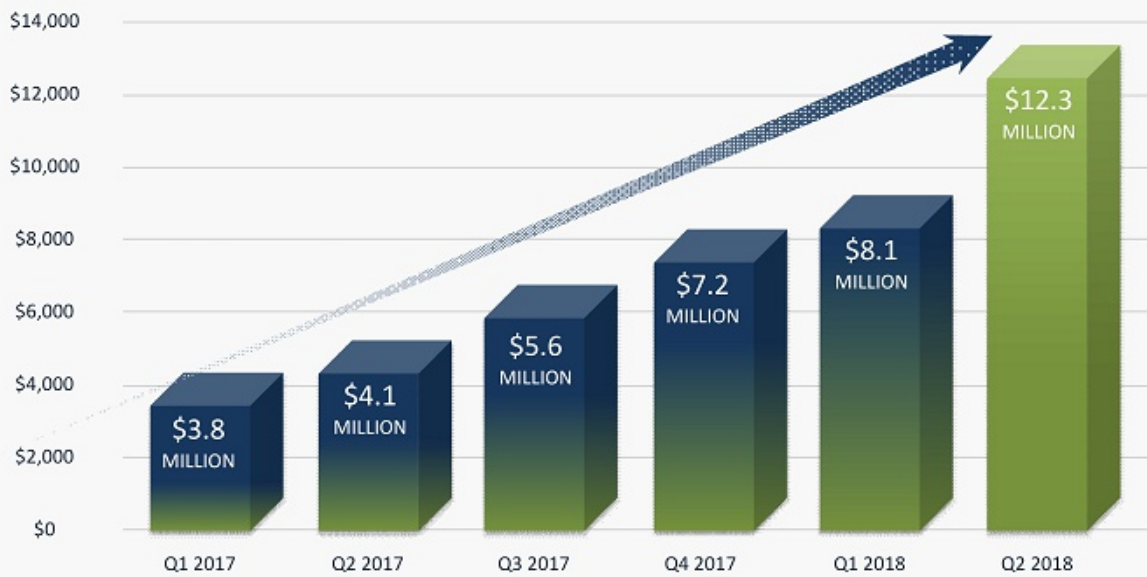
# NATURAL PRODUCTS RETAILERS – STORE COUNT





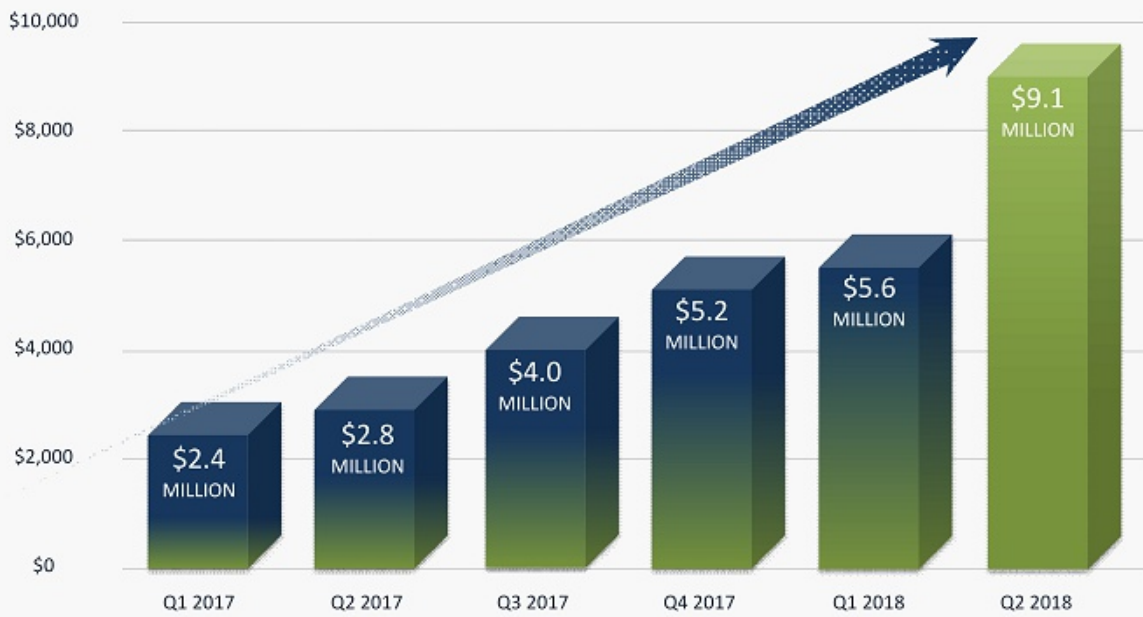
# SALES QUARTERLY COMPARISON

(in thousands)



