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Relmada Therapeutics, Inc.

In our latest report, we return to one of our favorites – the biotech industry! **Relmada Therapeutics, Inc.** (OTCQB: **RLMD**) recently moved from privately held to becoming a publicly traded company. With RLMD, we bring you a clinical stage biopharmaceutical company with a current portfolio that includes 4 drugs under development. Each of the drugs, **LevoCap ER**, **d-methadone**, **MepiGel**, and **BuTab ER**, will address what the company calls an "unmet need" in the treatment of pain.

Relmada Therapeutics has chosen to apply a unique low cost, low risk FDA drug development strategy to the **treatment of pain**, which is the largest drug prescription market in the world. The company's strategy should allow RLMD to bring 3 of its 4 products to market much faster than the standard drug development path allows.

In this report, we will lay out what we feel is an extremely promising biotech with a very bright future as a publicly traded company. Readers will learn the firm's unique strategy to drug development, understand more about the pain market in which Relmada Therapeutics will compete, get familiar with the 4 products in the company's pipeline, and we'll introduce you to RLMD's impressive leadership team and Scientific Advisory Board.

With this report, we are officially initiating coverage on RLMD and issuing a **Speculative Buy** rating on the company as we continue to follow the biopharmaceutical firm and its impressive story.

Relmada Therapeutics, Inc. 546 Fifth Avenue – 14th Floor New York, NY 10036 Website: www.relmada.com Email info@relmada.com Telephone: (212) 702-7163	OTCQB™
Company Ticker Symbol	RLMD
Current Price as of 10/09/2014	$3.00
52-Week High/Low	$1.50/3.49
Est. Outstanding Shares	40,301,717
Est. Public Float	34.6M
Market Capitalization	$120,905,151
Stock Market Media Group Rating	Speculative Buy

Company Overview

Relmada Therapeutics, Inc. is a clinical stage biopharmaceutical company headquartered in New York, New York.

RLMD entered the public arena in May 2014, and since that time, it has introduced investors to **4 novel pain drugs** that the company is developing through an FDA drug development strategy. This strategy combined with the firm's expertise benefits Relmada in the development of novel versions of already proven drug products together with new chemical entities that can potentially address areas of high unmet medical need in the treatment of **pain** – the largest drug prescription market in the world!

The aforementioned expertise is realized in the company's top notch management team and its Scientific Advisory Board which we'll cover later in this report. Management is headed by Chief Executive Officer, Sergio Traversa, PharmD, MBA, and his more than 25 years of experience in the

healthcare sector in both the US and Europe, and its President and Chief Scientific Officer, Eliseo Salinas, MD, MSc, who has an impressive track record of developing successful drugs.

RLMD – Development Strategy

RLMD plans to further develop its new and proprietary drug products primarily through the **FDA 505(b)(2) regulatory approval pathway**.

The 505(b)(2) process allows Relmada Therapeutics to take pain medicines that have already been approved and make small modifications to them (allowed by FDA) with the expectation that the company can significantly improve efficacy, patient safety and patient convenience.

This strategy will assist RLMD in bringing 3 of the "repurposed drugs" in its current pipeline to market much faster and at a fraction of the cost of typical drug development.

The FDA pathway employed by Relmada is relatively **low risk** because the drugs being improved upon by the company have already been proven to be safe.

Because Relmada Therapeutics will have to pay for fewer studies in order to develop its drugs, the company's process offers a **low cost** solution.

And, with fewer studies to conduct, this strategy is **faster** if done correctly. Relmada's expertise in developing drugs could potentially help the company bring a repurposed drug to market in as little as 3 years.

