

## **Annual General Meeting**

#### August 2014





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## **Calmare Therapeutics Incorporated (CTI)**

We are a bio-therapeutic company focused on the development and commercialization of our proprietary and patented flagship medical product:

the Calmare® Pain Therapy device





#### Today, the Company is ...

- headquartered in Fairfield, CT since 1968
- publicly traded and in good standing on the OTCQX ("CTTC")
- the exclusive holder of global distribution and sales rights of the Calmare pain therapy device: 510(k) clearance
- a U.S. Dept. of Defense contractor: GSA No.: V797P-4300b





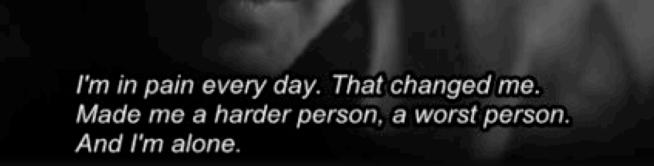
#### the ONLY medical device company

## treating pain by

#### NOT treating the pain at all.







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#### Chronic neuropathic pain is a major health issue with up to

#### 25% of the US population suffering from chronic pain. Pain Levels

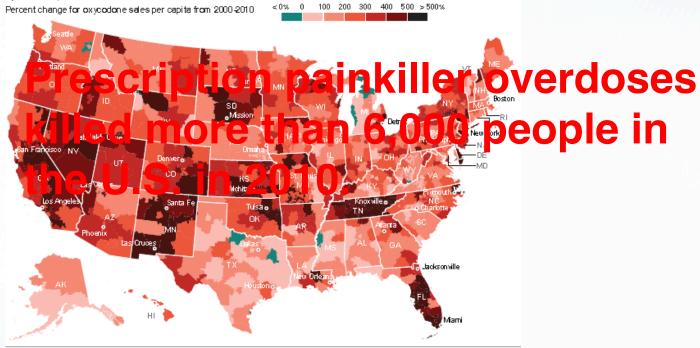




#### Today, pain is treated with prescription drugs but ...

#### Painkiller nation: prescription sales boom across U.S. from 2000 to 2010

Sales of the nation's two most popular prescription painkillers, oxycodone and hydrocodone, have exploded across the U.S. in the last decade, according to an Associated Press analysis of data provided by the Drug Enforcement Administration. This map shows increases in per-capita sales of oxycodone, the key ingredient in OxyConth, Percovet and Percodan.



SO URCE: AP analysis; Drug Endorcement Administration

Phill Holm / Michelle Minkoff • AP



PAINKILLER NATION 040512: An AP analysis of Drug Enforcement Administration data highlighting the increase use of the addictive pain killer oxycodone across the U.S. form 2000 to 2010; 5o x 6 1/2 inches; with BCUS-Painkiller Nation; PH, MM; ETA11 a.m.

Editor's Note: It is mandatory to include all sources that accompany this graphic when repurposing or editing it for publication



#### **Pain Management Therapy**



"We do not yet have medications or other treatments that can effectively alleviate chronic pain with speed or efficiency in the majority of patients.

Doctors treat patients with a trial-and-error approach, initially prescribing drugs with fewer side effects, reflecting the lack of effective treatment options."

Dr. David Borsook, MD. PhD Director of Pain, Children's Hospital Mass General Hospital, Boston. Mass.



#### **Ok. No drugs.** Then, what is the answer?



"If you want a better answer, ask a better question!"



#### **The Calmare® Pain Therapy Device**

Our proprietary, patented, non-invasive medical device developed to treat high intensity oncologic and neuropathic pain without the harmful side effects of narcotic painkillers.



- Immediate to prolonged pain relief
- Procedure regimen:
  - 10 to 15 treatments over 2 weeks
  - 1 or 2 "Booster" treatments (Year One), subject to diagnosis and pain severity
- 510(k) cleared for sales in the U.S.
- CE marked for sales in Europe
- E.M.E.N.A. distribution



#### How does Calmare<sup>®</sup> work?

- 1. Certified practitioners place surface electrodes on the patient's skin close to the pain source in order to access their C-fiber
- 2. Our patented multi-processor sends algorithmically-derived pain messages to the brain along the patient's C-fibers