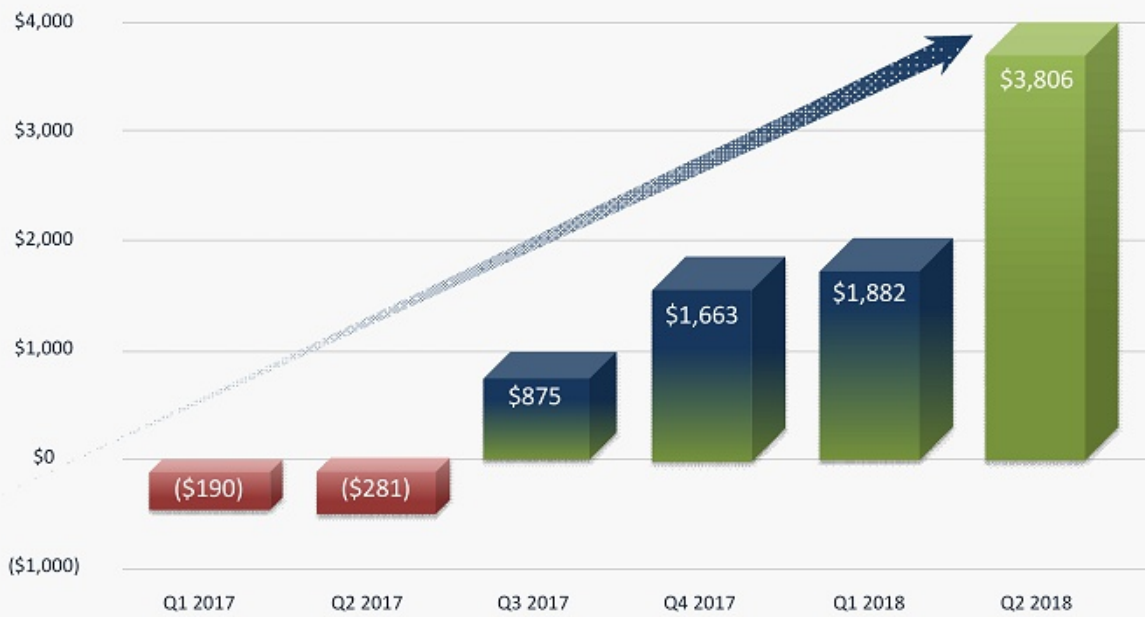
# GROSS PROFIT QUARTERLY COMPARISON

(in thousands)