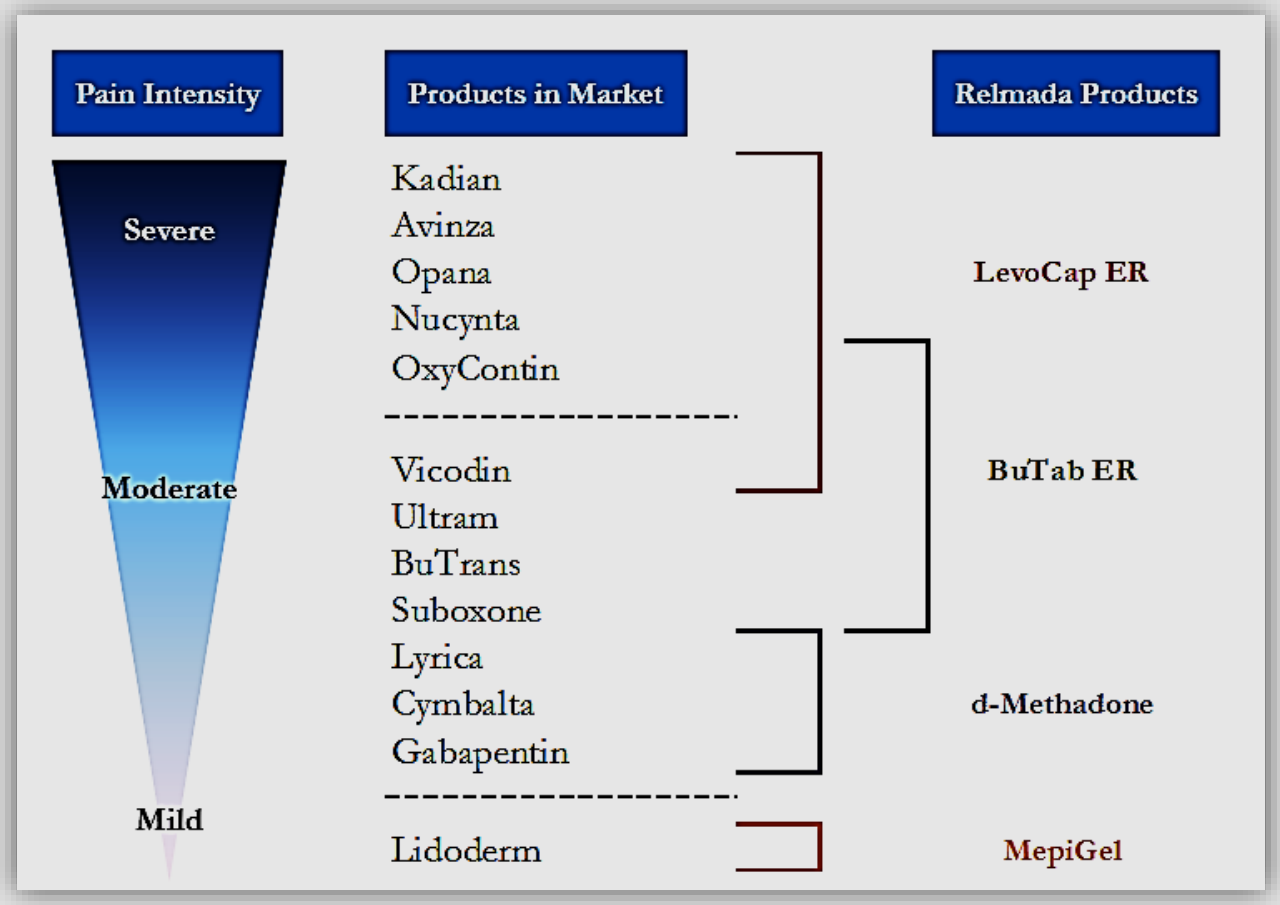
Relmada will take advantage of this strategy by leveraging its considerable industry experience, analgesic therapy knowledge and development expertise to identify, develop and commercialize product candidates with strong market potential that can fulfill the needs of the ever-expanding pain market.

While Relmada will use the 505(b)(2) to develop LevoCap ER, BuTab ER, and MepiGel, it will pursue the development of d-methadone using the traditional new drug application (NDA) process.