#### **Result:**

"Pain" signal – from pain site to brain – becomes "No-Pain" signal

# No known side effects reported in use with over 6,000 patients



#### Primary Calmare diagnoses ...

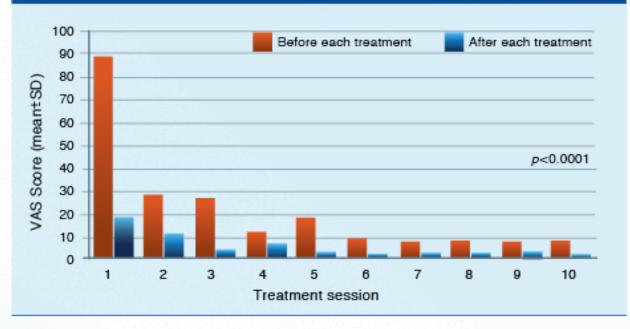
- 1. Chemotherapy-Induced Peripheral Neuropathy (CIPN)
- 2. Chronic Regional Pain Syndrome (CRIP)
- 3. Failed Back Surgery Syndrome
- 4. Chronic Post-herpetic Neuralgia (Shingles)
- 5. Sciatic and Lumbar Pain
- 6. Low Back Pain (LBP)
- 7. Post-Surgical Pain
- 8. Brachial Plexus Pain
- 9. Phantom Limb Syndrome
- 10. Neuropathic Pain





#### So how did we fare in the clinic?

**Calmare Treatment Pilot Study Results** 



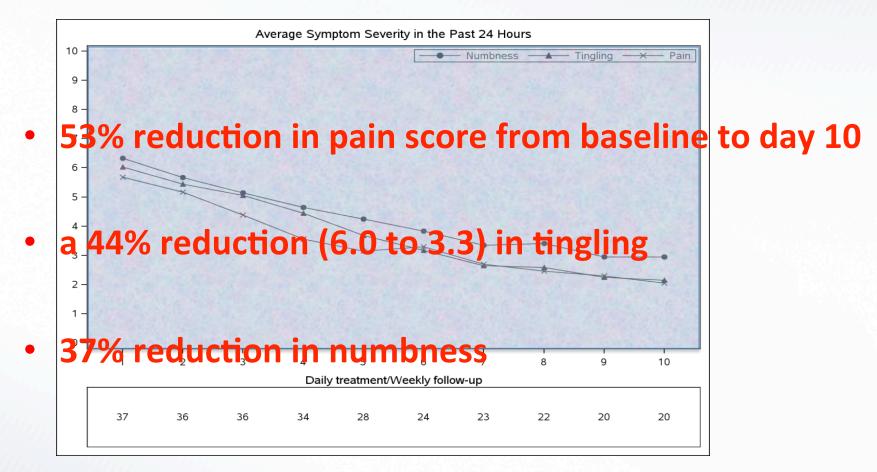
- 33 patients
- Pilot study
- Terminal cancer patients
- Severe drug
  resistance
- 10 treatments

Marineo G et al International Congress Series 1255(203) 381-388

# The pain was reduced to zero.



## **Ave. Daily CIPN Scores With Calmare Treatments**

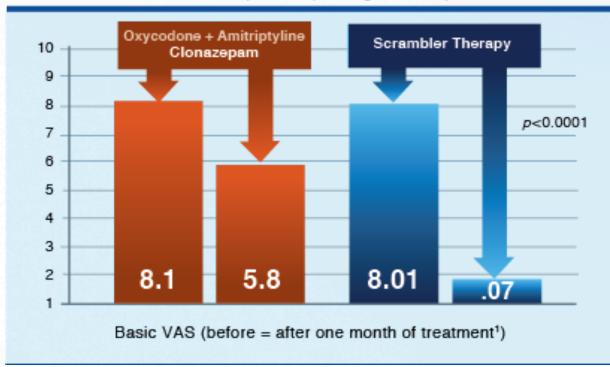


Pachman D, Loprinzi C, et al. Proc ASCO 2014, submitted



#### **Chronic Neuropathic Pain**

VAS for all patients (26/drugs + 26/ST)



Calmare v. Clonazepam:

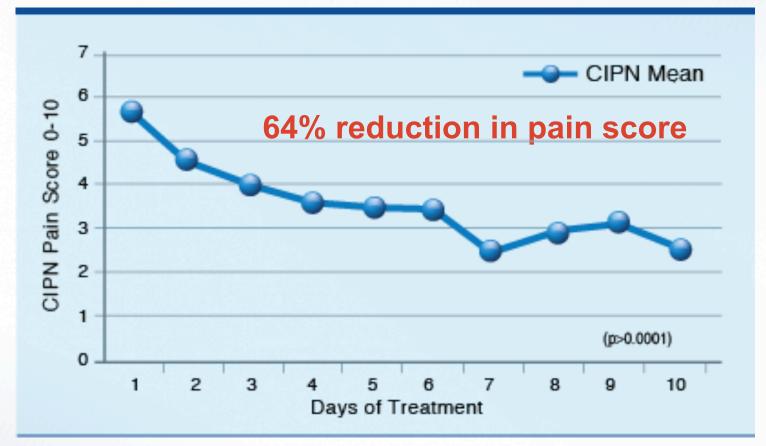
Drugs (control group) and one treated with Calmare (26/Drug – 26/ ST)

