Zacks Small-Cap Research

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Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

scr.zacks.com
10 S. Riverside Plaza, Ste 1600, Chicago, IL 60606

Calmare Therapeutics (CTTC-OTC)

CTTC: Re-Established Int'l Sales Help Push Revenue to 3-year High

Current Recommendation	**Neutral**
Prior Recommendation	Neutral
Date of Last Change	06/28/2011
Current Price (11/24/14)	$0.19
Target Price	**$0.50**

OUTLOOK

Calmare Therapeutics' current main focus lies with the marketing and distribution of the FDA-cleared and CE Marked Calmare pain therapy device. While several small studies provide some support of its efficacy, lack of broad reimbursement from private and public payers has been a significant headwind in accelerating commercialization of Calmare. A new CEO was brought onboard to orchestrate a turnaround which includes the plan to run two pivotal clinical studies to support an FDA PMA submission and improved reimbursement status. A near-term initiative to spark a resurgence in revenue growth includes streamlining the process to sell to U.S. government entities. While we think the new commercialization strategy makes sense, an investment in CTI is not without meaningful risk which is factored into our investment rating.

SUMMARY DATA

52-Week High	**$0.55**
52-Week Low	**$0.08**
One-Year Return (%)	**-52.38**
Beta	**0.93**
Average Daily Volume (sh)	**67,648**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$5**
Short Interest Ratio (days)	**1.75**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**18**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Business Svcs**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	62 A	150 A	327 A	233 A	772 A
2014	228 A	332 A	434 A	241 E	1,234 E
2015					1,408 E
2016					2,077 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.05 A	-$0.04 A	-$0.04 A	-$0.03 A	-$0.16 A
2014	-$0.04 A	-$0.03 A	-$0.05 A	-$0.03 E	-$0.14 E
2015					-$0.09 E
2016					-$0.08 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

WHAT'S NEW…

Q3 2014 Results: Revenue Jumps As Re-Established Int'l Territories Already Making Big Contribution…

Calmare Therapeutics reported financial results for the third quarter ending September 30, 2014. Revenue was the highest in three years and crushed our estimate. However, this did not translate into a beat on the bottom line due a big jump in interest expense and lower than average gross margin, the latter a result of greater international device placements which carry a lower sales price. But despite the miss on EPS we characterize the results as mostly positive, given that revenue, which increased 33% and 84% in the three and nine months ending 9/30/14, is a better metric to judge the operational performance of the company.

Key to the revenue growth in Q3 was the re-establishment of the international EMENA territories. As a reminder, loss of the EMENA territory was a major reason for revenue and unit sales plummeting 69% and 89%, respectively in 2012. CTI reclaimed these areas earlier this year and in late May signed a binding letter of intent with The Mediterranean for Integration and Technology to sell Calmare in the Middle East and North Africa.

In addition, in support of the theme of improvement in operational performance, CTI has been able to ramp recent revenue with very little increase in operating expenses. And we see no reason why this trend will not continue. On the earnings call management noted that they expect to have several announcements in the coming weeks related to a GSA agreement as well as details related to the previously proposed pivotal clinical study.

Q3 revenue of $434k was the highest since Q3 2011 and was well ahead of our $163k estimate. CTI sold eight Calmare units in Q3, including five internationally and three to the private sector in the U.S. Compared to Q3 2013 product sales and total revenue increased by 38% and 33%, respectively. Through the first nine months of 2014 total revenue was $994k, up 84% over the same period in 2013. And while we expect there may be some quarterly volatility, we think the initiatives that the company has recently put in place to revive sales of Calmare, including re-establishment of their international footprint, wider U.S. distribution, increased penetration of the U.S. government channel and building awareness of the potential benefits of Calmare therapy should result in continued, yet perhaps measured, sales growth. As noted, on the Q3 call management mentioned that they expect to make a GSA-related announcement in the coming weeks - while no specifics were provided, we interpret the message to be that this could help catalyze an increase in sales to the government channel.

Gross margin ticked down considerably in Q3 as a result of significantly greater international sales, which come at a lower net sales price. Product gross margin was 38% in Q3, compared to almost 69% through the first half of 2014 which had no international sales. Operating expenses have been fairly stable despite the recent significant revenue growth, the result of which has materially improved operating loss. Operating expenses at $768k were in-line with our estimate and up just 11% from the year-earlier period. The combination of ramping revenue and near-flat operating expenses have reduced operating loss to $1.7 million through the first nine months of 2014, down from an operating loss of $1.9 million and $2.3 million over the similar periods in 2013 and 2012, respectively.

Q3 net loss and EPS were $1.2 million and ($0.05), compared to our $728k loss and ($0.03) estimates. The difference mostly a result of ~$500k in additional interest expense related to modifications to terms of some of the outstanding debt. Per management's comments on the call, this was a one-time expense and, as such, we expect interest expense in Q4 to be significantly than the $575k incurred in Q3.

Cash used in operating activities was $237k in Q3. Ex-changes in working capital, cash used was $1.0 million - however, this $1.0 million burn rate includes the ~$500k in one-time interest expense and is not indicative of future expectations. CTI exited Q3 with $500 in cash and equivalents - however, management noted on the call that they expect to raise an additional ~$130k within the next few days.

We have made only minor changes to our model following the 10-Q filing. We are maintaining our Neutral rating and $0.50/share price target.

Favorable Court Ruling For Reimbursement of Calmare Therapy
On June 24, 2014 the Civil Court of New York, Richmond County ruled in favor of Forest Rehabilitation Medicine, a Calmare therapy provider, that the defendant, Allstate Insurance Company, is liable for payment to Forest for $3.5k related to the cost to treat a car accident victim with Calmare therapy.

The defendant made several claims as to why they are not liable for reimbursing plaintiff, including that since Calmare treatment has been mainly used with chemotherapy patients that it is not applicable in the context of a car accident victim and is not medically necessary. Defendant's witness (a board certified specialist in physical medicine and rehabilitation) further testified that his opinion was that Calmare therapy was medically questionable and that he believed the patient could have been sufficiently treated with conventional physical therapy. Interestingly, the defendant did not make any claims that Calmare therapy is ineffective, but indicated that similar results could have been accomplished with basic physical therapy.

The judge ruled in favor of Forest and ordered defendant to pay $3.5k plus attorney's fees. The basis for her judgment was that defendant failed to provide evidence of a lack of medical necessity and that Forest's witness (Dr, Jack D'Angelo, who specializes in physical medicine and rehabilitation and uses Calmare therapy in his practice) provided sufficient evidence that Calmare therapy is reliable.

The judge also cited in her judgment that the patient reported her pain level fell from 5-6 at initiation of treatment to 3 at completion. Indicating that this (i.e. - reduction in pain), coupled with no evidence that there is non-acceptance of Calmare therapy in the medical community, also figured into her judgment.

The judge commented that, "The Court certainly recognizes that anything new, whether it be a mechanical device or a scientific theory, will inevitably have "kinks" which need to be worked out over time. However, this fact should not fuel any unreasonable fear or disapproval of a device which has the potential to literally revolutionize how the medical field addresses and combats chronic pain. Therefore, in consideration of this, the Court finds no reason to deny the instant claim for reimbursement. The Court finds that Calmare Scrambler Therapy, in the instant action, was a medical necessity for Ms. Fertitta's pain management."

Favorable Judgments Could Be Precedent-Setting…

This favorable judgment follows that of an appeal won in mid-January by a Calmare practitioner in Staten Island whose claim for Medicare coverage of Calmare use had previously been denied. This related to a specific case of a patient that received Calmare therapy in 2011 for cancer/chemotherapy-related pain. The appellate judge ruled that there was sufficient evidence that Calmare therapy was necessary for this patient and for Medicare to issue reimbursement.

A lack of widespread or consistent reimbursement from both government and private payers has been a headwind in accelerating commercialization of Calmare. As we've noted in our coverage of CTI, we believe long-term viability of the company will require a substantially improved reimbursement status for Calmare as clinics, hospitals and physicians, en mass, are likely to be largely disinterested in purchasing the device under the current payment environment.

These recent legal judgments in favor of practitioners with the courts' basis being that Calmare therapy is necessary and effective is potentially the beginning of a trend and could eventually be precedents for future legal arguments and judgments for reimbursement of Calmare therapy. We caution, however, that while these cases are votes of confidence for potential improvement in reimbursement for Calmare, that we think it is too early to draw any conclusions in that regard.

Operational Update

The company has already made headway with expanding distribution as well as their commercial footprint since our March 12th initiation report. As we indicated, this will be key in order for the company to grow sales in the near-term and to help fund further clinical studies to support an FDA PMA filing.

In late March a pain clinic in Idaho became the most recent addition to the small but growing list of domestic providers of Calmare therapy. A few days later CTI announced that they expected to reestablish the international commercial footprint (Europe, Middle East and North Africa or EMENA territory) which was relinquished via the July 2012 amendment which gave most ex-U.S. commercial rights to Marineo.

We had not anticipated CTI would look to reclaim these international territories. CTI has indicated that the amendment was never signed by Marineo/Delta by a March 31, 2014 deadline and therefore is not enforceable. Instead, according to CTI the initial agreement, which provided CTI with exclusive worldwide rights to manufacture and sell Calmare, is by default the active agreement between the company and Marineo/Delta. Marineo/Delta disputed CTI's assertion in an April 8th press release and then on April 16th sent a cease and desist letter to CTI

requesting that CTI no longer sell, distribute or manufacture Calmare. CTI responded to the cease and desist letter disputing Marineo/Delta's claims.

There is clearly a contentious relationship between CTI and Marineo/Delta and risk that the latest dispute ends up in litigation - although we think it may be in both parties' interest to resolve the matter out of the courts.

As loss of the EMENA territory was a major reason for revenue and unit sales plummeting 69% and 89%, respectively in 2012, reestablishment of these international areas has the potential to significantly increase CTI's near-term revenue. And this appears to already be happening. In Q3 five of the eight unit sales were made internationally which helped push total revenue up to the highest level in three years.