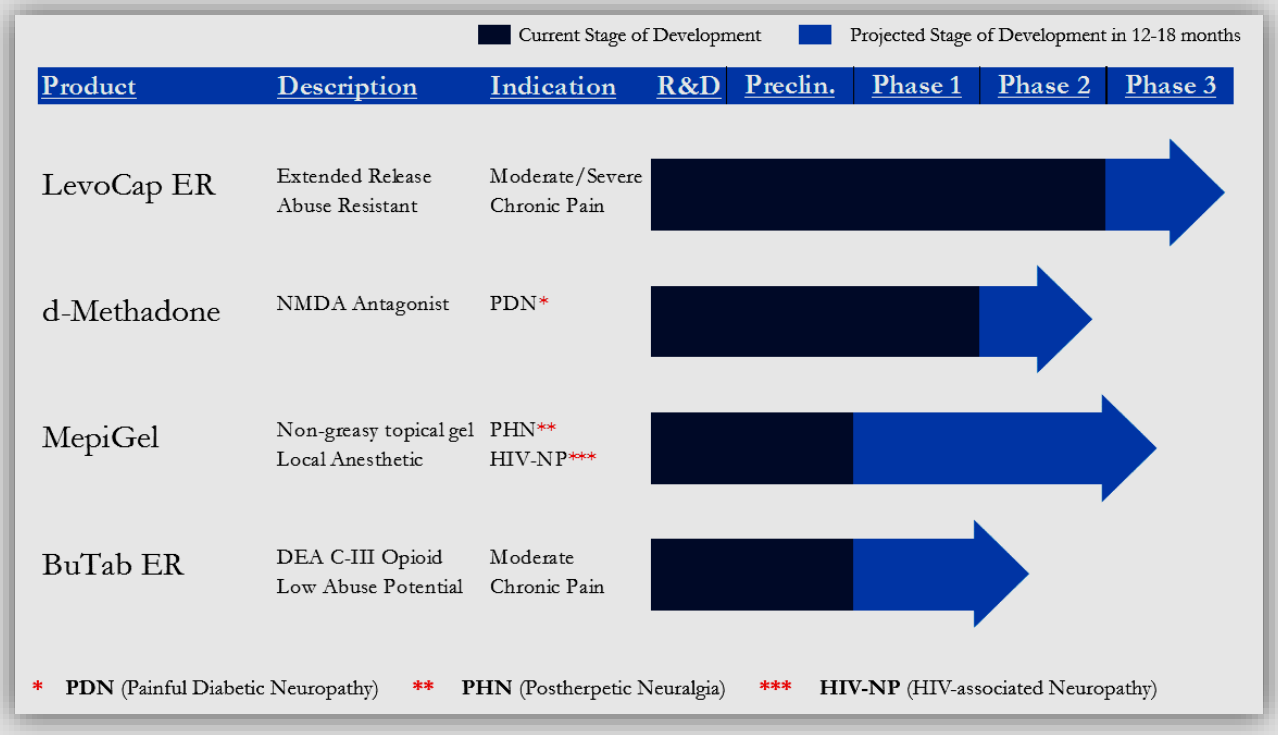
Relmada Therapeutics – Pipeline

RLMD is currently developing pain medicines for the treatment of chronic pain due to:

- Cancer
- Musculoskeletal Disorders (osteoarthritis, lower back pain)
- Peripheral Neuropathy (postherpetic neuralgia, painful HIV neuropathy, painful diabetic neuropathy)



Let's take a look at each of the medicines in the company's current pipeline. We'll start with a chart that demonstrates where each of Relmada Therapeutic's 4 products are in the drug development process, and then we'll give you an in-depth look at each of the biotech's drugs and the products currently on the market that each will compete with for sales if approved.



- Relmada's lead product is **LevoCap ER**, which is a proprietary once-a-day extended release dosage form of the opioid analgesic **levorphanol** in an abuse deterrent drug delivery system. It has activity at both opioid and non-opioid receptors making it potentially effective for cancer pain, chronic non-cancer pain like osteoarthritis, lower back pain, and neuropathic pain.

Unlike oxycodone, morphine, hydromorphone, oxymorphone, and hydrocodone… the company says levorphanol modulates pain through both the **ascending opioidergic pathways** and the **descending noradrenergic pathways** in one centrally acting analgesic.

While ascending and descending pathways in the human body may not make much sense to many, the benefit to patients is that levorphanol's multi-modal mechanism of action could potentially mean that LevoCap ER could be used alone by those patients who are now taking multiple drugs.

The company has demonstrated that LevoCap ER is significantly more potent than morphine at the μ (mu), δ (delta) and κ (kappa) receptor and its norepinephrine and serotonin reuptake inhibition is comparable to: tapentadol (Nucynta®) and tramadol (Ultram® ER, Ryzolt®).