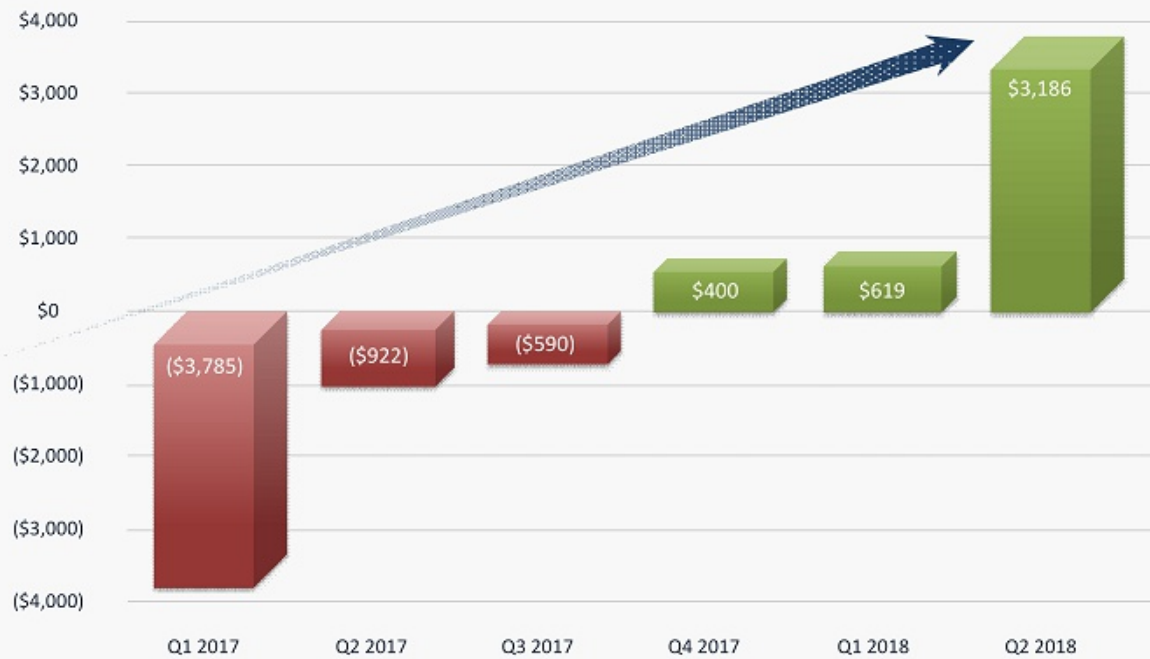
# ADJUSTED EBITDA QUARTERLY COMPARISON

(in thousands)



# NET INCOME QUARTERLY COMPARISON

(in thousands)



**PlusCBD Oil™ is Ranked the #1 Selling Hemp CBD Product  
According to SPINS Scan Data.**



SPINS is the leading provider of analytics reporting for the  
Natural, Organic and Specialty Products Industry.

# SPINS DATA\*



\*SPINS Trailing 12-Week Sales Data through 6/17/2018

RANK	BRAND**
1	Nordic Naturals
2	PlusCBD Oil™ 
3	Barleans
4	Garden Of Life
5	Carlson
6	Natures Way
7	CW
8	Amazing Grass
9	Private Label
10	Now

# PRODUCT SAFETY

- Dietary Supplement Health and Education Act of 1994 “DSHEA”
- Amended the Federal Food, Drug, and Cosmetic Act - to establish standards for dietary supplements
- Generally Recognized as Safe – “GRAS”



## Supplement Facts

According to the Dietary Supplement Health & Education Act (DSHEA), dietary supplement ingredients that were marketed in the United States before October 15, 1994 (the date the law was enacted) are presumed to be safe and do not need to file a New Dietary Ingredient Notification to FDA before going to market.

Council for Responsible Nutrition

[www.crnusa.org](http://www.crnusa.org)

## Generally Recognized as Safe (GRAS)

\*GRAS\* is an acronym for the phrase **Generally Recognized As Safe**. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.

## Published Paper

Hindawi  
Journal of Toxicology  
Volume 2018, Article ID 6143562, 26 pages  
<https://doi.org/10.1155/2018/6143562>



### Research Article

## An Assessment of the Genotoxicity and Subchronic Toxicity of a Supercritical Fluid Extract of the Aerial Parts of Hemp

Tennille K. Marx<sup>1</sup>, Robin Reddeman<sup>1</sup>, Amy E. Clewell<sup>1</sup>, John R. Endres<sup>1</sup>,  
Erzébet Béres<sup>2</sup>, Adél Vértési<sup>2</sup>, Róbert Glávits<sup>2</sup>, Gábor Hirka<sup>2</sup>, and Ilona Pásics Szakonyiné<sup>2</sup>

<sup>1</sup>AIBMR Life Sciences, Inc., 2800 E Madison St., Suite 202, Seattle, WA 98112, USA

<sup>2</sup>Tox-Coop Zrt., Magyar Jakabinsok Tere 4/B, Budapest 1122, Hungary

Correspondence should be addressed to John R. Endres; [john@aibmr.com](mailto:john@aibmr.com)

Received 6 December 2017; Revised 6 March 2018; Accepted 7 May 2018; Published 7 June 2018

Academic Editor: Lucio Guido Costa

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A series of in vivo studies were conducted on a supercritical CO<sub>2</sub> extract of the aerial parts of the Cannabis sativa plant, containing approximately 21% cannabidiol. The extract was tested for genotoxicity and subchronic toxicity in rats. The results showed that the extract was not genotoxic and did not induce any adverse effects in the rats. These findings suggest that the extract is safe for use in food and dietary supplements.

#### 1. Introduction

Cannabidiol (CBD) is a major cannabinoid found in Cannabis sativa. It is known for its potential health benefits, including its anti-inflammatory and analgesic properties. CBD is also known for its potential to reduce anxiety and improve sleep. However, there is still a need for more research to fully understand the safety and efficacy of CBD and its derivatives. The purpose of this study was to assess the genotoxicity and subchronic toxicity of a supercritical CO<sub>2</sub> extract of the aerial parts of the Cannabis sativa plant, containing approximately 21% cannabidiol. The extract was tested for genotoxicity and subchronic toxicity in rats. The results showed that the extract was not genotoxic and did not induce any adverse effects in the rats. These findings suggest that the extract is safe for use in food and dietary supplements.