International Distribution Agreement Signed, Could Result in Pick Up of ex-U.S. Sales…

In late May CTI announced that they signed a binding letter of intent with The Mediterranean for Integration and Technology to sell Calmare in the Middle East and North Africa. CTI notes that their prior relationship with Mediterranean resulted in a "substantive portion of the company's $3.1M of sales in 2011." And while this deal does not cover Europe, this agreement has already resulted in a major pick-up in ex-U.S. sales.

SNAPSHOT

Calmare Therapeutics, Inc. ("CTI", OTC ticker CTTC) was established in 1968 as a provider of patent and technology transfer and licensing services to companies with emerging products and technologies. While the company still generates a small amount of revenue from licensing certain technologies, CTI's current main focus lies with the marketing and distribution of the Calmare® pain therapy device.

Calmare is an FDA-cleared and CE Marked non-invasive medical device used for the treatment of chronic pain. While transcutaneous electrical nerve stimulation (TENS), efficacy of which has been the subject of significant debate, was the predicate device to gain 510(k) clearance of Calmare, the inventors of the Calmare technology believe that the method of action to achieving pain relief differs between the two technologies and favors Calmare in terms of efficacy, particularly as it relates to chronic pain. Calmare therapy has been evaluated in several small clinical studies which have largely indicated it is safe and effective in reducing chronic pain of certain conditions, including chemotherapy-induced neuropathy, an extremely unpleasant and debilitating side effect of chemotherapy with no current effective treatment.

Calmare therapy, which was discovered in the 1980's by Giuseppe Marineo, PhD, an Italian scientist and mathematician, uses low dose electric impulses delivered through electrodes applied to the skin to send a "no pain" message to the brain. It has been used to treat over 5,000 patients with a variety of pain conditions including chemotherapy-induced peripheral neuropathy, lower back pain and post-surgical pain.

The broad target market for Calmare therapy represents the approximate 100 million Americans who suffer from chronic pain. We characterize the more specific opportunities within this broad category to be the ~400k Americans (~800k worldwide) who suffer from chemotherapy-induced peripheral neuropathy and the estimated 4M - 10M Americans who take opioid pain killers on a regular basis for chronic pain.

CTI began distribution of Calmare in 2007 via a licensing agreement with the developer of the technology. CTI's revenue from sales of Calmare have been modest and, until a July 2012 amendment to the licensing agreement which gave most ex-U.S. rights to Marineo, were mostly generated from overseas. Domestic sales, until only very recently, had been even more lackluster and largely concentrated among a number of private pain clinics and U.S. military medical centers. While the several small studies provide some support of its efficacy, lack of broad reimbursement from private and public payers has been a significant headwind in accelerating commercialization of Calmare. Long-term viability of the company, in our opinion, will require a substantially improved reimbursement status for Calmare as clinics, hospitals and physicians, en mass, are likely to be largely disinterested in purchasing the device under the current payment environment.

CTI, hoping to reverse the dramatic slide in revenue and deteriorating financial condition of the company over the last couple of years, recently brought on a new CEO to help orchestrate a turnaround. A major focus is generation of additional clinical data to further promote the benefits and efficacy of Calmare pain therapy and to use this as support for FDA premarket (PMA) approval and improved reimbursement status. In this regard, the company recently announced intentions to run two pivotal clinical studies, details of which we expect will be revealed in the coming weeks or months. A near-term initiative to spark a resurgence in revenue growth includes streamlining the process to sell to U.S. government entities. The company also recently began reestablishing their international commercial footprint and reclaiming overseas territories lost via the July 2012 amendment - early success in this regard helped significantly in pushing up revenue in Q3. The new management has also been focused on cutting expenses, reducing cash burn and strengthening the balance sheet.

BACKGROUND

Calmare

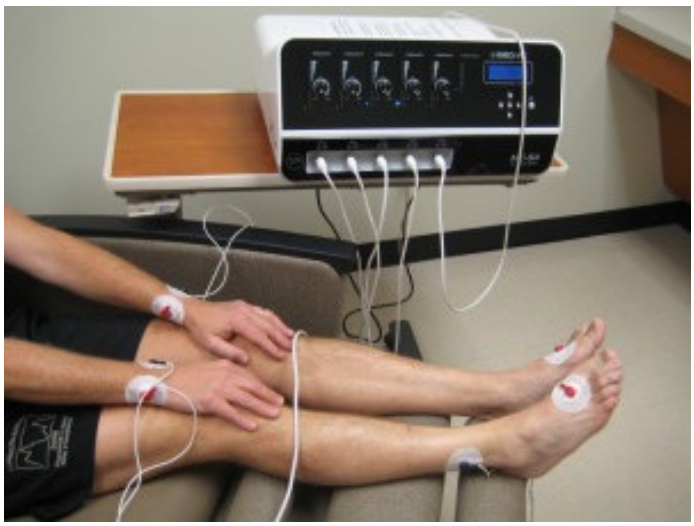
The patent protected[1] Calmare device uses a unique algorithm and multi-processor to send low-frequency electric impulses delivered to the nerve through five electrodes applied to the skin to simultaneously treat multiple areas of pain. The mechanism of action of Calmare therapy, also called Scrambler therapy, is thought to be effective in reducing symptoms of pain due to the electric impulses produced by the device interfering with pain signal

[1] U.S. patent 8,380,317, Marineo, Giuseppe. *Apparatus and method for quick pain suppression.* U.S. Patent and Trademark Office

transmission by mixing a non-pain information source into the nerve fibers. This is believed to re-associate (or scramble) the pain code sent from the site of pain to the brain.

The system consists of a module with five separate leads which are applied to different areas of the body (adjacent to the areas of pain) and can be individually set to various levels of intensity. Typical treatment protocol is for 10 to 15 sessions over a period of about two weeks with each session lasting for approximately for 30 to 40 minutes. Treatments are performed in health care clinics, hospitals and U.S. military medical centers by medical professionals who have been trained in its use.

Calmare



The exact method that Scrambler uses to provide pain relief is not known although the theory is that it produces an "artificial neuron" that acts as a "pain scrambler" which mixes in with the nerve fibers and masks the original pain information by modifying the content from a pain signal to a non-pain signal. The theory further suppositions that this method of action allows pain relief to be transmitted along the nerve fibers to areas larger than and adjacent to where the electrode patches are placed on the body.

Scrambler Differentiated From TENS
Supporters of Calmare, including the inventors of the technology and CTI, actively differentiate Scrambler therapy from the method of action of TENS, noting that Scrambler produces a no-pain signal while TENS just blocks pain signals at the site of electrode placement. The difference in efficacy being that Scrambler's no-pain signal will radiate to adjacent areas and be effective for weeks or even months but TENS's pain blocking is only effective for a short duration and only at the site of electrode placement.

There is good reason in differentiating Calmare's method of action and efficacy from that of TENS as there has been significant debate over the efficacy of TENS. In fact, in June 2012 the Centers for Medicare & Medicaid Services (CMS) announced that they would no longer provide reimbursement for TENS for chronic low back pain which is not a manifestation of a primary disease (such as from cancer metastasis), noting that "TENS is not reasonable and necessary for the treatment of chronic low back pain…" The result since the announcement has been a significant reduction in TENS usage and device sales/rentals.

The indicated use of Scrambler therapy listed in the 510(k) clearance is for: 1) symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain 2) symptomatic relief of acute pain and 3) symptomatic relief of post-operative pain.

Similar to Scrambler therapy, TENS is indicated for the relief of chronic intractable pain, post-traumatic and post-surgical pain. TENS therapy has been in existence since the 1970's and is primarily used for acute and chronic musculoskeletal pain including neck/back pain, knee pain, arthritis and muscle strains, among others. By contrast, Calmare has been mostly used for neuropathic pain (pain caused by certain diseases or nerve damage), such as chemotherapy-induced peripheral neuropathy, although it has been used in other chronic pain conditions such as lower back pain and phantom limb syndrome.

Clinicians can use the devices for any conditions which they deem it is appropriate. A document on the Calmare website titled *Recommended Treatment Protocol* lists several "neuropathic pain indications" and "oncological pain indications" for Scrambler therapy along with the recommended treatment protocol for each.

Indications and Treatment Protocol [2]

NEUROPATHIC PAIN INDICATIONS	TREATMENT PROTOCOL
Post-Surgical Neuropathic Pain (PSNP) Post-Herpetic Neuralgia (Sciatic and Lumbar Pain) Narrow Canal Syndrome SCS (Putative neuropathic pain) Failed Back Surgery Syndrome (FBSS) Pudendal Neuropathy Brachial Plexus Neuropathy Low Back Pain Phantom Limb Pain Syndrome	• Establish initial treatment program at 10 to 12 individual treatment sessions. • Treatment should be set at a frequency of one treatment per day. • Set treatment duration to 30 to 45 minutes. • Determine proper level of intensity to achieve maximum allowed without discomfort to patient. • Patient should be void of pain and discomfort during treatment. • Follow procedures in User Manual.

ONCOLOGIC PAIN INDICATIONS		TREATMENT PROTOCOL
Cancers:		• Establish initial treatment program at 10 to 12 individual treatment sessions. • Frequency of treatment is dependent upon patient's need for analgesia. • Set treatment duration to 45 minutes. • Determine proper level of intensity to achieve maximum allowed without discomfort to patient. • Patient should be void of pain and discomfort during treatment. • Follow procedures in User Manual.
Pancreatic	Colon	
Gastric	Ovarian	
Cervical	Lung	
Colorectal	Bladder	
Prostate	Kidney	
Rectal	Liver	
Uterine	Gall Bladder	
Laryngeal	Esophageal	

COMMERCIALIZATION

While CTI still generates a small amount of revenue from licensing certain technologies, their main focus is commercialization of Calmare.

CTI initially acquired exclusive worldwide rights to manufacture and sell Calmare in 2007 from Guiseppe Marineo, the inventor of Scrambler Therapy, and Delta Research and Development. In July 2012 the agreement was amended whereby CTI will focus its sales efforts on North America, Central and South America, Australia and New Zealand (the "focus" region) while CTI will "coordinate with" Marineo on areas outside these territories as he will be responsible for existing distribution agreements in the other areas of the world. The agreement with Marineo and Delta, initially set to expire in March 2016 was extended per terms of the amendment until March 2021.

CTI has an agreement with GEOMC Co, Ltd (Seoul, S. Korea) to manufacture the Calmare device. The current agreement expires in 2017.