According to Relmada, LevoCap ER also exerts NMDA antagonism, which may explain its efficacy in neuropathic pain and its ability to partially reverse tolerance to morphine.

LevoCap ER will compete in the same opioid market segment as current drugs like OxyContin®, Opana® ER, Embeda®, Kadian®, Avinza® and Exalgo®.

- The second of the 4 drugs being developed in Relmada Therapeutics' pipeline is **d-methadone**.

Relmada Therapeutics' d-methadone will compete in the **$5 billion neuropathic pain market**, currently dominated by Cymbalta, Lyrica and Lidoderm, which had combined sales of $10.5 billion across indications in 2013.

This medicine is the d optical isomer of **racemic methadone** and an antagonist at the N-methyl-D-aspartate (NMDA) receptor. NMDA antagonists have also been shown to reduce tolerance to opioid analgesics in experimental models which gives d-methadone the potential to provide pain relief without the addiction of methadone.

Racemic (d + l-methadone) methadone has been available in the US for over 60 years. Racemic methadone is a DEA scheduled C-II strong opioid similar to morphine used for the treatment of pain and for opioid addiction maintenance programs.

Unlike racemic methadone, d-methadone is virtually devoid of opioid activity but maintains N-methyl-D-aspartate (NMDA) receptor antagonism. Evidence from non-clinical studies suggests that NMDA receptor antagonists can prevent the CNS changes implicated in maintaining chronic pain states, especially neuropathic pain.

An open-label Phase I/II-A safety study with d-methadone provided promising results and clinical support for advancing the development of d-methadone into a Phase II-B "proof of concept" trial.

- **MepiGel** is the third of four of the company's drugs, and it's a proprietary topical dosage form of the local anesthetic **mepivacaine** for the treatment of painful peripheral neuropathies.

MepiGel would be the first topical gel dosage form of any local anesthetic for the treatment of neuropathic pain. It has already been granted two **Orphan Drug Designations by the FDA**, for the treatment of postherpetic neuralgia and for the painful HIV neuropathy. Once approved, these designations will give the company 7 years of marketing exclusivity in the US.

RLMD executives expect MepiGel to be used alone and in combination with oral therapies for neuropathic pain such as Lyrica® and Cymbalta®. MepiGel will compete in the same market segment as Lidoderm® patch, which had US sales of $948 million in 2012.

- Finally, the fourth drug on the list is **BuTab ER**, a proprietary extended release dosage form of **oral buprenorphine**. It is being developed for the treatment of chronic to moderately severe pain and opioid dependence.

It is a repurposed drug that can go directly into a Phase III clinical trial without the need for a Phase II trial.

Buprenorphine has been widely used both sublingually and by way of transdermal patch, but BuTab ER would be the only tablet form for use in the treatment of pain. Buprenorphine's unique pharmacology – partial μ agonist, δ agonist and κ antagonist – distinguishes it from other opioids.

Among its expected advantages over oxycodone, oxymorphone, morphine and hydromorphone the active opioids in OxyContin®, Opana® ER, Embeda®, and Exalgo®, respectively are:

- Reduced risk of physical dependence
- Reduced reinforcing properties
- Reduced drug liking by recreational drug users
- Reduced risk of respiratory depression in overdose.

BuTab ER will compete in the same severe pain market as OxyContin®, Opana® ER, Embeda®, Kadian®, Avinza® and Exalgo® which last year saw **opioid sales of $8.3 billion in the US**. But, it will do so with the advantage of the reduced risk of drug abuse.

Additionally, BuTab ER will compete with sublingual buprenorphine Suboxone®/Subutex® and methadone for the treatment of opioid dependence which enjoyed about **$1.4 billion in sales in 2013**.

Competing in the Pain Market

Relmada Therapeutics is competing in what is the largest prescription drug market in the world. In 2013 alone, 334 million pain prescriptions were written in the US, and pain represents the most frequent reason given for physician visits in this country.

RLMD has chosen to develop drugs in a market that affects more Americans than diabetes, heart disease and cancer combined.

According to the company, the annual economic cost of healthcare due to pain in the US, is in excess of $560 billion, and with approximately 100 million people suffering from chronic pain in the US, it's easy to understand why those costs are mounting.