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# PRODUCT SAFETY

IMPACT: GRAS self-affirmation has opened the market for...

- Omega-3
- CoQ10
- Collagen
- Krill Oil



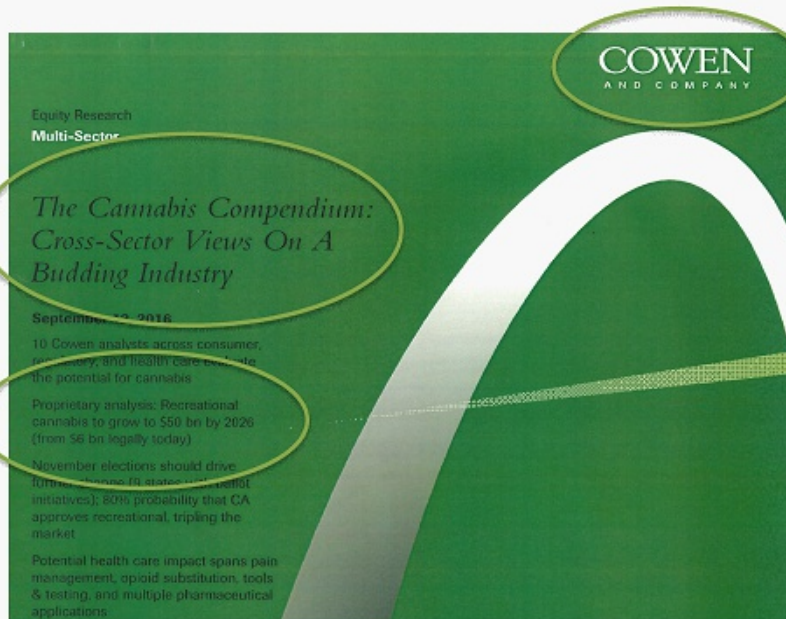
# 2018 FEDERAL FARM BILL

## Includes provisions that clarify legal framework for “Hemp”

- Water Rights for farmers
- Banking access for farmers and others
- Research – plant genetics, growing conditions, harvesting & processing techniques
- Crop Insurance
- Changes jurisdiction from FDA/DEA to the USDA
- Becomes an agricultural commodity