Beginning in 2008 CTI was selling Calmare in international markets via several distribution agreements. International distribution agreements had covered ~40 countries by 2010 although the company's largest international distributor, which covered 34 countries, was not meeting minimum sales quotas which prompted CTI to cancel the agreement and take back the unsold inventory of 55 devices. Shortly afterwards CTI and this distributor penned a new agreement which covered only two countries (the distributor re-purchased 53 of the 55 devices which is reflected in the significant increase in revenue from 2010 to 2011). CTI recently disclosed that international distribution agreements are in place that now cover 21 countries.

Calmare received FDA 510(k) clearance in February 2009 and for a short period afterwards, CTI sold the device in the U.S. through a domestic distributor. CTI subsequently became its own distributor for Calmare in the U.S. and at one time had as many as 30 commissioned reps selling the device. This sales force was trimmed, although CTI has not recently disclosed the number of domestic reps they have working for them.

Prior to the July 2012 amended agreement with Marineo/Delta which relinquished CTI's exclusive rights to territories outside the defined "focus" region, the vast majority of Calmare sales recorded by CTI were generated from international territories. This includes 114 of 126 (90%) total units sold in 2010 and 72 of 107 (67%) total units sold in 2011. In 2012, during which the amended licensing agreement was penned, CTI recorded sales of just 12 Calmare devices with 11 of those sold in the U.S. CTI did not disclose the U.S./international sales breakdown in any of the reporting periods in 2013.

The amended licensing agreement provides that either party (CTI and Marineo) can enter into new international territories and that party will have commercialization rights in that area. However, with Marineo servicing the

[2] http://www.calmarett.com/media/pdf/Treatment%20Protocol.pdf

existing international distribution agreements, the international opportunity all but dried up for CTI since mid-2012. Since then CTI has focused most of its efforts on the domestic market. CTI has had some limited success selling Calmare to private physician practices (mostly non-narcotic pain centers) and lists more than two dozen private practices that offer Calmare therapy. CTI has also made sales to the U.S. government including to the Department of Defense and Veterans Affairs.

CTI Reclaiming International Territories

In early April 2014 CTI announced that they expected to reestablish the international commercial footprint (Europe, Middle East and North Africa or EMENA territory) which was relinquished via the July 2012 amendment which gave most ex-U.S. commercial rights to Marineo.

CTI has indicated that the amendment was never signed by Marineo/Delta by a March 31, 2014 deadline and therefore is not enforceable. Instead, according to CTI the initial agreement (which provided CTI with exclusive worldwide rights to manufacture and sell Calmare), is by default the active agreement between the company and Marineo/Delta. Marineo/Delta disputed CTI's assertion in an April 8th press release and then on April 16th sent a cease and desist letter to CTI requesting that CTI no longer sell, distribute or manufacture Calmare. CTI responded to the cease and desist letter disputing Marineo/Delta's claims.

There is clearly a contentious relationship between CTI and Marineo/Delta and risk that the latest dispute ends up in litigation - although we think it may be in both parties' interest to resolve the matter out of the courts.

As loss of the EMENA territory was a major reason for revenue and unit sales plummeting 69% and 89%, respectively in 2012, reestablishment of these international areas has the potential to significantly increase CTI's near-term revenue. And this appears to already be happening. In Q3 five of the eight unit sales were made internationally which helped push total revenue up to the highest level in three years.

In late May 2014 CTI announced that they signed a binding letter of intent with The Mediterranean for Integration and Technology to sell Calmare in the Middle East and North Africa. CTI notes that their prior relationship with Mediterranean resulted in a "substantive portion of the company's $3.1M of sales in 2011." And while this deal does not cover Europe, this agreement has already resulted in a major pick-up in ex-U.S. sales.

Anemic Results, New CEO, Sparks Shift in Commercialization Strategy…

CTI's financial performance had been fairly ugly until just recently. 2011 was a peak year in terms of revenue but benefitted from a bulk sales order of 53 units (50% of total units sold that year). Despite the $3.4M in peak revenue in 2011, that year also saw one of the largest net losses (largely due to accruals for a lawsuit that has since been settled). Revenue plummeted 69% in 2012 with unit sales falling from 107 in 2011 to just 12 in 2012 (-89%). Net loss was a dismal $3.0M in 2012.

The loss of the majority of the international markets was a big blow and CTI has had a tough time selling in the U.S. market. With spotty third-party reimbursement covering use of Calmare, physicians have been loath to purchase the device, which we estimate retails for approximately $80k. As such the private medical centers that do own a Calmare device must rely heavily on out-of-pocket payments from patients, many of which are unwilling or do not have the means to pay the ~$1,500 it costs for a series of 10 treatments. CTI has acknowledged that the lack of significant and consistent reimbursement has been a serious impediment to sales of Calmare. Despite this massive headwind, the company did not meaningfully change tactics until recently.

In September 2013 CTI brought on a new CEO, Conrad Mir. Mir decided that instead of a main focus on selling to private clinics, CTI would turn greater attention to selling to government agencies that are not so reliant on Medicare or private insurance reimbursement. CTI recently completed the process to become a preferred vendor to the U.S. Department of Defense and hopes to begin closing sales with them in the very near-term.

Mr. Mir has made substantive changes that has sparked a resurgence in both domestic and international sales. Revenue through the first nine months of 2014 is up 85% from the same period in 2013.

Relative to the private medical market, CTI's renewed game plan is to pursue FDA premarket approval of Calmare in an effort to eventually gain coverage from Medicare and private insurers. And while PMA approval and insurance coverage will almost certainly not be near-term events, we view this as a much more logical strategy to exploit the U.S. market opportunity than to prolong the mostly unsuccessful strategy that the company had followed since Calmare first was 510(k) cleared. We cover this topic in more detail in our Reimbursement section.

And while a lack of widespread or consistent reimbursement from both government and private payers has been a headwind in accelerating commercialization of Calmare, recent legal judgments in favor of practitioners with the courts' basis being that Calmare therapy is necessary and effective is potentially the beginning of a trend and could eventually be precedents for future legal arguments and judgments for reimbursement of Calmare therapy. We caution, however, that while these cases are votes of confidence for potential improvement in reimbursement for Calmare, that we think it is too early to draw any conclusions in that regard.

CLINICAL DATA

Efficacy and safety of Calmare therapy is supported to some extent by several clinical studies. However, most of the studies completed to date are very small, single-site, single-blind pilot studies (i.e. - confidence of results may be questionable). And while most of these studies have indicated that Calmare therapy is safe, may be effective in reducing pain and may reduce use of pain drugs, we do not believe there is sufficient evidence to make any confident conclusions regarding its efficacy based on the trial data to date. In addition, no published studies have concluded that Calmare therapy was associated with improved quality of life, a potentially important determinant for a physician to prescribe a particular pain treatment.

But despite what we would characterize as a lack of obvious and convincing evidence of significant efficacy, the trial data to date clearly does show that patients treated with Calmare therapy reported significant improvement in pain symptoms. Most of these study participants experienced a reduction in pain scores of 50% or more following treatment with Calmare. FDA's significance threshold for a "large effect" of quality of life improvement (based on patient reported outcomes) is 20%. As such, a 50%+ reduction in pain scores, if confirmed in larger studies would presumably bode well for consideration as a determinant for positive improvement in quality of life.

Most of these studies have focused on chemotherapy-related pain/neuropathy, although patients with non-cancer related pain have also been studied. Data to-date has aided the sales effort (to a certain extent) and provided enough evidence of efficacy to justify committing resources towards larger, more robust-designed studies. CTI's near-term game plan is to complete two larger, pivotal studies to support FDA PMA approval and for use to lobby for broad-based third reimbursement. Below we discuss some of the completed studies with published manuscripts. We note that this is not a comprehensive list of Calmare/Scrambler studies that have completed or that have been published but we believe it is a fair and representative list for purposes of discussion relative to potential efficacy and safety of the device.

> ***Scrambler Therapy May Relieve Chronic Neuropathic Pain More Effectively Than Guideline-Based Drug Management: Results of a Pilot, Randomized, Controlled Trial***[3]

Published: Journal of Pain and Symptom Management. 43, 1. 87-95, January 2012

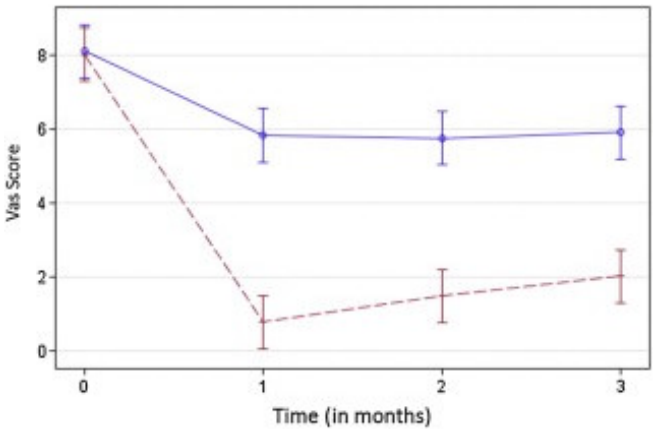
Design: 52 patients were recruited with (non-cancer related) chronic neuropathic pain rated ≥6 on a visual analogue scale (VAS) on at least 4 days/week despite standard treatment (including with antidepressants, anticonvulsants, and opioids). Patients were randomized (26 per arm) to either alternative drug therapy or Scrambler therapy. Randomization was not concealed and neither the patient nor clinician was blinded. Scrambler therapy consisted of 45-minute sessions daily for 10 consecutive days (M-F). Scrambler patients remained on their initial drug regimen.

Objective: Primary endpoint was change in VAS scores from entry to the scores at one, two and three months. Secondary endpoints included change in pain scores by the type of pain, area of pain, change in Allodynia (i.e. - pain response from a normally innocuous stimuli) and change in medication use and dosage.