Let's face it, better pain drugs are needed in the US and worldwide. Most patients with chronic pain are undertreated: only 55% say their pain is "under control" (Chronic Pain in America Study, American Academy of Pain Management, American Pain Society and Janssen, 1999) and only 23% say their medications are "very effective." (Voice of Chronic Pain Survey, American Pain Foundation).

It is this unmet medical need in the pain market that has opened the door for success for companies like Relmada Therapeutics.

Continuous suppression of pain through the use of around-the-clock opioid analgesics is now recommended in chronic pain treatment guidelines. Conventional (so called "immediate-release" or "short acting") opioid analgesics usually require dosing every 4-6 hours in chronic pain.

Extended release formulations (also known as "long acting", "sustained release" or "controlled release") are the standard of care in chronic pain. Extended release opioids can provide fewer interruptions in sleep, reduced dependence on caregivers, improved compliance and enhanced quality of life outcomes.

According to IMS Health, the 2013 U.S. market for opioid analgesics was $8.3 billion. Of this, extended release opioids accounted for approximately $4.3 billion. The market leader, controlled release oxycodone (primarily OxyContin®), had annual sales of $2.5 billion in 2013 (IMS Health).

Neuropathic pain is another area where Relmada looks to offer relief. With approximately 5 million people suffering from painful neuropathy in the US (GloboData), and few available treatment options, neuropathic pain represents an area of significant unmet medical need.

Current treatment of peripheral neuropathic pain involves several drug classes, including gabapentinoids, antidepressants, antiepileptic drugs, local anesthetics, capsaicin and opioids.

Many patients have suboptimal relief with monotherapy and treatment is frequently multi-modal, involving use of two or more drugs from different pharmacologic classes.

Almost entirely as a result of the success of Pfizer's Neurontin® (gabapentin), which had peak sales of $2.7 billion, neuropathic pain has become one of the most sought-after indications. Robust promotional efforts by Pfizer (Lyrica®), Eli Lilly (Cymbalta®) and Endo Pharmaceuticals (Lidoderm®) have improved physician and patient awareness of neuropathic pain and its management.

Relmada Therapeutics - Management Team

Chief Executive Officer

Sergio Traversa, PharmD, MBA – Before joining Relmada, Dr. Traversa was the co-founder and CEO of Medeor Inc., a spin-off pharmaceutical company from Cornell University.

Dr. Traversa has over twenty-five years of experience in the healthcare sector in both the US and Europe, ranging from management positions in the pharmaceutical industry to investing and strategic advisory roles.

He has held financial analyst, portfolio management and strategic advisory positions at large US investment firms specializing in healthcare, including Mehta and Isaly and Mehta partners, ING Barings, Merlin BioMed and Rx Capital. Dr. Traversa was a founding partner of Ardana Capital, a pharmaceutical and biotechnology investment advisory firm.

In Europe, he held the position of Area Manager for Southern Europe of Therakos Inc., a cancer and immunology division of Johnson & Johnson.

Prior to Therakos, Dr. Traversa was at Eli Lilly, where he served as Marketing Manager of the Hospital Business Unit. He was also a member of the CNS team at Eli Lilly, where he participated in the launch of Prozac and the early development of Zyprexa and Cymbalta.

Dr. Traversa started his career as a sales representative at Farmitalia Carlo Erba, the largest pharmaceutical company in Italy later sold to Pharmacia and now part of Pfizer.

Dr. Traversa holds a Laurea degree in Pharmacy from the University of Turin (Italy) and an MBA in Finance and International Business from the New York University Leonard Stern School of Business.

President and Chief Scientific Officer

Eliseo Salinas, MD, MSc – Joined Relmada Therapeutics in February 2014. Dr. Salinas has more than 20 years of experience developing therapeutic products for CNS disorders in many key jurisdictions worldwide, including the US, Canada, the European Union, and Japan.