G. Marineo, T. Smith, et al, JPSM 2011

72% of patients pain and drug free20% of patients on *reduced* drug dosages



#### **Calmare Therapy for Breast Cancer Patients (CIPN)**



Smith T. et al Journal of Pain And Symptom Management 2010



#### What do the independent clinicians say?

- Mayo Clinic: Charles Loprinzi, MD (Third Annual Cancer Pain Conference)
  - "(Calmare) therapy looks very promising in 3 pilot trials; a randomized trial is in development"
- Johns Hopkins Medical Institute: Tom Smith, MD (*Journal of Pain & Palliative Care* <u>Pharmacotherapy</u>. 2013;27:359–364)
  - "...Calmare therapy appeared to reduce both acute and chronic pain; and, substantially reduced the interference of pain with normal life in every scale measured.
- Virginia Commonwealth University: Angela Starkweather, Ph.D., (Associate Professor, <u>Presentation on Scrambler Therapy for Persistent Low Back Pain)</u>
  - A potentially effective non-pharmacological therapy for ameliorating pain intensity in patients with persistent low back pain ...





# This market is how big?





## The pain market ...

**\$28.6 billion:** Global pain management therapeutic market (CAGR of 5.3% between 2002 and 2010)

**116 million:** Amount of U.S. adults experiencing chronic pain daily

15 million: Amount U.S. adults suffering from neuropathic pain\*

CTI is targeting:

## 1% of the global market



#### What's in it for the physicians ... economically, of course?

#### Each New Patient: 12 treatments over 2 weeks Primary Treatment Cost: \$250 per patient = \$3,000<sup>1</sup> over 2 weeks (est.)





# What happens now?





## **The Plan**

#### GSA contract line item (1Q 2015):

- \$2.0 billion (announced Aug 2014): \$187 million available
- \$3.0 to 5.0 million in unused funds: available to pain (VA)

#### Raise \$8.0 million (2Q 2015):

<u>\$3.0 million bridge</u> (4Q 2014)

- \$2.0 million Pivotal Study (CIPN: 200 patients, multi-site, sham control)
- \$1.0 million Operations (CMO and two nurses practitioners)

<u>\$5.0 million offering</u> (2Q 2015)

- \$2.0 million Pivotal Study (CRIPs, Failed Lower Back)
- \$1.5 million R&D
- \$1.5 million Operations



#### 3 steps to break-even ...

#### A. Private practices in the United States

- Nurse/Sales Rep duo

#### B. U.S. military

- Authorized GSA vendor

#### C. International Calmare distributors

- Europe, Mid. East, No. Africa
- Far East and Oceana

# **1 Device per Week**



**Break** 

Even



#### Company progress ...

- ✓ Repaid senior Note<sup>2</sup>
- EMENA distributor
- ✓ Substantively reduced "burn"
- ✓ Streamlining sales process
- ✓ New financing/lease options
- ✓ Raised operational funds

- ✓ Key Hires:
  - i. CFO
  - ii. US Sales Head
  - iii. EMENA Sales Head
  - iv. Product Marketing
  - v. Military BPA specialist

<sup>2</sup> The retirement of the "Tonaquint Note" As disclosed in 1<sup>st</sup> Quarter 2014 financials



#### **Financial Data (select)**

Stock Price (5/23/14)	<b>\$0.42</b>
52-week Hi-Lo	
Ave. Daily Trading Vol. (3m)	25,309
Market Cap (5/23/14)	\$9.4 million
Shares Outstanding	22.5 million
Float	15.2 million
Authorized Shares	40.0 million
Total Revenues (TTM; a/o 1Q 14)	\$936,000
Total Debt (a/o 1Q 14)	\$3.1 million





#### **Our Board of Directors**

**Peter Brennan**, *Chairman* – As Chairman of the Board of Directors of CTI, Peter brings financial and governance leadership to the company. He spent the last 30 years working in the investment management business and is the founder of Damel Investments LLC which invests in small capitalized technology companies. He was the Chairman of the Governance committee of the New York Society of Security Analysts. As well he was a founding member of the Capital Market Policy Council of the CFA Institute. Mr. Brennan received his MBA from the University of Chicago, and his BA from Haverford College.