Results: Results on the primary endpoint showed the control group experienced a 28% reduction in VAS pain scores at one month from baseline, compared to a 91% reduction in VAS pain scores from baseline to one month with the Scrambler group. Pain scores for the two and three month time periods were also significantly lower in the Scrambler group as compared to the control group. Pain scores in the control group at the one, two and three month time periods were 5.8, 5.8 and 5.9, respectively in the control group compared to 0.8, 1.5 and 2.0 in the Scrambler group (chart / graph below[2]). The differences were all statistically significant ($p<0.001$ by ANOVA).

[3] Marineo G, Iorno V, Gandini C, Moschini V, Smith T. Scrambler Therapy May Relieve Chronic Neuropathic Pain More Effectively Than Guideline-Based Drug Management: Results of a Pilot, Randomized, Controlled Trial. Journal of Pain and Symptom Mgmt, Jan 2012, 43,1; 87-95

Blue = control Red = Scrambler



Time of Assessment (months)	Group	
	Control	Scrambler Therapy
T0, entry	8.11/10 ± 1.03	8.01 ± 1.12
T1, one month	5.84/10 ± 1.34	0.78 ± 1.78
T2, two months	5.76/10 ± 1.40	1.49 ± 2.39
T3, three months	5.91/10 ± 1.44	2.03 ± 3.14

Results on the secondary endpoints indicated Scrambler therapy was effective in reduction of different types and areas of pain and had a positive effect on Allodynia. Scrambler therapy was associated with a significant reduction in pain medication dose. In the Scrambler group opioids were completely eliminated in 11 of 17 patients and reduced by 50% in one patient (unchanged in 5 patients). Anticonvulsants were eliminated in 17 of 24 patients and reduced in one patient (unchanged in 6 patients). Antidepressants were eliminated in 9 of 19 patients and reduced in four patients (unchanged in 6 patients). Dosage variation was statistically significant (P<0.0001 by ANOVA).

Conclusion: The study investigators acknowledged certain limitations of the study including that while it was randomized, it was not a double-blind sham trial (i.e. - placebo-controlled) - which is considered the gold-standard in evaluating efficacy. They noted further that the due to the nature of treatment with Scrambler, it would be difficult to devise a sham trial. Nonetheless, the investigators believe the trial does have merit and did indicate pain relief efficacy of Scrambler therapy. Also commenting that while further study is required to understand how Scrambler therapy causes pain relief, based on their observations Scrambler provides new "nonpain" information (i.e. - patients have new sensations in the pain area), it provides pain relief quickly and for days or even months, and the patient feels the nonpain information over an area larger than the electrode patch (which may suggest the nonpain information is sent through the lines of nerve transmission).

The investigators concluded that "this small, pilot, randomized trial encourages further development of both treatment and of knowledge regarding Scrambler therapy. This knowledge will provide a better understanding of the mechanisms of action and new opportunities for the treatment of all forms of pain. It also provides more knowledge of effect size for further randomized placebo- or sham-controlled trials, which are underway."

> ***Electrical Stimulation Therapy Using the MC5-A Scrambler in Reducing Peripheral Neuropathy Caused by Chemotherapy***[3]

Published: Journal of Pain and Symptom Management. 40, 6. 883-891, December 2010

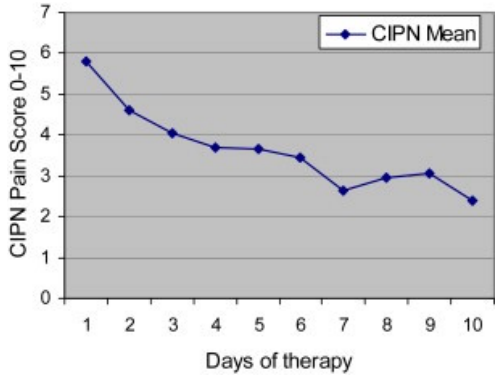
Design: Single-arm study. 18 patients with chemotherapy induced peripheral neuropathy (CIPN) with pain scores ≥5 (out of 10) were recruited (the 2 exclusions were not-treatment related). Duration of CIPN ranged from 3 months to 8 years with all patients having stable CIPN for at least the prior 3 months. 16 patients were evaluable. Scrambler therapy was administered at a single site for one hour over 10 working days. . Patients were followed for 3 months. Data were collected at day 1, the end of weeks 1 and 2 of treatment, and weeks 4, 8 and 12.

Objective: There is no effective therapy for CIPN, which effects 30% - 40% of chemotherapy patients. The objective of this study was to evaluate the impact of CIPN associated with Scrambler therapy. Primary objective was to determine if Scrambler reduced CIPN pain by 20% - a level that is considered important to oncologists. Pain was assessed by a numeric scale (0-10) where each patient would score their pain before and after each daily treatment. Secondary endpoints included the use of different

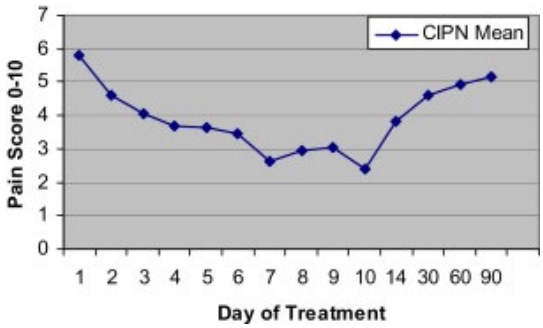
[3] Electrical Stimulation Therapy Using MC-5A Scrambler in Reducing Peripheral Neuropathy Caused by Chemotherapy. ClinicalTrials.gov. ID NCT00952848. http://clinicaltrials.gov/ct2/show/results/NCT00952848?term=scrambler&rank=5&sect=X015

measurement scales for quantifying CIPN (as there is no gold-standard), the impact on quality if life, the change in use of pain drugs associated with Scrambler therapy, toxicity, and confirmation that there was no worsening of the overall symptoms.
Results: The primary endpoint, a reduction in the numeric rating scale pain of 20% by the end of the study was met by 15 of the 16 patients. Significant at p<0.0001. The data also showed a reduction in the pain score each day and a decreasing trend in the pain over the 10 days after the start of treatment. The day 0 score of 5.81 (+/- 1.11) fell by 59% (significant at p<0.0001) to 2.38 (+/- 1.82) at the end of 10 days. (chart / graph below).

Measure	Before	After	*P*-value, Statistical Test
Reduction in pain by 20%	0	15/16 (94%)	<0.0001, Fischer's exact test
CIPN pain score	5.81 ± 1.11	2.38 ± 1.82 (−59%)	<0.0001, paired *t*-test
Adjusted pain scores	4.9 ± 0.4	1.8 ± 0.4 (−64%)	<0.0001, repeated-measures analysis
Daily reduction in pain scores	3.74 ± 0.38	2.72 ± 0.38 (1.02, −27%)	<0.001, repeated-measures analysis



The study also showed that most patients had pain return gradually to pretreatment levels one to two months following conclusion of treatment (graph at right).



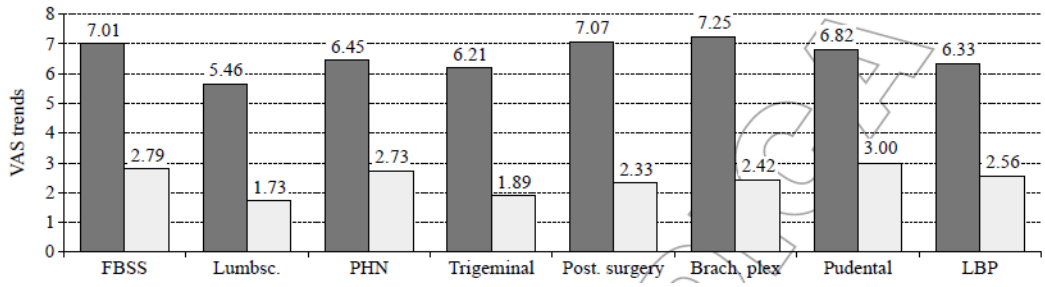
On the secondary endpoints there was little change, including no difference in morphine equivalent dose from day 1 to day 10, no change in quality of life and no change in symptoms of pain.

Conclusion: Investigators concluded that Scrambler therapy appears to dramatically reduce pain in CIPN patients with no toxicity. They did acknowledged certain weaknesses of the study including that it was single site, unblinded and had a short follow-up window.

> ***Scrambler Therapy***[4]
Published: Minerva Anestesiologica. Jan 2005
Design: Single-arm study. 226 patients recruited with intense drug-resistant neuropathic pain: 180 with specific non-cancer neuropathies, 46 with "other" (non-defined) neuropathies. The specific non-cancer neuropathies included failed back surgery syndrome (FBSS), sciatic and lumbar painpost-herpetical (PHN), trigeminal neuralgia, post-surgery nerve lesion neuropathy, prudenal neuropathy, brachial plexus neuropathy, and low back pain (LBP). Patients were stratified into pain groups based on VAS pain scores: pain relief responders (pain relief >50%), partial responders (pain relief 25% - 49%) and non-responders (pain relief <24%). Pain intensity was evaluated before and after each treatment. Treatment consisted of one to six therapy sessions of five treatments of 30 minutes each.
Objective: Statistical significance of pain relief based on VAS

[4] Sabato AF, Marnieo G, Gatti A. Scrambler Therapy. Minerva Anestesiologica. Jan 2005. 71,7-8: 479-82

Results: Results showed 80.9% of patients were responders, 10.2% were partial responders and 9.7% were non-responders. Statistically significant ($p<0.001$) pain relief was achieved for all neuropathies. Pre (grey bar) and post (white bar) pain scores per type of neuropathy are shown in the chart below.
Conclusion: Investigators concluded that, in addition to showing statistically significant pain relief, there were no undesirable effects, all patients demonstrated excellent compliance with treatment, and that these study results support more extensive trials of Scrambler



In addition to the studies above, there are also ongoing Scrambler studies and/or studies where data analysis has yet to be fully completed. We list these in the box below. We also provide some discussion about one of these studies, a randomized, sham-controlled study for which interim data was presented at the 2013 American Society of Clinical Oncology (ASCO) meeting.