Under Dr. Salinas' leadership, 15 programs obtained regulatory approval in the US and other major international markets. Before joining Relmada, Dr. Salinas was:

- Executive Vice President, Head of Development and Chief Medical Officer of Elan Pharmaceuticals;
- Senior Vice President - Head of Research and Development and Chief Medical Officer of Adolor Corporation;
- Executive Vice President, Specialty Pharma, Research and Development and Chief Scientific Officer of Shire PLC, and
- Held roles of increasing responsibility in research and development at Wyeth-Ayerst Research, including head of worldwide CNS Clinical Development.

Dr. Salinas earned his medical degree from the University of Buenos Aires, Argentina, performed a residency in psychiatry in Paris at the Clinique des Maladies Mentales et de l'Encéphale, and obtained a master's degree in pharmacology from the Université Pierre et Marie Curie, Académie de Paris, France.

Chief Financial Officer

Douglas J. Beck, CPA – Joined Relmada in December 2013. Prior to joining the company, Beck was:

- CFO of iBio, Inc, a publicly traded biotech company, from May 2011 to February 2013.
- CFO of Lev Pharmaceuticals, Inc., a publicly traded biotech company from May 2005 to February 2009 (the company was acquired by ViroPharma, Incorporated in October 2008 for $617 million.)
- Employed as an independent consultant at different firms.

Douglas Beck serves on the SEC Practice Committee and the Chief Financial Officers Committee for the New York State Society of CPAs. Beck holds a B.S. from Fairleigh Dickinson University.

Relmada Therapeutics – Scientific Advisory Board

Troels Jensen, MD

Troels Jensen is the Past-President of the International Association for the Study of Pain, and Professor of Experimental and Clinical Pain Research, Aarhus University, Denmark.

Dr. Jensen received his MD from the University of Aarhus, completed his residency in Neurology, Neurosurgery, and Neurophysiology at University Hospitals in Aarhus and Copenhagen and his postgraduate clinical fellowship at the Hôpital de la Salpetriere in Paris.

He has authored more than 300 scientific papers in peer-reviewed journals on neurophysiology, neuropharmacology and mechanisms and treatment of neuropathic and muscle pain. Dr. Jensen is editor of several books on pain and he has served as Section Editor for the journal PAIN. He serves on the editorial board and reviewer for several international journals.

Dr. Jensen leads the Danish Pain Research Center at Aarhus University, Denmark. He was the President of the Scandinavian Association for the Study of Pain from 1989 to 1994.

Arthur G. Lipman, PharmD

Arthur G. Lipman is a Professor of Pharmacotherapy, College of Pharmacy and Director of Clinical Pharmacology at the Pain Management Center, University of Utah Hospitals and Clinics.

Before moving to Utah, Dr. Lipman was Drug Information Director at the Yale-New Haven Medical Center and he held concurrent faculty appointments at the Yale University School of Medicine, Yale University Graduate School of Nursing and University of Connecticut School of Pharmacy.

He served on both the Acute and Cancer Pain Management Guideline Panels of the U.S. Department of Health and Human Services, co-chaired the Arthritis Pain Management Clinical Guidelines Panel of the American Pain Society, and is a member of the International Association for the Study of Pain Acute Pain Taskforce.

Dr. Lipman has published over 300 articles, chapters and reviews, and is editor of the Journal of Pain and Palliative Care Pharmacotherapy.

Richard Payne, MD

Richard Payne is a Professor of Medicine, Duke University and Director of the Duke Institute on Care at the End of Life. Dr. Payne is an internationally known expert in the areas of pain relief, care for those near death, oncology, and neurology.

Prior to his appointment at Duke, he was Professor of Neurology and Pharmacology at Cornell University Medical College and Chief, Pain & Palliative Care Service at Memorial Sloan-Kettering Cancer Center.

Dr. Payne has held various academic appointments, including Chief of Neurology at the Cincinnati VA Medical Center, and Vice-Chairman, Department of Neurology at the University of Cincinnati Medical School and Chief of the Pain and Symptom Management Section and Professor of Neurology at the University of Texas, MD Anderson Cancer Center.

Dr. Payne has served on the Editorial Board of numerous journals including Pain, American Pain Society Journal, Journal of Pain and Symptom Management, Pain Forum and Journal of Pain. He has published over 200 scientific communications, including abstracts, manuscripts, book chapters and books.