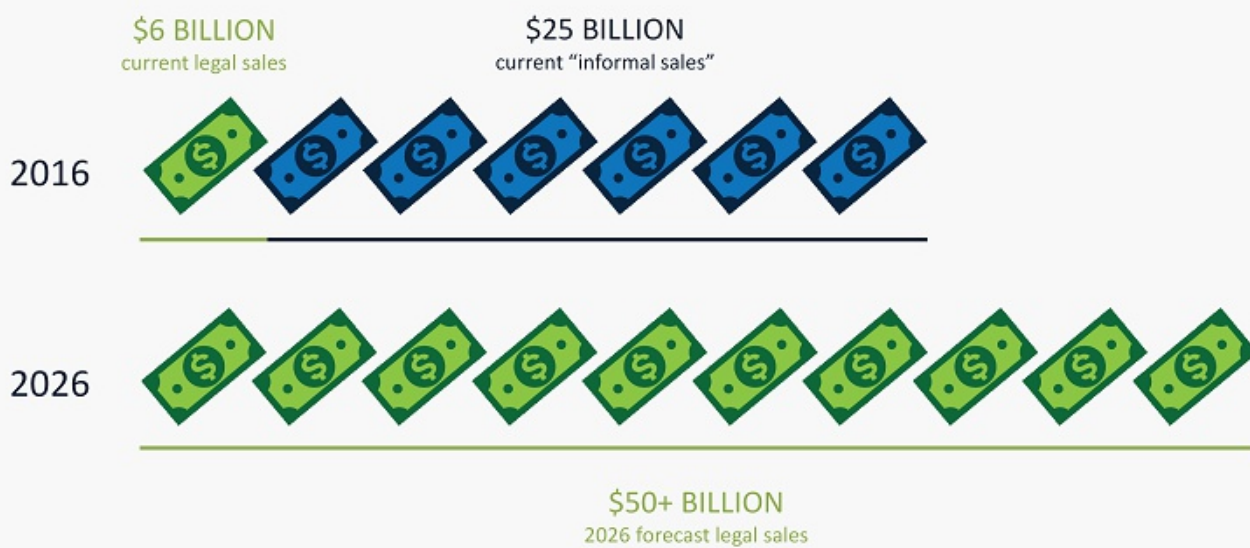


# WALL STREET – GETTING INVOLVED



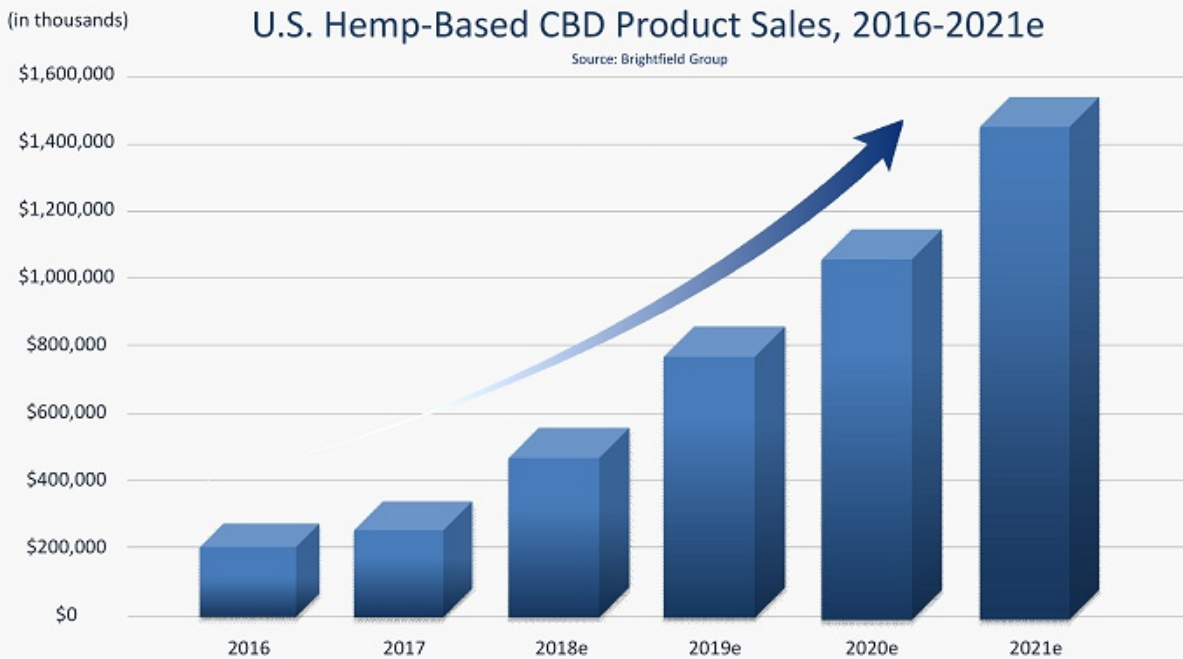
**Estimated legal  
cannabis sales of \$50  
billion by 2026.  
Currently, sales are \$6  
billion.**

# WALL STREET – GETTING INVOLVED



Source: Cowen Estimates

# INDUSTRY GROWTH



\$1.57 Billion U.S. Hemp-Based CBD Product Sales by Channel in 2021e



# DRUG DEVELOPMENT DIVISION

# DRUG DEVELOPMENT PROGRAM

## Overview

- CVSI-007 – lead drug candidate
- Cannabidiol (CBD) and nicotine combination
- Medical indication – to support cessation of smokeless tobacco use and addiction
- Proprietary technology (patent pending)
- Seeking 505(b)(2) drug approval pathway

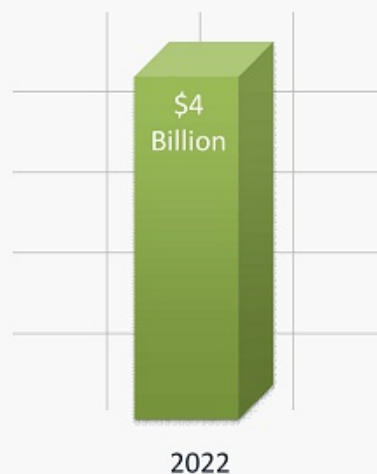


# MARKET POTENTIAL

No current FDA-approved drugs to treat smokeless tobacco use and addiction.

- There are only 2 smoking cessation FDA-approved drugs – Chantix (Pfizer) and Zyban (GSK)
- Until recently, both Chantix and Zyban had “black box warnings” that call attention to serious or life-threatening risks in taking these approved products.