Calmare / Scrambler Ongoing Studies

Start Date	Name	Phase	Design	Site	Patients	Status
Feb 2011	Scrambler Therapy in Reducing Peripheral Neuropathy Caused by Chemotherapy	2	Efficacy, Single-Group, Single blind	Mayo Clinic	10	Active, not recruiting
Mar 2011	Scrambler Therapy in Treating Chronic Pain in Patients With Rash From Varicella Zoster Virus Infection	NA	Efficacy, Single-Group, Open Label	Mayo Clinic	10	Active, not recruiting
Mar 2011	Scrambler Therapy in Treating Pain and Peripheral Neuropathy in Patients Previously Treated With Chemotherapy	NA	Safety/Efficacy, Single-Group, Open Label	Mayo Clinic	150	Recruiting
Apr 2011	MC-5A for Chemotherapy Induced Peripheral Neuropathy	2	Randomized, Safety/Efficacy, Parallel, Double-blind	U of Wisconsin	40	Active, not recruiting
Mar 2013	Trial of Scrambler Therapy or Sham Treatment for Low Back	NA	Randomized, Efficacy, Single-Group, Double-blind	VCU	32	Recruiting

> ***A Randomized, Double-Blind Study of Scrambler Therapy Versus Sham For Painful CIPN***[5]
Presented: ASCO 2013 Annual Meeting, General Poster Session, Patient and Survivor Care
Design: Randomized, double-blind (patients and evaluators), sham-controlled. Patients with CIPN for > 6 months with pain scores ≥4/10 on numerical rating score (NRS). 14 patients randomized (7 to each arm) with no baseline differences to either sham or Scrambler treatment. Patients received up to 10 daily sessions of 50 minutes with either Scrambler or "a novel active sham device constructed to deliver a just perceptible electrical sensation." Sham output is neither a TENS nor MC5A (i.e. - Calmare/Scrambler) and is designed to be nontherapeutic." Active and sham treatments were applied to the effected limbs. Pain was measured (NRS) before, daily during, after and 3 months post-treatment
Objective: Primary endpoint was change in pain. secondary endpoints include quantitative neurosensory testing (QST), validated patient-report measures and cytokines.

[5] Campbell T, et al. Univ of Wisc. A Randomized, Double-Blind Study of Scrambler Therapy Versus Sham For Painful CIPN. 2013 ACSO Annual Meeting. ASCO University. Abstract 9635.

Results: Results showed that there was no statistically significant difference between pain scores of the treatment and sham groups. It also showed no statistically significant difference in pain scores per day.
Conclusion: Investigators concluded that "In a small pilot study, MC5A (i.e. - Scrambler) was not significantly different from sham therapy for the primary outcome. The sham is feasible and provides a mechanism for future controlled studies with MC5A." secondary endpoints were not reported on.
Our Comments: 1) Presentation abstract mentions that sham "output was neither a TENS nor MC5A (Scrambler)" although it is not clear exactly what the sham device was, what the sham device looked like or what kind of output (i.e. - stimulation, etc.) sham provided. 2) Following the ASCO presentation the *Scrambler Therapy Official Scientific and Clinical Information Site*, a website owned by Giuseppe Marineo (whom retains a financial interest in the Calmare technology), issued a rebuttal[6] of the trial conclusion, noting that the trial design was flawed and therefore the data was unreliable for basis of any conclusions. The crux of Marineo's basis is that he believes a Scrambler device was used as the sham and that clinicians used the device on all patients (in both the sham and treatment groups) incorrectly (i.e. - followed a sham protocol) which resulted in data from all patients that, in Marineo's belief, represented what would be expected of sham usage (i.e. - no obvious efficacy). 3) As there is not enough information publicly available relative to what the sham device was or how it was used or whether Scrambler was correctly used with the active treatment group, it is not possible for us to determine the soundness of Marineo's claims (or for that matter, supportability of the conclusions of the trial investigators). 4) We do note, however, that a consistent reason cited by other trial investigators as to why more double-blind, sham-controlled Scrambler studies have not been done is difficulty in developing a sham device that both patients and clinicians will not be able to differentiate from (in terms of appearance, output, sensation, treatment protocol, etc) a Scrambler device

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REIMBURSEMENT

In July 2011 the American Medical Association's (AMA) Current Procedural Code Editorial Panel established a new Category III current procedural terminology (CPT) code, 0278T, for reporting use of Scrambler therapy. The code descriptor is, *Transcutaneous electrical modulation pain reprocessing (scrambler therapy)*. CPT III codes are temporary codes used for new technologies and allow for data collection in order to help determine how widespread the technology is being used.

Physicians that use devices covered by a CPT III code, such as Calmare, can bill Medicare under this code although, unlike CPT I codes, CPT III codes do not have a reimbursement value assigned to them. Medicare has broad discretion over whether or how much to reimburse claims and different jurisdictions can have different reimbursement policies. While AMA states that "it is not reasonable to categorically deny payment for CPT Category III codes", Medicare often will not reimburse for claims under CPT III codes. Private insurers may follow Medicare guidelines or establish their own reimbursement policies for a particular therapy. For devices covered under CPT III codes, private insurers often consider these experimental or investigational devices and will not provide reimbursement.

Medicare reimbursement for Calmare therapy is very jurisdiction-dependent, is inconsistent (even within the same jurisdiction and when billed from the same clinic), and typically covers less than one-half the cost of each therapy session when it does it pay. And while we have no specific information relative to the prevailing reimbursement guidelines of private payers (although we have found policies of specific insurers that exclude reimbursement for Calmare), we think it is likely that it is no better than Medicare (and potentially worse).

As such, currently practitioners using Calmare therapy largely rely on patients paying out of pocket. Pricing is set by the individual practices. From our cursory research, it appears that pricing per treatment is in the range of approximately $125 - $175 so over the course of ten treatments patients could expect to spend as much as $1,750 out of pocket. The lack of third-party reimbursement has almost certainly been a major headwind to sales of Calmare.

Favorable Judgments Could Be Precedent-Setting…
Despite this headwind, recent court rulings in favor of Calmare practitioners could potentially be the beginning of a trend and eventually be precedents for future legal arguments and judgments for reimbursement of Calmare therapy.

[6] http://www.scramblertherapy.org/example.htm

The most recent judgment came on June 24, 2014 in the Civil Court of New York, Richmond County. The court ruled in favor of Forest Rehabilitation Medicine, a Calmare therapy provider, that the defendant, Allstate Insurance Company, is liable for payment to Forest for $3.5k related to the cost to treat a car accident victim with Calmare therapy.

The defendant made several claims as to why they are not liable for reimbursing plaintiff, including that since Calmare treatment has been mainly used with chemotherapy patients that it is not applicable in the context of a car accident victim and is not medically necessary. Defendant's witness (a board certified specialist in physical medicine and rehabilitation) further testified that his opinion was that Calmare therapy was medically questionable and that he believed the patient could have been sufficiently treated with conventional physical therapy. Interestingly, the defendant did not make any claims that Calmare therapy is ineffective, but indicated that similar results could have been accomplished with basic physical therapy.

The judge ruled in favor of Forest and ordered defendant to pay $3.5k plus attorney's fees. The basis for her judgment was that defendant failed to provide evidence of a lack of medical necessity, that Forest's witness (Dr, Jack D'Angelo, who specializes in physical medicine and rehabilitation and uses Calmare therapy in his practice) provided sufficient evidence that Calmare therapy is reliable.

The judge also cited in her judgment that the patient reported her pain level fell from 5-6 at initiation of treatment to 3 at completion. Indicating that this (i.e. - reduction in pain), coupled with no evidence that there is non-acceptance of Calmare therapy in the medical community, also figured into her judgment.

The judge commented that, "The Court certainly recognizes that anything new, whether it be a mechanical device or a scientific theory, will inevitably have "kinks" which need to be worked out over time. However, this fact should not fuel any unreasonable fear or disapproval of a device which has the potential to literally revolutionize how the medical field addresses and combats chronic pain. Therefore, in consideration of this, the Court finds no reason to deny the instant claim for reimbursement. The Court finds that Calmare Scrambler Therapy, in the instant action, was a medical necessity for Ms. Fertitta's pain management."

This favorable judgment follows that of an appeal won in mid-January by a Calmare practitioner in Staten Island whose claim for Medicare coverage of Calmare use had previously been denied. This related to a specific case of a patient that received Calmare therapy in 2011 for cancer/chemotherapy-related pain. The appellate judge ruled that there was sufficient evidence that Calmare therapy was necessary for this patient and for Medicare to issue reimbursement.

In mid-January 2014 CTI press-released a recent case where a Calmare practitioner in Staten Island won an appeal for a claim for Medicare coverage of Calmare use which had previously been denied. This related to a specific case of a patient that received Calmare therapy in 2011 for cancer/chemotherapy-related pain. The appellate judge ruled that there was sufficient evidence that Calmare therapy was necessary for this patient and for Medicare to issue reimbursement. While CTI indicated that they believe this case may help support further reimbursement in the future, we would not expect substantial and widespread Medicare and private reimbursement to materialize absent more compelling clinical data supporting use of the therapy.

But while we think these recent legal judgments in favor of practitioners with the courts' basis being that Calmare therapy is necessary and effective is potentially the beginning of a trend and could eventually be precedents for future legal arguments and judgments for reimbursement of Calmare therapy, we caution that is too early to draw any conclusions that these cases will facilitate broader reimbursement for Calmare.

Path Towards Improved Reimbursement…

Improved Medicare reimbursement will require issuance by AMA of a category I CPT code. Utilization information (i.e. - how many clinicians are using it and how frequently) of Calmare gathered from the CPT III code will be used by AMA to determine eligibility to transition to a category I CPT code. AMA will also want to see additional proof of clinical efficacy including peer-reviewed articles published in U.S. journals demonstrating effectiveness of Calmare therapy. We have no insight into utilization statistics to-date. It is also unclear as to the scope of additional clinical data that AMA will want to see, although this likely will include sham-controlled studies. We caution that the process to transition to a CPT I code could be lengthy, costly and may end up unsuccessful.

Based on an internet search, we found several major private insurers that have coverage policies that exclude reimbursement for Scrambler therapy based on lack of sufficient clinical evidence to support its use. This is despite the already completed clinical trials and published manuscripts. Some of the coverage policies that we found

specifically mentioned weaknesses in the studies' designs as a limiting factor in providing confidence in the respective conclusions. Private insurers regularly review their coverage guidelines, however, so positive and compelling clinical data from a robust-designed clinical trial may result in favorable changes to their policy towards reimbursement of Scrambler therapy in the future.