From 2003-2004, Dr. Payne was president of the American Pain Society. He is a fellow of the American Academy of Hospice and Palliative Medicine, The American Academy of Neurology, and the American Academy of Pain Medicine.

Dr. Payne has received a Distinguished Service Award from the American Pain Society; the Humanitarian Award from the Urban Resources Institute; and the Janssen Excellence in Pain Award.

Frank Porreca, PhD

Frank Porreca is Professor of Pharmacology and Anesthesiology, College of Medicine at the University of Arizona and an internationally recognized pharmacologist.

He is an Executive Editor-in-Chief of Life Sciences and the Pharmacology Section Editor of the journal PAIN.

Dr. Porreca has received numerous awards and recognition for his research, including; Distinguished Professor, Mayo Clinic in 2004, Founder's Day Speaker, University of Arizona in 2001, F.W. Kerr Award, American Pain Society in 2000, 9th Covino Lecturer, Harvard University in 2000, Sterling Professor Pharmacology, Albany Medical School in 2000 and the NIH MERIT Award in 2000.

He is inducted as a Research Fellow by the American Academy for the Advancement of Sciences. Dr. Porreca has published over 250 manuscripts, 28 book chapters and hundreds of scientific abstracts. Dr. Porreca is a sought after speaker at both national and international basic and clinical research meetings.

Arthur Weaver, MD

Arthur Weaver is a Clinical Professor of Medicine (Emeritus), Division of Rheumatology at the University of Nebraska Medical Center in Omaha, Nebraska.

Board-certified in internal medicine and rheumatology, Dr. Weaver has been an active Fellow of the American College of Rheumatology (ACR) for many years, serving on the Board of Directors and as President of the ACR.

Dr. Weaver received his medical degree from Northwestern University and his residency and fellowship in internal medicine and rheumatology from the Mayo Clinic.

He has served as a principal investigator in over 115 clinical trials, published over 150 manuscripts and abstracts in rheumatology and made over 1500 scientific presentations in the field of clinical rheumatology.

Dr. Weaver is a recipient of numerous awards, including the Arthritis Foundation Founders Award, the Mayo Clinic Philip Hench award for excellence in rheumatology and the American College of Rheumatology Pauldine Phelps Award. Dr. Weaver is a sought after speaker at both national and international meetings.

Nathaniel Katz, MD, MS

Nathaniel Katz, MD, MS, is the President and CEO of Analgesic Solutions, an organization that guides pharmaceutical companies on the efficient development and commercialization of better treatments for pain. From 2000-2004, Dr. Katz served as Chair of the Advisory Committee, Anesthesia, Critical Care, and Addiction Products Division, at the FDA.

He received his medical degree from the Medical College of Pennsylvania and his M.S. in Biostatistics at Columbia University.

After his neurology residency at Tufts-New England Medical Center he entered a Pain Management fellowship in the Department of Anesthesia at Brigham & Women's Hospital and then served as a Staff Neurologist in the Pain Management Center of Brigham & Women's Hospital. Subsequently,

he founded the Pain & Symptom Management Program at Dana Farber Cancer Institute, and the Pain Trials Center unit) at Brigham & Women's Hospital.

Dr. Katz's interests include clinical research methods, analgesic clinical trials, neuropathic pain, cancer pain and opioid therapy for chronic pain. He is an internationally recognized expert in pain management and analgesic clinical trials, and he has conducted and published numerous clinical investigations of treatments for pain, with a particular focus on opioids and risk management.

Raymond Sinatra, MD, PhD

Raymond Sinatra, MD, PhD, is the Professor of Anesthesiology at Yale University Medical School. Dr. Sinatra received his MD and PhD in neuroscience at SUNY Downstate School of Medicine.

He completed his residency in Anesthesiology and Fellowship in Pain Management at Brigham & Women's Hospital, Harvard Medical School.

Dr. Sinatra is Senior Editor of two textbook on pain, Acute Pain: Mechanisms and Management and Acute Pain Management. He has authored over 200 scientific papers, review articles, abstracts and textbook chapters on pain management and obstetrical anesthesiology.

Dr. Sinatra serves as a reviewer for several journals and he has been a principal investigator for dozens of clinical trials evaluating novel analgesics and analgesic delivery systems. He is a frequent presenter at national and international meetings on pain management.

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