Estimated Smokeless Tobacco Treatment Market





# CURRENT FDA - APPROVED TREATMENTS

2016 REVENUE: Approximately \$1 billion



**WARNING: SERIOUS NEUROPSYCHIATRIC EVENTS**  
*See full prescribing information for complete boxed warning.*

- Serious neuropsychiatric events have been reported in patients taking CHANTIX. (5.1 and 6.2)
- Advise patients and caregivers that the patient should stop taking CHANTIX and contact a healthcare provider immediately if agitation, hostility, depressed mood, or changes in behavior or thinking that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior while taking CHANTIX or shortly after discontinuing CHANTIX. (5.1 and 6.2)
- Weigh the risks of CHANTIX against benefits of its use. CHANTIX has been demonstrated to increase the likelihood of abstinence from smoking for as long as one year compared to treatment with placebo. The health benefits of quitting smoking are immediate and substantial. (5.1 and 6.2)



**ZYBAN<sup>®</sup>**  
 (nortriptyline hydrochloride)  
 Sustained-Release Tablets

**PRESCRIBING INFORMATION**

**Suicidality and Antidepressant Drugs**  
 Although ZYBAN is not indicated for treatment of depression, it contains the same active ingredient as the antidepressant medications WELLBUTRIN<sup>®</sup>, WELLBUTRIN SR<sup>®</sup>, and WELLBUTRIN XL<sup>®</sup>. Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of ZYBAN or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. ZYBAN is not approved for use in pediatric patients. (See WARNINGS: Clinical Worsening and Suicide Risk, PRECAUTIONS: Information for Patients, and PRECAUTIONS: Pediatric Use.)

# UNMET MEDICAL NEED

## Urgent Unmet Medical Need

- Smokeless tobacco is carcinogenic (risk of esophageal, oral and pancreatic cancers).
- Smokeless tobacco is one of the most addictive and potent ways of consuming nicotine (an average-size dip in the mouth for just 30 minutes can deliver as much nicotine as smoking three cigarettes).
- Smokeless tobacco is strongly addictive (equal to cocaine and heroin).
- Smokeless tobacco is an epidemic as recognized by the surgeon general.



*There are currently NO FDA-approved drugs to support cessation of smokeless tobacco use and addiction.*

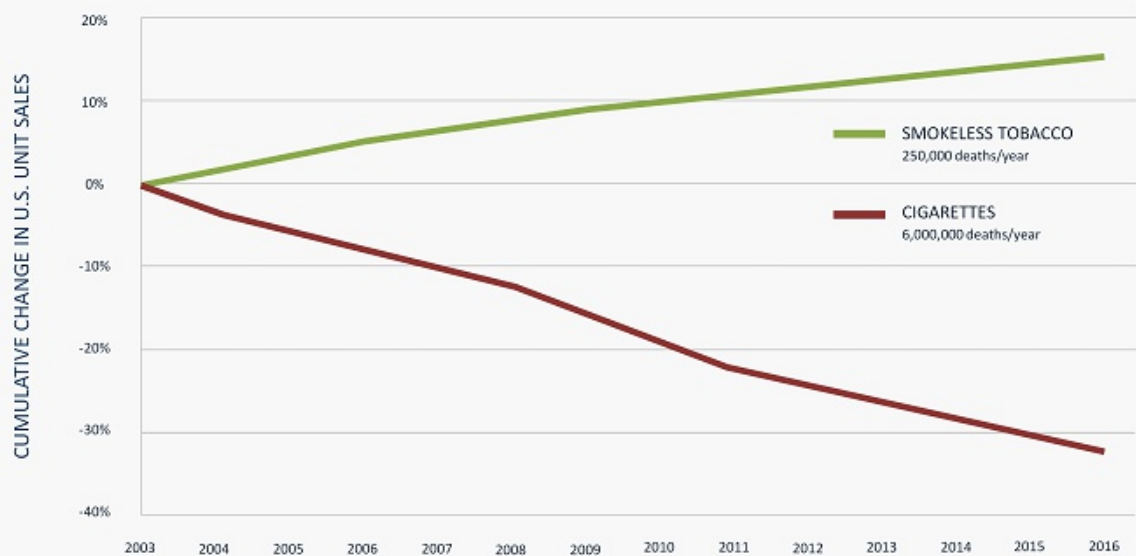
# EPIDEMIC: SMOKELESS TOBACCO USE

## Selected Epidemic Statistics

- Serious impact on youth:  
5.8% of males 12-17 years of age reported use of smokeless tobacco.
- 49% of all military personnel used a tobacco product in the last 12 months.
- 12.8% of all military personnel used smokeless tobacco in the last month.