CTI noted as recently as November 2013 on their Q3 2013 earnings call that they are working on development of two pivotal studies in a quest to support an application for FDA premarket approval (PMA). On the Q3 2014 call management mentioned that they expect to announce more details of the proposed pivotal study in the coming weeks. PMA approval should provide the runway to transitioning to a CPT I code and gaining private reimbursement but will require robustly-designed trials, likely sham-controlled, double-blind studies. While the trial designs have yet to be announced, CTI did note that one of the studies will be co-sponsored and the other almost entirely funded by a partner institution.

Sensible Approach But No Guarantees…

Although we view this route as the most sensible towards gaining reimbursement, it is not without risk and will likely be time consuming. The quest towards PMA approval may be lengthy, potentially spanning years, may never materialize and could be costly for CTI. While we expect to hear more specifics relative to the trial designs in the coming weeks or months, commencement of patient enrollment may not happen for some time (although we have no particular insight into potential timelines). The trials themselves could last as long as a year or more. Data analysis and publication of manuscripts (assuming the data is positive) would likely consume at least several more months or potentially several quarters. Compilation and submission of a PMA application and decision from FDA will likely encompass a year or more of time. And finally, issuance of a CPT I code could be a months-long or quarters-long process. And despite the studies being at least partially funded by co-sponsors, this could still be a costly endeavor for CTI.

MARKETS

The breadth of the market for Calmare is somewhat ambiguous. Broadly it could be defined as anyone suffering from almost any chronic or acute pain condition where the therapy is not contraindicated. This could be as many as 100M people in the U.S. alone. We think a more realistic characterization of the market for the therapy is in CIPN and intervention in chronic conditions being treated with opioids. CTI has yet to announce the design of the pivotal studies which are expected to be used to support a future PMA application but given that much of the historical clinical data supports use in CIPN, we think it's reasonable to expect that this will be a focus indication (we think it is likely that there will be other pain indications represented in the studies in addition to CIPN). We estimate the U.S. CIPN target market at approximately 400k people per year.

We see the opioid market as potentially attractive given that it spans a wide variety of chronic pain conditions and Calmare may be an effective substitute for these potentially dangerous and addictive medications, use of which continues to grow. We estimate the U.S. opioid market at approximately 4.7M people.

CIPN

Chemotherapy induced peripheral neuropathy is a side effect of commonly used chemotherapy drugs which effects sensory nerves and causes extremely unpleasant sensations such as that of pins and needles, numbness in the feet and hands, pain and burning. Commonly, the neuropathy will initiate in the toes and feet and then spread to lower and upper extremities. Patients suffering from CIPN often have a significant deterioration in quality of life and functional ability. The disabling effects of CIPN also can prompt limiting the dose of chemotherapy used.

We estimate approximately 1M people receive chemotherapy every year in the U.S. and approximately 40% of chemotherapy patients suffer from CIPN, which puts the domestic CIPN market at approximately 400k. A rough estimate for the worldwide market is double that number, or 800k. CIPN has been addressed with a variety of drugs and interventional therapies for both prevention (i.e. - protection of nerves) and treatment but none has been specifically indicated for CIPN.

A comprehensive article[7] published in the November/December 2013 edition of CA: A Cancer Journal for Clinicians on the subject of CIPN which included discussion about new approaches for prevention and treatment notes that

[7] Park Susanna B. et al. Chemotherapy-induced peripheral neurotoxicity: A critical analysis. CA: A Cancer Journal for Clinicians. Nov/Dec 2013. 63:6. 419-437

there no neuroprotective (i.e. - prevention) therapies have been confirmed to be effective and "there has been limited success to support the introduction of neuroprotective therapies in clinical trials for CIPN." Relative to novel treatments that are being studied (which includes Scrambler therapy), the article notes that "the role of these interventions in treating patients remains unclear." Given the lack of effective prevention/treatment and assuming CTI can demonstrate significant efficacy in the upcoming pivotal studies, we view CIPN as a real opportunity for Calmare.

Opioids

Opioids are usually prescribed after all other medications and therapies have failed. But while opioids are typically very effective in relieving acute pain, they may have limited effect with chronic pain. Their effectiveness also often diminishes over time, resulting in less-and-less pain relief for chronic pain sufferers. This can result in the patient taking higher doses, potentially building up tolerance and eventually resulting in addiction. As such, doctors are often not comfortable with prescribing opioids for long periods of time.

One source[8] estimates that over 4M Americans take opioids on a regular basis and 10M adults may take them in a given week. Perhaps interestingly is that this survey found that 47% of users were taking opioids for more than two years - clearly indicating they were using it for a chronic pain condition.

Using this as a rough estimate for the potential U.S. market for Calmare in replacing opioids for chronic pain sufferers equates to a market of approximately 4.7M (10M x 47%) people. The relatively large market of chronic pain medication users, the diminishing efficacy and dangerous side effects of pain killers, and lack of a more effective alternative means this could be another attractive opportunity for Calmare.

FINANCIAL CONDITION

CTI is light on cash, heavy on debt and payables and burns a relatively substantial amount of cash. The recent financing arrangements described below should give the company some short-term breathing room but CTI will need to raise additional capital in the very near term. The levered balance sheet and near-term cash needs adds significant risk to the long-term viability of the company.

As of the most recent reporting period (ending 9/30/2014) the company had approximately $500 in cash and equivalents - although management noted on the Q3 call that additional financing is expected to increase the cash balance to about $130k in the next few days.

Cash burn was $1.6M in fiscal 2013 and $237k in Q3 2014. Ex-changes in working capital, these figures were $2.3M and $1 million - although the $1 million figure includes ~$500k in one-time interest expense and is not indicative of future expectations. Conrad Mir, the newly appointed CEO, has made it a point that, along with a new commercialization strategy, he also intends to reduce cash burn and firm up the balance sheet.

Debt consists of $2.5M in notes payable issued to CTI's Chairman as well as ~$400k in various short-term convertible notes. The Chairman notes were issued in three tranches during 2011, 2012 and 2013 and had original 90-day maturities but the maturities have been extended several times. The recent filings indicate the maturities have been extended into 2014. The notes pay 6% simple interest and (6 months following issuance) are convertible into common stock at $1.05/share.

The company is also carrying a large accounts payable balance. A/P owed to GEOMC, CTI's Korean manufacturer, stood at $4.2M at 9/30/2014. This is largely unchanged since the end of 2012. Management noted on the Q3 2014 earnings call that they have approximately 400 Calmare units in inventory, which represents at least several years worth of sales at the average unit placement rate over the last few years. As such, we do not expect the A/P balance owed to GEOMC to increase any further over the short to mid-term.

As of 9/30/2014 CTI also had a $1.1 million "general" A/P balance and a $2.0M current liability, the latter owed to ASC Recap related to the LPA described below.

Recent Financing Arrangements

[8] Phend C. Opioid Painkiller Used By Nearly 5% of American Adults. MedPage Today. 8/29/2008

In early 2013 CTI entered into a two year equity purchase agreement (EPA) with Southridge Partners II, LP. Under the EPA CTI can require Southridge to purchase up to $10M in the company's common stock. Southridge's purchase price is equal to 90% of the lowest bid price ten days following notice from CTI for Southridge to make the purchase. The aggregate number of shares owned by Southridge can not exceed 9.99% of CTI's total outstanding shares. Based on the share count o/s at 11/21/14, Southridge's maximum share ownership would be approximately 2.6M shares. At the current trading price ($0.19) of the stock, Southridge would not be able to purchase more than $500k worth of shares (and potentially much less than this as footnotes in the 2013 10-K indicate that Southridge may already own several hundred thousand shares as a result of debt conversions and fees paid in shares to Southridge by CTI - although it is not clear whether Southridge still owns those shares).

In March 2013 CTI entered into a liabilities purchase agreement (LPA) with Southridge. Under the LPA, CTI has agreed to issue to ASC Recap LLC, an affiliate of Southridge's, common shares for settlement of accounts payable purchased by ASC from creditors of the company. CTI notes that this LPA has the potential to eliminate almost $2.1M of their obligations owed to existing creditors. The process began during Q3 2013 when ASC Recap sold shares that it had been issued from CTI and paid creditors ~$80k from proceeds from the sale (subsequently reducing the total creditor balance from ~$2.1M to $2.0M) - the Q3 10-Q notes that no further shares have been issued to ASC since the Q3 sale.

OUTLOOK

We do not expect that sales of Calmare to government agencies will generate enough revenue to sustain the company for the long-term or bring them to cash flow break-even. Re-establishment of a portion of the company's legacy international footprint via the distribution agreement with The Mediterranean for Integration and Technology for the Middle East and North America resulted in a meaningful pick-up in revenue in Q3. And while this agreement does not re-establish CTI's footprint in Europe, we expect this could be a catalyst going forward. Absent a significant revenue contribution from EMENA (Europe, Mid-East, North Africa), we believe CTI will need to continue to raise additional funds for at least the next three years to continue operations and to help fund the pivotal studies. We do not envision break-even cash flow from sales solely to the domestic market until CTI can generate meaningful demand from the broader chronic pain market, which will likely depend on successful PMA approval of Calmare and subsequent insurance coverage.

Conrad Mir was brought on board in September 2013 to essentially turn the company around. One of the first orders of business has been to address the cash burn and balance sheet. The other was to find a way to grow revenue, both for the near and long terms.

Mir has already had success in growing revenue and reducing expenses and cash burn. We expect this will be an ongoing focus. In terms of growing revenue, we see this as somewhat of a three-pronged approach; initial focus for the domestic market will be on the U.S. government channel to help sustain the company through the pivotal studies and, assuming positive results from these studies and eventual PMA approval, the next focus will be to re-exploit the private healthcare channel - something that had been all but unsuccessful in the past due to lack of sufficient third-party reimbursement. The third of the three prongs relates to increasing international sales - which was all but lost with the July 2012 amendment but now looks to be on the rebound. The move by CTI to nullify the amendment and sign a recent distribution deal covering the Middle East and North Africa may be the beginning of a resurgence in ex-U.S. revenue. Upside to international sales could come from meaningful revenue from the recent Mediterranean agreement and if CTI successfully re-establishes distribution in Europe.