**Rustin Howard**, *Director* – Rus has over 25 years of experience in technology and hi-growth business development and has served on several boards and advisory councils for business and charitable organizations. He is a principal of Whitesand Investments LLC, an angel investment organization. He founded and served as chairman & CEO of Phyton, Inc., where paclitaxel was developed, the active ingredient of Bristol-Myers Squibb's multi-billion dollar anticancer drug, Taxol<sup>®</sup>. Rus is the chairman of DeepGulf, Inc., and co-owner and officer of Silver Bullet Technology. Previously, he was president and CEO of BioWorks Inc., a biotechnology company he founded. He is a member of the New York Biotechnology Association and served as the federal liaison for the government affairs committee of the New York Biotechnology Association and Biotechnology Industry Organization (BIO). He serves on several boards and was formerly on the board of the Make-A-Wish Foundation of Northwest Florida. Rus earned his MBA from Cornell University's Johnson Graduate School of Management, where he focused his studies on Entrepreneurship, and managing innovation and technology.

**Conrad Mir**, *Director*, *President & CEO* – Conrad has over twenty years of investment banking, financial structuring, and corporate reengineering experience. He has served in various executive management roles and on the Board of Directors of several companies in the biotechnology industry. Most recently, Before coming to CTI, Conrad was the CFO of Pressure BioSciences, Inc., (OTCQB: PBIO), a medical sample preparation company. Before that, he was chairman and CEO of Genetic Immunity, Inc., a plasmid, DNA company in the HIV space, and the executive director of Advaxis, Inc., (OTCQB: ADXS), a vaccine company. Over the last five years, he was responsible for raising over \$40 million in growth capital and broadening corporate reach to new investors. Conrad has worked for several investment banks including Sanford C. Bernstein, First Liberty Investment Group, and Nomura Securities International. He studied English and Economics with concentrations in Mathematics and Physics at New York University.

**Robert Moussa,** *Director* – Bob, who has over 30 years experience in the healthcare and medical device industry, joined the Board of Directors in 2012. He currently serves as chairman of the Board of Directors and chief executive officer of Dilon Diagnostics. He has extensive experience launching new products and directing operations in the diagnostic, nuclear medicine and medical device markets. Bob has served in a variety of executive positions with Mallinckrodt, Inc., a \$2.4 billion healthcare and chemical company, including president and chief executive officer of Mallinckrodt Medical, Inc., Mallinckrodt's largest business unit with over \$1 billion dollars in revenues. Mr. Moussa received his Baccalaureate from the Collège du Sacré-Cœur, Beirut, Lebanon, and his B.S. in Business Administration from Ealing University, London, England.

**Carl O'Connell**, *Director* – Carl was the former president & CEO of CTI. Before his service with the Company. Mr. O'Connell was the President & CEO of the U.S. healthcare division of ITOCHU Corporation, the Japanese conglomerate. Prior to that, he was the global vice president for Stryker Spine, and president of Carl Zeiss Surgical Inc. His diverse responsibilities include global marketing, sales, manufacturing, leadership development, regulatory affairs, corporate quality systems and research and product development functions. Carl has worked to transform and grow his companies into leaders in their respective markets as well as establishing leadership platforms in Neurosurgery, Ophthalmology, Orthopedics-Spine, E.N.T. and Dentistry. Carl is also an advisor for the Chicago based private equity firm WaterStreet Healthcare, and GE Healthcare for their Interventional Neurosurgery Imaging Technologies. He received a bachelor's degree in Psychology and an M.B.A. from Mount St. Mary's College, Maryland.

Stan Yarbro, PhD, *Director* – Stan has extensive experience in market development of high technology solutions to a worldwide customer base. He recently retired as EVP of Worldwide Field Operations for Varian Semiconductor Equipment Associates, a position he had held since 2004. Prior to Varian, Dr. Yarbro served in various executive capacities at KLA-Tencor Corporation, in the semi-conductor industry. He currently serves on the boards of FSI International and Carbon Design Innovations. He previously served on the boards of Electrogas, Inc., and Molecular Imaging where he worked closely with the organizations to develop and improve sales and marketing strategies. He holds a Ph.D. in Analytical Chemistry from Georgia Institute of Technology, and a B.S. in Chemistry from Wake Forest University.



# Thank you!

#### **Conrad Mir**

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