# TOBACCO USE TRENDS



Source: Euromonitor International, National Survey on Drug Use and Health Centers for Disease Control and Prevention

# NICOTINE ADDICTION – FINANCIAL IMPACT

## Financial Impact

- \$300 Billion+ per year  
Direct medical care and lost productivity

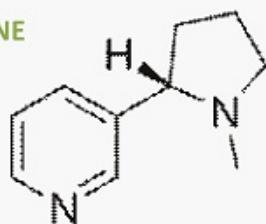


Sources: CDC and *Tobacco Use and the Military*

# NICOTINE & CANNABIDIOL

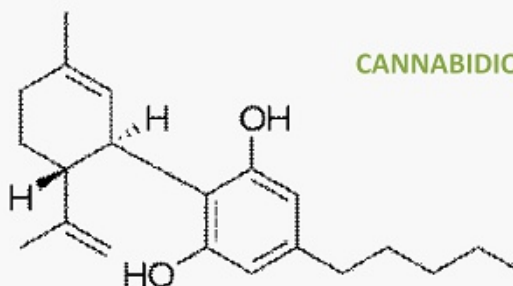
Using patent-pending technology, CV Sciences' drug candidate (CVSI-007) combines cannabidiol (CBD) and nicotine to focus on a significant unmet medical need in treating smokeless tobacco use/addiction.

NICOTINE



+

CANNABIDIOL



# NICOTINE USE & ADDICTION

## Overview

- Physical Dependence  
relaxant, stimulant, increased heart rate and blood pressure, decreased appetite
- Emotional Dependence  
“oral stimulation” of tobacco product used
- Mental Dependence  
nicotine is a mild “antidepressant”



# NICOTINE PK/PD - ANTIDEPRESSANT

Nicotine reaches the brain in 7-10 seconds

Nicotine is a mild antidepressant

- Mechanism of Action: monoamine oxidase ("MAO") inhibitor
- MAO is an enzyme that breaks down dopamine and other "feel good" neurotransmitters that produce pleasure and reward
- Lower levels of MAO result in higher dopamine levels

Nicotine half-life is approximately 1 hour

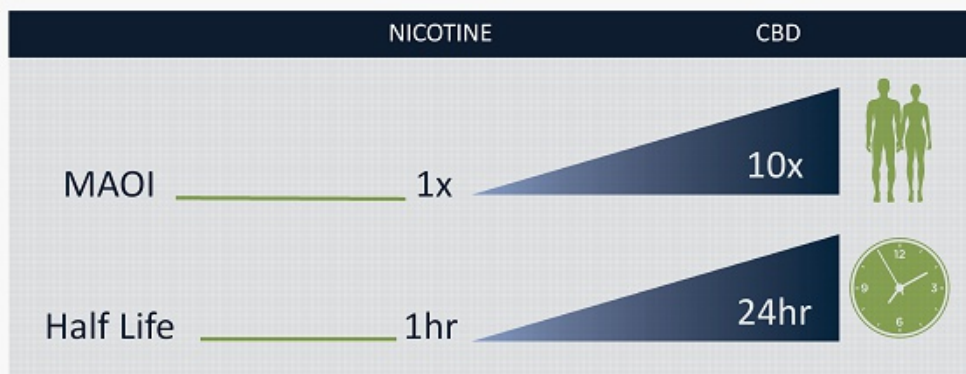
- Nicotine's PK/PD properties enhance its abuse potential with rapid distribution to the brain, drug levels peaking very quickly, and the acute effects dissipating quickly, requiring continued dosing.





# PROPRIETARY TECHNOLOGY

Internal PK/PD research on CBD contributed to our patent-pending technology



The expanded therapeutic range of combining nicotine and CBD, creates a product that effectively addresses all three nicotine addictions.

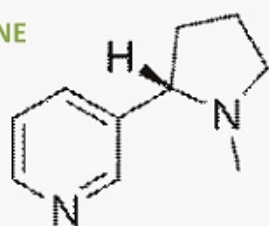
# BREAKING NICOTINE ADDICTION

## Successfully treating nicotine addiction with nicotine/CBD combination therapy

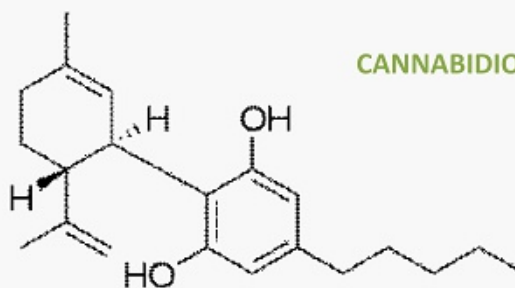
CVSI-007 provides a therapeutic range that provides effective flexibility in treating the addiction rather simply replacing one nicotine product for another.