CTI has a GSA contract already in place and is an authorized vendor to the U.S. military. Sales to this channel have yet to show real promise and requires significant leg-work and sales effort. To address this and make the sales process much more streamlined, CTI recently began initiating the process of filing for a purchase order agreement. On the Q3 2014 call, management noted that they expect to make an announcement regarding this in the coming weeks (i.e. - before the end of 2014). This would potentially open up the sales channel to any agency in the U.S. government and would presumably require substantially less sales effort on the part of CTI.

Relative to the private healthcare market, we think it's clear that Mir has (wisely) decided that the company's approach in the past of trying to sell to this channel without available meaningful reimbursement was a strategy that had little chance of success. CTI is now re-grouping and dedicating efforts and financial resources towards two pivotal studies that they expect to use to support an FDA PMA filing. Upside to near-term domestic sales could

come from improved reimbursement as a result of recent, and potentially future, court judgments ruling in favor of Calmare therapy providers and against insurers which attempt to deny claims for payment based medically necessity and effectiveness of the therapy.

CTI has provided few details of their planned pivotal studies, first referenced on the company's Q3 2013 earnings call in late November, other than noting that one will be co-sponsored by the trial site institution and the other almost completely funded by the other institution. On the Q3 call management mentioned that they expect to release more specifics on the plans for the study in the coming weeks. As FDA will require compelling evidence of efficacy to grant PMA approval, our expectations are that these will be robustly-designed, relatively large, randomized, sham-controlled studies.

Domestic Revenue May Remain Tepid Unless PMA Approval Happens…
Our modeled revenue through 2017 represents the assumption that CTI generates growth in unit placements mostly from the U.S. government sales channel. We expect the private healthcare market to continue to offer limited upside opportunity over the mid-term due to the lack-of-reimbursement headwind. CTI has noted that they expect to introduce a next-gen Calmare unit which would provide the added benefit of additional consumable sales (electrodes, etc.), which could potentially provide an upside recurring revenue opportunity. And, we reiterate that recent legal judgments in favor of Calmare providers for reimbursement claims against both public and private payers, could have the effect of loosening up the reimbursement environment for Calmare therapy.

As we discussed earlier in this report, we think the strategy towards PMA approval and gaining insurance reimbursement makes sense but note that this could be lengthy, costly and potentially never materialize. As the trial designs may have yet to be finalized, commencement of these studies may not even happen for some time. The trials themselves could last as long as a year or more. Data analysis and publication of manuscripts (assuming the data is positive) would likely consume at least several more months or potentially several quarters. Compilation and submission of a PMA application and decision from FDA will likely encompass a year or more of time. And, finally, issuance of a CPT I code could be a months-long or quarters-long process. As such, we think it is possible that significant revenue from the private healthcare channel may not materialize until potentially 2018.

VALUATION / RECOMMENDATION

We view CTI's focus markets as the ~5M Americans that suffer from CIPN and/or are taking opioid pain medications for long periods of time. We assume an inflection point in revenue growth upon PMA approval of Calmare and subsequent third-party reimbursement. We think this could materialize in late 2017 or 2018. Our 2018 revenue estimate of $7.8M equates to approximately 1% cumulative penetration of our defined focus markets. Our DCF models out to 2024 where we project 4% market penetration, equal to approximately $37.5M in revenue.

We think $37.5M in revenue by 2024 is very much an attainable number, assuming success in gaining PMA approval and subsequent insurance reimbursement. As a comparator, one can look at a small pure-play TENS manufacturer (ZYXI) that was able to ramp revenue from $8M in 2007 to almost $40M in 2012. TENS had benefitted from favorable Medicare and private insurance reimbursement until just recently when policies began excluding use for lower back pain.

As it is very early in terms of CTI's timelines in initiating and completing the studies, when or if PMA approval would be granted and when or if insurance reimbursement would materialize, there is significant risk that our projected outlook and related financial model could prove materially different than how the future unfolds. We think if CTI is successful in the PMA and insurance reimbursement, our revenue forecasts could prove conservative. As validation we again point to TENS, which is somewhat of a generic technology supported by somewhat ambiguous clinical efficacy data. Two fairly dominant players control much of the market yet a very small company was able to quintuple revenue in five years.

PMA approval would afford CTI the only technology in their approved space and the clinical data to support its use. But while we think our revenue estimates may be conservative if all goes to plan, we think our model is fair given the risk that CTI fails to gain PMA approval. Our estimates are subject to change depending on how the future unfolds.

We use a 10-year DCF model to value CTI. We look for revenue of approximately $1.8M in 2015, $8.6M in 2018 and $39.1M in 2024. We use a 10% discount rate and 2% terminal growth rate. Based on our 10-year DCF, CTI is valued at approximately $0.50 per share.

Our rating accounts for what we believe is higher than average risk for a micro-cap investment given the company's levered balance sheet, near-term debt, elevated accounts payable balance, uncertainty relative to near-term financing and the early stage of the company's new commercialization strategy and pathway towards PMA approval. Similar to our financial projections and related per share price target, our investment recommendation is subject to change. Consideration of an upgrade would likely include tangible operational and financial progress with (what we characterize as) CTI's turnaround strategy as well as an overall meaningful improvement in the company's risk profile.

FINANCIAL MODEL

Calmare Therapeutics Inc.

	2013 A	Q1A	Q2A	Q3A	Q4E	2014 E	2015 E	2016 E	2017 E
Total Revenues	$771.9	$227.5	$332.0	$434.0	$240.5	$1,234.0	$1,802.0	$2,457.0	$3,480.2
YOY Growth	*-27.8%*	*266.6%*	*121.1%*	*32.8%*	*3.3%*	*59.9%*	*46.0%*	*36.3%*	*41.6%*
Cost of Goods Sold	$272.7	$70.2	$98.1	$247.2	$97.2	$512.8	$681.7	$927.1	$1,307.3
Gross Income	$499.1	$157.3	$233.9	$186.8	$143.3	$721.2	$1,120.3	$1,529.9	$2,172.9
Product Gross Margin	*58.2%*	*68.2%*	*68.9%*	*38.2%*	*55.0%*	*55.5%*	*59.5%*	*60.0%*	*60.5%*
Operating Expenses	$3,019.9	$660.7	$807.5	$767.9	$845.0	$3,081.1	$4,150.0	$4,510.0	$4,200.0
% of Revenue	*391.2%*	*290.4%*	*243.2%*	*177.0%*	*351.4%*	*249.7%*	*230.3%*	*183.6%*	*120.7%*
Operating Income	($2,520.7)	($503.5)	($573.6)	($581.1)	($701.7)	($2,359.9)	($3,029.7)	($2,980.1)	($2,027.1)
Operating Margin	*-326.6%*	*-221.3%*	*-172.8%*	*-133.9%*	*-291.8%*	*-191.2%*	*-168.1%*	*-121.3%*	*-58.2%*
Gain on Asset Sale	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Loss on debt settlement	$0.0	$132.3	$43.3	$5.5	$0.0	$181.1	$0.0	$0.0	$0.0
Interest expense	$210.0	$104.8	$148.0	$574.8	$110.0	$937.6	$375.0	$325.0	$325.0
Total Other Expense (Income)	$151.4	$222.9	$217.2	$648.0	$110.0	$1,017.0	$375.0	$325.0	$325.0
Pre-Tax Income	($2,672.2)	($726.3)	($790.8)	($1,229.1)	($811.7)	($3,376.9)	($3,404.7)	($3,305.1)	($2,352.1)
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($2,672.2)	($726.3)	($790.8)	($1,229.1)	($811.7)	($3,376.9)	($3,404.7)	($3,305.1)	($2,352.1)
YOY Growth	*-11.0%*	*-75.8%*	*1.2%*	*81.5%*	*34.8%*	*97.0%*	*0.8%*	*-2.9%*	*-28.8%*
Net Margin	*-346.2%*	*-319.2%*	*-238.2%*	*-283.2%*	*-337.5%*	*-273.7%*	*-188.9%*	*-134.5%*	*-67.6%*
EPS	($0.16)	($0.04)	($0.03)	($0.05)	($0.03)	($0.14)	($0.09)	($0.08)	($0.05)
YOY Growth	*-21.4%*					*-44.4%*	*-33.1%*	*-12.6%*	*-43.1%*
Diluted Shares O/S	16,977	20,036	23,083	24,975	27,500	23,898	36,000	40,000	50,000

Brian Marckx, CFA

LEADERSHIP

Conrad F. Mir

President, CEO, and Director

Mr. Mir has over 20 years experience in the financial industry. Over that time, he was responsible for having restructured half a dozen companies. He is an investment banker by trade and has served as a C-level member of executive management for the past ten years. Conrad has been a board of directors member of such companies as Aran Laboratories, O6 Technologies and Genetic Immunity Incorporated. He has expertise in the immunotherapeutic, cancer, infectious disease and medical device space.

Prior to joining Calmare Therapeutics, Conrad was the CFO of Pressure BioSciences, Incorporated (OTC: PBIO), an instrumentation company that services the healthcare, military and homeland security industry. In this capacity, his mandate called for structuring financial instruments that afforded the company operational and expansion funds, and reengineered current operations and broadened institutional contacts that resulted in sell-side research coverage. Mr. Mir co-engineered a company-led, $2.0 million convertible preferred financial instrument and orchestrated a $500,000 convertible debt, bridge financing.

Prior to that, Conrad was the chairman and CEO of Genetic Immunity Incorporated – a privately-held biotechnology company focused on the discovery, development and commercialization of a new class of immunotherapeutic biologics for the treatment of chronic viral infections and cancer. At Genetic Immunity, Mr. Mir re-engineered the Company into a US-headquartered biotechnology company, incorporated in Delaware from a Hungarian-based R&D laboratory. He raised over US$3.0 million from a foreign institution and orchestrated the warrant exercise of the company's largest paid-in capital institutional investor. As of the fourth quarter of 2012, the company was successfully sold to a publicly-traded Hungarian holding company.

Prior to that, he was the executive director at Advaxis Incorporated (OTC:ADXS.ob) – a biotechnology company focused on developing immunotherapies for cancer and infectious diseases. Under his watch, he was responsible for structuring and raising $36.1 million via a company-managed, multi-tranche debt and equity financing. These monies were used to fund operations and two phase II clinical trials. The success of this raise helped increase Advaxis' share price from an historical low of $0.01 to a historical high of $0.25. Contemporaneous with the company's stock price appreciation, the average daily trading volume increased from 10,000 shares to a historical high of 9.3 million with resistance at the 1.4 million share level for over one year. As part of such a comprehensive reengineering effort, the shareholder register similarly increased from 400 shareholders with no institutions to over 5,200 shareholders and over 4 institutions and two equity analyst reports.

Before his time as a senior professional, Mr. Mir had worked for several investment banks including Sanford C Bernstein, First Liberty Investment Group and Nomura Securities International. He holds a BA/BS in Economics and English with special concentrations in Mathematics and Physics from New York University. He is a classically trained pianist and teacher, and student of the martial arts. He is married with two children, chairman of the alumni council of Tau Kappa Epsilon fraternity and a member of NIRI.

Ian Rhodes

Chief Financial Officer

Prior to joining CTI, Mr. Rhodes served as vice president, chief accounting officer and treasurer with Arch Capital in White Plains, NY, where he spearheaded Arch's International Financial Reporting Standards (IFRS) implementation efforts and subsequently provided oversight of SEC and GAAP technical accounting matters. Earlier, Mr. Rhodes served as senior audit manager for PricewaterhouseCoopers LLP in NYC and Los Angeles. In that capacity, he was lead manager for one of the three New York Insurance Practice teams, assisting practice leaders to set practice direction, deploy resources and address other practice matters. He managed teams of more than 20 professionals across multiple locations.

Mr. Rhodes has a Bachelor of Science degree in Business Administration from Seton Hall University.

Rustin Howard

Director, Chairman of Nominating Committee, member of Audit Committee and member of Compensation Committee

Mr. Howard 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 principal of Whitesand Investments LLC, an angel investment organization that operates as a traditional venture fund.

In 1990, he founded and served as CEO and Chairman of Phyton, Inc., a world leader in the use of proprietary plant cell fermentation technology, including the production of paclitaxel, the active ingredient of Bristol-Myers Squibb's multi-billion dollar anticancer drug, Taxol®. Phyton was sold to DFB Pharmaceuticals, Inc. in 2003.

Additionally, Mr. Howard is the Chairman of DeepGulf, Inc., and a co-owner and officer of Silver Bullet Technology. DeepGulf builds underwater pipelines and associated facilities in deep and ultra-deep offshore oil and gas production fields. Silver Bullet Technology, where he has been primarily responsible for corporate and financial oversight as well as strategic planning, manufactures and sells software for the banking and payment processing industry. Previously, he served as president and CEO of BioWorks Inc., a biotechnology company he founded to develop, produce, and sell products that replace chemical pesticides.

He earned his MBA from Cornell University's Johnson Graduate School of Management, where he focused his studies on Entrepreneurship, and managing innovation and technology.
As a member of the New York Biotechnology Association he 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 including the Belmont Art Center, the Pensacola Opera, and was formerly on the board of the Make-A-Wish Foundation of Northwest Florida.

Robert G. Moussa

Director, Chairman of Compensation Committee, member of Audit Committee and member of Nominating Committee

Robert Moussa currently serves as Chairman and Chief Executive Officer of Dilon Diagnostics, having spent more than 30 years in the healthcare field. In addition to his role at Dilon, he has held a number of senior positions at both Sherwood Medical Industries and Mallinckrodt Medical. Mr. Moussa has extensive experience launching new products in the diagnostic, nuclear medicine and medical device markets.
Before joining Dilon Technologies, Inc., Mr. Moussa served as President and Chief Executive Officer of Robert Moussa & Associates, a consulting firm serving the pharmaceutical, biotechnology and healthcare industries. Prior to founding this firm, he served in a variety of executive positions with Mallinckrodt, Inc., St. Louis, Missouri, a $2.4 billion healthcare and chemical company. Mr. Moussa's most recent assignment at Mallinckrodt was President - International, a position he held from 1995 through 1997. Previously he served as President and Chief Executive Officer - Mallinckrodt Medical, Inc., Mallinckrodt's largest business unit with over $1 billion dollars in revenues (1992-1996). Before joining Mallinckrodt Medical in 1992, Mr. Moussa served as Mallinckrodt, Inc.'s Group Vice President - International Medical Products, Vice President and General Manager - Medical Products Europe, General Manager of Critical Care, Director of Business Operations and General Sales Manager. Prior to joining Mallinckrodt, Mr. Moussa held a number of positions during the period 1969 through 1976 with Sherwood Medical, United Kingdom, most recently as Director of Marketing.
Mr. Moussa received his Baccalaureate from the Collège du Sacré-Cœur, Beirut, Lebanon, in 1966 and his Bachelor of Science in Business Administration from Ealing University, London, England, in 1969. He has also completed executive seminars at the University of California at Berkley, the Aspen Institute, the Wharton Executive School and the Center for Creative Leadership.

Carl O'Connell

Director

Carl O'Connell has over 26 years of experience working in leadership positions in healthcare and the medical device arena. Prior to joining Calmare Therapeutics, Carl served as President for the US healthcare division of the Japanese conglomerate, ITOCHU Corporation, and previously as Global Vice President for Stryker Spine, and President for Carl Zeiss Surgical Inc. His responsibilities have spanned from 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, ENT and Dentistry. He received a bachelor's degree in Psychology and an M.B.A. from Mount St. Mary's College, Maryland.
Carl has been involved in preparing, presenting and negotiating new business opportunities with private equity, venture groups for funding, as well as consulting with start-up ventures and also with Fortune 500 companies such as GE Healthcare during the business planning and execution phases.
Carl was born in Dublin Ireland and competed in the 1988 Olympics in Decathlon. He is married, has 2 children and lives in Irvington, New York

Stan Yarbro, Ph.D.

Director, Chairman of Audit Committee, member of Compensation Committee and member of Nominating Committee

Stan Yarbro has extensive experience in market development of high technology solutions to a worldwide customer base. He recently retired as Executive Vice President, 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 and has 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.
Dr. Yarbro holds a Ph.D. in Analytical Chemistry from Georgia Institute of Technology and a B.S.in Chemistry from Wake Forest University.

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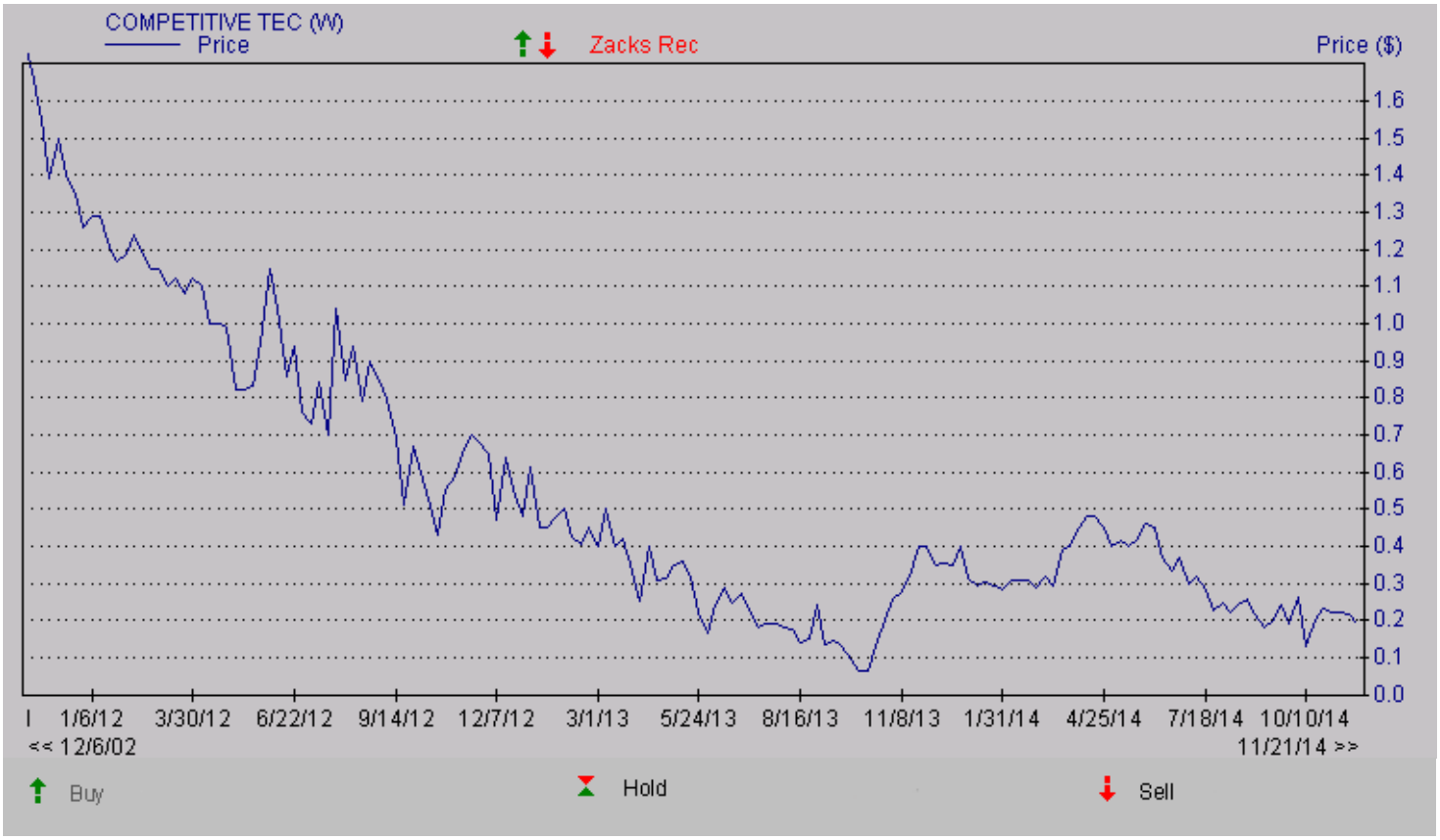

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