1. **Nicotine** – physical addiction (include nicotine)
2. **Oral Stimulation** – emotional addiction (oral format)
3. **Antidepressant** – mental addiction ( $\approx 10x$  MAO Inhibitor)

NICOTINE



CANNABIDIOL



# NICOTINE ADDICTION RELAPSE

No current FDA-approved drugs  
(to treat smokeless tobacco use/addiction)

OTC Treatments –  
Nicotine Replacement Therapies (NRTs)



*NRTs are the most widely used pharmacological product in treating nicotine addiction. Replacing cigarettes or smokeless tobacco products with another nicotine-only product, such as an NRT that is available OTC, has shown very high relapse rates.*



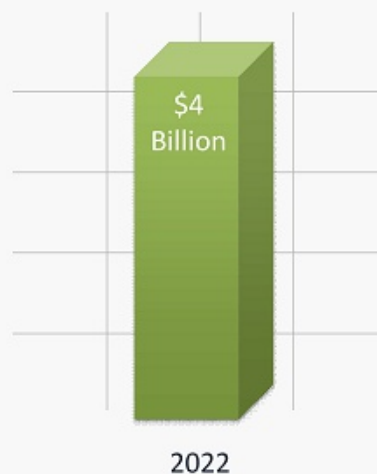
Studies have shown up to 93% of over-the-counter NRT users relapse and return to tobacco use within 6 months.

# TARGET MARKET

## Smokeless Tobacco Market

- Approximately \$5.3 billion annual U.S. retail sales of smokeless tobacco products.
- Approximately 10 million Americans use smokeless tobacco with enormous and growing worldwide use.
- Current multi-billion dollar treatment market and growing.

Estimated Smokeless Tobacco Treatment Market



# EPIDIOLEX APPROVAL

## EPIDIOLEX® (cannabidiol) oral solution

- First FDA approval of Cannabidiol



# DRUG DEVELOPMENT TIMELINE

- Engaged with the FDA
- Complete nonclinical toxicology studies in 2018/2019
- Submit Investigational New Drug (IND) application in early 2019
- Begin clinical trials in 2019

# FDA PRESS RELEASE – AUGUST 3, 2018

## Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps the agency is taking to support the development of novel nicotine replacement drug therapies to help smokers quit cigarettes

Posted on Aug 3, 2018 in [FDA Press Releases](#)

As a public health agency, there is no greater impact we can have to improve the health of our nation than to significantly reduce the rate of tobacco-related disease and death. Through the U.S. Food and Drug Administration's comprehensive framework for regulating nicotine and tobacco, we're developing policies that support the possibility of a world where combustible cigarettes could no longer create or sustain addiction. A key part of this framework are steps to pave the way for products that help currently addicted smokers move away from the deadliest form of nicotine delivery.

Part of this work requires that we recognize that nicotine, while highly addictive, is delivered through products posing a continuum of risk – with combustible cigarettes at one end, to nicotine replacement therapy (NRT) products at the other. We're working on multiple fronts to recognize the role that more novel forms of nicotine delivery could play in achieving our public health goals, as part of an appropriately regulated marketplace. This not only includes encouraging innovation of potentially less harmful tobacco products for those adults who still seek to use nicotine (such as e-cigarettes), but also taking a closer look at our overall approach to the development and regulation of NRT products that are regulated as drugs, and designed to safely reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking.

**The development of novel NRT products, regulated as new drugs, is a critical part of our overall strategy on nicotine.**

We know that about [70 percent of adult smokers in the U.S. want to quit](#). In fact, nearly half try to quit each year. But few succeed. Use of FDA-approved NRT products is generally considered to double the likelihood of a successful quit attempt (with variations between products). Our ultimate goal is to help more smokers completely quit cigarettes.

# POSITIVE FACTORS

1. Outstanding Financial and Operational performance
2. Strong Balance Sheet
3. These fundamentals are institutionally relevant
4. Potential uplisting to Nasdaq
5. Huge market expansion for Consumer Products - \$1.6B by 2021
6. 2018 Farm Bill
7. EPIDIOLEX® approval
8. No FDA approved drugs for smokeless tobacco addiction
9. Smokeless tobacco cessation - \$4 billion market



# CONTACT



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